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.: 0794.13 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); see Attachment 1.)

From January 1977 through November 2013, EPA received 19,250 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 post section 8(e) data to EPA's TSCA 8(e) webpage on newly discovered chemical hazards/risks (http://epa.gov/oppt/tsca8e/pubs/8eandfyisubmissions.html). Since September of 2001, OPPT has made the information available primarily via 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, 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.

In addition, EPA is offering an electronic reporting option for use both by those who are required to submit a notification of substantial risk under TSCA section 8(e) and by those who wish to voluntarily submit "For Your Information" (FYI) notices by registering and submitting information electronically using the Agency's Central Data Exchange (CDX), as described below in Part 4.

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/tsca8e) 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. EPA currently maintains a TSCA 8(e) web page (http://epa.gov/oppt/tsca8e/pubs/frequentlyaskedquestionsfaqs.html#2010) on environmental releases and other aspects of section 8(e) reporting that is periodically updated with new questions that have arisen since the publication of the guidance document.

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). Between January 1977 through November 2013, EPA has received and screened19, 250 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, 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 international community) who 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 database, the TSCA Docket, and the TSCA section 8(e) web page at http://www.epa.gov/opptintr/tsca8e. 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 was expected to reduce some of the 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 January 29, 2013 (77 FR 71415, November 30, 2012). EPA received no comments during the comment period.

3(c) Consultations

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 and based on OPPTS Regulatory Coordination Staff guidance, EPA submitted questions to nine parties via email. The individuals contacted were:

Name	Company/Association
Betsy Duncan	Lyondell Chemical Company betsy.duncan@lyondellbasell.com
Bill Kojola	AFL-CIO bkojola@aflcio.org
Alicia M. Fitzpatrick	Dow Chemical Company afitzpatrick@dow.com
Rebecca J. Bernstein	Arkema Inc. Rebecca.bernstein@arkema.com
Janet Cerra	BASF janet.cerra@basf.com
Olga V. Naidenko	Environmental Working Group olga@ewg.org
Elizabeth J. Moran	America Chemistry Council (ACC) Elizabeth_moran@americanchemistry.com
Judith L. Kranetz	Rhodia Inc. Judith.kranetz@us.rhodia.com
Patricia Nevrincean	FMC Corp. pat_nevrincean@fmc.com

The Agency received no responses to its request for comment. A copy of EPA's consultation email to the above potential respondents is included below as Attachment 2.

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's 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 and FYIs to increase processing efficiency for both the Agency and the regulated community. The option to submit TSCA section 8(e) Notices and FYIs electronically using the Chemical Information Submission System (CISS) reporting tool and electronic submission via CDX will change the way that companies interact with the Agency. Companies will be registered with EPA to submit their data electronically to the Agency via CDX and the Agency in turn will be able to communicate back electronically with submitters. This promotes efficiency in communications and cost savings in submissions and correspondence. EPA believes the adoption of electronic communications will reduce the reporting burden on industry by reducing both the cost and the time required to review, edit and transmit data to the Agency. All information sent via CDX will be transmitted securely to protect CBI. Furthermore, if anything in the submission has been claimed CBI, a sanitized copy of the notice must be provided by the submitter. The Agency will also benefit from receiving electronic submissions. Data systems that currently are populated manually will now be populated electronically, reducing the potential for human error that exists when data are entered by hand. Agency personnel will also be able to communicate more efficiently with submitters electronically, compared to using U.S. mail.

Chemical Information Submission System (CISS)

EPA developed the CISS reporting tool for use in submitting data electronically to the Agency. The tool is available for use with Windows, Macs, Linux, and UNIX based computers, using "Extensible Markup Language" (XML) specifications for efficient data transmission across the Internet. The CISS is a tool that provides user-friendly navigation, works with CDX to secure online communication, creates a completed Portable Document Format (PDF) for review prior to

submission, and enables data, reports, and other information to be submitted easily as PDF attachments.

All information sent by the submitter via CDX is transmitted securely to protect CBI. Furthermore, if anything in the submission is claimed as CBI, a non-CBI copy of the submission must be provided by the submitter. The guidance document will instruct users on how to submit and substantiate CBI information using CISS.

The Agency ensures secure transmission of the data, reports, and other documents sent from the user's desktop through the Internet via the Transport Layer Security (TLS) 1.0 protocol. TLS 1.0 and subsequent versions updated as needed are widely used approaches for securing Internet transactions by the National Institute of Standards and Technology (NIST) as a means for protecting data sent over the Internet.

In addition, CISS enables the submitter to electronically sign, encrypt, and transmit submissions, which EPA subsequently provides back to the submitter as an unaltered copy of record. This assures the submitter that the Agency has received exactly what the submitter sent to EPA. The CISS reporting tool encrypts using a module based on the 256-bit Advanced Encryption Standard (AES) adopted by NIST. Details about AES can be found on the NIST website at *http://csrc.nist.gov/publications/fips/fips197/ fips-197.pdf*, and EPA may incorporate other encryption modules into future versions of the tool. Information submitted via CDX is processed within EPA by secure systems certified for compliance with Federal Information Processing Standards.

Fielded CISS Meta-data for 8(e) and "For Your Information" (FYI) Submissions

In order to facilitate the efficiency in communications and cost savings in submissions and correspondence for both EPA and respondents, EPA has incorporated the following data elements into the reporting tool.

1. Submission Type	*Identifies the submission, including the type of submission and whether it is the initial submission, a follow-up or a final report.*
2. Summary of Attachment	*Allows the respondent to provide a summary or abstract of the attached study or report, any internal company tracking number, an EPA tracking number, and an indication of the number of studies submitted.*
3. Chemical Identification	*Identifies the chemical(s) addressed in the submission.*
4. Title of Attachment	*Identifies the title of the attached study or report.*
5. Indexing Terms	*Allows the respondent to identify the proper terms to use for indexing purposes, which facilitates the search and retrieval of the information.*
6. Submitter Information	*Identifies the submitter and/or technical contact, including name, title, company, mailing address, phone and e-mail address.*
7. Comments	*Allows the submitter to provide any additional comments, so as to avoid the need for or use of a separate cover letter.*

Each of these data elements are already incorporated into a voluntary instrument for certain TSCA submissions and approved under OMB Control No. 2070-0156[1] (Voluntary Cover Sheet for TSCA Submissions). As explained in that ICR, the voluntary cover sheet was initiated and developed by industry representatives – in particular, the American Chemistry Council (ACC) – in an effort to begin familiarizing companies with standard requirements and concepts of electronic reporting. ACC developed the voluntary "TSCA Health and Safety Study Cover Sheet," and its data elements, as a first step in standardizing data and terms to promote the acceptance and implementation of electronic TSCA submissions to and communications with the Agency. EPA and industry representatives agreed that the submission of this information will achieve efficiencies through industry-industry and industry EPA cooperation, will engender more efficient systems and result in significant money and time savings. These data elements and indexing terms that were featured in the voluntary form have been adopted as submission metadata in the CISS electronic reporting tool.

To further facilitate more efficient reporting and industry-EPA cooperation, the indexing terms are now aligned with the international standards developed by the Organisation of Economic Cooperation and Development (OECD) for reporting chemical test summaries. A crosswalk between the former TSCA Voluntary Cover Sheet indexing terms and the OECD standards, known as the OECD Harmonised Templates (www.oecd.org/ehs/templates/), is provided in Attachment 3. These indexing terms will be updated periodically to correspond to the most recent standards developed by the OECD.

EPA staff will be the primary users of the standardized meta-data. EPA employees will use the meta-data collected through CDX in manner very much like they use the information presently collected previously via the voluntary cover sheet, i.e., to identify the submission when it reaches EPA without having to examine portions of a submission that may be very lengthy and complex, and to subsequently use the information to distribute, locate and track the submission as the submission moves through Agency reviews and decision points, to index the data, and to identify the data within EPA databases in making the data publicly available.

(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

[1] The collection of information related to the voluntary cover sheet was previously approved by OMB under OMB Control No. 2070-0156. That OMB Control Number was discontinued as of November 30, 2013. See http://www.reginfo.gov/public/do/DownloadNOA?requestID=253621.

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.

(iii) Terms of Clearance

OMB terms of clearance, as stated in OMB's action notice most recently approving this information collection activity in 2010, requested that the EPA:“prior to resubmission of this information collection request, the agency re-consider the practical utility of the submission of preliminary results of laboratory testing when such preliminary results are not a sufficient basis upon which to take regulatory or other action and whether alternate submission may suffice for the purposes of this section of the statute.”

In response, EPA believes that the information enclosed in the preliminary results of a submission is a valuable part of the review process and should not be altered. The practical use of preliminary results has been addressed in Part VI of the March 16, 1978, Federal Register (http://www.epa.gov/opptintr/tsca8e/pubs/tsca3161978.pdf), in the June 2003 guidance, (68 FR 33129), and further clarified in a frequently asked questions listed on the Agency’s website (http://epa.gov/oppt/tsca8e/pubs/frequentlyaskedquestionsfaqs.html).

The initial processing of section 8(e) submissions includes a screening level evaluation of the submitted data, these evaluations are not risk assessments, nor do they consider other available toxicity data on the chemical or exposure-related information on the chemical/mixture in reviewed. The results of screening level evaluations are used for priority-setting to select cases for more detailed assessment. TSCA 8(e) submissions are considered an early warning indication of a potential issue that may become of significant concern. Preliminary data may be used for chemical advisories to communicate potential health risks and the need for exposure controls. While EPA is conducting a review of a chemical based on existing scientific literature, if preliminary results submitted under 8(e) raise different concerns, it can serve to alert the Agency that EPA needs to delay review or consider a need to adjust decisions as the results are updated and finalized. It may also be used for chemical summaries to identify data availability for chemical hazard and exposure assessments for both the existing and new chemicals programs, and used in screening processes for voluntary programs such as Design for the Environment (DfE) and the Green Chemistry programs. However, it is rare that one study or parts of studies are sufficient for taking regulatory action.

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 will continue to use Case Numbers to identify TSCA section 8(e) submissions through the newly revised format: 8EHQ-YYMM-XXXX. Previously issued Case Numbers will remain the same, such as initial submissions were assigned as Sequence A; supplemental and follow-up submissions were assigned Sequence B, C, D, etc. Internal EPA tracking of section 8(e) submissions will still be 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 database 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/tsca8e.

Under established Freedom of Information Act (FOIA) procedures, EPA responds to requests from industry, other stakeholders and the public. And 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

EPA receives mandatory submissions under TSCA section 8(e)

Pursuant to TSCA section 8(e)(15 U.S.C. 2607(e)), "Any person who manufactures, 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 Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

EPA also receives For Your Information (FYI) voluntary submissions

EPA has received For Your Information (FYI) submissions covering a wide variety of chemical substances and mixtures from chemical companies, trade associations, unions, public interest groups, civic associations, private citizens, academic institutions, state and other federal agencies, as well as similar organizations and agencies in foreign countries. These submissions contain information on human exposure, epidemiology, toxicity test results, monitoring studies, environmental fate, and other information that may be important to risk assessment.

FYI submissions are often submitted to the Agency when a person or company that is not required to submit would like to bring information on a chemical to EPA's attention. Chemical companies, trade associations, public interest groups, and academic institutions are among those who submit FYIs. These entities who wish to submit information to the Agency electronically will have to register with CDX or otherwise submit information by paper.

In addition, FYI submissions are submissions from a classification system that was established by EPA to distinguish voluntary submissions from "substantial risk" notices submitted formally to EPA under TSCA Section 8(e), discussed above. The FYI classification was created by EPA to capture submissions by persons or organizations not subject to the reporting requirements, but who wished to inform EPA of a potential risk.

6(a) Estimating Submitter Burden

In the previous ICR, EPA estimated that it should have taken approximately 49 hours per submission to judge and concur on the section 8(e)-applicability of obtained information plus 2 additional hours to prepare and submit the necessary information. The first figure was 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. Considering that the respondent's decision-making/concurrence activities for determining section 8(e)-applicability/reportability has already taken place for the initial submission, the activities surrounding the submission of follow-up/supplemental information related to the initial submission are viewed by the Agency as being less burdensome. Consequently, 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, was estimated to be 5 hours per notice, assuming 3 hours to assemble the required information, 1 hour to prepare the submission, and 1 hour for review.

For the current ICR renewal, EPA utilized data on the number of section 8(e) submissions for fiscal years 2011 through 2013. The average annual number of initial 8(e) submissions was 332 (341+385+271=997/3). The average annual number of supplemental and follow-up 8(e) submissions was 270 (347+174+289=810/3).

In the previous ICR renewal, it was determined that, for initial section 8(e) submissions, submission equivalents were calculated to project section 8(e) submissions, based on the previous three years of section 8(e) submissions. The projection captured data that were not ultimately submitted as TSCA 8(e). The current ICR will only use the actual number of section 8(e) submissions that were submitted to EPA, thereby avoiding an inflated estimate of section 8(e) submissions. The overall burden associated with reviewing the actual number of 8(e)s will be accounted for in each instance; however, the calculation of submission equivalents to capture projected submissions will not be included.

EPA used the same method to estimate the number of mandatory TSCA section 8(e) responses and voluntary FYI responses (i.e., average annual responses based on submissions received between 2011 and 2013). EPA estimates that it will receive 11 (9+13+ 12=34/3) FYI submissions per year. Furthermore, zero supplemental FYI reports were submitted during fiscal

years 2011, 2010 and 2011. However, EPA is conservatively estimating that an average of 1 (1+1+1=3/3) supplemental FYI submission will be received during the ICR period. EPA believes that the burden associated with filing a voluntary FYI submission is on par with the burden related to filing a mandatory submission because the voluntary submissions usually contain information on human exposure, epidemiology, toxicity test results, monitoring studies, environmental fate, and other information that may be pertinent to risk assessment. Therefore, the burden associated with filing an FYI submission in paper is estimated to be 51 hours per response (49 hours for managerial/technical review, data evaluation, decision-making, concurrence and drafting the submission; 2 hours for general clerical support).

Electronic Reporting Results in Program Change Burden Reductions

Respondents who adopt electronic reporting save between approximately 0.94 and 1.94 hours per response, resulting a new burden per response of 49.06 (51.00-0.94) for initial 8(e) and FYI submissions and 4.06 (5.00-0.94) for follow-up/supplemental 8(e) and FYI submissions, for those submitted electronically. There is no reduction of burden at the management and technical levels of respondent activities because the reporting tool does not significantly alter their response actions. The burden savings associated with electronic reporting using the CISS web-based reporting tool are realized at the clerical/administrative level.

Table 1. Estimated Annual Burden Associated with 8(e) Submissions

Information Collections	Annual Responses	Burden Hours per Response	Burden Hours per Year
Section 8(e) – Initial			
90 percent submitted electronically	*299*	*49 managerial/technical*	*14,651*
		1.06 clerical	*317*
10 percent submitted in paper	*33*	*49 managerial/technical*	*1,617*
		2 clerical	*66*
SUBTOTAL	**332**		**16,651**
Section 8(e) – Follow-up/Supplemental			
90 percent submitted electronically	*243*	*4 managerial/technical*	*972*
		0.06 clerical	*15*
10 percent submitted in paper	*27*	*4 managerial/technical*	*108*
		1 clerical	*27*
SUBTOTAL	**270**		**1,122**
TOTAL	**602**		**17,773**

Table 2. Estimated Annual Burden Associated with FYI Submissions

Information Collection	Annual Responses	Burden Hours per Response	Burden Hours per Year
FYI Submissions – Initial			
90 percent submitted electronically	*10*	*49 managerial/technical*	*490*
		1.06 clerical	*11*
10 percent submitted in paper	*1*	*49 managerial/technical*	*49*
		2 clerical	*2*
SUBTOTAL	**11**		**552**
FYI Submissions – Follow-up			
90 percent submitted electronically	*1*	*4 managerial/technical*	*4*
		0.06 clerical	*0*
10 percent submitted in paper	*0*	*4 managerial/technical*	*0*
		1 clerical	*0*
SUBTOTAL	**1**		**4**
TOTAL	**12**		**556**

CDX Registration Activities to Enable Electronic Reporting

EPA estimates that management, technical and clerical staff at companies submitting section 8(e) notices and FYIs would incur the following one-time burden to complete CDX registration activities (including obtaining a CDX electronic signature). Some section 8(e) and FYI submitters may already have registered to use the e-TSCA web reporting tool in CDX (and obtained an accompanying electronic signature) in order to comply with the mandatory electronic reporting requirements of EPA's e-PMN rule and/or IUR/CDR rule. Those submitters will not need to repeat the CDX registration and e-signature process in order to file section 8(e) and FYI notices. While there may be some overlap in the specific individuals that have already completed CDX activities, EPA is using a conservative assumption that all submitters who will file electronically will need to register with CDX and, thus, incur associated burdens. This assumption may overestimate the burdens and costs actually experienced by respondents. To estimate the number of CDX registrants who will submit initial and follow-up 8(e) and voluntary FYI submissions, EPA used the total number of distinct 8(e) and FYI submitters (for both initial and follow-up submissions) for fiscal years 2011, 2012 and 2013 and divided by 3 to come up with an estimated number of annual respondents. This calculation yielded a conservative estimate of 71 (186+26=212/3) annual respondents/CDX registrants.

The one-time CDX burden includes the following:

CDX Registration – Based on the Cross-Media Electronic Reporting Regulation (CROMERR) Cost Benefit Analysis, EPA assumed that companies would spend eleven minutes per employee to register with CDX (EPA, 2004). Furthermore, EPA assumed that an average of four technical staff members and one manager would need to register for each company, resulting in 55 minutes of burden per company.

CDX electronic signature (labor burden) – Based on the CROMERR Cost Benefit Analysis, EPA assumed that companies would spend 15 minutes preparing, submitting, and filing an electronic signature agreement (Authentication of Identity) form to EPA per employee

(EPA, 2004). One manager and four technical staff members per company would incur this burden, totaling 75 minutes of burden per company. In addition, EPA used its best professional judgment to estimate that a manager would spend an additional 30 minutes accessing, preparing, and submitting verification forms (Verification of Authorization) for all authorized submitters to EPA. The total burden incurred by companies submitting and then verifying electronic signature agreements would be 105 minutes. It should be noted that the burden associated with CDX Electronic Signatures does not include costs associated with contacting EPA's CDX help desk to notify a change of submitter status, should one occur.

Table 3. Estimated Annual Burden Associated with New CDX Registration Activities

Information Collection	Estimated Number of Annual Respondents	Number of Responses/ Respondent	Estimated Burden Hours per Response				Estimated Burden Hours /Year
			Managerial	Technical	Clerical	Total	
CDX Registration Activities							
CDX Registration	71	1	0.18	0.73	-	0.91	65
CDX E-Signature	71	1	0.75	1.00	-	1.75	124
TOTAL	**71**	**1**	**0.93**	**1.73**	**-**	**2.66**	**189**

Based on the figures presented in the preceding tables, the total estimated number of annual responses is 685, which include: initial and follow-up/supplemental section 8(e) submissions; initial and follow-up voluntary FYI submissions; and CDX registration. The total industry reporting burden (in hours/year) for initial and follow-up/supplemental section 8(e) submissions, as well as initial and follow-up voluntary FYI submissions, is 18,518 hours.

6(b) Estimating Submitter Costs

EPA estimates that a respondent incurs costs up to $72.88/hour in managerial/technical labor costs and $29.51/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 2012. 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 *

Labor Category	2012 Hourly Rate
Managerial	$ 72.88
Technical	$ 64.39
Clerical	$ 29.51
EPA staff	$ 77.36

*See Appendix A for derivations.

Based on the total estimated reporting burden of 18,518 hours/year and the hourly labor rates listed above, the annual cost for submitters to comply with section 8(e) is estimated to be $1,329,705, as follows:

Table 4. Total Annual Reporting Costs

Labor Category	8(e) Initial Hours/Year	8(e) Follow-up Hours/Year	FYI Initial Hours/Year	FYI Follow-up Hours/Year	Total Hours/Year	Wage Rate	Total Cost/Year
Managerial/ Technical	*16,268*	*1,080*	*539*	*4*	*17,891*	*$72.88/hr*	*$1,303,896*
Clerical	*383*	*42*	*13*	*0*	*438*	*$29.51/hr*	*$12,925*
TOTAL	**16,651**	**1,122**	**552**	**4**			**$1,316,821**

Table 5. Total Annual CDX Registration Activities Costs (Labor Costs)

Labor Category	CDX Registration	CDX E-Signature	Total Hours/Year	Wage Rate	Total Cost/Year
Managerial	*12.78*	*53.25*	*66.03*	*$72.88/hr*	*$4,812*
Technical	*51.83*	*71.00*	*122.83*	*$64.39/hr*	*$7,909*
Clerical	-	-	-	*$29.51/hr*	-
TOTAL	**64.61**	**124.25**			**$12,721**

Non-labor costs include a $0.44 stamp and a $0.02 standard business envelope for each of five required electronic signature agreements. The total non-labor cost for electronic signature agreements equals $2.30. This amounts to $163 in non-labor costs per year.

6(c) Estimating EPA Burden and Costs

EPA estimates that it takes a GS-13, Step 5, staff member between 4 to 13 hours to process, copy, file, and initially review and/or answer questions on each paper submission. This ICR uses the average of those two endpoint burden hours ((4+13) ÷ 2 = 8.5 hours) to estimate the per-submission burden to the Agency to process, copy, file, and review paper submissions. Since ten percent of the 615 submissions per year are assumed to be received on paper, EPA estimates the total annual burden for paper submissions to be 519 hours (61 submissions x 8.5 hours).

The remaining ninety percent of submissions received electronically are assumed to incur a lower per-submission burden. Potential Agency burden savings associated with the electronic reporting of section 8(e) notices and FYI submissions were characterized based on information in the CDX Business Case Analysis regarding the estimated monetary benefit from using CDX. Of the six Program Data Flows studied in the CDX Business Case Analysis, monetary benefits from using CDX as compared to a paper submission baseline were quantified for two flows: TRI (Toxic Release Inventory) and e-NOI (electronic Notice of Intent under the National Pollution Discharge Elimination System). Benefits ranged from eleven percent savings (e-NOI) to 22 percent savings TRI compared to the cost of the baseline process. For this ICR, EPA assumed an average annual burden savings of 16.5 percent. This percentage savings results in a total annual burden of 3,932 hours for electronic submissions.

Based on the total annual burden of 4,451 hours (519 + 3,932 = 4,451) and an hourly labor rate of $77.36 for a GS-13 Step 5 staff member, the total annual Agency cost for section 8(e) and FYI submissions is $344,329.

6(d) Bottom Line Burden Hours and Costs

Table 6. Bottom Line Annual Burden Hours and Costs

Activity	Annual Responses	Annual Burden Hours	Annual Cost
INDUSTRY			
Section 8(e) Initial	*332*	*16,651*	*$1,316,821*
Section 8(e) Follow-up	*270*	*1,122*	
FYI Initial	*11*	*552*	
FYI Follow-up	*1*	*4*	
CDX Registration and CDX E-Signature	*71*	*189*	*$12,884*
INDUSTRY TOTAL	**685**	**18,518**	**$1,329,705**
Paper Submissions	*61*	*519*	*$40,150*
Electronic Submissions	*554*	*3,932*	*$304,180*
AGENCY TOTAL	**615**	**4,451**	**$344,329**

6(e) Change in Burden

EPA estimates a net decrease in the annual respondent burden of 11,997 hours when compared to the information collection request most recently approved by OMB (30,515 – 18,518 = 11,997). This net decrease reflects a net program change decrease of 330 hours per year that reflect the anticipated widespread adoption of an electronic reporting option, as well as a net adjustment decrease of 11,667 hours per year that reflect changes to the estimated number of annual responses. More, specifically, the reduction in burden is a direct result of the following factors:

a) Decreased number of initial section 8(e) submissions. The total number of initial section 8(e) submissions dropped from 390 to 332. Moreover, the previous ICR used submission equivalents instead of the number of actual submissions to account for the need to review data that is not ultimately submitted under TSCA section 8(e). However, this ICR uses the number of actual submissions, instead.

b) Increased number of follow-up 8(e) submissions. This ICR shows an increase in the number of follow-up/supplemental 8(e) submissions, from 136 to 270.

c) The previous ICR did not account for the FYI submission classification, which was established by EPA to distinguish voluntary submissions. EPA collects an average of 11 FYI submissions per year.

d) Electronic reporting. Notifications of substantial risk under section 8(e) and voluntary "For Your Information" (FYI) submissions may soon be filed electronically using

EPA's electronic document submission system, CDX. Use of this electronic reporting option will streamline and reduce the administrative costs and burdens of submitting paper-based notifications of substantial risks and FYI submissions. EPA assumes 90 percent of respondents will adopt the electronic reporting option, and see a burden savings of 0.94 hours per 8(e)/FYI submission. This ICR presents estimates of those reductions in burden and cost, which account for most of the difference in the annual burden estimate when compared to the previous ICR.

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 for paper-based submissions. The annual public burden associated with electronic reporting of TSCA section 8(e) notifications of substantial risk is estimated to average 50.06 hours per initial section 8(e) submission and 4.06 hours per follow-up/supplemental section 8(e) submission. Same estimates are true for FYI submissions. Burden is defined in 5 CFR 1320.3(b). An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control 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.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2012-0674, which is available for online viewing at www.regulations.gov, or in person 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 WJC 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.

You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. Submit your comments, referencing Docket ID No. EPA-HQ- OPPT-2012-0674 and OMB Control No. 2070-0046, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Pollution Prevention and Toxics Docket, Environmental Protection Agency Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

APPENDIX A

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 2012.

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-1. 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.[2]

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 2012, the average wage rate for professional/technical labor was $38.53; the average fringe benefit was $19.31. Fringe benefits as a percent of wages were $19.31/38.53 or approximately 50 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 2012 fully loaded wage for professional/technical labor is $38.53× (1+ 0.50 + 0.17) = $64.39.

Fully loaded costs for managerial and clerical labor are calculated in a similar manner, as shown in Table A-1.

[2] *Employer Costs for Employee Compensation Supplementary Tables for December 2012* (BLS, 2013).

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 2013 (OPM, 2013). 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 $161,446.

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-1 Derivation of Loaded Wage Rates

EPAB Labor Category	Data Sources	Date	Wage	Fringe Benefit	Fringes as % wage	Over-head % 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-12	$43.95	$21.46	49%	17%	1.66	$72.88
Professional/ Technical	BLS *ECEC*, Private **Manufacturing industries**, "Professional and related"[2]	Dec-12	$38.53	$19.31	50%	17%	1.67	$64.39
Clerical	BLS *ECEC*, Private **Manufacturing industries,** "Office and Administrative Support"[2]	Dec-12	$17.64	$8.87	50%	17%	1.67	$29.51
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-12	$100,904/year $48.35/hour	--	[Included in 60% overhead]	60%	1.6	$161,446/year $77.36/hour

Notes:

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

[2]*Employer Costs for Employee Compensation Supplementary Tables: December 2012*, US Bureau of Labor Statistics, accessed December 3, 2013 (BLS, 2013).

[3]The Federal salary is the unloaded Federal GS-13 Step 5 salary for calendar 2012, from the Office of Personnel Management salary table for Washington-Baltimore-Northern Virginia (OPM, 2012). 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, 2013. U.S. Bureau of Labor Statistics. *Employer Costs for Employee Compensation Supplementary Tables: December 2012* (December 3, 2013) at http://www.bls.gov/ncs/ect/sp/ecsuphst.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, 2013. Office of Personnel Management, *Salary Table 2012-DCB, Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV.* Accessed from http://www.opm.gov/oca/12tables/html/gs.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.

ATTACHMENT 1

Toxic Substances Control Action Section 8(e)

15 U.S.C. 2607(e)

From the U.S. Code Online via GPO Access
[wais.access.gpo.gov]
[Laws in effect as of January 7, 2003]

TITLE 15--COMMERCE AND TRADE

CHAPTER 53--TOXIC SUBSTANCES CONTROL

SUBCHAPTER I--CONTROL OF TOXIC SUBSTANCES

Sec. 2607. Reporting and retention of information

* * *

(e) Notice to Administrator of substantial risks

Any person who manufactures, processes, or distributes in commerce as 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 Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

ATTACHMENT 2

Copy of Consultations Message Sent by EPA to Potential Respondents

Date: December 3, 2012

From: Amuel Kennedy/DC/USEPA/US

To: Addressees

Subject: Request for Comments on Information Collection Request Renewal for Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e); EPA ICR No. 0794.13, OMB Control No. 2070-0046

On November 30, 2012, EPA published a Notice in the Federal Register (74 FR 7227) for Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e) Request for Comment on Renewal of Information Collection Activities.; EPA ICR No. 0794.13, OMB Control No. 2070-0046."
(http://www.gpo.gov/fdsys/pkg/FR-2012-11-30/pdf/2012-29011.pdf) This Notice refers to EPA's intention to request renewed Office of Management and Budget (OMB) clearance of an information collection related to reporting and recordkeeping requirements for TSCA Section 8(e) submissions.

In addition to public notice and comment requirement that the above Notice initiates, OMB regulations at 5 CFR 1320.8(d)(1)) require agencies 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 will also note that, if you take this opportunity to provide input, your name, affiliation, e-mail address, phone number and any information you provide (e.g., copies of e-mails) will be incorporated and attached to the ICR supporting statement, which will be a public document. In addition, the OMB Desk Examiner for the ICR in question may contact you to verify the accuracy of any comments EPA identifies in the ICR.

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 TSCA CBI affect your choice or use of an electronic medium? Would you be more inclined to submit TSCA CBI on diskette than on paper and what benefits would you realize (e.g., burden reduction, greater efficiency in compiling information, etc).

Do you agree with EPA's estimated burden and costs (the ICR addresses only the 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 as used by EPA inaccurate or inappropriate, explain your rationale.

You can access the Federal Register Notice, the ICR supporting document, and any public comments received to date at: http://www.regulations.gov/fdmspublic/component/main

- select Advanced Search link at the top of the page
- select Docket from drop-down menu
- select EPA in the Agency drop-down menu
- enter EPA-HQ-OPPT-2012-0674 in the Docket ID field
- scroll down to Submit
- then click on the Docket ID in the search results for a listing of the documents within the docket

Your timely response will be greatly appreciated. If you have any comments in response to the above questions, or with respect to any other part of the information collection, please respond by return e-mail by January 29, 2013. EPA will consider those responses, as well as any public comment received in response to the Federal Register Notice identified above, in preparing a final document for OMB review.

Thank you for your assistance.

Sincerely yours,

Amuel Kennedy

ATTACHMENT 3

Crosswalk for TSCATS Indexing Terms from the TSCA Voluntary Cover Sheet to Chemical Information Submission System (CIS) Indexing Terms from the OECD Template

5.1 Study/TSCATS Indexing Terms and Corresponding CIS Term							
TSCATS Term		**CIS Term**		**TSCATS Term**	**CIS Term**	**TSCATS Term**	**CIS Term**
Health Effects		**Health Effects**		**Environmental Effect**	**Ecotoxicity**	**Environmental Fate**	**Environmental Fate**
5.2 Study/TSCATS Indexing Terms and Corresponding CIS Terms[i]							
TSCATS Term	**CIS Term**	**TSCATS Term**	**CIS Term**	**TSCATS Term**	**CIS Term**	**TSCATS Term**	**CIS Term**
Health Effect Study Type	**Health Effects**	**Health Effect Study Type**	**Physical-Chemical Properties**	**Environmental Effect Study Type and Subject Organism**	**Ecotoxicity**	**Environmental Effect Study Type**	**Environmental Fate**
Basic Toxic kinetics		Appearance/Physical		Short-term toxicity to fish		Photo transformation in air	
Dermal Absorption		Melting Point		Long-term toxicity to fish		Hydrolysis	
Acute Toxicity: oral		Boiling Point		Short-term toxicity to aquatic invertebrates		Photo transformation in water	
Acute Toxicity: inhalation		Density		Long-term toxicity to aquatic invertebrates		Photo transformation in soil	
Acute Toxicity: dermal		Particle size distribution		Toxicity to aquatic algae and cyanobacteria		Biodegradation in water: screening test	
Acute Toxicity: other routes		Vapor Pressure		Toxicity to aquatic plants other than algae		Biodegradation in water and sediment: simulation tests	
Skin irritation/corrosion		Partition Coefficient		Toxicity to microorganisms		Biodegradation in soil	
Eye irritation		Water Solubility		Toxicity to other aquatic organisms		Mode of degradation in actual use	
Skin sensitization		Solubility in Organic Solvent		Sediment toxicity		Bioaccumulation: aquatic/sediment	

Respiratory sensitization	Surface Tension	Toxicity to terrestrial arthropods	Bioaccumulation: terrestrial
Repeated Dose toxicity: oral	Flash Point	Toxicity to soil macroorganisms except arthropods	Adsorption/desorption
Repeated Dose toxicity: inhalation	Auto Flammability	Toxicity to terrestrial plants	Henry's Law constant
Repeated Dose Toxicity: dermal	Flammability	Toxicity to soil microorganisms	Distribution Modeling
Repeated Dose Toxicity: other routes	Explosiveness	Toxicity to birds	Other Distribution Data
Genetic Toxicity in vitro	Oxidizing Properties	Toxicity to other above-ground organisms	Monitoring Data
Genetic Toxicity in vivo	Oxidation Reduction Potential	Biological effects monitoring	Field Studies
Carcinogenicity	Stability in organic solvents and identity of relevant degradation products	Biotransformation and kinetics	Additional Information on Environmental Fate and Behavior
Toxicity to Reproduction	Storage stability and reactivity towards container material	Additional ecotoxicological information	Other
Other	Other	Other	

Developmental Toxicity/tertogenecity	Stability: thermal, sunlight, metals		
Toxicity to reproduction: other studies	pH		
Neurotoxicity	Dissociation constant		
Immunotoxicity	Viscosity		
Specific investigations: other studies	Additional physic-chemical information		
Health surveillance data			
Epidemiological data			
Direct observations: clinical cases, poisoning incidents and other			
Sensitization data (humans)			
Exposure related observations in humans: other data			
Toxic effects on livestock and pets			
Additional toxicological information			

[i] The CISS indexing terms are derived from the OECD Harmonised Templates (www.oecd.org/ehs/templates/).