December 17, 2008

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: Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment (TSCA Section 8(c))

EPA ICR No.: 1031.09 OMB Control No.: 2070-0017

1(b) Short Characterization

Section 8(c) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2607(c), P.L. 94-469 (see Attachment 1), requires that "any person who manufactures (including imports), processes, or distributes in commerce any chemical substance or mixture" must 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."

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 requires manufacturers (defined by statute to include importers) 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

The recordkeeping and reporting activities associated with this collection of information are required by statute. The TSCA section 8(c) reporting and recordkeeping requirements are of central importance in the administration of TSCA section 8 as a whole. Without the ability to administer these paperwork requirements, EPA would not be able to meet its obligation under TSCA.

Since the statute does not contain an automatic reporting provision, EPA must either inspect company files or require reporting of records that relate to specific substances of concern in order to obtain and use information about allegations of significant adverse reactions. EPA's authority to inspect and require such reporting is codified in 40 CFR 717.17. EPA will review relevant TSCA section 8(c) records in connection with its TSCA 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. Copies of the documents will then be prepared for inclusion in EPA's public docket and distributed, as appropriate and 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

By using the TSCA section 8(c) reporting authority, EPA can examine such records whenever a chemical is discovered to present possible risks to human health or the environment. Information contained in the TSCA section 8(c) allegation records will have several uses. The information collected will be used on a case-specific basis to evaluate 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 subjects of TSCA section 8(e) notices 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.

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 5-year and 30-year recordkeeping feature of the statute.

3 NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

Information recorded and reported on alleged adverse effects on health or the environment is specific for compliance with the TSCA section 8(c) rule. Records required to be maintained under this rule 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. 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. TSCA section 8(c) requires that allegations of adverse reactions to the health of employees be kept for 30 years, and all other relevant allegations be kept for 5 years.

There are no other EPA programs or other agencies/departments that require this specific set of information on alleged adverse effects to be recorded and maintained for this retention period nor does any other government program have direct authority to access such information. If any records or reports relating to the allegation are required by another agency, then copies of those records or reports must be maintained in the TSCA section 8(c) allegation record. For example, if an employee allegation results in a requirement for the firm to record the case on Occupational Safety and Health Administration (OSHA) Form 301, or equivalent form, which must be maintained by the firm for only 5 years (see 29 CFR part 1904 for recording and reporting requirements for occupational injuries and illnesses under the Occupational Safety and Health Act of 1970), then a copy of that OSHA record must be included in the allegation record.

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 August 18, 2008 (73 FR 34733, June 18, 2008). EPA received no comments during the comment period.

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 (now called the American Chemistry Council), 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 was 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 via notice and comment rulemaking based upon recommendations by members of the industry and after full consideration of comments from representatives of industry, labor groups, environmental groups, and the general public.

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. TSCA section 8(c) has also been discussed at a variety of other seminars and meetings with industry over the last 15 years.

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 original or renewal ICR OMB for review and approval. In accordance with this regulation, EPA will pursue additional consultations with interested parties during the development of the renewal of this collection. EPA solicited comments from the following potential respondents and data users with respect to the renewal of this ICR:

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
jessine.monaghan@ge.com

Thomas Neltner
Improving Kids Environment
neltner@ikecoalition.org

Kathleen Roberts
American Chemistry Council

Kathleen_Roberts@americanchemistry.com

Jennifer Sass
National Resources Defense Council
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 nine potential respondents is included below as Attachment 3 to this Supporting Statement.

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 (less than 2 per year) for TSCA section 8(c) reporting. However, reporting requests may occur more frequently because individual notices or letters containing such TSCA section 8(c) requests may be clustered in the same year. If EPA were limited to only two such actions per year, it would prevent the Agency from exercising its responsibility under the law. The information will be collected on a case-specific basis to evaluate suspected adverse health or environmental effects of a chemical substance or mixture already under assessment by OPPT or when a chemical not under assessment by OPPT is discovered to present possible risks to human health or the environment. For example, chemical disasters are obviously unpredictable and 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 (including importers), 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 Part 2.

3(g) Sensitive Questions

This section is not applicable. The information does not include responses to questions 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 and 32411 (*Chemicals and Allied Products Manufacturers* and *Petroleum Refining*, respectively).

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 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 under the section 8(c) rule.)
d. Copies of any further required records relating to the allegation (e.g., records 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. Entities 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 the alleged "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, importation or processing of a substance or mixture in question. Respondents then must 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 those records and mail it with a cover letter to EPA. The company should 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. At present 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 (including importers) 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 in the Federal Register a reporting requirement relating to a chemical substance or mixture, or requests such reporting by letter, then manufacturers (including importers) 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 could initially 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 Burden and Cost

Steps required to estimate burden associated with these activities include estimating the number of affected firms and employees, 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

For previous TSCA section 8(c) ICR analyses, 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 initially 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. However, for the previous and current ICR renewals, EPA used publicly available data from the Bureau of the Census to allow for transparency in its analyses.

The first step in the analysis was to gather information on the number of firms and employees from the Bureau of the Census's *County Business Patterns* for NAICS code 325 (Chemical and Allied Products) and NAICS code 32411 (Petroleum Refining and Related Industries). The most recent dataset available is from 2005. EPA chose those NAICS codes to define the firms that manufacture (including import) and process chemical substances.

The number of employees for these firms was calculated using employment figures from *County Business Patterns* for those firms that fall under NAICS 325 or NAICS 32411. Data from *County Business Patterns* show that compared to the previous ICR renewal, the number of firms has risen very slightly, while the number of employees has fallen by approximately four percent.

The following table presents the number of firms and employees for 2005:

[1] [1] U.S. EPA. "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.

Table 1. Numbers of Firms and Employees for NAICS 325 and 32411 for 2005

Number of Firms	Total Number of Employees	Average Number of Employees per Firm
13,521	871,709	64

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 the number of firms, multiplied by a standard annual allegation rate per firm.

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 be made by 0.5 percent of the employees at an average firm.

For the 1983 ICR, EPA assumed that the rate of allegations 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 number of allegations per firm is presented below. The total number of allegations is calculated by multiplying the total number of firms (13,521) by the average annual number of allegations per firm (.43), for a total of 5,814 allegations per year.

Table 2. Estimated Total Number of Allegations for 2005

Firms	Avg. Number of Employees	Average Annual # of Allegations per Firm			Total Allegations
		Employee	Public	Total	
13,521	64	0.32	0.11	0.43	5,841

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 initially 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. To date, only two reporting notices have been issued under TSCA section 8(c)[4] and these two notices covered two chemicals and two chemical categories. A total of 31 reports have

[4]U.S.EPA. "Chemical on Reporting Rules Database (CORR)," CCD and CSB, June 1990; and U.S.EPA. "Chemical on Reporting Rules Database (CORR): Update," CCD and CSB; October 31, 1992.

been received under TSCA section 8(c)[5, 6]. This represents an average of only about 1.3 reports per year since the rule was promulgated in 1983.

Estimated Wage Rates

The basic methodology used to derive loaded wage rates for technical, managerial, and clerical personnel is described more fully in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program*.[7] These rates differ from those used in previous versions of the TSCA 8(c) ICR, and represent a more accurate picture of industry wages, based on public information.

In March 2004, the Bureau of Labor Statistics (BLS) began using the North American Industry Classification System (NAICS) codes instead of the Standard Industrial Classification (SIC) System, and the Standard Occupational Classification (SOC) system instead of the Occupational Classification System (OCS). The following table shows the crosswalk between old and new occupational titles.

[5] U.S.EPA. [Untitled Computer Printout], IMD; June 3, 1992.
[6] Sherlock, Scott, Information Management Division. Phone conversation with Wendy Hoffman based upon "TSCA Reports to Congress for EPA Fiscal Years 1992-93;" August 1994.
[7] See: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (U.S.EPA/OEI/EAD/ASB, June 10, 2002) and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (U.S. EPA/OPPT/EETD/EPAB. August 2002.

EPAB Labor Category	BLS Old Title (OCS)	BLS New Title (SOC)
Managerial	Executive, administrative, and managerial	Management, business, and financial
Professional/Technical	Professional specialty and technical	Professional and related
Clerical	Administrative support, including clerical	Office and administrative support

Wages and fringe benefits for managerial, professional/technical, and clerical labor were taken from the BLS *Employer Costs for Employee Compensation* (ECEC) data for September 2007, for manufacturing industries.[8] The cost of fringe benefits (paid leave, insurance and other items) specific to each labor category is taken from the same BLS series.

An additional loading factor of 17 percent is applied to wages to account for overhead. This approach is used for consistency with OPPT's economic analyses for two major rulemakings.[9] This overhead loading factor is added to the benefits amount, and the total is then applied to the base wage to derive the fully loaded wage. The fully loaded wage for technical labor, for example, is $33.25 + $16.54 + (33.25 x .17) = $55.44. Fully loaded wages for managerial and clerical labor were calculated in a similar manner (see Table 3).

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 referred to above (see Table 4).

[8] BLS 2007. Employer Costs for Employee Compensation Supplementary Tables, September 2007. Supplementary Table 2. http://www.bls.gov/ncs/ect/sp/ecsuptc4.pdf.

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

Table 3. Derivation of Loaded Hourly Wage Rates

Labor Category	Data Sources	Wages and Fringe / Hour[1]			Overhead as % of Wage[2]	Fringe + Overhead Factor	Loaded Wage Rate
		Date	Wages	Fringe Benefits			
Technical	*BLS Employer Costs for Employee Compensation*. All workers in manufacturing; Professional and related.	Sept. 2007	$33.25	$16.54	17%	$22.19	$55.44
Managerial	*BLS Employer Costs for Employee Compensation*. All workers in manufacturing; Management, business, and financial.	Sept. 2007	$41.40	$19.74	17%	$26.78	$68.18
Clerical	*BLS Employer Costs for Employee Compensation*. All workers in manufacturing; Office and administrative support.	Sept. 2007	$16.40	$8.28	17%	$11.07	$27.47

[1] Wages and fringe benefits are from BLS website http://www.bls.gov/ncs/ect/sp/ecsuptc4.pdf.

[2] An overhead rate of 17 percent applied to wages is used for consistency with EPAB economic analyses for two major rulemakings: "Wage Rates for Economic Analyses of the Toxics Release Inventory Program," June 10, 2002, and the "Revised Economic Analysis for the Amended Inventory Update Rule: Final Report;" August 2002.

Note: Calculations are based on unrounded values, so the total may not equal the product of the rounded factors.

i. Unit Recordkeeping Burden and Cost

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.[9] 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 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.

The unit cost per allegation is $252.37.

ii. Unit Reporting Burden and Cost

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 (including imports) 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).

The unit cost for reporting, per report, is $467.25

iii. Unit Federal Register Notice Review 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 4).

The unit cost for Federal Register notice review is $17.05.

Table 4. Unit Respondent Burden and Cost Estimates

Activity	Clerical Hours	Technical Hours	Manager Hours	Total Hours	Total Cost
Recordkeeping, per allegation	0.50	0.00	3.50	4.00	$252.37
Reporting, per report	1.00	2.00	5.00	8.00	$479.25
Federal Register Notice review, per Notice	0.00	0.00	0.25	0.25	$17.05
Total unit burden per respondent	**1.50**	**2.00**	**8.75**	**12.25**	**$748.67**

Total Industry Burden and Cost

i Total Recordkeeping Burden and Cost

The unit burden for recordkeeping is multiplied by the total number of allegations. Total annual recordkeeping burden is 23,256 hours (5,814 allegations x 4 hours per allegation).

Table 5. Total Industry Recordkeeping Burden

Number of Firms	Total Allegations	Hours per Allegation	Total Burden Hours
13,521	5,814	4	23,256

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. Total annual recordkeeping cost is $1,467,299, which includes managerial and clerical labor.

Table 6. Total Industry Recordkeeping Costs

Number of Firms	Allegations per Firm	Cost per Allegation	Total Cost
13,521	0.43	$252.37	$1,467,299

ii. Total Reporting Burden and Cost

EPA assumes that 1.3 TSCA section 8(c) reports will be required annually, based on the 31 reports received in the 24–year history of the rule (31÷24 = 1.3). Total reporting burden hour is 1.3 reports x 8 hours per report (from Unit Reporting Burden and Costs), or 10 hours.

Table 7. Total Industry Reporting Burden

Annual Number of Reports	Hours per Report	Total Burden Hours
1.3	8	10

The cost of submitting these reports is determined by multiplying the annual number of reports by the unit reporting cost, which includes managerial, technical and clerical labor. The total cost is $623.02.

Table 8. Total Industry Reporting Cost

Annual Number of Reports	Cost per Report	Total Cost
1.3	$479.25	$623.02

iii. Total Federal Register Notice Review Burden and Cost

Historically, the Agency has published an average of only 0.08 notices each year since 1983 as EPA has only published two notices to date. Using that figure, each firm would require only slightly more than one minute, or 0.02 hour of managerial labor per year for notice review in the current ICR period. The total industry burden is 270 hours.

Table 9. Federal Register Notice Review Burden

Number of Firms	Notices per Year	Hours per Notice	Total Hours
13,521	0.08	0.25	270

The total cost to industry of reviewing the Federal Register notices is estimated as shown below using the unit cost for Federal Register review at $17.05 and multiplying by 0.08 notices each year since 1983.

Table 10. Federal Register Notice Review Cost

Number of Firms	Cost per Firm	Total Cost
13,521	$1.36	$18,389

Total Federal Register notice review cost is $18,389, which includes managerial labor.

Table 11. Total Annual Burden to Industry

Collection Activity	Hours per Respondent	Respondents per Year	Hours per Year
Recordkeeping	4.00	5,814 (1)	23,256
Reporting	8.00	1.3	10
Notice Review	0.25	1,082(2)	270
Total Annual Burden Hours	**12.25**		**23,536**

(1) Calculated as 13,521 firms subject to recordkeeping x 0.43 average number of allegations per firm each year is 5,814.

(2) Historically, EPA has issued an average of only 0.08 notices per year. Therefore, on an average annual basis, 1,082 of the estimated total of 13,512 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 12. Total Industry Costs and Burdens

Collection Activity	Total Annual Cost	Total Annual Burden Hours
Recordkeeping	$1,467,299	23,256
Reporting	$623	10
Federal Register Review	$18,389	270
Total	**$1,486,311**	**23,536**

Regulatory Flexibility Analysis

TSCA section 8(c) does not include a specific exemption for small businesses (annual parent company sales of less than $40 million). The costs of TSCA section 8(c) for an average company are listed below. The costs for a small business can be expected to be less.

Table 13. Average Total Costs per Firm

Type of Cost	Cost
Average recordkeeping cost	$108.52[(1)]
Reporting cost per firm	$0.05[(2)]
Federal Register notice review cost per firm	$1.36[(3)]
Average total cost per firm	**$109.93**

[(1)] Calculated as the average cost per allegation times the average number of allegations per year ($252.37 x 0.43 = $108.52). Smaller firms with fewer employees can expect fewer allegations, and thus lower costs.
[(2)] Calculated as the total industry reporting costs divided by the total number of firms ($623.02÷13,521 = $0.05).
[(3)] Calculated as the total industry review costs divided by the total number of firms ($18,389÷13,521 = $1.36).

The average annual recordkeeping, reporting, and review costs to an average firm are $109.93. A firm would have to have less than $10,000 in annual sales for these costs to amount to 1 percent of annual sales. Based on previous ICRs, an average small firm can be expected to have greater than $10 million in annual sales. Therefore, these requirements do not appear to impose a significant burden on small firms.

6(c) Estimating Agency Burden and Cost

The total annual cost to EPA for TSCA section 8(c) for each of the three years covered by this ICR is estimated to be $54,872. This figure was calculated from cost estimates provided in the 1986 and 1989 ICRs. These costs were adjusted based on wages and salaries in 2007 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 31 reports have been received. Based on historical data, over the life of the rule an average of only 0.08 notices have been issued per year and an average of only 1.3 reports received. EPA expects that reporting activity under TSCA section 8(c) will remain at this low level during the period covered by this ICR renewal. 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 decision meetings and either the development of letters, separate Federal Register notices, or the insertion of boilerplate segments in other rule preambles.

- Time will be required to process submissions based upon 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 Information and Testing Branch (CITB) of the Chemical Control Division (CCD).

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 burden and the associated annual costs to the government for activities related to TSCA section 8(c).

Table 14. Annual Burden and Cost to the Federal Government

Activity	**Hourly Wage**	**Burden Hours**	**Annual Cost**
Administrative maintenance	$63.82/88.71$ (1)	288	$20,372
Education/Outreach	$53.66 (2)	240	$12,878
Compliance monitoring	$53.66 (2)	400	$21,464
Develop reporting notices	$53.66 (2)	1.1	$59
Document control functions	$53.66 (2)	0.75	$40
Notice review, referral and data entry	$53.66 (2)	1.1	$59
Totals		931	$54,872

(1) This activity is estimated to require 208 hours at the GS-13 level and 80 hours at the GS-15 level. The 2007 base wage for a GS-13, Step 1 is $82,961, plus 60 percent overhead and benefits of $49,777, for a total of $132,738. Dividing this by the 2,080 hours in a work year yields an hourly wage rate of $63.82. The base wage for a GS-15, Step 1 is $115,317, plus overhead and benefits of $69,190, for a total of $184,507. Dividing this by the 2,080 hours in a work year yields an hourly wage rate of $88.71.
(2) The estimated total cost to the EPA of a full time employee (FTE) at a GS 12, Step 1 level for 2007 is $111,662. This includes a base wage of $69,764, and 60 percent for overhead and benefits, or $41,858. Dividing this by the 2,080 hours in a work year yields an hourly wage rate of $53.66.

6(e) Reasons for Change in Burden

The total estimated respondent burden has decreased by 1,012 hours (from 24,548 hours to 23,536 hours) compared to the ICR most recently approved by OMB. This decrease is an adjustment and reflects a reduced estimated burden for respondents based on several factors.

- The number of firms in the affected NAICS codes rose very slightly since the last ICR (13,445 to 13,521), but the total number of employees fell by four percent (909,562 to 871,709). Because the allegation rate is based on the number of employees, the decrease in the number of employees resulted in a decrease in total allegations (6,050 to 5,814), and thus a reduction in burden.

- The burden associated with reviewing Federal Register notices has also seen a small reduction. Based on EPA's history of issuing notices over the life of the rule, and because no new notices were published during the previous three-year ICR period, the average annual number of notices the Agency is expected to issue in the current ICR renewal period fell from an estimated 0.1 in the most recent ICR, to 0.08 notices per year estimated in this renewal.

- An additional small reduction is attributable to reduced industry reporting requirements, which have fallen from an estimated 1.5 reports per year (31 reports total ÷21 years of the rule), to 1.3 reports per year, over the 24 years of the rule (31 reports ÷ 24 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 total annual public burden for this collection of information is estimated to be about 23,536 hours, with the burden ranging between approximately 1 minute and 8 hours per response depending upon the type(s) of activity that a respondent must complete. 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. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

To comment on 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, EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2008-0221. The docket is available for public viewing at the Pollution Prevention and Toxics Docket in the EPA Docket Center (EPA/DC). The EPA/DC Public Reading Room is located in the EPA West Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280. An electronic version of the public docket is available at www.regulations.gov. Use www.regulations.gov to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the docket ID number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Please include the EPA Docket ID No. EPA-HQ-OPPT-2008-0221 and OMB control number 2070-0017 in any correspondence.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachment 1 **15 USC 2607(c)** - *TSCA section 8(c)* - This attachment is available as part of the electronic copy of the ICR's Supporting Statement.

Attachment 2 **40 CFR 717** – *Records and Reports of Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment* – This attachment is available as part of the electronic copy of the ICR's Supporting Statement.

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

Attachment 4 **Display Related to OMB Control #2070-0017 - Listings of Related Regulations in 40 CFR 9.1**

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.

EPA ICR No. 1031.09; OMB Control No. 2070-0017

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.

EPA ICR No. 1031.09; OMB Control No. 2070-0017

ATTACHMENT 3

Copy of Consultations Message Sent by EPA to Potential Respondents

TO: Addressees
FROM: Gerry Brown, U.S. EPA
SUBJECT: TSCA Section 8(c), Allegations of Significant Adverse Reactions to Human Health or the Environment
DATE: July 15, 2008

On June 18, 2008, EPA published a Notice in the Federal Register (**73 FR 34733**) for **Agency Information Collection Activities; Proposed Collection; Comment Request: Allegations of Significant Adverse Reactions to Human Health or the Environment, TSCA Section 8(c).** (Attachments). The Notice provides a 60-day public comment period. In addition to the Notice and comment requirement, agencies also are required under Office of Management and Budget regulations (**5 CFR 1320.8(d)(1)**) to consult with potential respondents and data users about specific aspects of an Information Collection Request (ICR) before submitting it to OMB for review and approval, regardless, in the case of ICR renewals, of whether changes have or have not been made to the collection activity.

As part of this required consultation, I am contacting you to solicit your input. I also must note that, if you take this opportunity to provide input, your name, affiliation, and phone number and any information you provide (e.g., copies of emails) will be incorporated and attached to the ICR supporting statement which will be a public document. In addition, you may be contacted by the OMB Desk Examiner for the ICR to verify the accuracy of any comments as reported in the ICR by EPA.

EPA solicits your input on the following questions:

Are the data EPA seeks under this ICR available from any public source, or already collected by another EPA office or by another agency? If so, where can the data be found?

Is it clear what is required for data submission? If not, are there any suggestions for clarifying instructions?

Would you be interested in an electronic/data submission option? What type of alternative would you be most likely to utilize – web form, diskette, CD-ROM?

For electronic submission, how should signature requirements be handled – Private Key Infrastructure, PINS and passwords, signed paper cover sheet? How does CBI affect your choice or use of an electronic medium? Would you be more inclined to submit CBI on diskette than on paper and what benefits would you realize (burden reduction? Greater efficiency in compiling information? Etc).

Do you agree with EPA's estimated burden and costs (ICR addresses only costs associated with paperwork)? Are the Bureau of Labor Statistics (BLS) labor rates accurate? If you have any reason to consider the BLS labor rates inaccurate or inappropriate as used by EPA, explain your rationale.

Your timely response will be greatly appreciated! We hope to get your responses back by August 15, 2008 so we can consider those responses, as well as any public comments resulting from the FR notice, at the same time. Thank you for your assistance!

Federal Register Notice

http://www.regulations.gov/search/search_results.jsp?css=0&N=0&Ntk=All&Ntx=mode+matchall&Ne=2+8+11+8053+8054+8098+8074+8066+8084+8055&Ntt=TSCA%20Section%208(c)&sid=11B0D592CB14

Docket OPPT-2008-0221

http://www.regulations.gov/fdmspublic/component/main

EPA ICR No. 1031.09; OMB Control No. 2070-0017

ATTACHMENT 4

Display Related to OMB Control #2070-0017 - Listings of Related Regulations in 40 CFR 9.1

40 CFR 9

Display Related to OMB Control #2070-0017
Listings of Related Regulations in 40 CFR 9.1

As of May 10, 1993, the OMB approval numbers for EPA regulations in Chapter I of Title 40 of the Code of Federal Regulations (CFR) appear in a listing in 40 CFR 9.1 (58 FR 27472). This listing fulfills the display requirements in section 3507(f) of the Paperwork Reduction Act (PRA) for EPA regulations. The listing at 40 CFR 9.1 displays this OMB Control number for the following regulations:

Records and Reports of Allegations That Chemical Substances Cause Significant Adverse Reactions to Health or the Environment	
717.5	2070–0017
717.7	2070–0017
717.12	2070–0017
717.15	2070–0017
717.17	2070–0017