1**Supporting 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.: 0575.13 OMB Control No.: 2070-0004

1(b) Short Characterization

Under TSCA Section 8(d) (Attachment A, 15 USC 2607(d)), EPA has the authority to promulgate rules to require producers, importers, and processors to submit lists and/or copies of ongoing and completed, unpublished health and safety studies. EPA's Model TSCA Section 8(d) "Health & Safety Data Reporting Rule" (Attachment B, 40 CFR 716) was developed to gather health and safety information on chemical substances and mixtures needed by EPA to carry out its TSCA mandates (e.g., to support OPPT's Existing Chemicals Program and Chemical Testing Program and to set priorities for TSCA risk assessment/management activities).

The Model Rule describes the requirements and procedures for submitting lists and copies of unpublished health and safety studies under section 8(d) of TSCA. EPA amends the TSCA section 8(d) rule periodically to add chemical substances and mixtures. The Model Rule requires manufacturers and (if specified) processors and distributors 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. EPA may also use its TSCA Section 8(d) authority to gather information needed by other EPA Program Offices and other Federal Agencies. Chemicals that are designated or recommended for testing under TSCA section 4 by the TSCA Interagency Testing Committee (ITC) may be added to the rule via immediate final rulemaking (up to 50 substances per year). Non-ITC chemicals can be added to the Section 8(d) rule via notice and comment rulemaking.

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.

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 who propose to manufacture, process or distribute, any chemical substances or mixtures to submit to EPA lists and copies of health and safety studies in their possession. OPPT needs these studies to determine the kinds of test data may be needed in order to properly assess the risks of particular chemicals, which ultimately enable the Agency to set priorities for TSCA risk

assessment and risk management activities. 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 are evaluated in conjunction with other available data. EPA and other federal agencies use the data to construct a complete picture of the known effects of the chemical substance. OPPT determines what kinds of testing, if any, are needed. OPPT's review of submitted TSCA section 8(d) studies ensures that EPA bases its testing requirements on the most complete information available and does not require manufacturers, processors, and/or distributors to undertake new testing to develop data that may already exist.

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 EPA has received substantial risk notification under TSCA section 8(e), or other chemicals for which data are needed to support a risk management activity 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 studies submitted have also been utilized by the following offices: 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 risk assessment or risk management purposes, EPA will not require TSCA section 8(d) reporting.

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 Model Rule, 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 March 26, 2012 (77 FR 3766, January 25, 2012). EPA received no comments during the comment period.

3(c) Consultations

EPA met on several occasions during 1988 and 1989 with interested industry members to discuss aspects of reporting, monitoring and modeling health and safety studies under the TSCA section 8(d) model rule. The result of these meetings was two interpretative guidance question-and-answer documents that clarify the modeling and monitoring studies that are and are not subject to reporting at 40 CFR part 716.

In September 1996, EPA held a public meeting and solicited comments from industry to discuss a variety of revisions to TSCA section 8(d). This meeting focused on reducing the burden associated with the reporting regulations under TSCA section 8(d) while still providing EPA and other federal agencies with the data necessary for risk characterization. These revisions were implemented in a Direct Final Rule entitled "Revisions to Reporting Regulations under TSCA Section 8(d)" (63 FR 15765, April 1, 1998). These revisions became effective June 30, 1998.

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 nine parties via email. The individuals contacted were:

Robert Kiefer
Director, Regulatory and Technical Affairs
American Chemistry Council
700 2nd Street, NE
Washington, D.C. 2002
Tel.: 202-249-6414 (direct)
Fax: 202-478-2503
Email: Robert_kiefer@americanchemistry.com

Ernie Rosenberg
President and CEO
American Cleaning Institute
1331 L Street, N.W., Suite 650
Washington, D.C. 20005
Tel.: (202)662-2505
Fax: (202) 347-4110
E-mail: erosenberg@cleaninginstitute.org

Douglas Fratz
Vice President, Scientific and Technical Affairs
Consumer Specialty Products Association
900 17th Street, NW, Suite 300
Washington, D.C. 20006
Tel.: (202)833-7304
E-mail: dfratz@cspa.org

Dan Newton
Manager, Government Relations
SOCMA
1850 M Street NW, Suite 700
Washington, DC 20036
Tel.: 202-721-4158
Fax: 202-296-8548
Email: newtond@socma.com

William McLin
Executive Director
Asthma & Allergy Foundation of America
8201 Corporate Drive, Suite 1000
Landover, MD 20785
Tel.: (202) 466-7643, ext. 273
Email: bill@aafa.org

Nsedu Witherspoon
Executive Director
Children's Environmental Health Network
110 Maryland Avenue, NE, Suite 505
Washington, DC 20002
Tel.: (202) 543-4033 (main)
Email: nobot@cehn.org

Richard Denison
Senior Scientist
Environmental Defense
1875 Connecticut Ave., N.W.
Suite 600
Washington, D.C. 20009
Phone: 202-387-3500, ext. 3348
Fax: 202-234-6049
Email: rdenison@edf.org

Ken Cook, President
Environmental Working Group
1436 U St., N.W., Suite 100
Washington, D.C. 20009
Phone: 202-667-6982
E-mail: ken@ewg.org

Linda Greer
Natural Resources Defense Council
1200 New York Avenue, Suite 400
Washington, DC 20005
Phone: 202-289-6868; FAX: 202-289-1060
Email: lgreer@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 (40 CFR 716.30 and 716.35) for the submission of hard copies. EPA published a Notice of Proposed Rulemaking on April 17, 2012 (77 FR 22707) that would require TSCA section 8(d) respondents to file their submissions electronically through the Agency's Central Data Exchange.

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 members 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), 32411 (petroleum refiners), and 331 (metal manufacturing)..

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), revised to reflect recent experience with the program. There are two procedures for using program information to update bases for estimates. First, for the estimate of the frequency of chemical additions, the number of chemicals added to the TSCA section 8(d) Reporting List over time is reviewed. Note that this count is readily updated upon implementation of new rules. However, for the remainder of the estimates --reflecting reporting implications per chemical addition -- updates await completion of EPA "call-ins" for the health reports. In this analysis, the number of chemical additions is based on historical review, while the estimates for reporting implications are the same as in the previous ICR, given that there has been no activity in the section 8(d) information collection since 2006.

EPA has added chemicals to the TSCA section 8(d) list on an episodic basis. As shown in Table 1, chemicals were added to the list three times since 1996. EPA uses a basis of 70 chemicals per year for the 2012-2015 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 TSCA Section 8(d) Reporting List, by Year and by ICR Reporting Period

Year	1996	1997-2003	2004	2005	2006*	2007-2011	Average/Year
Number of Chemicals	47	0	15	0	208	0	17

* 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.

ICR Period (Nov) 2006 - (Oct) 2009		**ICR Period (Nov) 2009 - (Oct) 2012**		**BASIS ICR Period (Nov) 2012 - (Oct) 2015**	
Total	#/yr	Total	#/yr	Total	#/yr
208	69	0	0	210	70

The estimates in this ICR renewal are based primarily on the reporting for the 208 chemicals added to the TSCA section 8(d) list in 2006, and serve as the basis for a typical case TSCA section 8(d) collection. From this experience, EPA has observed that chemicals with high production volumes tend to have more unpublished health and safety data than other chemicals that may be considered for inclusion on the TSCA section 8(d) list. As shown in Table 2, the average number of studies submitted per company was nearly twice as high for the HPV chemicals in the 2006 rule compared to the chemicals in the 2004 rule. Although continued use of the 2006 basis may possibly overestimate costs and burden of future reporting, it is the most recent experience and will be used as the basis for this typical case analysis.

Table 2. Reporting Statistics for Recent TSCA Section 8(d) Rules

	2004 rule	**2006 rule**
Number of chemicals added to 8(d) list	15	208
Number of chemicals for which 8(d) reports were submitted	3	54
Number of companies submitting 8(d) reports	3	59
Total number of 8(d) studies submitted	14	527
Average number of studies submitted per company	5	9
Average page length of studies submitted	67	20
Median page length of studies submitted	20	14

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 3 summarizes the models and bases, as applied to the 2012-15 ICR renewal.

[1] According to 40 CFR part 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.

Table 3: Reporting Implications per Chemical Added

Generic Model	ICR 2009-12 Model Sources*	ICR 2009-2012 Detailed Model	ICR 2012-15 Model Sources	BASIS ICR 2012-15
No. 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
No. 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; # 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%

In addition, EPA will promulgate a final rule requiring the submission of unpublished health and safety data by manufacturers and importers of cadmium and cadmium compounds within 60 days of the publication of the 2012 final rule. The respondent universe for this final rule is somewhat different was estimated based on census data on NAICS industry categories that are believed to be manufacturers and importers of consumer products that may contain cadmium. The number of firms and establishments in those NAICS categories are shown in Table 4 below.

Table 4. Size of the Responding Industries

Industry NAICS Code	Industry Description	Companies	Establishments or sites
325188	All other basic inorganic chemical manufacturing	390	637
325131	Inorganic dye and pigment manufacturing	66	87
325199	All other basic organic chemical manufacturing	569	729
331419	Primary smelting and refining of nonferrous metal (except copper and aluminum)	143	166
331492	Secondary smelting, refining and alloying of nonferrous metal (except copper and aluminum)	216	246
Total		**1,384**	**1,865**

6(a) Estimating Respondent Burden

Firms will undertake the following actions in response to a TSCA section 8(d) listing:

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.

The unit burden associated with each of these tasks is discussed in more detail below and then summarized in Tables 5 and 6. These unit burden estimates are average values. As with any average, some firms will be above the average and others will be below it. 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 than the average.

(i) Typical Case

Step 1. 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 thus may 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 time frame 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 two hours of managerial time for each firm manufacturing a listed chemical.

Step 2. 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 three managerial hours per firm.

Step 3. 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 three hours of technical time per site. Per Table 3, there is an average of 1.5 sites per firm 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).

Step 4. 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 been completed yet, 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. Because the major burden of compiling this list was incurred during the file search, the only significant remaining burden is the clerical time involved in transcribing the lists. The transcription is estimated to require an average of one hour of time per firm.

Step 5. Photocopy Studies. As shown in Table 3, there is a per-firm average of 9 studies with an average page length of 20 pages, for an average of 180 pages per firm. Copying the studies to be submitted is estimated to require an average of 1 hour of clerical time per firm for each study.

Step 6. 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 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. It is estimated that 8 to 16 hours of technical time are needed to develop and QA/QC a robust summary, depending on the type of study conducted. This analysis 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 10% of studies may include a robust summary. As shown in Table 3, there is a per-firm average of 9 studies which yields 0.9 robust summaries per firm. Rounding to one robust summary per firm, the estimated average burden per firm for robust summaries is 12 hours of technical time (1 robust summary * 12 hours/summary).

Step 7. Review Responses for Confidential Business Information. Firms will need to review responses for possible confidential business information (CBI) and delete any material that is considered by the firm to be CBI from one copy of the study. (Another copy must be submitted without deletions.) As shown in Table 3, there is a per-firm average of 9 studies with an average page length of 20 pages. CBI review is estimated to take an average of one hour of managerial time for each study. This results in an estimate that CBI review will require an average of 1 hour of managerial time per firm for each study.

Step 8. 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. Photocopying is estimated to require an average of 0.1 hours per firm of clerical labor and CBI review will require an average of one hour of managerial time.

Table 5 summarizes unit burden estimates. These estimates assume that reporting is similar to the 2006 experience (see Tables 1-3). Note also that not all respondents incur every aspect of reporting burden. The proportion of affected respondents are indicated by weights in Table 5, with a weight of one assigned to steps which affect all respondents.

Table 5. Unit Burden for TSCA Section 8(d) Reporting (Typical)

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. Study Title Lists	0.168	1	clerical
5. Photocopy Studies	0.168	1	clerical
6. Robust Summaries	0.008	12	technical
7. CBI Review	0.168	9	managerial
8. Post-Reporting Period Submission	0.008	1 0.1	managerial clerical
*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 *** 1 hour per study * 9 studies			

(ii) Cadmium and Cadmium Compounds

EPA used the methods and estimates from the typical case ICR analysis that were described earlier in section 6(a)(i) of this supporting statement, but applied to the particular circumstances of the final rule. The ICR estimates were modified to adjust to current wages and to reflect the estimated number of data collection related activities for this particular rule. The number of firms required to review the rule to determine whether they are subject to its reporting requirements is estimated to be 1,384. About half of that number are expected to be required to search for reports, and about 28 studies are expected to be found. The specific burden and cost estimates for this rule are shown in Table 13, which is Table 3-16 from the economic analysis.

Table 6. Respondent Unit Costs for TSCA Section 8(d) Reporting for Manufacturers and Importers of Cadmium and Cadmium Compounds

Collection Activity	Average Burden Hours per Firm	Labor Category
1. Review of Rule	2 hours	managerial
2. Site Identification	3 hours	managerial
3. Site File Search	3 hours	technical
4. Study Title Lists	1 hour	clerical
5. Photocopy Studies	0.11 hour	clerical
6. Robust Summaries	12 hours	technical
7. CBI Review	1 hour (per submitted study)	managerial
8. Post-Reporting Period Submission	1 hour	managerial
	0.1 hours	clerical
Note: Not all respondents perform all activities.		

6(b) Estimating Respondent Costs

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.

(i) Typical Case

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 2010. 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 7 presents these results with fully loaded rates for managerial labor at $69.65/hr; for technical labor at $60.95/hr; and for clerical labor at $28.99/hr.

Table 7: Loaded Industry Wage Rates (2010)

EPAB Labor Category	Data Sources[d]	Date	Hourly Wage	Fringe Benefit	Fringes as % wage	Over-head % 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**, "Mgt, Business, and Financial"	Avg of Mar, June, Sept, Dec	$42.97	$19.38	45%	17%	1.62	$69.65
Professional/ Technical	BLS *ECEC*, Private **Manufacturing industries**, "Professional and related"	Avg of Mar, June, Sept, Dec	$36.50	$18.25	50%	17%	1.67	$60.95
Clerical	BLS *ECEC*, Private **Manufacturing industries,** "Office and Administrative Support"	Avg of Mar, June, Sept, Dec	$17.29	$8.77	50%	17%	1.68	$28.99

Notes:
[a] Wage data are rounded to the cent in this table; however, in calculations, 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-Mach 2011,* US Bureau of Labor Statistics, June 8, 2011 (pp 17,18,20) (http://www.bls.gov/ncs/ect/sp/ecsuphst.pdf, accessed July 13, 2011).

A typical firm submitting a response will engage in review of the rule, site identification, site file search, preparing study title lists, photocopying studies, and CBI review, and possibly submit a robust summary 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 (see Table 3), the average annual cost for a firm is estimated at $744 for 11.5 hours of burden.

(ii) Cadmium and Cadmium Compounds

Table 8. Derivation of Loaded Wage Rates

Labor Category	Data Sources	Hourly Wage	Fringe Benefit	Fringes as % wage	Over-head % wage	Fringe overhead factor	Loaded Wages
		(a)	(b)	(c) =(b)/(a)	(d)	(e)=(c)+(d)+1[1]	(f)=(a) x (e)
Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial"[1]	$43.01	$20.40	47.43%	17%	1.644	$70.72
Professional/ Technical	BLS ECEC, Private Manufacturing industries, "Professional and related"[1]	$38.48	$19.64	51.04%	17%	1.680	$64.66
Clerical	BLS ECEC, Private Manufacturing industries, "Office and Administrative Support" [1]	$17.69	$8.93	50.48%	17%	1.675	$29.63

Notes: [1] *Employer Costs for Employee Compensation Supplementary Tables: December 2007,* US Bureau of Labor Statistics, March 12, 2008 at http://www.bls.gov/ncs/ect/sp/ecsuptc5.pdf

Fully loaded costs for managerial and clerical labor for manufacturers and importers of cadmium and cadmium compounds are calculated in a similar manner. As shown in Table 8, the estimated fully loaded wage rates are $70.72 per hour for managerial staff, $64.66 per hour for technical staff, and $29.63 per hour for clerical staff.

Table X calculates the average unit costs for respondents by combining the unit burden estimates from Table 6 with the loaded wage rates from Table 8.

6(c) Estimating Agency Cost

The activities routinely conducted by EPA related to processing and storage of the information collected under this rule include processing and analyze rule submissions, 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 2011 hourly wage rate for this level of employee in the Washington, D.C. locality is $48.35 per hour. Adding 60% for benefits and overhead yields a loaded annual wage rate of $77.36 per hour.[2]

(i) Typical Case

The estimated annual cost to the federal government for TSCA section 8(d) data collection typically totals $5,415, for 70 hours as presented in Table 9.

[2] The EPA wage rate is calculated based on the GS-13 Step 5 wage rate for calendar 2011, 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).

Table 9. Estimating Agency Burden and Costs (Typical Case)

Collection Activity	FTEs	Hours at (at $77.36/hour)	Annual Cost
Data processing and system support	0.025	50	$3,868
Storage and distribution	0.010	20	$1,547
TOTALS	**0.035**	**70**	**$5,415**
Source: OPM 2011 hourly rate table for the Washington-Baltimore-Northern Virginia Locality Pay Area, with 60% for benefits and overhead added.			

(ii) Cadmium and Cadmium Compounds

The estimated annual cost to the federal government for the TSCA section 8(d) data collection for the 2012 final rule concerning cadmium and cadmium compounds is $23,332 for 301.6 hours, as presented in Table 10.

Table 10. Estimating Agency Burden and Costs (Cadmium and Cadmium Compounds)

Collection Activity	FTEs	Hours (at $77.36/hour)	Annual Cost
Data processing and system support	0.025	216.32	$16,735
Storage and distribution	0.01	85.28	$6,597
TOTALS	**0.035**	**301.60**	**0**

6(d) Estimating the Respondent Universe and Total Burden and Costs

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 17 chemicals per year. In more recent ICR renewal periods, the frequency of additions has been higher (see Table 1).

(i) Typical Case

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 2012 to 2015, for a total of 210 chemicals over the three-year ICR period.

The total number of responses over the next three years is projected based on the frequency of chemical additions (stated above) and anticipated reporting implications, as observed in 8(d) reports submitted in response to the 2006 rule (see Table 3). Applying the Table 3's average of 1.7 manufacturers per chemical to the average of 70 chemicals per year that are assumed to be added to the section 8(d) list over the next three years results in an estimate that there will be 119 manufacturers per year with chemicals added to the section 8(d) list during the time frame covered by this ICR.

Assuming the reporting bases of Table 3, with 17 percent of the manufacturers of listed chemicals, or 20 firms (0.17 * 119 manufacturers), will submit reports each year. Of these 20 firms, an estimated total of 180 studies will be submitted annually (20 firms* 9 studies per firm). From this group of firms, one firm will submit a robust summary per year. And one 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 activities is summarized in Table 11.

Refer to Section 6(a) for detailed descriptions of the steps. Note that not all respondents incur every aspect of reporting burden. For this analysis, the conditions of the 2006 rule and its reporting implications (per Table 3) along with the condition of 70 chemical additions per year are assumed.

Table 11: Number of Firms Affected, by Activity (70 Chemicals Added Per Year; Table 3 Bases)

Collection Activity	BASIS ICR 2012-15 No. of Firms
1. Review of Rule	119
2. Site Identification	119
3. Site File Search	119
4. Study Title Lists	20
5. Photocopy Studies	20
6. Robust Summaries	1
7. CBI Review	20
8. Post-Reporting Period Submission	1

The number of firms or studies described above is combined with the estimated average unit burden hours and cost from Tables 5 and 7 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 12.

Table 12. Annual Respondent Cost and Burden Hour Estimates (Typical Case)

Information Collections	Response Activities	Burden / Response (Hours)	Labor Category	Cost per Response	No of Responses*	Total Burden (Hours)	Total Cost
Compliance determination and data search	1. Review of Rule	2	managerial	$139	119	238	$16,578
	2. Site Identification	3	managerial	$209	119	357	$24,867
	3. Site File Search	4.5	technical	$274	119	536	$32,641
Subtotal					*119*	*1,131*	*$74,086*
Submission of health and safety studies during the reporting period	4. Study Title Lists	1	clerical	$29	20	20	$580
	5. Photocopy Studies	1	clerical	$29	20	20	$580
	6. Robust Summaries	12	technical	$731	1	12	$731
	7. CBI Review	9	managerial	$627	20	180	$12,538
Subtotal					*21*	*232*	*$14,429*
Notification and Submission of health and safety studies initiated and/or completed after the reporting period	8. Post-Reporting Period Submission	1	managerial	$70	1	1	$70
		0.1	clerical	$3	1	0.1	$3
Subtotal					*1*	*1*	*$73*
Total					**141**	**1,364**	**$88,588**

***** "No. of responses" for searching files is presented only to compute total burden. Some firms that search their files do not have any studies that must be reported under the TSCA section 8(d) rule.

(ii) Cadmium and Cadmium Compounds

As indicated in section 6(a)(ii) of this supporting statement, EPA estimates that manufacturers and importers of cadmium and cadmium compounds will submit 28 studies. The vast majority of the estimated 1,384 respondent firms are not expected to have responsive information to submit to EPA.

Table 13. Respondent Cost and Burden Hour Estimates

Collection Activity	Unit Burden Hours	Unit Cost	Number of Firms or sites per activity	Total Burden Hours	Total Cost
	(a)	(b)	(c)	(d) = (a)*(c)	(e) = (b)*(c)
Review of Rule	2.00	$141.44	1,384 Firms	2,768	$195,753
Site Identification	3.00	$212.16	595 Firms	1,785	$126,235
Site File Search	3.00	$193.98	802 Sites	2,406	$155,572
Study Title Lists	1.00	$29.63	28 Firms	28	$830
Photocopy Studies	0.11	$3.26	28 Studies	3.08	$91.28
CBI Review	1.00	$70.72	28 Studies	28	$1,980
Post-Reporting Period Submission	1.11	$73.98	1 Firms	1.11	$73.98
Total				**7,019**	**$480,535**

Note: Not all respondents perform all activities. Also, the ICR assumed 2.4 sites per company in the calculations of certain burden hours (e.g., Site File Search), whereas the economic analysis for this rule estimated the number of sites per company for each distinct NAICS category (see Table X).

6(e) Bottom Line Burden Hours and Cost

EPA estimates that, based on the 2006 rule addressing 208 HPV chemicals and in consideration of the 2012 rule addressing cadmium and cadmium compounds, the annual paperwork burden is 8,383 hours

Respondent Burden and Costs
Respondent annual burden hours (typical) = 1,364 hours
Respondent = 7,019 hours
Total respondent burden = 8,383 hours

Respondent annual costs (typical) = $88,588
Respondent costs (cadmium and cadmium compounds) = $480,535
Total respondent costs = $569,123

Agency Burden and Costs
Agency burden hours (typical): 70 hours
Agency burden hours (cadmium and cadmium compounds): 301.60 hours
Total agency burden: 371.6 hours

Agency annual costs (typical) = $5,415
Agency costs (cadmium and cadmium compounds) = $23,332
Total agency costs: $28,747

6(f) Reasons For Changes in Burden

There is an increase of 7,930 hours (from 456 hours to 8,383 hours) in the total estimated respondent burden compared with that currently in the OMB inventory. Much of the burden increase identified in this ICR is associated with a single TSCA section 8(d) collection for manufacturers and importers of cadmium and cadmium compounds in 2012 (7,019 hours). The remaining 908 hour increase is due to a revised basis for the rate of chemical additions (from 20 to 70 chemicals per year) and to the episodic nature of rulemakings that add chemicals to the TSCA section 8(d) list. In light of most recent history of additions by ICR Period, EPA is basing estimates for this ICR on 70 chemical additions per year -- similar to the 2006-2009 ICR period -- and on reporting implications similar to those brought on by chemical additions to TSCA 8(d) in the 2006 rule.

6(g) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0004, is typically estimated to average about 9.7 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. In addition, the OMB control numbers for EPA's regulation in Title 40 of the CFR, after initial display in the final rule, are listed in 40 CFR part 9.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2011-0777, which is available for online viewing at www.regulations.gov, or in person viewing at the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the 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-2011-0777 and OMB Control No. 2070-0004, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Document Control Office (DCO), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Mail Code: 7407T, 1200 Pennsylvania Ave., NW, Washington, D.C. 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

ATTACHMENTS

All of the attachments listed below can be found in the docket for this ICR (unless otherwise noted); accessible electronically through www.regulations.gov. On the main page, select **Advanced Search** from the menu bar at the top and select **Docket Search**. Enter the **Docket ID** Number, **EPA-HQ-OPPT-2011-0777** in the **Docket ID** field. Click on the **Submit** button. From the results page, you will be able to link to the docket view or directly open select documents found in the docket.

ATTACHMENT 1 - Toxic Substances Control Act Section 8(d), 15 U.S.C. 2607(d)

ATTACHMENT 2 - Health and Safety Data Reporting, 40 CFR 716

ATTACHMENT 3 - Copy of Consultations Message Sent by EPA to Potential Respondents