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: TSCA Section 8(c) Health and Safety Data Reporting Rule

EPA ICR No.: 1031.07

OMB Control No.: 2070-0017

1(b) Short Characterization

Section 8(c) of TSCA, 15 U.S.C. 2607(c), P.L. 94-469 (see Attachment 1), requires that "any person who manufactures, processes, or distributes in commerce any chemical substance or mixture" must keep "records of significant adverse reasons to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture."

EPA promulgated 40 CFR 717, "Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment; Subpart A -- Recordkeeping and Reporting," on August 22, 1983 (48 FR 38178) (see Attachment 2). This rule became effective on November 21, 1983. The rule requires manufacturers and processors of chemical substances and mixtures to keep records of "significant adverse reactions" alleged to have been caused by such substances or mixtures. The rule also prescribes the conditions under which a firm must submit or make the records available to a duly designated representative of the Administrator.

TSCA section 8(c) requires that allegations of adverse reactions to the health of employees be kept for thirty years, and all other allegations be kept for five years.

2 NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

TSCA section 8(c) requires any person who manufactures, processes, or distributes in commerce any chemical substance or mixture to maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture.

Since the rule contains no automatic reporting provision, the only way EPA can obtain and use the information contained in company files is to either inspect the files or require reporting of records that relate to specific substances of concern. 40 CFR 717.17 contains such authority to inspect and require such reporting. EPA will review relevant TSCA section 8(c) records in connection with its existing chemical assessment activities.

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.

2(b) Use/Users of the Data

Information contained in the TSCA section 8(c) allegation reports will have several uses. The information collected will be used on a case specific basis to corroborate suspected adverse health or environmental effects of a chemical substance or mixture already under assessment by OPPT. Most of these substances will be "existing" chemicals, e.g., chemicals for test rule consideration, substances that are the subject of a section 8(e) notice of substantial risk, or substances or mixtures brought to the attention of OPPT by other EPA programs, other government agencies, industry, or the public. However, TSCA section 8(c) reports also may be required on "new" chemicals as one means of monitoring for any suspected or potential hazards identified during the premanufacture notification (PMN) review period.

By using TSCA section 8(c)'s reporting authority, EPA can examine such records whenever a chemical is discovered to present possible risks to human health or the environment.

On a case-specific basis, requiring reporting of TSCA section 8(c) records will also serve as a discovery function. It will help identify trends of adverse affects across the industry that may not be apparent to any one company. It will also serve as a long-term trend identification function because of the 30-year recordkeeping feature of the statute.

As the recordkeeping and reporting provisions of section 8(c) are of central importance in the administration of section 8 of TSCA, EPA would not be able to meet its obligation under TSCA without having the capability to carry them out.

3 NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

Information recorded and reported is kept specifically for compliance with the TSCA section 8(c) rule. There are no other EPA programs or other agencies/departments that would have this specific information nor does any other program have direct authority to access such information.

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 June 17, 2002 (67 FR 18604, April 16, 2002; and 67 FR 34705, May 15, 2002). EPA received one comment during the comment period, from the American Chemistry Council. EPA addresses the comment and EPA's response to it in an attachment to this ICR; see Attachment 3.

3(c) Consultations

Prior to proposing the TSCA section 8(c) rule, EPA held information meetings with the following groups:

- Oil, Chemical, and Atomic Workers Union
- AFL/CIO
- Environmental Defense Fund
- American Textile Manufacturing Association
- Chemical Manufacturers Association
- Chemical Specialty Manufacturers Association
- Rubber Manufacturers Association
- National Congress of Petroleum Retailers
- National Association of Chain Drugstores

During the public comment period, EPA received 160 comments from a wide variety of groups including the Chemical Manufacturers Association, American Petroleum Institute, chemical manufacturers and processors, chemical industry representatives, and environmental and labor organizations. In addition, EPA held public meetings on the proposed rule in Washington, D.C., Newark, New Jersey, and Houston, Texas.

In promulgating the final TSCA section 8(c) rule, EPA contacted Allied Chemical, American Cyanamid, Monsanto, Proctor and Gamble, Stauffer Chemical, and Union Carbide to obtain industry estimates on the number of expected allegations and company indirect costs. In addition, the TSCA section 8(c) final rule concept was reviewed by the Administrator's Toxic Substance Advisory Committee, which is composed of representatives of business and environmental groups.

Since promulgation, provisions of the final rule have been thoroughly discussed in briefings with representatives of the chemical industry. Also, certain aspects of the rule were subsequently modified based upon recommendations by members of the industry and after full consideration of comments from representatives of both industry and environmental groups.

OPPT has provided continuing interpretive guidance to interested parties whenever the need has arisen. In July of 1986, OPPT conducted a seminar for industry representatives on TSCA that included information exchange regarding TSCA section 8(c). Another such industry seminar was conducted in 1990.

3(d) Effects of Less Frequent Collection

Currently, EPA uses its authority to collect information pursuant to the TSCA section 8(c) rule sparingly. It would be irresponsible and contrary to the intent of TSCA to arbitrarily limit the number of collections available to EPA under TSCA section 8(c). Currently, EPA anticipates issuing infrequent requests (<2/year) for TSCA section 8(c) reporting. However, reporting requests may occur more frequently because individual rulemakings containing such TSCA section 8(c) notices may be clustered in the same year. If EPA were limited to only two such rules or actions per year, it would prevent the agency from exercising its responsibility under the law. In addition, chemical disasters such as the Bhopal incident are obviously unpredictable. OPPT must reserve the capability to require records submission on an as-needed basis in order to gather relevant information related to such matters. TSCA section 8(c) allegation records are part of such related information.

3(e) General Guidelines

The record retention provisions of TSCA section 8(c) and 40 CFR part 717 exceed the Paperwork Reduction Guidelines (5 CFR 1320.6) in that they require respondents to maintain records other than health, medical, or tax records, for more than three years. TSCA section 8(c) authorizes EPA to require persons (i.e., manufacturers, processors, or distributors) to maintain records of adverse reactions to the health of employees for a period of 30 years from the date such reactions were first reported or known to the person maintaining the record. Any other record of such adverse reactions (e.g., to the environment, non-employees) is required to be retained for a period of 5 years. 40 CFR part 717 incorporates these record retention provisions authorized by TSCA.

3(f) Confidentiality

Respondents may assert a claim of business confidentiality with respect to all or part of an allegation submission. Such submissions will be handled in accordance with the provisions at 40 CFR art 2.

3(g) Sensitive Questions

This section is not applicable. The information does not include information of a sensitive nature.

4 THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondent NAICS Codes

Respondents affected by this collection activity are mainly NAICS categories 325 - Chemicals and Allied Products Manufacturers and 32411- Petroleum Refining.

4(b) Information Requested

(i) Data Items

Records maintained pursuant to 40 CFR Part 717 must consist of the following:

a. The original allegation as received.
b. An abstract of the allegation and other pertinent information as follows:

    1. The name and address of the plant site that received the allegation.
    2. The date the allegation was received at that site.
    3. The implicated substance, mixture, article, company process or operation, or site discharge.
    4. A description of the alleger (e.g., employee, neighbor), including age and sex, if ascertainable.
    5. A description of the alleged health effects, including explanation of how the effects became known and the route of exposure, if explained in the allegation.

c. The results of any self initiated investigation with respect to an allegation. (EPA does not require such investigation.)
d. Copies of any further required records relating to the allegation (e.g., record required under OSHA).

Each person who is required to keep records under this part must submit copies of those records to EPA as required by the Administrator or appropriate designee. EPA will notify those responsible for reporting by letter or will announce any such requirements by notice in the Federal Register.

(ii) Respondent Activities

Respondents must do two things: (1) maintain records of significant adverse reactions, and (2) submit copies of these allegation records when required by EPA.

Persons subject to the rule must record significant reactions alleged to have been caused by substances or mixtures that they manufacture, import, or process. These firms must establish a recordkeeping system for such allegations and monitor incoming complaints to determine if they meet the criteria for filing. Allegations that are filed must be retained for 30 years if they are employee related and for 5 years for all other types/sources of allegations.

Firms subject to the rule must keep their TSCA section 8(c) records at company headquarters or at a site central to their chemical operations. A multi-site company will usually require the responsible official at the individual plant site to forward potentially recordable TSCA section 8(c) allegations to a designated TSCA coordinator at their operations headquarters. Depending on the

size of the company, such allegations will be reviewed by a committee to determine if the allegations relate to the company's product, operations, or discharges. If so, the effects cited in the allegation are compared against the rule's definition and examples of "significant adverse reaction." If the allegation meets this test, it is recorded. The actual allegation record is to be comprised of an abstract of the allegation along with a record of any company initiated investigation and other pertinent documents. The rule does not require further investigation. EPA requires that allegations be filed so that they may be readily retrievable by "cause" of the reaction. EPA does not, however, require a specific form under this rule.

Firms subject to this rule must maintain an awareness of their reporting requirements. A reporting requirement will take the form of a letter directed to selected respondents or it will be a notice in the Federal Register. Respondents are responsible for monitoring the Federal Register for such notices. Whenever feasible, EPA will also notify those companies that can be identified with the production or processing of a substance or mixture in question. Respondents must then determine if they manufacture or process the chemical substance or mixture. If so, they must conduct a search of their TSCA section 8(c) files to determine if there are any relevant records of significant adverse reactions alleged to have been caused by the substance or mixture. If such records are present, they must make a photocopy of the abstract of the records and mail it with a cover letter to EPA. The company will note that they have submitted such records to EPA so that future duplicative reporting will not occur.

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

5(a) Agency Activities

OPPT is the primary user of the information gathered under the authority of this rule. In addition, information may be gathered for other EPA program offices/regions, and other Federal or state health or environmental agencies.

EPA personnel involved in monitoring recordkeeping, initiating reporting requests, and reviewing responses will be staff of the Chemical Information and Testing Branch (CITB) of the Chemical Control Division (CCD), the Director of CCD and the Director of the Office of Pollution Prevention and Toxics (OPPT). (For more information about the Chemical Testing Program, go to: http://www.epa.gov/opptintr/chemtest/index.htm.)

As OPPT receives submissions, they will be logged in and reviewed for confidentiality considerations. Copies of submissions will be made available to offices within OPPT that are assessing the substances of concern. Non-confidential versions of the submissions will be placed in a public docket and will be available for review by other government agencies and the public.

5(b) Collection Methodology and Management

EPA has not been able to identify a more efficient, less expensive or more flexible means of obtaining the required data. There is no new technology applicable to the collection of this information that would minimize the collection burden.

Any reporting requirements will have a minimum reporting schedule of forty-five days as outlined in the regulation. Neither the rule nor EPA requires the use of any particular methodology or technology for the retention or transmittal of TSCA section 8(c) records.

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

5(c) Small Entity Flexibility

Unlike section 8(a) of TSCA, Congress did not include a specific exemption of small businesses in TSCA section 8(c). This rule does not exempt small manufacturers or processors of chemicals from its provisions. This is due to EPA's belief that workers, plant neighbors and consumers may be adversely affected by products, emissions, etc., produced or created by firms of all sizes.

However, the TSCA section 8(c) rule was written to concentrate the recordkeeping and reporting burdens on those firms generally associated with the mainstream chemical industry. EPA specifically eliminated most distributors and effectively limits the number of processors subject to the rule. By doing so, EPA has eliminated a large number of small businesses from the purview of the rule without compromising its objectives.

5(d) Collection Schedule

If EPA publishes a reporting requirement relating to a chemical substance or mixture, or requests reporting by letter, then manufacturers and processors of such substance or mixture must submit a copy of relevant allegation records in their files. TSCA section 8(c) reporting requirements will be developed on an as-needed basis and will require only the submission of an abstract of the allegation record, which is generally one page in length, not the full allegation file.

6 ESTIMATING THE BURDEN AND COST OF THE COLLECTION

This section presents the estimates of the industry burden hours and costs associated with TSCA section 8(c) activities. The specific action required to comply with a TSCA section 8(c) reporting are assumed to include review of the Federal Register for notices regarding specific chemicals, recording pertinent information on allegations and storing such records, and reporting allegations to EPA when required.

6(a) Estimating Respondent Cost and Burden

Steps required to estimate burden associated with these activities include estimating the number of affected firms, the number of allegations, and number of reports. Unit estimates of burden for the various activities are also required. These unit estimates are then coupled with the number of allegations, reports, and notice reviews to develop total burden estimates for the industry.

Estimates of costs require estimation of wage rates for personnel who are expected to participate in TSCA section 8(c) activities. These, coupled with the burden hours associated with the various tasks, provide the basis for industry cost estimates.

Estimate of the Number of Firms

EPA investigated potential data sources of numbers of firms/plants and their employment and parent company sales to estimate the number of firms subject to TSCA section 8(c) requirements. EPA concluded that a Dun and Bradstreet database, Dun's Market Identifiers, (DMI), provided the most complete and timely data.[1] The DMI data base contains employment data for each of a firm's plants as well as parent firm sales data.

The DMI database was analyzed in detail for the previous ICRs[2, 3]. The first step in the analysis was the creation of a database containing records for each plant site engaged in manufacturing or processing activities described by NAICS code 325 (Chemical and Allied Products) or NAICS code 32411 (Petroleum Refining and Related Industries). EPA chose those NAICS codes to define the firms who manufacture and process chemical substances.

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[1] USEPA. Comparison of Data Sources for Characterizing Manufacturers and Processors, Draft Report, Prepared by Centaur Associates, Inc. under EPA contract No. 68-02-3980, Washington, DC, November 6, 1986.

[2] Ed Coe, Economic Impact Analysis of the TSCA Section 8(c) Significant Adverse Reaction Recordkeeping and Reporting Rule, OTS/ETD/RIB, prepared by Kearney/Centaur, EPA Contract No. 68-02-4297, Alexandria, VA, May 1989.

[3] Abt Associates, Inc. "ICR Burden Estimates: SIC 28 and SIC 2911." Memorandum to Wendy Hoffman, RIB/OPPT/EPA, September 22, 1995.

From the DMI database, EPA also developed a distribution of firms by annual sales. Consistent with the small business definition for information collection rules under section 8(a) of TSCA, firms with annual sales of less than $40 million were classified as small firms, while those owned by companies with sales of greater than $40 million were classified as large firms (CFR 704.3).

The number of employees for these firms was calculated using only employment figures from those plants that fall under NAICS 325 or NAICS 32411. Many firms or parent companies have facilities that do not engage in chemical activities. Because these employees are not expected to make allegations regarding substances at the chemical plants, they have not been included in the estimated number of employees. The estimated average number of employees was further broken down between small and large firms.

The following table lists the number of firms and employees by size category identified by DMI data analysis.

Table 1. Numbers of Firms and Employees by Firm Size

Firm Size	Number of Firms	Number of Employees
Small	10,957	47 (average)
Large	1,330	435 (average)
Total	12,287	1,000,000+ (estimate)

Estimate of the Number of Allegations of Significant Adverse Health Reactions

The total number of allegations was based upon the average number of employees per firm and number of firms in each size category, multiplied by a standard annual allegation rate per employee.

The Agency received numerous public comments following the issuance of the initial TSCA section 8(c) proposal, including many comments about the Agency's estimate of the number of allegations. In response to these comments, EPA contacted a number of firms to develop a consensus estimate. According to the 1983 ICR, the consensus opinion of the firms contacted was that recordable TSCA section 8(c) allegations are likely to made by 0.5 percent of the workforce.

For the 1983 ICR, EPA assumed that the allegation rate made by the general public would be about one-third the employee allegation rate. Based on the average number of employees per firm, the estimated annual per firm allegations for each of the firm size categories is presented below. For example, for small firms, the calculation is 47 employees x 0.005 allegations per employee = 0.24 average annual number of employee allegations per firm.

Table 2. Estimated Number of Allegations

Firm Size	Number of Employees	Average Annual # of Allegations		
		Employee	Public	Total
Small	47	0.24	0.08	0.32
Large	435	2.20	0.73	2.93

For the 10,957 small firms and 1,330 large firms, the weighted average annual number of allegations per firm is 0.602 ([(10,957*.32) + (1,330*2.93) / 12,287].

Estimate of the Number of Reports

For previous TSCA section 8(c) ICR analyses, EPA estimated that it would issue a maximum of six industry-wide notices per year requiring reporting on a maximum of 100 chemicals. The Agency estimated that an average of approximately five firms per chemical would actually be subject to reporting, resulting in the submission of an industry-wide total of 500 reports. However, to date, only a very limited amount of reporting has been required under TSCA section 8(c), and this is not expected to change during the period covered by this ICR[4] . To date, only two reporting rules have been issued under TSCA section 8(c)[5] . These rules covered two chemicals and two chemical categories. A total of 31 reports have been received under TSCA section 8(c)[6] [7]. This represents an average of only about 1.75 reports per year since the rule was promulgated in 1983.

Estimated Wage Rates

The basic methodology for estimating the industry wage rates used in this analysis was developed for the Comprehensive Assessment Information Rule (CAIR).[8] It is the same methodology

[4] Abt Associates, Inc. "ICR Burden Estimates: SIC 28 and SIC 2911." Memorandum to Wendy Hoffman, RIB/OPPT/EPA, September 22, 1995.

[5] USEPA, Chemical on Reporting Rules Database (CORR), CCD and CSB, June 30, 1990, and EPA, Chemical on Reporting Rules Database (CORR): Update, CCD and CSB, October 31, 1992.

[6] USEPA, [Untitled Computer Printout], IMD, June 3, 1992.

[7] Sherlock, Scott, Information Management Division. Phone conversation with Wendy Hoffman based upon TSCA Reports to Congress for EPA Fiscal Years 1992-93, August 1994.

[8] USEPA, "Response times and Labor Costs Final Data Element List Comprehensive Assessment Information Rule," prepared by Centaur Associates, Inc. under Contract No. 68-02-3980, Washington, D.C., April 30, 1985, pp. 94-106.

used in the previous ICR, with some refinements. [9]

Wage data used to develop the basic industry wage rates are derived from the U.S. Department of Labor, Bureau of Labor Statistics (BLS), Employment Cost Index 2000 for all goods-producing private industries. The annual salary estimates were adjusted to 2000 dollars using the BLS Employment Cost Index (ECI) for white-collar occupations for all private industries.

An overhead rate of 17 percent was applied to all wages based on information provided by the chemical industry and chemical industry trade associations. Benefit rates were applied to wages as follows: managerial, 41 percent; technical, 43 percent; and clerical, 44 percent. Total loading factors are 58 percent for managerial labor, 60 percent for technical labor, and 61 percent for clerical labor.

All loaded annual salaries are divided by 2,080 hours, the average number of hours worked per year by a full-time employee, to yield a loaded hourly wage for each labor category. The previous and updated hourly wage and load rates (overhead and benefits) are presented below.

Table 4. Hourly Wage and Load Rates

Labor Category	Previous ICR Rates (Dec. 1998)	Updated Rates (2000)	2000 Load Rates
Managerial	$ 90.65	$95.55	58%
Technical	$ 67.12	$65.96	60%
Clerical	$ 26.79	$27.37	61%

Unit Burden Hours and Costs

Unit costs for each of the burdens associated with the TSCA section 8(c) requirements are calculated in this section using the wage rates presented above (see Table 5).

i.. Unit Recordkeeping Burden and Costs

Based on the original TSCA section 8(c) analysis, EPA estimates that a firm's TSCA section 8(c) coordinator will spend 2 to 3 hours to determine the status of an allegation.[10] For the purposes of this analysis, it is assumed that 3 hours are needed. This level of effort will occur for all allegations received. If the allegation is found to be recordable, the coordinator completes a form, has it typed

[9] See Lehman, Timothy. "Methodology for Section 8(a) Cost and Burden Analysis," May 1995.

[10] EPA, Economic Analysis of TSCA Section 8(c) Significant Adverse Reaction Recordkeeping Rule, OTS/ETD/RIB, January 1983.

and checks it for accuracy. This will require 0.5 hours of clerical time and an additional 0.5 hours of managerial time. Assuming that all allegations are recordable, a total of 4 hours are expended per allegation (3.5 hours managerial plus 0.5 hours clerical). Storage costs for the allegations are believed to be negligible.

ii. Unit Reporting Burden and Costs

Based on the original TSCA section 8(c) analysis, EPA estimates that a management level company official will spend one hour reviewing the Federal Register notice or letter from EPA to determine whether the company manufactures or processes substances subject to the reporting requirement.

Technical personnel would then spend an estimated two hours conducting a search of the company's TSCA section 8(c) files for any relevant allegation records. Once the file search is complete, EPA estimates that a managerial employee would spend two hours preparing a transmittal letter and other explanatory material to accompany the allegation records. An upper level management official would spend an additional two hours reviewing these materials. One hour of clerical labor would be required to prepare and mail the response. A total of eight hours is expended per report (five managerial hours, two technical hours and one clerical hour) (See Table 5).

iii. Unit Reviewing Burden and Cost

Based on the original TSCA section 8(c) analysis, EPA estimates that 0.25 hour of managerial labor would be required to review each Federal Register notice (see Table 5).

Table 5. Unit Respondent Burden and Cost Estimates

Activity	Clerical Hours	Technical Hours	Manager Hours	Total Hours	Total Cost
Recordkeeping, per allegation	0.5		3.5	4.0	$348.11
Reporting, per report	1.0	2.0	5.0	8.0	$637.04
Federal Register Notice review, per Notice			0.25	0.25	$ 23.89
Total unit burden per respondent	1.5	2.0	8.75	12.25	$1,009.04

Total Industry Costs and Burden

The total annual cost to the industry have been calculated for small firms with annual sales less than $40 million, and for large firms with annual sales of $40 million or higher.

i. Total Recordkeeping Costs and Burden

The unit cost for recordkeeping is multiplied by the average annual number of allegations per firm. This figure is then multiplied by the number of firms for each size category. The totals for each category are also summed. These results are presented in the table below.

Table 7. Total Industry Recordkeeping Costs

Firm Size	# of Firms	Aver. # of Allegations per Firm	Average Cost per Allegation	Total Cost
Small	10,957	0.32	$348.11	$1,220,557
Large	1,330	2.93	$348.11	$1,356,550
Total	12,287			$2,577,107

Table 8. Total Industry Recordkeeping Burden

# of Firms	Weighted Average Annual # of Allegations	Hours per Allegation	Total Burden Hours
12,287	0.602	4	29,587

Total annual burden hours is 29,587 hours (the product of the three items in the table).

ii. Total Reporting Burden and Cost

The EPA assumes that 1.75 TSCA section 8(c) reports will be required annually. The cost of submitting these reports is determined by multiplying the annual number of reports by the unit reporting cost.

Table 9. Industry Reporting Cost

Annual # of Reports	Cost per Report	Total Cost
1.75	$637.04	$1,114.82

Total burden hours are 1.75 reports x 8 hours/report (from Unit Reporting Burden and Costs) = 14 hours.

iii. Federal Register Notice Review Burden and Cost

Historically, the Agency has published an average of only 0.11 notices each year. Therefore, each firm would require only slightly more than two minutes, or 0.03 hour of managerial labor**,** per year for notice review. The total cost to industry of reviewing the Federal Register notices is estimated below.

Table 10. Federal Register Notice Review Cost

Firm Size	# of Firms	Cost per Firm	Total Review Cost
Small	10,957	$2.87	$31,447
Large	1,330	$2.87	$ 3,817
Total	12,287	$2.87	$35,264

Total Federal Register notice review cost is $35,264

Table 11. Federal Register Notice Review Burden

# of Firms	# Notices/Firm	Hours/Notice	Total Hours
12,287	0.11	0.25	338

Total burden is estimated to be 338 hours.

Table 12. Annual Burden to Industry

Collection Activity	Hours per Respondent	Respondents per Year	Hours per Year
Recordkeeping	4.00	7,397(1)	29,587
Reporting	8.00	1.75	14
Notice Review	0.25	1,351(2)	338
Annual Burden Hours	12.25		29,939

(1) Calculated as 12,287 firms subject to Recordkeeping x 0.602 weighted average number of allegations per firm each year = 7,397.
(2) Historically, EPA has issued an average of only 0.11 notices per year. Therefore, on an average annual basis, 1,351 of the estimated total of 12,287 firms subject to TSCA section 8(c) would conduct notice reviews.

iv. Total Industry Burden and Costs

The total economic burden on the regulated community imposed by TSCA section 8(c) is the sum of the three components identified above (recordkeeping, reporting and Federal Register notice review. These costs, shown in the table below, would be incurred in each of the three years covered by this ICR.

Table 13. Total Industry Costs and Burden

Collection Activity	Total Annual Cost	Total Annual Burden
Recordkeeping	$2,577,107	29,587
Reporting	$1,115	14
Federal Register Review	$35,264	338
Total	$2,613,486	29,939

Regulatory Flexibility Analysis

TSCA section 8(c) does not include a specific exemption of small businesses. The costs of TSCA section 8(c) for small businesses (annual parent company sales of less than $40 million), which were calculated in the previous section of this analysis, are listed below.

Table 14. Average Total Costs per Small Firm

Type of Cost	Cost
Avg. recordkeeping costs	$132.28[(1)]
Reporting costs per firm	$ 0.09[(2)]
Federal Register notice review costs per firm	$ 2.87[(3)]
Avg. total cost per firm	$135.24
Avg. sales per small firm	$12 million

(1) Calculated as the average cost per allegation times the average number of allegations per year ($348.11 x 0.38 = $132.28).
(2) Calculated as the total industry reporting costs divided by the total number of firms ($1,115/12,2287 = $0.09). This cost is independent of firm size.
(3) Calculated as the total industry review costs divided by the total number of firms ($35,264/12,2287 = $2.87). This cost is independent of firm size.

The average recordkeeping, reporting and review costs to small firms are less than 0.001 percent of their annual sales ($112.12/$12 million). Therefore these requirements do not appear to

impose a significant additional burden on small firms.

6(c) Estimating Agency Burden and Cost

Annual costs to the EPA for TSCA section 8(c) for each of the three years covered by this ICR are estimated to be $41,812. The cost to the EPA for TSCA section 8(c) was calculated from cost estimates provided in the 1986 and 1989 ICRs. These costs were adjusted based on the 2001 GS-Schedule.

Annual costs to EPA associated with the recordkeeping portion of the rule include general administration of the rule, education and outreach activities, and compliance monitoring. Costs associated with reporting involve preparation of reporting notices, Federal Register printing costs, document control, and document review. Annual costs to EPA were derived based on an analysis of the cost of performing these various activities. The various elements involved in calculating EPA costs are described in more detail below.

- Each year, general administration of the rule involves approximately one-tenth of a staff specialist's time plus approximately one weeks time each for two management personnel at the branch, division and OPPT Office Director's level.

- Education and outreach activities will include ongoing rule support by the Environmental Assistance Division (EAD) in OPPT.

- Compliance monitoring costs primarily involve the costs of the TSCA section 8(c) portion of inspection carried out by regional personnel and other administrative costs for headquarters personnel to target and review results of such inspections.

- EPA previously estimated that a maximum of six industry-wide reporting notices involving a total of 100 chemicals would be developed each year. However, to date only two notices involving two chemicals and two chemical categories have been issued. EPA also estimated that the notices would generate a maximum 500 reports per year. To date, however, a total of only 30 reports have been received. Based on historical data, over the life of the rule an average of only 0.11 notices have been issued per year and an average of only 1.75 reports received. The Agency believes that reporting activity under TSCA section 8(c) will remain at this low level during the period covered by the ICR. Therefore, EPA costs associated with reporting have been adjusted to reflect this large decrease in the level of expected activity. Labor involved in developing the reporting notices will require several decision meetings and either the development of letters, separate Federal Register notices, or the insertion of brief boilerplate segments in other rule preambles.

- Time will be required to process submissions based upon such reporting requirements and to review them for confidentiality considerations.

- The Federal Register notices will be reviewed by the office directly requesting the information as well as by the Chemical Testing and Information Branch (CTIB). Information in the submission will be coded into a computer data base by CTIB staff and non-confidential versions of the submissions records will be retained by CTIB as well as by the OPPT public files.

EPA will incur costs related to the above activities in each of the three years covered by the ICR. The following table provides the projected annual costs to the government for activities related to TSCA section 8(c). These costs and their associated burden are presented in Table 15.

Table 15. Annual Burden and Cost to the Federal Government

Activity	**Hourly Wage**	**Burden Hours**	**Annual Cost**
Administrative maintenance	$48.62/$67.59 (1)	288.0	$15,521
Education/Outreach	$40.89 (2)	240.0	$9,814
Compliance monitoring	$40.89 (2)	400.0	$16,356
Develop reporting notices	$40.89 (2)	1.1	$45
Document control functions	$40.89 (2)	0.75	$31
Notice review, referral and data entry	$40.89 (2)	1.1	$45
Totals		931	$41,812

(1) This activity is estimated to require 208 hours at the GS-13 level and 80 hours at the GS-15 level. The base wage for a GS-13, Step 1 is $63,211, plus 60 percent overhead and benefits of $37,927, for a total of $101,138. Dividing this by the number of hours in a work year, 2080, yields an hourly wage rate of $48.62. The base wage for a GS-15, Step 1 is $87,864, plus overhead and benefits of $52,718, for a total of $140,582. Dividing this by the number of hours in a work year, 2080, yields an hourly wage rate of $67.59.
(2) The estimated total cost to the EPA of an average full time employee (FTE) at a GS 12, Step 1 level for 2001 is $85,050. This includes a base wage of $53,156, and 60 percent for overhead and benefits, or $31,894. Dividing this by the number of hours in a work year, 2080, yields an hourly wage rate of $40.89.

6(e) Reasons for Change in Burden

There is a decrease of 340 hours (from 30,279 hours to 29,939 hours) in the total estimated respondent burden compared with that identified in the information collection request most recently approved by OMB. This decrease primarily reflects a reduced estimated burden for respondents in reviewing Federal Register notices. Based on experience over the life of the rule, the average annual number of notices the Agency is expected to issue fell from an estimated 0.22 in the most recent ICR, to 0.11 notices per year estimated in this renewal. An additional small reduction is attributable to reduced industry reporting requirements, which have fallen from an estimated two reports per year (31 reports total/15 years of the rule), to 1.7 reports per year, over the 18 years of the rule (31 reports/18 years). None of the unit burden estimates have been changed since the previous ICR renewal, nor do these changes reflect any actual changes in the collection activity.

6(f) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0034, is estimated to range between 0.25 hours and 8.0 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 regulations, after initial display in the final rule, are listed in 40 CFR part 9.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (Mail Code 2822), 1200 Pennsylvania Ave. N.W., Washington, D.C. 20460. Include the OMB control number in any correspondence, but do not submit the requested information to this address. The requested information should be submitted in accordance with the instructions accompanying the form, or as specified in the corresponding regulation.

ATTACHMENT 1

Toxic Substances Control Act
Section 8(c)

15 USC 2607(c)

US Code as of: 01/23/00

Sec. 2607. Reporting and retention of information

* * *

(c) Records

Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

ATTACHMENT 2

Records and Reports of Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment

40 CFR 717

Code of Federal Regulations
Revised as of July 1, 2000

TITLE 40--PROTECTION OF ENVIRONMENT

CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY (CONTINUED)

PART 717--RECORDS AND REPORTS OF ALLEGATIONS THAT CHEMICAL SUBSTANCES CAUSE SIGNIFICANT ADVERSE REACTIONS TO HEALTH OR THE ENVIRONMENT--Table of Contents

Section 8 (c) of the Toxic Substances Control Act (TSCA) requires manufacturers, processors, and distributors of chemical substances and mixtures:

(a) To keep "records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture."

(b) To "permit inspection and submit copies of such records," upon request of any designated representative of the Administrator. This rule implements section 8(c) of TSCA. It describes the records to be kept and prescribes the conditions under which certain firms must submit or make the records available to a duly designated representative of the Administrator.

Sec. 717.3 Definitions.

The definitions set forth in section 3 of TSCA and the following definitions apply to this part:

(a) Allegation means a statement, made without formal proof or regard for evidence, that a chemical substance or mixture has caused a significant adverse reaction to health or the environment.

(b) Firm or company means any person, that is subject to this part, as defined in Sec. 717.5.

(c)(1) Known human effects means a commonly recognized human health effect of a particular substance or mixture as described either in:

(i) Scientific articles or publications abstracted in standard reference sources.

(ii) The firm's product labeling or material safety data sheets (MSDS).

(2) However, an effect is not a "known human effect" if it:

(i) Was a significantly more severe toxic effect than previously described.

(ii) Was a manifestation of a toxic effect after a significantly shorter exposure period or lower exposure level than described.

(iii) Was a manifestation of a toxic effect by an exposure route different from that described.

(d) Manufacture or process means to manufacture or process for commercial purposes.

(e)(1) Manufacture for commercial purposes means to import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes, among other things, such "manufacture" of any amount of a chemical substance or mixture:

(i) For distribution in commerce, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development, or as an intermediate.

(2) Manufacture for commercial purposes also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substances or mixture and impurities that remain in that substance or mixture. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.

(f) Person includes any individual, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, and any department, agency, or instrumentally of the Federal Government.

(g) Process for commercial purposes means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included. If a chemical substance or mixture containing impurities is processed for commercial purposes, then those impurities are also processed for commercial purposes.

(h) Retailer means a person who distributes in commerce a chemical substance, mixture, or article to ultimate purchasers who are not commercial entities.

(i) Significant adverse reactions are reactions that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment.

(j) Site means a contiguous property unit. Property divided only by a public right-of-way is considered one site. There may be multiple manufacturing, processing, or distribution activities occurring within a single site.

(k) Substance means a chemical substance or mixture unless otherwise indicated.

Sec. 717.5 Persons subject to this part.

(a) Manufacturers. (1) All manufacturers of chemical substances are subject to this part except as provided in Sec. 717.7(a). If manufacture of a chemical substance occurs at any site owned or controlled by a firm then that firm is subject to this part.

(2) A manufacturer must collect:

(i) Any allegation identifying a chemical substance it manufactures and any allegation identifying the operations in the manufacture of any chemical substance it manufactures.

(ii) Any allegation identifying any of its own processing or distribution in commerce activities with respect to any chemical substance it manufactures.

(iii) Any allegation identifying emissions, effluents, or other discharges from activities described in this paragraph.

(iv) Any allegation identifying a substance produced coincidentally during processing, use, storage or disposal of a chemical substance it manufactures.

(3) For the purpose of this part, owned or controlled means ownership of 50 percent or more of a firm's voting stock or other equity rights, or the power to control the management and policies of that firm.

(b) Processors. (1) A person who processes chemical substances, who is not also a

manufacturer of those chemical substances, is subject to this part if (i) the person processes chemical substances to produce mixtures, or (ii) the person repackages chemical substances or mixtures.

(2) As a processor subject to this part such person must collect:

(i) Any allegation identifying any mixture it produces and distributes in commerce and any allegation identifying any chemical substance or mixture it repackages and distributes in commerce.

(ii) Any allegation identifying any of its own further processing or distribution in commerce activities of the products described in paragraph (b)(2)(i) of this section.

(iii) Any allegation identifying emissions, effluents, or other discharges from activities described in this paragraph.

(iv) Any allegation identifying a substance produced coincidentally during the processing, use, storage or disposal of the products described in paragraph (b)(2)(i) of this section.

(c) SIC code. SIC codes applicable to this part are published in Standard Industrial Classification Manual--1972 and the 1977 Supplement. This manual and supplement may be obtained from the U.S. Government Printing Office, Washington, D.C. 20402--stock number 4101-0006 and stock number 003-005-0170-0 respectively. Where there is a conflict between the SIC code use of a term and the definition of that term in this part, the definition in this part applies.

[48 FR 38187, Aug 22, 1983, as amended at 50 FR 46769, Nov. 13, 1985]

Sec. 717.7 Persons not subject to this part.

(a) Manufacturers. (1) Persons or site activities are exempt from this part if the means by which they manufacture a chemical substance solely involves mining or other solely extractive functions, e.g., those companies or sites within a company whose sole function is to mine mineral ores, extract petroleum or natural gas, quarry non-metallic minerals (including extraction of salts from seawater or brines), mine or otherwise extract coal, or separate gases from the atmosphere. This exemption may include, but is not necessarily limited to, firms engaged in activities as described in SIC Division B--Mining and SIC Code 2813--Industrial Gases.

(2) A person is not subject to this part if the chemical substances that person causes to be produced are limited to:

(i) Chemical substances that result from chemical reactions that occur incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(ii) Chemical substances that result from chemical reactions that occur incidental to storage or disposal of other chemical substances, mixtures, or articles.

(iii) Chemical substances that result from chemical reactions that occur upon end use of other chemical substances, mixtures, or articles such as adhesives, paints, miscellaneous cleaners or other housekeeping products, fuel additives, water softening and treatment agents, photographic films, batteries, matches, or safety flares, and that are not themselves manufactured or imported for distribution in commerce for use as chemical intermediates.

(iv) Chemical substances that result from chemical reactions that occur upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints, or other chemical substance formed during the manufacture of an article destined for the

marketplace without further chemical change of the chemical substance.

(v) Chemical substances that result from chemical reactions that occur when (A) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation-inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH adjuster, sequestrant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (B) a chemical substance, which is intended solely to impart a specific physicochemical characteristic, functions as intended.

(b) [Reserved]

(c) Sole distributors. A person solely engaged in the distribution of chemical substances is exempt from this part, unless such person is also a manufacturer or processor subject to this part. For example, a “distributor” who repackages chemical substances or mixtures is considered to be a processor and, thus, is not a sole distributor. Sole distributors may include, but are not limited to, those firms that distribute chemical substances as described in the wholesale trade SIC codes 5161--Chemicals and Allied Products, 5171--Petroleum Bulk Stations and Terminals, and 5172--Petroleum and Petroleum Products Wholesalers, Except Bulk Stations and Terminals.

(d) Retailers. A person who is a retailer is exempt from this part unless such person is also a manufacturer or a processor subject to this part.

[48 FR 38187, Aug 22, 1983, as amended at 50 FR 46770, Nov. 13, 1985]

Sec. 717.10 Allegations subject to this part.

(a) Allegations subject to this part are those allegations received on or after November 21, 1983 by persons subject to this part.

(b) Allegations subject to this part are those that:

(1) Are submitted either in writing and are signed by the alleger, or are submitted orally. In the case of an oral allegation, the firm must transcribe the allegation into written form, or it must inform the alleger that such allegation may be subject to this part and request that the alleger submit such allegation to the firm in writing and signed.

(2) Implicate a substance that caused the stated significant adverse reaction by one of the following:

(i) Naming the specific substance.

(ii) Naming a mixture that contains a specific substance.

(iii) Naming an article that contains a specific substance.

(iv) Naming a company process or operation in which substances are involved.

(v) Identifying an effluent, emission, or other discharge from a site of manufacturing, processing or distribution of a substance.

(c) Allegations subject to this part may be made to a firm by any person, such as an employee of the firm, individual consumer, a neighbor of the firm's plant, another firm on behalf of its employees or an organization on behalf of its members.

(d) EPA intends that firms should, to the maximum practical extent, provide allegers with information regarding the ultimate disposition of their allegations. For example, firms could provide a brief notice to the alleger stating that a record was created under this part based upon their allegation, or that a record was not created and briefly explain the reasons why not.

Sec. 717.12 Significant adverse reactions that must be recorded.

(a) Except as provided in paragraph (b) of this section, significant adverse reactions to human health that must be recorded include but are not limited to:

(1) Long-lasting or irreversible damage, such as cancer or birth defects.

(2) Partial or complete impairment of bodily functions, such as reproductive disorders, neurological disorders or blood disorders.

(3) An impairment of normal activities experienced by all or most of the persons exposed at one time.

(4) An impairment of normal activities which is experienced each time an individual is exposed.

(b) Firms are not required to record significant adverse reactions that are known human effects as defined in Sec. 717.3(c).

(c) Except as provided in paragraph (d) of this section, significant adverse reactions to the environment that must be recorded, even if restricted to the environs of a plant or disposal site, include but are not limited to:

(1) Gradual or sudden changes in the composition of animal life or plant life, including fungal or microbial organisms, in an area.

(2) Abnormal number of deaths of organisms (e.g., fish kills).

(3) Reduction of the reproductive success or the vigor of a species.

(4) Reduction in agricultural productivity, whether crops or livestock.

(5) Alterations in the behavior or distribution of a species.

(6) Long lasting or irreversible contamination of components of the physical environment, especially in the case of ground water, and surface water and soil resources that have limited self-cleansing capability.

(d) Firms are not required to record a significant adverse reaction to the environment if the alleged cause of that significant adverse reaction can be directly attributable to an accidental spill or other accidental discharge, emission exceeding permitted limits, or other incident of environmental contamination that has been reported to the Federal Government under any applicable authority.

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984; 58 FR 34204, June 23, 1993]

Sec. 717.15 Recordkeeping requirements.

(a) Establishment and location of records. A firm subject to this part shall establish and maintain records of significant adverse reactions alleged to have been caused by chemical substances or mixtures manufactured or processed by the firm. Such records shall be kept at the firm's headquarters or at any other appropriate location central to the firm's chemical operations.

(b) Content of records. The record shall consist of the following:

(1) The original allegation as received.

(2) An abstract of the allegation and other pertinent information as follows:

(i) The name and address of the plant site which received the allegation.

(ii) The date the allegation was received at that site.

(iii) The implicated substance, mixture, article, company process or operation, or site discharge.

(iv) A description of the alleger (e.g., “company employee,” “individual consumer,” “plant

neighbor”). If the allegation involves a health effect, the sex and year of birth of the individual should be recorded, if ascertainable.

(v) A description of the alleged health effect(s). The description must relate how the effect(s) became known and the route of exposure, if explained in the allegation.

(vi) A description of the nature of the alleged environmental effect(s), identifying the affected plant and/or animal species, or contaminated portion of the physical environment.

(3) The results of any self-initiated investigation with respect to an allegation. (EPA does not require persons subject to this part to investigate allegations received, and no provision of this part shall be construed to imply that EPA recommends, encourages or requires such investigation.)

(4) Copies of any further required records or reports relating to the allegation. For example, if an employee allegation results in a requirement for the firm to record the case on Occupational Safety and Health Form 101 or appropriate substitute (see 29 CFR part 1904 for requirements under the Occupational Safety and Health Act of 1970), a copy of that OSHA record must be included in the allegation record.

(c) File structure. Records must be retrievable by the alleged cause of the significant adverse reaction, which cause may be one of the following:

(1) A specific chemical identity.

(2) A mixture.

(3) An article.

(4) A company process or operation.

(5) A site emission, effluent or other discharge.

(d) Retention period. Records of significant adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. This provision requires persons subject to this part to retain for 30 years an employee health related allegation, arising from any employment related exposure, whether or not such allegation was submitted by or on the behalf of that recordkeeper's own employee. Any other record of significant adverse reactions shall be maintained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record.

(e) Transfer of records. (1) If a firm ceases to do business, the successor must receive and keep all the records that must be kept under this part.

(2) If a firm ceases to do business and there is no successor to receive and keep the records for the prescribed period, these records must be transmitted to EPA. See Sec. 717.17(c) for the address to which such records must be sent.

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984; 58 FR 34204, June 23, 1993]

Sec. 717.17 Inspection and reporting requirements.

(a) Inspection. Firms must make records of allegations available for inspection by any duly designated representative of the Administrator.

(b) Reporting. Each person who is required to keep records under this part must submit copies of those records to the Agency as required by the EPA Administrator or appropriate designee. EPA will notify those responsible for reporting by letter or will announce any such requirements

for submitting copies of records by a notice in the Federal Register. Such letter or notice will be signed by the Administrator or appropriate designee, and will specify which records or portion of records must be submitted. The reporting period will be specified by the letter or notice but in no case will such reporting period be less than 45 days from the date of the letter or the effective date of the notice.

(c) How to report. When required to report, firms must submit copies of records (preferably by certified mail) to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 401 M St., SW., Washington, DC., 20460, ATTN: 8(c) Allegations.

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984; 52 FR 20084, May 29, 1987; 53 FR 12523, Apr. 15, 1988; 58 FR 34204, June 23, 1993; 60 FR 34464, July 3, 1995]

Sec. 717.19 Confidentiality.

(a) Any person submitting copies of records may assert a business confidentiality claim covering all or part of the submitted information. Any information covered by a claim will be disclosed by EPA only as provided in procedures set forth at part 2 of this title.

(b) If no claim accompanies a document at the time it is submitted to EPA, the document will be placed in an open file available to the public without further notice to the respondent.

(c) To asset a claim of confidentiality for information contained in a submitted record, the respondent must submit two copies of the document.

(1) One copy must be complete. In that copy, the respondent must indicate what information, if any, is claimed as confidential by marking the specific information on each page with a label such as “confidential,” “proprietary,” or “trade secret” and briefly state the basis of the claim.

(2) If some information is claimed as confidential, the respondent must submit a second copy of the record. The second copy must be complete, except that all information claimed as confidential in the first copy must be deleted.

(3) The first copy will be for internal use by EPA. The second copy will be placed in an open file to be available to the public.

(4) Failure to furnish a second copy when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent will be given 30 days from the date of receipt of notification to submit the required second copy. If the respondent fails to submit the second copy within the 30 days, EPA will place the first copy in the public file.

ATTACHMENT 3

Comment Received from American Chemistry Council during the Public Notice and Comment Period, and EPA's Response

[Verbatim extract from comment, letter from American Chemistry Council, dated June 14, 2002]

Re: Request for Comment on Information Collection Request (ICR): TSCA Section 8(c) Health and Safety Data Reporting Rule (EPA ICR No. 1031.07, OMB No. 2070-0017, Docket Control No. OPPT 2002-0002, AR No. AR-239) (67 FR 18604, April 16, 2002)

Dear Sir or Madam:

The American Chemistry Council is pleased to submit these comments on EPA's Information Collection Request (ICR): TSCA Section 8(c) Health and Safety Data Reporting Rule. The Council believes that EPA has not appropriately considered all the factors involved with TSCA Section 8(c) reporting requirements and suggests that a reanalysis of the burden be considered. The current estimate included in the ICR is too low and as a consequence, the cumulative regulatory impact of TSCA on industry is greater than indicated in EPA's documentation.

The American Chemistry Council represents the leading companies engaged in the business of chemistry. Council members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. The Council is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $460 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other business sector.

The American Chemistry Council's member companies manufacture, process and distribute chemical substances regulated under the Toxic Substances Control Act (TSCA). As such, they are obligated to adhere to TSCA 8(c), which requires that companies maintain records of significant adverse reactions to health or the environment alleged to have been caused by the companies' substances. Allegations of adverse reactions to the health of employees must be kept for thirty years and all other allegations must be kept for five years. Consequently, the Council's members are directly affected by and have a significant interest in this ICR.

According to the Federal Register notice,

..."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."

Clearly, reporting burden is more than simply sending in a written report to the Agency. It includes ensuring staff understanding of what is required of them under the regulation, it includes storage of records associated with submitted reports, and it includes development of procedures to collect the needed information. Most importantly, it must include a means to affirmatively implement the regulatory requirements. Nonetheless, EPA's calculation of burden for this ICR focuses solely on the number of allegations related to TSCA 8(c). The burden estimate does not include any consideration of time needed for internal training of personnel, for developing reporting procedures, or for storage and maintenance of records.

To ensure that TSCA 8(c) requirements are fully met, companies need to spend significant amounts of time in training staff. Proper training is essential to ensure that TSCA 8(c) allegations are appropriately documented and maintained. Training must occur for all staff that would have the opportunity to address potential allegations. This includes plant managers and medical staff, as well as customer service and sales personnel. Some companies extend this training to non-plant staff as well. By not including staff training as a burden in its ICR estimate, EPA seriously underestimated the overall cost associated with TSCA 8(c).

Furthermore, despite the fact that records are required to maintained (*sic*) for five to thirty years, depending on the type of allegation, EPA does not include any estimates related to burden. In fact, the Supporting Statement indicates, "...storage costs for the allegations are believed to be negligible." Given the extremely long storage requirements for allegations, EPA should devote more analysis to the burden presented by this requirement. Accurately maintaining and securing files that are subject to EPA inspection and compliance verification requires a significant amount of time and resources – particularly when the length of retention time can be measured in decades. EPA's dismissal of this burden is inappropriate.

Finally, EPA's calculation of managerial burden appears to be generated using a "single-actor" model. The Supporting Statement outlines costs associated with one person being responsible for reading a Federal Register notice concerning a TSCA 8(c) rule. However, in medium to large companies, there will be several such managers – all reading the same Federal Register report and going through the same motions outlined with the single manager. EPA's cost estimate neglects to address the increased managerial burden for larger companies.

In this and all its ICRs, EPA should strive to provide OMB with information that reflects actual industry practices and associated costs. In the TSCA 8(c) report, the total burden to industry is underestimated. Before the ICR is presented to OMB, EPA should reanalyze the factors associated with TSCA 8(c) reporting and appropriately adjust the burden estimate. By doing so, EPA will provide OMB and the public with a more accurate assessment of the cumulative burden of TSCA regulations.

If you have any questions on the Council's concerns, please fell free to contact Kathleen Roberts at 703/741-5222.

Sincerely,
/s/
Larry W. Rampy
Co-Leader
Product Stewardship Team

[EPA analysis and response]

August 28, 2002

MEMORANDUM

SUBJECT: Response to Comment Received on the TSCA Section 8(c) Information Collection Request Renewal (1031)

FROM: Charles M. Auer, Director
Chemical Control Division (7405)

TO: Angela Hoffman, Director
Regulatory Coordination Staff (7101)

BACKGROUND

Section 8(c) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2607(c), P.L. 94-469 requires that any person who manufactures, processes, or distributes in commerce any chemical substance or mixture must keep records of significant adverse reactions to health or the environment, as prescribed by 40 CFR 717, alleged to have been caused by the substance or mixture. TSCA section 8(c) requires that allegations of significant adverse reactions to the health of employees be kept for thirty years, and all other allegations be kept for five years. The rule also prescribes the conditions under which a firm must submit or make the records available to a duly designated representative of the Administrator.

Only the American Chemistry Council (ACC) responded to the **Federal Register** notice (67 FR 18604, April 16, 2002) announcing EPA's intent to submit the ICR renewal for TSCA section 8(c) to OMB. ACC's comments and EPA's responses are contained herein.

COMMENTS/RESPONSES

1. In the opening paragraph, the ACC states "The current estimate included in the ICR is too low and as a consequence, the cumulative regulatory impact of TSCA on industry is greater than indicated in EPA's documentation."

   EPA believes that the annual hours estimates calculated for the record-keeping, reporting, and notice review associated with TSCA section 8(c) are based on best available data at the time of calculation. If the ACC has better or more accurate data, EPA would be willing to evaluate and consider these in estimating burdens. Any specifics would be greatly appreciated.

2. In the fifth paragraph, the ACC says "The burden estimate does not include any consideration of time needed for internal training of personnel, for developing reporting procedures, or for storage and maintenance of records." Subsequent paragraphs in the ACC's letter further discuss each of these concerns in very general terms.

   EPA follows all requirements of the Paperwork Reduction Act in developing the methodologies used in estimating required respondent activities of recordkeeping, reporting, and notice review associated with this specific ICR.

   EPA agrees that training is very important. Burden includes the time to train. Section 8(c) instruction would be part of any existing and ongoing training programs related to TSCA or worker safety and health. Section 8(c) requirements are little changed since initial implementation in 1983; those changes being the result of industry recommendations. Again, specific information would guide us in further assessing any additional burden of section 8(c) as a component of providing TSCA or health and safety training.

   Given the estimated average number of annual allegations for a large firm is less than 3 per year, EPA believes that its statement of negligible storage and maintenance costs are valid. An ICR renewal concerns itself with only three years at a time; thus, an average of fewer than 9 allegations would be received for storage and maintenance during this renewal period.

3. The ACC in its third from last paragraph says "Finally, EPA's calculation of managerial burden appears to be generated using a 'single-actor' model.." as it relates to them reading a Federal Register concerning a TSCA 8(c) rule. They go on to say that in medium to large companies several such managers would all be doing the same thing.

In the ICR, EPA does state that respondents are responsible for monitoring the Federal Register for possible reporting requirements. The ICR also says that EPA will attempt to identify and notify any companies that would be subject to reporting. In the nineteen years since implementation of the rule, only 31 reports have been received based on a request; none in over ten years.

In addition, the TSCA section 8(c) rule states that firms are to keep significant adverse reaction allegations "at the firm's headquarters or at any other appropriate location central to the firm's chemical operations" (CFR 717.15). Thus any reporting requirements are the responsibility of a central location which for burden estimation should be virtually a single actor.

We appreciate the general comments in the letter submitted by the American Chemistry Council. If you have any questions about this matter, please contact Gerry Brown at 202-564-8086 or Dave Williams at 202-564-8179.

cc: Frank Kover
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