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.: 0575.12 OMB Control No.: 2070-0004

1(b) Short Characterization

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 The Model Rule describes the requirements and procedures for submitting lists and copies of unpublished health and safety studies under section 8(d) of TSCA (40 CFR 716).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

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

All studies submitted to EPA will be verified and the contents of the submissions recorded and inspected for the inclusion of confidential business information. Photocopies 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 microfiched and stored for archival purposes.

EPA will use the studies to support its investigation of the risks posed by listed chemicals and, in particular, to support its decisions on whether to require industry to test chemicals under section 4 of TSCA.

2 NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

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

2(b) Use/Users of the Data

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

In addition, EPA will require that copies of health and safety studies be submitted on other chemicals that are under investigation either in the early stages of risk assessment or when action to control exposure is being considered by EPA or another federal agency. These chemicals may be ones for which persons have submitted substantial risk notification under TSCA section 8(e), or other chemicals for which data are needed to support a control measure under sections 5 and 6 of TSCA or under other EPA-administered statutes. If this information collection did not exist, EPA would not be able to obtain the necessary information for evaluating the need for testing under section 4 of TSCA or controlling chemical substances under TSCA sections 5 and 6.

In the past, the 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 assessment or control purposes, EPA will not require TSCA section 8(d) reporting. However, if that information is not sufficient, or is obtained in a way that makes EPA doubt its validity, then the Agency must require the submission of non-published health and safety studies.

The health and safety studies to be submitted under the TSCA section 8(d) rule are not available from any other source. The TSCA section 8(d) rule requires the listing and submission of studies that are conducted in-house by industry or by industry contractors and not published in the scientific literature. Under the revisions to the Model Rule promulgated in September 1986, respondents do not have to list or submit any studies that have been published in the scientific literature, or submitted previously to OPPT on a non-confidential basis. Studies that respondents previously have submitted on a non-confidential basis to other EPA offices or programs need only be listed.

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

In proposing to renew this ICR, EPA provided a 60-day public notice and comment period that ended on February 23, 2009 (73 FR 79081, December 24, 2008). EPA received no comments during the comment period.

3(c) Consultations

Existing Chemical Assessment Division (ECAD) staff 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 private parties and one federal employee via email. The individuals contacted were:

James Cooper
Synthetic Organic Chemical Manufacturers Association
cooperj@socma.com

Richard Denison
Environmental Defense
rdenison@environmentaldefense.org

Douglas Fratz
Consumer Specialty Products Association
dfratz@cspa.org

Susan Hearn
Dow Chemical Company
shearn@dow.com

Jessine Monaghan
General Electric
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Thomas Neltner
Improving Kids Environment
neltner@ikecoalition.org

Kathleen Roberts
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Jennifer Sass
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jsass@nrdc.org

Derek Swick
API
swickd@api.org

John D. Walker
Interagency Testing Committee
U.S. Environmental Protection Agency
walker.johnd@epa.gov

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

- Review and select chemicals;
- Develop and issue an amendment to the TSCA section 8(d) rule to add the substances or mixtures;
- Answer respondents' questions;
- Process and analyze rule submissions, including requests for confidentiality; and
- 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 is continuing to explore alternative reporting procedures involving electronic submission.

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

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

4(c) Small Entity Flexibility

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

4(d) Collection Schedule

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

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

5 THE RESPONDENTS AND THE INFORMATION REQUESTED

5(a) Respondents/NAICS Codes

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

5(b) Information Requested

(i) Data Items

Persons who manufacture (including import) chemical substances and mixtures, or propose to do so, and processors of such substances and mixtures (if specifically identified in a particular rule) must submit copies of the unpublished health and safety studies in their possession for the listed substances or mixtures. They must also submit lists of reportable studies that they initiate or, about which they know, for each of the listed substances or listed mixtures.

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

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

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

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

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

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

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

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

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

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

(ii) Respondent Activities

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

- Conduct an initial review of the rule to determine if its company must report;
- Conduct a corporate review to identify which company sites must be searched to locate the appropriate health and safety studies;
- Search its files at each site to locate the studies;
- Compile and transcribe a list of studies being submitted, studies in progress, and studies known to exist but not known to be in the respondent's possession;
- Photocopy the studies;
- Review the studies and title lists for possible confidential business information;
- After initial study submissions, notify EPA when other studies are initiated; and
- Submit studies completed after the initial reporting period.

6 ESTIMATING THE COST AND BURDEN OF THE COLLECTION

The methodology used in 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. 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. Most recently, EPA added 208 High Production Volume (HPV) chemicals to the list in 2006.[1]

[1] ? 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.

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

Year	Number of Chemicals	Year	Number of Chemicals
1996	47	2003	0
1997	0	2004	15
1998	0	2005	0
1999	0	2006	208
2000	0	2007	0
2001	0	2008	0
2002	0	Average	20.8

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. 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. If the chemicals that are added to the TSCA section 8(d) list over the next three years are more like the 2004 list than the 2006 list, basing predictions on the 2006 results may overestimate the cost and burden of future reporting.

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

6(a) Estimating Respondent Burden

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

- Determine whether the firm may be required to report. If so, review the rule in more detail;
- Conduct a corporate review to identify which firm sites must be searched to locate the appropriate health and safety studies;
- Search the files at appropriate sites to locate relevant studies;
- 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;

- Photocopy the studies being submitted;
- Voluntarily prepare robust summaries of the studies;
- Review the responses for possible confidential business information; and
- Submit studies completed after the reporting period.

The unit burden associated with each of these tasks is discussed in more detail below and summarized in Table 3.

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.

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

Step 2. 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. 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. Based on reporting under EPA's TSCA Inventory Update Rule (IUR), manufacturers of the 208 chemicals added to the section 8(d) list in 2006 had an average of 1.5 sites per firm manufacturing a listed chemical. Assuming that this is representative of the chemicals that will be added to the TSCA section 8(d) list under this ICR 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. 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. Photocopying Studies. As shown in Table 2, companies reporting under the 2006 TSCA section 8(d) rule submitted an average of 9 studies with an average page length of 20 pages, for an average of 180 pages per company. Copying the studies to be submitted is estimated to require an average of 1 hour of clerical time per firm.

Step 6. 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 2, companies reporting under the 2006 TSCA section 8(d) rule submitted an average of 9 studies. Assuming that future reporting is similar to the 2006 experience, the estimated average burden per firm for robust summaries is 11 hours of technical time (0.1 summaries/study * 9 studies/firm * 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 2, companies reporting under the 2006 TSCA section 8(d) rule submitted an 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. Assuming that future reporting is similar to the 2006 experience, this results in an estimate that CBI review will require an average of 9 hours of managerial time per firm.

Step 8. Post-Reporting Period Submission of 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 3. Unit Burden for TSCA Section 8(d) Reporting

Collection Activity	Average Burden per Firm
1. Review of Rule	2 hours managerial
2. Site Identification	3 hours managerial
3. Site File Search	4.5 hours technical
4. Study Title Lists	1 hour clerical
5. Photocopy Studies	1 hour clerical
6. Robust Summaries	11 hours technical
7. CBI Review	9 hours managerial
8. Post-Reporting Period Submission	1 hour managerial 0.1 hours clerical
Note: Not all respondents perform all activities.	

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.

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. 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 for December 2007.

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. For example, the average hourly wage rate for professional/technical labor was $33.14 and the average fringe benefit was $16.65. Fringe benefits as a percent of wages were $16.65/$33.14, or approximately 50 percent.

Table 4. Derivation of Loaded Wage Rates

Labor Category	Data Sources	Wage	Fringe Benefit	Fringes as % wage	Over-head % wage	Fringe overhead factor	Loaded Wages
		(a)	(b)	(c) =(b)/(a)	(d)	(e)=(c)(d)[1]	(f)=(a) x (e)
Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial"[1]	$41.93	$20.15	48%	17%	1.65	$69.21
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional and related"[1]	$33.14	$16.65	50%	17%	1.67	$55.42
Clerical	BLS ECEC, Private Manufacturing industries, "Office and Administrative Support" [1]	$16.47	$8.32	51%	17%	1.68	$27.59

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 are calculated in a similar manner. As shown in Table 4, the estimated fully loaded wage rates are $69.21 per hour for managerial staff, $55.42 per hour for technical staff, and $27.59 per hour for clerical staff.

Table 5 calculates the average unit costs for respondents by combining the unit burden estimates from Table 3 with the loaded wage rates from Table 4.

Table 5. Respondent Unit Costs

Collection Activity	Average Burden Hours per Firm	Managerial $69.21/hr	Technical $55.42/hr	Clerical $27.59/hr	Total
1. Review of Rule	2 hours managerial	$138.42			$138.42
2. Site Identification	3 hours managerial	$207.63			$207.63
3. Site File Search	4.5 hours technical		$249.39		$249.39
4. Study Title Lists	1 hour clerical			$27.59	$27.59
5. Photocopy Studies	1 hour clerical			$27.59	$27.59
6. Robust Summaries	11 hours technical		$609.62		$609.62
7. CBI Review	9 hours managerial	$622.89			$622.89

8. Post-Reporting Period Submission	1 hour managerial 0.1 hours clerical	$69.21		$2.76	$71.97
Note: Not all respondents perform all activities.					

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, but not submitting a robust summary or a post-reporting period submission. Assuming that 20 chemicals per year are added to the TSCA section 8(d) list and that reporting is similar to the 2006 experience, the annual cost for a typical firm is estimated to be $1,274.

6(c) 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 average of approximately 20 chemicals per year. This ICR assumes that an average of 20 chemicals per year will be added to the section 8(d) list from 2009 to 2011, for a total of 60 chemicals over the three year ICR period.

The number of responses over the next three years is projected based on the 8(d) reports submitted in response to the 2006 rule. According to TSCA IUR data[2], 344 firms reported manufacturing (including importing) one or more of the chemicals listed on the 2006 TSCA section 8(d) rule, an average of 1.7 manufacturers per chemical (344 firms / 208 chemicals). There were 59 firms, or 17% of the number of manufacturers, that submitted studies in response to the TSCA section 8(d) rule (59 respondents / 344 manufacturers). The 59 firms submitted a total of 527 studies, an average of approximately 9 studies per reporting firm.

Applying the average of 1.7 manufacturers per chemical to the average of 20 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 34 manufacturers per year with chemicals added to the section 8(d) list during the time frame covered by this ICR.

Assuming that reporting over the next three years is similar to the 2006 experience then 17 percent of the manufacturers of listed chemicals, or 6 firms (0.17 * 34 manufacturers), will submit reports each year. The 6 firms are estimated to submit a total of 54 studies annually (6 firms* 9 studies per firm). One of these respondents (5% of 6 firms) is also assumed 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 described below.

Step 1. Review the Rule. Unless EPA specifies otherwise, the coverage of section 8(d)

[2] 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. To represent the 10 year period prior to the 2006 TSCA section 8(d) rule, this analysis used TSCA IUR data from the 1998, 2002, and 2006 reporting cycles. The IUR data used for this analysis was not limited to reporting from chemical manufacturers and petroleum refiners.

rules is limited to chemical manufacturers and petroleum refiners. Most firms in these industries do not manufacture a listed chemical, and many will spend a de minimis amount of time determining that. There will be a smaller group of firms that manufacture a listed chemical and will need to spend time reviewing the rule to understand its specific requirements such as the type(s) of health and safety data needed, the chemical grade or purity of the test material, and the time frame of the reporting period (typically 60 days but it can be up to two years).

The group of firms that must review the specific requirements of the rule is approximated as the number of firms that manufacture (including import) a listed chemical. If 20 chemicals are added to the TSCA section 8(d) list, EPA estimates that 34 manufacturers will need to perform such a review.

Step 2. Corporate Review for Site Identification. If 20 chemicals are added to the TSCA section 8(d) list, EPA estimates that 34 manufacturers will conduct an additional review to determine which corporate sites must be searched to locate any appropriate health and safety studies.

Step 3. Site File Search. Firms that manufacture a listed chemical must search the files at appropriate sites to look for studies that are responsive the TSCA section 8(d) rule. If 20 chemicals are added to the TSCA section 8(d) list, EPA estimates that 34 manufacturers will need to search their files for the appropriate studies.

Steps 4, 5, and 7. If 20 chemicals are added to the TSCA section 8(d) list, EPA estimates that 6 firms will prepare a study title listing, photocopy studies, and review studies for confidential business information.

Step 6. Robust Summaries. Submitting a robust summary is a voluntary activity. If 20 chemicals are added to the TSCA section 8(d) list, EPA assumes that the 6 firms will provide robust summaries for an average of 10% of the total number of studies that are submitted.

Step 8. Post-Reporting Period Submission of Ongoing or Newly Initiated Studies. EPA assumes that 5% of respondents will submit a study after the end of the reporting period because the study was ongoing or newly initiated during the reporting period. With 6 respondents per year, this is equivalent to one firm per year submitting a post-reporting period study.

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

Table 6. Annual Respondent Cost and Burden Hour Estimates

Information Collections	Response Activities	Burden per Response	Cost per Response	Number of Responses	Total Burden Hours	Total Cost
Compliance Determination and Data Search	1. Review of Rule 2. Site Identification 3. Site File Search	2 hours +3 hours +4.5 hours *9.5 hours*	$138.42 +$207.63 +$249.39 *$595*			
Subtotal				34*	323	$20,230
Submission of health and safety studies during the reporting period	4. Study Title Lists 5. Photocopy Studies 6. Robust Summaries 7. CBI Review	1 hour + 1 hour + 11 hours + 9 hours *22 hours*	$27.59 + $27.59 + $609.62 + $622.89 *$1,288*			
Subtotal				6	132	$7,728
Notification and Submission of health and safety studies initiated and/or completed after the reporting period	8. Post-Reporting Period Submission	*1. 1 hours*	*$72*	1	1.1	$72
Total					**456.1**	**$28,030**
***** "Number 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.						

6(d) Bottom Line Burden Hours and Cost Tables

As shown in Table 7, if EPA adds 20 chemicals per year to the TSCA section 8(d) list during the time period covered by this ICR, there will be an estimated total of 456.1 burden hours per year at a cost of $28,030 per year. There are an estimated 34 respondents that search their files, at an average burden of 9.5 hours each; 6 responses during the reporting period (from 6 respondents submitting one response each)[3] at an average burden of 22 hours per response; and one response (from a single respondent) with a post-reporting period submission at an average burden of 1.1 hours.

[3] A response can include more than one study. Based on the 2006 experience (when there were an average of 9 studies submitted per company), EPA estimates that the 6 respondents will submit a total of 55 studies, 54 during the reporting period and one after the reporting period. Alternatively, EPA could have estimated the number of studies based on the average number of studies per chemical added to the TSCA section 8(d) list. In 2006, 208 chemicals were added to the TSCA section 8(d) list and 527 studies were submitted, an average of approximately 2.5 studies per chemical. Using this basis would yield an estimate that adding 20 chemicals to the TSCA section 8(d) list will result in 51 studies being submitted, 50 during the reporting period and one after the reporting period.

Table 7. Bottom Line Burden Hours and Cost Tables

Type of Response	Burden per Response	Cost per Response	Number of Responses	Total Burden	Total Cost
Search files	9.5 hours	$595	34*	323.0	$20,230
Submit studies during the reporting period	22 hours	$1,288	6	132.0	$7,728
Submit studies after the reporting period	1.1 hours	$72	1	1.1	$72
Total			**41**	**456.1**	**$28,030**
***** "Number 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.					

As noted earlier, basing the future burden estimates on the reporting from the 2006 rule may overestimate reporting burden and cost if number and characteristics of the chemicals that are added to the TSCA section 8(d) list during the next three years are not like the 208 HPV chemicals that were added in 2006. For purposes of comparison, EPA added 15 chemicals to the TSCA section 8(d) list in 2004 (only slightly less than the 20 chemicals predicted to be added per year for the next three years). But as shown in Table 1, the 2004 rule generated only 3 responses representing 14 studies, compared to the 7 responses (6 during the reporting period and one after the reporting period) representing 55 studies.

6(e) Estimating Agency Cost

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

- Answer respondents' questions;
- Process and analyze rule submissions, including requests for confidentiality; and,
- Maintain and distribute the 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 2007 hourly wage rate for this level of employee in the Washington, D.C. locality is $43.12 per hour. Adding 60% for benefits and overhead yields a loaded annual wage rate of $69 per hour.[4]

The estimated annual cost to the Federal government for TSCA section 8(d) data collection is summarized in Table 8.

[4] The EPA wage rate is calculated based on the GS-13 Step 5 wage rate for calendar 2007, from the Office of Personnel Management salary and wage tables for Washington-Baltimore-Northern Virginia at http://www.opm.gov/oca/07tables/html/dcb_h.asp. 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 8. Agency Annual Cost Estimates

Collection Activity	FTEs	Hours (at $69/hour)	Annual Cost
Data processing and system support	0.025	50	$3,450
Storage and distribution	0.01	20	$1,380
GRAND TOTALS	**0.035**	**70**	**$4,830**

6(f) Reasons For Changes in Burden

There is a decrease of 13,891 hours (from 14,347 hours to 456 hours) in the total estimated respondent burden compared with that currently in the OMB inventory. This change is due to the episodic nature of rulemakings that add chemicals to the TSCA section 8(d) list. EPA has added chemicals to the TSCA section 8(d) list in only three of the last 13 years, adding an average of 20 chemicals per year over that time period. The ICR for the 2006 to 2008 time period assumed that an average of 100 chemicals per year would be added to the TSCA section 8(d) list (or 300 chemicals over the three year ICR period), because EPA was planning on adding 243 HPV chemicals to the TSCA section 8(d) list. This was an unusually large number of chemicals to be added to the TSCA section 8(d) list. Because EPA does not anticipate adding such a large number of chemicals during this three year ICR period, the burden estimated for this ICR has decreased. It is now more consistent with the number of chemicals that EPA added to the TSCA section 8(d) list during the 2003 to 2005 ICR period.

6(g) 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. According to the Paperwork Reduction Act, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. For this collection it includes the time needed to review instructions; develop, acquire, install and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appears above. 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-2008-0868, 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 Docket Center 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-2008-0868 and OMB Control No. 2070-0004, to 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.

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-2008-0868** 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 - Consultation Process: EPA's Solicitation for Comments