

**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: Notification of Substantial Risk of Injury to Health and the
Environment under TSCA Section 8(e)**

EPA ICR No.: 0794.12 OMB Control No.: 2070-0046

1(b) Short Characterization

Section 8(e) of the Toxic Substances Control Act (TSCA) states, “any person who manufactures, [imports,] processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information” (15 U.S.C. 2607(e)).

From January 1977 through June 2005, EPA received 16,063 initial section 8(e) submissions covering a large number of chemical substances and mixtures on a wide range of chemical toxicity/exposure information. This includes approximately 10,500 submissions EPA received following a 1992 Compliance Audit Program, described below in Part 2(a). Although EPA’s receipt of section 8(e) information does not necessarily trigger immediate regulatory action under TSCA or other authorities administered by EPA, all section 8(e) submissions receive screening level evaluations by EPA’s Office of Pollution Prevention and Toxics (OPPT) to identify priorities for further Agency action and appropriate referrals to other programs.

OPPT routinely disseminates section 8(e) data to EPA’s Program and Regional Offices and other federal agencies (e.g., NIOSH, OSHA, CPSC, FDA, NTP) on newly discovered chemical hazards/risks. Since June 2001, OPPT has made these referrals primarily via e-mails of biweekly tables summarizing all new section 8(e) submissions. There is also public outreach and information access to section 8(e) data through the TSCA Public Docket and online data bases that include TSCA 8(e) records, as well as through the TSCA 8(e) web page that includes all biweekly reports of new 8(e) submissions back to June 2001 with PDF links to the submissions.

2 NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Section 8(e) of TSCA continues to be an important and useful tool for early warning and identification of potential substantial risk situations allowing EPA and others to focus their

limited resources on chemicals or mixtures of highest concern. The submission of section 8(e) information makes it possible for the Agency and others to learn quickly about potential new chemical hazards/risks posed by exposure to chemical substances, to conduct more complete assessments and, if needed, effective action to eliminate or reduce such risks in a timely manner.

The statutory authority for this information collection is section 8(e) of TSCA (U.S. Public Law 94-469; 90 Stat. 2029; 15 U.S.C. 2607(e)). No formal rule-making by the Agency was required to implement section 8(e), in that section 8(e) was a self-activating reporting provision of TSCA that became immediately effective on January 1, 1977 (the effective date of the Act). However, in order to facilitate compliance with section 8(e), EPA clarified the kinds of information that constitute substantial risk information, specified the types of information exempt from the reporting requirements, and outlined standard reporting procedures, in published proposed guidance (42 FR 45362; September 9, 1977). After holding several public meetings and considering the public comments on the proposed section 8(e) guidance, the Agency published its final “Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk” (43 FR 11110; March 16, 1978). In June 1991, EPA published a “Section 8(e) Reporting Guide” to further assist the regulated community in complying with section 8(e). The 1991 Reporting Guide references examples of submitted information and EPA’s comments on these submissions to help persons subject to section 8(e) better understand the types of information that are reportable under section 8(e). The 1991 Guide also includes dose ranges and exposure factors to consider in determining the section 8(e) reportability of acute lethality data.

In February of 1991, the Agency initiated a voluntary section 8(e) “Compliance Audit Program” (CAP). This compliance program, which followed several section 8(e) enforcement cases indicating that some companies were not complying with section 8(e) reporting requirements, was designed to 1) achieve EPA’s goal of obtaining any outstanding section 8(e) data, and 2) provide maximum encouragement to companies to voluntarily audit their files for section 8(e)-reportable information. The section 8(e) CAP involved consent agreements/orders pursuant to section 15 of TSCA, stipulated monetary penalties and an overall penalty ceiling. 123 companies elected to participate voluntarily in the Agency’s section 8(e) CAP activity. The CAP was terminated on May 15, 1996 and settlements with CAP participants were announced on October 15, 1996.

In implementing the section 8(e) CAP, EPA determined that there was a need to suspend and refine those portions of the 1978 section 8(e) Policy Statement that deal specifically with the reportability of chemical releases to the environment and the detection of toxic chemicals in environmental media. On July 13, 1993 (58 FR 37735), EPA published proposed guidance on the detection of toxic chemicals in environmental media. EPA received comments from 49 companies and industry associations. Based on the submitted comments and a number of meetings with industry representatives, EPA revised the proposed guidance and made it available for additional public comment through a notice in the Federal Register published on March 20, 1995 (60 FR 14756). In response, EPA received an additional 22 comments. While the comments offered additional refinements to the revised guidance, their basic tenor was that industry was in support of the changes.

Beginning in 1996, there was an ongoing collaboration between EPA and industry to develop a question and answer (Q&A) document to promote industry understanding of and compliance with the Agency's anticipated revised section 8(e) reporting criteria for environmental release and contamination information. The intent was to make the Q&A publicly available before the revised guidance was published. However, the finalized Q&A document was not yet available when the revised guidance, "TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance" (68 FR 33129-33139), was published on June 3, 2003. The revised guidance included a re-publication of the 1978 Policy Statement and incorporated revisions that address the reporting of information on the release of chemical substances to the environment and the detection of toxic chemicals in environmental media. Also included in the June 2003 Reporting Guidance is a change in the deadline for reporting "substantial risk" information to the Agency (from 15 working days to 30 calendar days) and the circumstances under which certain information need not be reported to EPA under section 8(e) of TSCA. In a subsequent Federal Register Notice, "TSCA Section 8(e) Reporting Guidance; Correction, Clarification of Applicability, and Announcement Regarding the Issuance (of) Questions and Answers" (70 FR 2162-2164), EPA announced certain corrections to the June 2003 Reporting Guidance (due to transcription errors from the 1978 Policy Statement that appeared in the June 2003 Guidance), stated that the applicability date for the June 2003 Guidance Document was the publication date, and announced the availability on the TSCA 8(e) web page (<http://www.epa.gov/oppt/tzca8e>) of a Q&A document on the section 8(e) reportability of releases of chemical substances to the environment and the detection of toxic chemicals in environmental media. This Q&A document included only a few of the items drafted earlier by industry stakeholders with EPA participation, but EPA will be adding Q&As to the TSCA 8(e) web page on environmental releases and other aspects of section 8(e) reporting following further comment and review.

2(b) Use/Users of the Data

Since 1977, the Agency and members of the chemical industry have devoted significant efforts in fulfilling their respective responsibilities under section 8(e). Since January 1, 1977, 16,063 initial section 8(e) notices (includes CAP and non-CAP submissions) covering a broad range of toxicity and exposure-related data on a wide range of chemicals and chemical mixtures, have been received by the Agency, screened, and received follow-up attention as needed.

All incoming section 8(e) submissions are reviewed by EPA shortly after receipt. The initial processing of section 8(e) submissions includes a screening level evaluation of the submitted data. Such evaluations are not risk assessments, nor do they consider other available toxicity data on the chemical or exposure-related information on the chemical/mixture being reviewed. The results of screening level evaluations are used for priority-setting to select cases for more detailed assessment, as well as to identify referrals to other Offices and Agencies.

EPA utilizes section 8(e) submission information for hazard/risk identification purposes in the initial stages of the TSCA chemical screening and review program. Section 8(e) data are also used in ongoing EPA hazard and exposure assessments of both existing and new chemicals, in the SIDS international testing program, in the High Production Volume (HPV) Challenge Program, and in support of regulation development under TSCA, e.g., development of chemical

testing rules under section 4 of TSCA, as well as regulation development under other authorities administered by the Agency. In addition, section 8(e) submissions have been the basis for chemical advisories to communicate potential health risks and the need for exposure controls, as well as for chemical summaries to identify data availability for chemical hazard and exposure assessment.

Regardless of the type of section 8(e) follow-up action or activity taken, all reported information not claimed as TSCA confidential business information is made available to other EPA Program and Regional Offices, other federal agencies and others (e.g., chemical industry, trade unions, environmental groups, general public, and the international community) that may be interested in the subject chemical or mixture. EPA offices and other federal agencies routinely utilize section 8(e) data in implementing their regulatory programs. The principal vehicles for making the information publicly available are the TSCATS data base, the TSCA Docket, and the TSCA section 8(e) web page at <http://www.epa.gov/opptintr/tasca8e>. The TSCA 8(e) web page includes all published section 8(e) guidance and full text copies of all new section 8(e) submissions.

EPA's proactive implementation of section 8(e) has also resulted in heightened corporate awareness of the potential risk of injury posed by exposure to chemical substances. This increased corporate awareness has led to a variety of voluntary corporate actions designed to protect human health and/or the environment. Many companies have reported to EPA that the following types of risk reduction/pollution prevention measures were initiated in direct response to the submitted chemical toxicity and/or exposure data:

- Notification of workers, customers and others;
- Revision of product labels and Material Safety Data Sheets;
- Modification of manufacturing, processing, and/or handling;
- Ceasing production/use either temporarily or permanently;
- Initiation of additional toxicity or exposure studies to further define potential risks.

3 NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

There is no other source of data that can be used in place of the data submitted to EPA under the section 8(e) statutory reporting requirement. The "substantial risk" information required to be reported to EPA is unpublished information not already known to the Agency. In addition, information need not be submitted under section 8(e) if the information has been reported already to EPA pursuant to another mandatory information reporting requirement of TSCA or some other authority administered or delegated to the States by EPA. In the June 3, 2003 Reporting Guidance, the Agency clarified the circumstances under which certain information need not be reported to EPA under section 8(e) of TSCA. This is expected to result in some additional reduction of the overall respondent reporting burden for section 8(e).

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 April 14, 2009 (74 FR 7227, February 13, 2009). EPA received comments from BASF Corp. These comments are addressed in Attachment 2.

3(c) Consultations

EPA personnel have participated in numerous public meetings and other fora to discuss the section 8(e) Policy Statement and the Agency's implementation of section 8(e). Large EPA-sponsored public meetings at which section 8(e) was a primary topic of discussion were held in 1978, 1986, 1987, 1990 and 1992 with chemical industry representatives and other interested parties. EPA staff also met on numerous occasions with members of the chemical industry to discuss section 8(e) in the context of the section 8(e) Compliance Audit Program. In addition, EPA staff have participated in more than 30 industry-sponsored meetings at which section 8(e) of TSCA was the major or primary topic of discussion.

EPA proposed amendments to the section 8(e) policy statement in 1993 and again in 1995. The proposed amendments dealt specifically with clarifications on reporting requirements for occurrences of environmental exposure or contamination. The Agency received numerous public comments on these proposed amendments and developed a "Comment and Response Document for Revised Policy Statement of Section 8(e) of TSCA" (OPPT-2002-0067-0002) to record these comments and the Agency's responses (see Attachment 3). EPA has also collaborated with industry in preparing a question and answer document dealing with revisions to the 1978 Policy Statement and from 1994 to the present section 8(e) has been on the agenda of the "Living with TSCA" conferences held annually for all TSCA stakeholders.

Additionally, under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an ICR to OMB for review and approval. In accordance with this regulation, EPA submitted questions to nine parties via e-mail. The individuals contacted were:

Janet Cerra
BASF
janet.cerra@basf.com

Betsy Duncan
Lyondell Chemical Company
betsy.duncan@lyondellbasell.com

Michael Hulse
Shell Chemical LP
michael.hulse@shell.com

Judith L. Kranetz
Rhodia Inc.
Judith.Kranetz@us.rhodia.com

Deanna J. Luebker, Ph.D.
3M
djluebker@mmm.com

Marie Paquette
Ciba Specialty Chemical North America
marie.paquette@ciba.com

Debra Randall
Arkema Inc.
debra.randall@arkema.com

Nancy Sandrof
American Chemistry Council
Nancy_Sandrof@americanchemistry.com

Karluss Thomas
Silicones Environmental, Health and Safety Council of North America
kthomas@sehsc.com

EPA received no responses to its solicitation for consultations. A copy of EPA's consultation e-mail to the above potential respondents is in Attachment 3.

3(d) Effects of Less Frequent Collection

TSCA section 8(e) reporting is not cyclical, but rather is self-implementing. The statute states that persons covered under the section 8(e) reporting requirement shall immediately notify the EPA Administrator upon obtaining reportable information. As stated previously, section 8(e) continues to be an extremely important and useful EPA tool for early identification of potential substantial risk situations and allows the Agency as well as others to focus their resources on those chemicals or mixtures of highest concern. The consequences of EPA not receiving section 8(e) data immediately following receipt by a respondent are serious. The Agency would be prevented from learning about and publicizing new information about substantial risks to health or environmental injury posed by exposure to chemical substances and/or mixtures. Further, EPA would not be in a position to adequately assess and, if necessary, take action to effectively eliminate or reduce such risks in an expeditious manner.

3(e) General Guidelines

The required reporting that takes place under section 8(e) does not appear to exceed the Paperwork Reduction Act-imposed guidelines that are found at 5 CFR 1320.6.

3(f) Confidentiality

Any person submitting a notice to EPA under section 8(e) may assert a claim of business confidentiality covering information contained in the submission. Any information covered by a claim will be disclosed by EPA only to the extent and by means of the procedures set forth at 40 CFR Part 2. If no confidentiality claim accompanies a section 8(e) notice, the submission is placed in the TSCA Docket and is available to the public without further notice to the submitting organization. The Agency has established and actively implements well-publicized standard procedures for the handling and safeguarding of information claimed as TSCA Confidential Business Information (TSCA CBI).

3(g) Sensitive Questions

Under section 8(e), EPA does not seek submission of information with regard to sexual behavior or attitudes, religious beliefs, or other matters usually considered to be of a private nature.

4 RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

A statutory section 8(e) reporting obligation can be incurred by any person who manufactures, imports, processes or distributes a TSCA-covered chemical substance or mixture. EPA's section 8(e) Policy Statement defines the term "person" broadly to include "any natural person, corporation, firm, company, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body and any department, agency, instrumentality of the Federal Government." Although this definition is quite broad in terms of subject persons, section 8(e) reporting obligations are most typically incurred by companies engaged in activities classified by NAICS Codes 325 - Chemicals and Allied Products Manufacturers and 32411- Petroleum Refining.

4(b) Information Requested

(i) Data Items

There is no required collection instrument or reporting form on which section 8(e) information must be submitted to EPA; however, the section 8(e) Policy Statement requires all respondents to ensure that a written section 8(e) notice:

- is sent to EPA by a method verifying the Agency's receipt;
- states that it is being submitted under section 8(e) of TSCA;
- contains the name, address, job title, phone number and signature of the person reporting, and the name and address of the establishment with which the person is associated;

- identifies the chemical substance(s) or mixture including, if known, the Chemical Abstract Service (CAS) Registry Number(s);
- summarizes adverse health/environmental effects being reported including a description of the nature and extent of the risk; and
- contains the specific source/summary of the supporting data.

EPA is continuing its efforts to implement optional electronic reporting of section 8(e) submissions to increase processing efficiency for both the Agency and the regulated community.

(ii) Respondent Activities

The overall purpose of section 8(e) reporting is to ensure that new information that reasonably supports a conclusion that a chemical substance or mixture presents a “substantial risk” of injury to health or the environment is brought to EPA’s attention immediately upon discovery. It should be noted again that section 8(e) applies to all chemical manufacturers, importers, processors, and distributors and applies also to information that a subject person possesses or about which that person has knowledge. Although compliance with section 8(e) does not require subject persons to search for information or to make extraordinary efforts to acquire information, section 8(e) does apply to information that is “obtained” (i.e., information that a person possesses or about which that person knows). Following a review of existing information and a decision that such information is of the type required under section 8(e), respondents must notify EPA in writing immediately. EPA’s June 2003 Reporting Guidance defines the term “immediately” in the context of written section 8(e) reports to mean within 30 calendar days of the date on which the information was obtained; the immediate reporting of an emergency incident of environmental contamination by a toxic substance is defined as a phone report to EPA or to the National Response Center as soon as a person knows about the incident.

5 INFORMATION COLLECTION - EPA ACTIVITIES, COLLECTION METHODOLOGY AND INFORMATION MANAGEMENT

5(a) Agency Activities

As explained in additional detail in the following sections, the Agency’s section 8(e) activities involve answering general and specific section 8(e)-related questions, development and maintenance of computerized information tracking (including data extraction, entry and quality assurance/control), microfilming, confidential (restricted-access) and non-confidential (public-access) section 8(e) information filing, initial evaluation of all submitted section 8(e) information (including review of TSCA Confidential Business Information (CBI) substantiations), and the posting of section 8(e)-related information on the Internet for public access.

5(b) Collection Methodology and Information Management

EPA uses Document Control Numbers (DCNs) to identify TSCA submissions; section 8(e) has the following format: 88-YYXXXXXXXX. The assigned 7-digit ascending numbers begin each year with 0000001. EPA also identifies section 8(e) submissions by 8EHQ Numbers,

which are chronological from January 1977. The format is 8EHQ-MMY-XXXXX. Initial submissions are assigned as Sequence A; supplemental and follow-up submissions are assigned Sequence B, C, D, etc. Internal EPA tracking of section 8(e) submission information is handled via non-confidential and confidential computerized data bases.

In order to assure that the public is kept apprised of new adverse chemical-related toxicity and exposure information, the Agency provides public access to and actively disseminates non-confidential section 8(e) submission information in many ways. Examples of EPA's public access/outreach activities follow.

Non-confidential section 8(e) initial and follow-up/supplemental submissions, status reports, submission summaries, and EPA follow-up letters can be viewed/copied in the TSCA Public Docket located at EPA Headquarters. Non-confidential section 8(e)-related documents can also be obtained by writing to EPA's Freedom of Information Office.

Relevant non-confidential information from section 8(e) submissions is routinely entered into TSCATS (Toxic Substances Control Act Test Submissions), a publicly available computerized data base that serves as an on-line index of unpublished health and safety studies submitted to EPA under TSCA. The most recent version of the TSCATS data base is available on the web at <http://yosemite.epa.gov/oppts/epatscat8.nsf/ReportSearch?OpenForm>. The submitted studies themselves are stored and available on microfiche. Microfiche copies of the studies referenced in the TSCATS data base are available from either CIS or the National Technical Information Service (NTIS) in Springfield, VA. EPA has also been creating full electronic (PDF) copies of all new section 8(e) submissions since June 2001. Electronic copies of these most recent section 8(e) submissions are available to the public from the TSCA Public Docket, as well as from the section 8(e) web site at <http://www.epa.gov/oppt/tsc8e>.

Under established Freedom of Information Act (FOIA) procedures, EPA responds to requests from industry, other stakeholders and the public. In cooperation with the Organization for Economic Cooperation and Development's (OECD) information-gathering "Switchboard" project, EPA responds as well to international requests for section 8(e) and other unpublished health and safety data on chemicals of concern to OECD members.

As stated previously, EPA routinely notifies other federal agencies on incoming section 8(e) information via biweekly tabular reports of new section 8(e) submissions and by targeted referrals. As the direct result of these public outreach activities, several of these other agencies actively publicize the information even further. For example, the National Library of Medicine (NLM) at the National Institutes of Health makes section 8(e) information available via its publicly available computerized Hazardous Substances Data Bank (HSDB) and Toxline data bases. In addition, the National Institute for Occupational Safety and Health (NIOSH) cites section 8(e) notices in the printed and on-line computerized versions of the "Registry of Toxic Effects of Chemical Substances" (RTECS) data base.

5(c) Small Entity Flexibility

The statutory obligation to report information under section 8(e) of TSCA applies to all manufacturers, importers, processors, and/or distributors of TSCA-covered chemical substances and mixtures. The statutory language of section 8(e) itself does not allow for any reporting exemption or burden minimization based on the size or earnings of a respondent. However, nearly all reporting is by large and medium size companies. This is mainly because only larger companies have the financial resources to conduct toxicity testing that comprises most section 8(e) reporting. Since there is no routine reporting or recordkeeping provisions for section 8(e), the true burden on most small entities is practically nonexistent.

5(d) Collection Schedule

Considering that section 8(e) submissions are received by the Agency on an ad hoc basis, there is no standard reporting cycle. Submitters are required to comply with section 8(e) immediately when they come into possession of or know about section 8(e)-reportable information. If section 8(e) information were not made available immediately to EPA, the Agency's ability to learn about, publicize, effectively assess, and respond appropriately to newly discovered chemical-related risks would be severely impeded, if not completely thwarted.

6 ESTIMATING THE BURDEN AND COST OF COLLECTION

For the current ICR renewal, EPA utilized data on the number of section 8(e) submissions for fiscal years FY 2006-2008. The averaged annual number of initial 8(e) submissions was 390 (418+379+373=1170/3). The averaged annual number of supplemental and follow-up 8(e) submissions was 136 (123+132+154=409/3).

In the previous ICR renewal, it was determined that for initial section 8(e)s, submission equivalents were also estimated to account for the need to review data that are not ultimately submitted as TSCA 8(e). For initial section 8(e)s, the number of submission equivalents is used instead of the number of actual submissions. Estimating that the number of cases not submitted is 50% of the number of cases submitted, the number of initial section 8(e) submission equivalents per year for FY 2006-2008 is increased from 390 to 585 (390 x 1.5).

6(a) Estimating Submitter Burden

The following discussion provides the basis for the Agency's upper-bound estimate of approximately 30,515 total hours of annual reporting burden for submitters in complying with section 8(e).

EPA believes that it should take approximately 49 hours per submission to judge and concur on the section 8(e)-applicability of obtained information plus 2 additional hours to prepare/submit the necessary information. The first figure is based on an average of 45 hours per submission of managerial and technical staff time to review and evaluate data and an additional 4 hours for staff training on TSCA 8(e) regulatory requirements. An additional 2 hours per

submission reflects general clerical support. Using the calculated average of 585 initial section 8(e) submission equivalents per year, the total number of hours required for initial section 8(e) reporting is estimated to be 29,835 (585 x 51) hours.

INITIAL SUBMISSIONS SUBTOTAL

Burden Item	Hours/Submitter	Submissions/Year	Hours/Year
Managerial/technical review, data evaluation, decision-making, concurrence and drafting an initial section 8(e) submission	49	585	28,665
General clerical support (typing, copying and transmitting an initial section 8(e) submission)	2	585	1,170
	51	585	29,835

Considering that the respondent’s decision-making/concurrence activities for determining section 8(e)-applicability/reportability has already taken place with the initial submission, the Agency views the activities surrounding the submission of follow-up/supplemental information in response to EPA questions on the initial section 8(e) submission, or as a result of further investigation/evaluation by the company, as being less burdensome. The submission of follow-up/supplemental information is estimated to be 5 hours per notice, assuming 3 hours to assemble the required information, 1 hour for management review, and 1 hour to prepare and transmit the submission. Using the calculated average of 136 follow-up/supplemental submissions per year, the total number of hours required for follow-up/supplemental section 8(e) reporting is estimated to be 680 (136 x 5) hours.

FOLLOW-UP AND SUPPLEMENTAL SUBMISSIONS SUBTOTAL

Burden Item	Hours/Submitter	Submissions/Year	Hours/Year
Managerial/ technical review, concurrence and drafting a follow-up/ supplemental section 8(e) submission.	4	136	544
General clerical support (typing, copying and transmitting a follow-up/ supplemental section 8(e) submission)	1	136	136
	5	136	680

In summary, the total number of section 8(e) initial submission equivalents plus follow-up/supplemental submissions is 721 (585 + 136) submissions per year. Based on the figures presented in the preceding tables, the total submitter burden (in hours/year) for initial and follow-up/supplemental section 8(e) submissions to EPA is as follows:

TOTAL HOURLY BURDEN/YEAR

<u>Initial Submissions</u>	+	<u>Follow-Up/Supplemental Submissions</u>	=	<u>Total Hours/Year</u>
29,835 hours/year	+	680 hours/year	=	<u>30,515</u>

6(b) Estimating Submitter Costs

EPA estimates that a respondent incurs costs up to \$69.21/hour in managerial/technical labor costs and \$27.59/hour in clerical labor costs in submitting information to EPA under section 8(e). These hourly costs take into account the involvement of the respondent’s managerial, technical and clerical personnel and takes into account standard labor wage rates (including fringe benefits) using Bureau of Labor Statistics (BLS) wage rates for the Private Manufacturing industries adjusted for the year 2007. It should be noted that section 8(e) reporting does not involve operating/maintenance or capital costs to the respondent. The hourly labor wage rates used in the computations appear below.

Hourly Labor Rates *

<u>Labor Category</u>	<u>Hourly Rate</u>
Managerial	\$ 69.21
Technical	\$ 55.42
Clerical	\$ 27.59
EPA staff	\$ 68.99

*See Appendix A for derivations

Based on the total estimated reporting burden of 30,515 hours/year and the hourly labor rates listed above, the annual cost for submitters to comply with section 8(e) is estimated to be \$2,057,588 as follows.

TOTAL ANNUAL COSTS

Burden Item	Submitter Hours/Year (Initial) (a)	Submitter Hours/Year (Supplemental) (b)	Total Hours/Year (c)	Wage Rate (d)	Total Cost/Year (e)
Managerial/technical review, data evaluation, decision-making, concurrence and drafting a section 8(e) submission	28,665	544	29,209	\$69.21/hr	\$2,021,555
General clerical support (typing, copying, and sending a section 8(e) submission)	1,170	136	1,306	\$27.59/hr	\$36,033
Totals¹			30,515		\$2,057,588

1. Totals in this row indicate combined managerial/technical and clerical burden.
2. Column c=a+b, e=c*d (except for the bottom row)

6(c) Estimating EPA Burden and Costs

Based on reasonable costs for reports received by EPA as the result of general section 8 rule-making activities, EPA estimates the cost per submission can range from \$275 to \$900. This assumes that it takes a GS-13 Step 5 staff member between 4 and 13 hours to process, copy, file, and initially review and/or answer questions on each section 8(e) submission (4 * \$68.99 and 13 * \$68.99). Therefore, EPA estimates its total annual cost for these activities involving 721 incoming section 8(e) submissions (585 initial plus 136 follow-up/supplemental notices per year) to range from \$198,275 - \$648,900 per year as follows:

EPA BURDEN/COSTS

<u>Initial/Follow-Up/Supplemental Submissions per Year</u>	x	<u>Cost of EPA Processing/ Review</u>	=	<u>Total Cost/Year</u>
721 submissions/year	x	\$275-\$900/Submission	=	\$198,275 - \$648,900/year

6(d) Bottom Line Burden Hours and Costs

(i) Submitters' Annual Burden (Hours and Costs)

(a) Hours

Initial Section 8(e) Submissions

51 hours x 585 submissions = 29,835 hours

Follow-up/Supplemental Section 8(e) Submissions

5 hours x 136 submissions = 680 hours

Submitters' Total Annual Hourly Burden

29,835 hours + 680 hours = 30,515 hours

(b) Costs

Submitters' Total Annual Cost

29,209 managerial hours x \$69.21/hour = \$2,021,555

1,306 clerical hours x \$27.59/hour = \$36,033

\$2,021,555 + \$36,033 = \$2,057,588

(ii) EPA's Annual Burden/Cost

Initial Section 8(e) Submissions

585 submissions x \$275-\$900/submission = \$160,875 - \$526,500

Follow-up/Supplemental Section 8(e) Submissions

136 submissions x \$275-\$900/submission = \$37,400 - \$122,400

EPA's Total Annual Estimated Burden/Cost

721 submissions x \$275-\$900/submission = \$198,275 - \$648,900

6(e) Reasons for Change in Burden

There is an increase of 12,380 hours (from 18,135 hours to 30,515 hours) in the total estimated respondent burden compared with that identified in the information collection request most recently approved by OMB. This increase in burden hours is primarily due to an increase in submissions for the following reasons. First, there has been increased awareness of the statutory requirement due to the increased publicity of enforcement actions and public access to information about chemical hazards, e.g., through programs like the High Production Volume (HPV) Challenge Program.

Secondly, the estimate in submitter annual costs associated with this ICR is higher than the previous section 8(e) ICR because of the above considerations as well as the increased hourly

labor rates. The previous estimate was based on a simpler BLS data series whereas the current ICR uses an overhead rate of 17% based on assumptions in *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (Rice, 2002) and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPAB, 2002). 2007 is the most recent year for which wage rates were available not subject to revision by BLS.

6(f) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0046, is estimated to average 51 hours per initial section 8(e) submission and 5 hours per follow-up/supplemental section 8(e) submission. 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; disclose and provide information; adjust existing procedures to comply with any previously applicable instructions and requirements; train personnel to respond to a collection of information; complete and review the information collection; 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.

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-2008-0896. 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 through the Federal Docket Management System (FDMS) at www.regulations.gov. Use FDMS 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-2008-0896 and OMB control number 2070-0046 in any correspondence.

APPENDIX A

WAGE RATES

WAGE RATES

This appendix describes the derivation of the fully loaded labor rates used in calculating costs of labor. Costs for this report are for year-end 2007.

A.1 Derivation of Loaded Wage Rates

Unit labor costs are calculated by adding fringe benefits and overhead to the wage or salary to derive a fully loaded labor cost. The basic method is described in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (Rice, 2002). The resulting loaded labor rates are given in Table A-. Costs are calculated for several labor categories: Managerial, Professional/ Technical, Clerical, and EPA staff.

A.1.1 Derivation of Labor Rates for Managerial, Professional/Technical, and Clerical Labor

Wages and fringe benefits for managerial, professional/technical, and clerical labor were taken from the Bureau of Labor Statistics (BLS) *Employer Costs for Employee Compensation* (ECEC) data, for December, for manufacturing industries.¹

The cost of fringe benefits such as paid leave and insurance, specific to each labor category, are taken from the same ECEC series. Fringe benefits as a percent of wages are calculated separately for each labor category. For example, for December 2007, the average wage rate for professional/technical labor was \$33.14; the average fringe benefit was \$16.65. Fringe benefits as a percent of wages were $\$16.65/\33.14 , or approximately 50.2 percent.

An additional loading factor of 17 percent is applied to wages to account for overhead. This approach is used for consistency with Office of Pollution Prevention and Toxics economic analyses for two major rulemakings: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (Rice, 2002) and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPAB, 2002). This overhead loading factor is added to the benefits loading factor, and the total is then applied to the base wage to derive the fully loaded wage. For example, the December 2007 fully loaded wage for professional/technical labor is $\$33.14 \times (1 + 0.502414 + 0.17) = \55.42 .

Fully loaded costs for managerial and clerical labor are calculated in a similar manner, as shown in Table A-.

¹ *Employer Costs for Employee Compensation Supplementary Tables for December 2007* (BLS, 2008a).

A.1.2 Derivation of Labor Rates for EPA Staff

Agency labor costs are calculated based on annual federal salaries for the Washington-Baltimore area published by the Office of Personnel Management effective January 2007 (OPM, 2007). The average salary for one Full Time Equivalent (FTE) staff is estimated as the salary for a GS-13 Step 5 employee.

Multiplying the annual pay by an assumed loading factor of 1.6 to reflect federal fringe benefits and overhead, the loaded annual salary of EPA staff was calculated to be \$143,976.

The Agency loading factor is from an EPA guide, *Instructions for Preparing Information Collection Requests (ICRs)* (OPPE, 1992, page 30, footnote 9). The 60 percent assumption was labeled “the benefits multiplication factor” in the EPA Guide, but has been used in many EPA Office of Pollution Prevention and Toxics ICRs to reflect both fringe benefits and overhead for federal staff. For example, it was used in an August 2000 document supporting ICR No. 1139.06, with the following explanation:

“The annual costs per FTE are derived by multiplying the annual pay rate by 1.6 (the benefits multiplication factor). The multiplication factor used is recommended in EPA's Office of Policy, Planning, and Evaluation's Instructions for Preparing Information Collection Requests (ICRs) (June 1, 1992). An EPA internal phone call between Carol Rawie (OPPT/EETD/RIB) and Carl Koch (OPPE/RMD/IMB) on May 3, 1994, indicated that the 1.6 factor included not only benefits but also overhead.” (ICR No.1139.06)

Table A- Derivation of Loaded Wage Rates

EPAB Labor Category	Data Sources	Date	Wage	Fringe Benefit	Fringes as % wage	Overhead % wage ¹	Fringe + overhead factor	Loaded Wages
			(a)	(b)	(c) =(b)/(a)	(d)	(e)=(c)+(d)+1	(f)=(a) x (e)
Managerial	BLS ECEC, Private Manufacturing industries , “Mgt, Business, and Financial” ²	Dec-07	\$41.93	\$20.15	48.06%	17%	1.65	\$69.21
Professional/ Technical	BLS ECEC, Private Manufacturing industries , “Professional and related” ²	Dec-07	\$33.14	\$16.65	50.24%	17%	1.67	\$55.42
Clerical	BLS ECEC, Private Manufacturing industries , “Office and Administrative Support” ²	Dec-07	\$16.47	\$8.32	50.52%	17%	1.68	\$27.59
EPA staff FTE	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV, area, GS-13 Step 5 pay rates, with 60% overhead. ³	Jan-07	\$89,985/year \$43.12/hour	--	[Included in 60% overhead]	60%	1.6	\$143,976/year \$68.99/hour

Notes:

¹An overhead rate of 17% was used based on assumptions in *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (Rice, 2002), and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPAB, 2002).

²*Employer Costs for Employee Compensation Supplementary Tables: December 2007*, US Bureau of Labor Statistics, March 12, 2008 (BLS, 2008a).

³The federal salary is the unloaded federal GS-13 Step 5 salary for calendar 2007, from the Office of Personnel Management salary table for Washington-Baltimore-Northern Virginia (OPM, 2007). The 60% fringes-and-overhead rate is from an EPA guide, *Instructions for Preparing Information Collection Requests (ICRs)* (OPPE, 1992, page 30, footnote 9).

APPENDIX A REFERENCES

- BLS, 2008a. U.S. Bureau of Labor Statistics. *Employer Costs for Employee Compensation Supplementary Tables: December 2007* (March 12, 2008) at <http://www.bls.gov/ncs/ect/sp/ecsuptc5.pdf>
- EPAB, 2002. U.S. EPA, Office of Pollution Prevention and Toxics, Economic and Policy Analysis Branch. *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report*. Washington, DC. August 2002.
- ICR No. 1139.06. *[Information Collection Request for] TSCA Existing Chemical Test Rules, Consent Orders, Test Rule Exemptions, and Voluntary Test Data Submissions: Supporting Statement for Request for OMB Review under the Paperwork Reduction Act*. Attachment 5, Wage Rates Estimation, August 29, 2000.
- OPPE, 1992. U.S. EPA, Office of Policy, Planning, and Evaluation. *Instructions for Preparing Information Collection Requests (ICRs)*. Washington, DC, June 1, 1992.
- OPM, 2007. Office of Personnel Management, *Salary Table 2007-DCB, Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV*. Accessed from <http://www.opm.gov/oca/07tables/html/dcb.asp>
- Rice, 2002. Cody Rice. *Wage Rates for Economic Analysis of the Toxics Release Inventory Program*. Washington, DC: U.S.EPA, Office of Pollution Prevention and Toxics, Economic and Policy Analysis Branch, June 10, 2002.