February 15, 2017

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.: 0794.16 OMB Control No.: 2070-0046

Docket ID No.: EPA-HQ-OPPT-2015-0744

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 2015, EPA received and screened 20,070 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 TSCA 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.

Section 8(e) data on newly discovered chemical hazards/risks is available via EPA's Chemical Data Access Tool (CDAT) (https://java.epa.gov/oppt_chemical_search/). There is also public outreach and information access to section 8(e) data through the TSCA Public Docket, and online databases that include section 8(e) records. OPPT is also currently in the process of migrating these section 8(e) submissions and posting future section 8(e) submissions to EPA's Chemview database (http://java.epa.gov/chemview).

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 section 8(e) and by those who wish voluntarily to 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) 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 (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" further to 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 was 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). 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 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 section 8(e) information on environmental releases and other aspects of section 8(e) reporting. This information is available via the Chemical Data Access Tool (CDAT) (https://java.epa.gov/oppt_chemical_search/).

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 2015, EPA has received and screened 20,070 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 federal 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,

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, the 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 Chemical Data Access Tool (CDAT) at https://java.epa.gov/oppt_chemical_search/.

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 2003 Reporting Guidance, the Agency clarified the circumstances under which certain information need not be reported to EPA under section 8(e). 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 September 6, 2016 (81 FR 43601, July 5, 2016). EPA received two comments, from the Environmental Working Group and the American Chemistry Council, during the comment period. EWG stated that it supports EPA's intention to renew OMB approval of its TSCA section 8(e) information collection authority. ACC commented on the burden estimate, CBI security, and recommended changes to EPA's TSCA section 8(e) guidance and website. EPA did not make changes in response to public comments. Copies of the comments and EPA's response to the comments are included as Attachment 2.

3(c) Consultations

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:

Scott Jensen
American Chemistry Council
Scott_Jensen@AmericanChemistry.com

Jenny Gaines, Director
Public Relations & Media
SOCMA
gainesj@socma.com

Dan Turner, Corporate Media Contact
DuPont USA
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Eric Wohlschlegel, Director
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Melissa Scanlan
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Stacy Cooks, External Affairs Coordinator
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James Proctor
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Ken Cook, President
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David Goldston, Director
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Natural Resources Defense Council
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EPA received no responses to its solicitation for consultations. A copy of EPA's consultation e-mail to the above nine potential respondents is included in Attachment 3.

3(d) Effects of Less Frequent Collection

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 exceed the Paperwork Reduction Act-imposed guidelines 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 of a sensitive 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 and Coal Products Manufacturing.

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. With the TSCA e-reporting initiative in place for other information collections, submitters of section 8(e) information have taken advantage of the new reporting option with virtually all reports submitted via CDX. The option to submit section 8(e) notices and FYIs electronically using the Chemical Information Submission System (CISS) reporting tool and electronic submission via CDX changes the way that companies interact with the Agency. Companies are registered with EPA to submit their data electronically to the Agency via CDX and the Agency in turn is 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 reduces 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 is 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 also benefits from receiving electronic submissions. Data systems that previously were populated manually are now populated electronically, reducing the potential for human error that exists when data are entered by hand. Agency personnel are also 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 in FIPS 197 pdf on the NIST website at http://csrc.nist.gov/publications/PubsFIPS.html 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 section 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.*

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 (http://www.oecd.org/ehs/templates/) is provided in Attachment 2. 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 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 <u>all</u> 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 will continue to use case numbers to identify 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 were 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, Virginia. 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, and via the Chemical Data Access Tool (CDAT) (https://java.epa.gov/oppt_chemical_search/). OPPT is currently in the process of migrating these section 8(e) submissions and posting future section 8(e) submissions to EPA's Chemview database (http://java.epa.gov/chemview).

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

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 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

As stated earlier in this document, essentially all submissions are being received in electronic format, therefore, estimates to follow are on the basis of 100% e-reporting. All unit burden estimates are electronic unit burden estimates, where applicable.

8(e) Submissions and Follow up Submissions

As in the previous ICR, EPA estimates that it should take approximately 49 hours per submission to judge and concur on the section 8(e)-applicability of obtained information and to prepare and submit the necessary information. This figure is based on an average of 45 hours per submission of managerial staff time to review and evaluate data and an additional 4 hours for staff training on section 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 4 hours per notice to assemble the required information and to prepare and review the submission. Additionally, the unit burden for recordkeeping is estimated at an additional 1.06 hours of clerical staff time for 8(e) initial submissions and at 0.06 hours for follow up submissions.

To quantify the number of submissions for the current ICR renewal, EPA utilizes data on the number of section 8(e) submissions for fiscal years 2013 through 2015. The average annual number of initial section 8(e) submissions and follow-up section 8(e) submissions are 408, and 86 respectively, as computed to provide the annual basis for this ICR renewal. Table 1 provides a summary of estimates for unit burden and the annual burden associated with the mandatory section 8(e) submissions.

Table 1. Section 8(e) Submission Unit Burden and Total Burden

Information Collection(s)	Hours per Submission (100% e-reporting)	Unit Burden (Hours	Number of Responses	Number of Respondents	Annual Burden

	Managerial	Technical	Clerical	)			
Section 8(e) – Initial	49	0	1.06	50.06	408	59	20,441
Section 8(e) – Follow-up/Supplemental	4	0	0.06	4.06	86	19	348
TOTAL					494	59	20,789

Voluntary FYI Submissions and Follow up Submissions

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 also estimated at an average of 45 hours per submission of managerial staff time to review and evaluate data plus an additional 4 hours for staff training on section 8(e) regulatory requirements. Similarly, the FYI follow-up submission is estimated at 4 hours per notice, assuming 3 hours to assemble the required information, 1 hour to prepare and review the submission. As is the case for 8(e) submissions, the estimates for FYI submissions are on the basis of 100% electronic reporting with recordkeeping estimated at an additional 1.06 hours of clerical staff time for FYI initial submissions and at 0.06 hours for FYI follow up submissions.

To quantify the number of submissions for the current ICR renewal, EPA utilizes data on the number of FYI submissions for fiscal years 2013 through 2015. The average annual number of initial FYI submissions and follow-up FYI submissions are 12, and 1 respectively,[1] as computed to provide the annual basis for this ICR renewal. Table 2 provides a summary of estimates for unit burden and the annual burden associated with the voluntary FYI submissions.

Table 2. FYI Submission Unit Burden and Total Burden

Information Collection(s)	Hours per Submission (100% e-reporting)			Unit Burden (Hours)	Number of Responses	Number of Respondents	Total Annual Burden
	Managerial	Technical	Clerical				
FYI Submission – Initial	49	0	1.06	50.06	12	9	584
FYI Submission – Follow-up	4	0	0.06	4.06	1	1	4
TOTAL					13	9	588

CDX Registration Activities to Enable Electronic Reporting

EPA estimates that technical staff at companies submitting section 8(e) notices and FYIs would incur the following one-time burden to complete CDX registration activities (including

[1] Although no follow-up FYI submissions were received during fiscal years 2013, 2014, and 2015, EPA conservatively estimates an average of one submission annually during the next ICR period.

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. The one-time CDX burden includes the following:

CDX registration – Based on the TSCA section 5 ICR renewal, EPA assumed that companies would spend about eleven minutes per employee to register with CDX (EPA, 2015).

CDX electronic signature (labor burden) – Based on the TSCA section 5 ICR renewal, EPA assumed that companies' technical staff would spend 21 minutes preparing, submitting and filing an electronic signature agreement (Authentication of Identity) form to EPA, per employee (EPA, 2015).

To estimate the number of CDX registrants who will submit initial and follow-up section 8(e) and voluntary FYI submissions, EPA averages the total number of distinct section 8(e) and FYI submitters (for both initial and follow-up submissions) for fiscal years 2013, 2014 and 2015 to obtain the average of 65 annual registrations for the basis of this ICR renewal. Table 3 provides a summary of estimates for unit burden and the annual burden associated with CDX registrations.

Table 3. Estimated Annual Burden Associated with CDX Registration Activities

Activity	Estimated Burden Hours per Response				Number of Responses	Estimated Number of Annual Respondents	Annual Burden
	Managerial	Technical	Clerical	Total			
CDX Registration Activities							
CDX Registration	0	0.18	0	0.18	65	65	12
CDX E-Signature	0	0.35	0	0.35			23
TOTAL	**0**	**0.53**	**0**	**0.53**	**65**	**65**	**35**

Based on the figures presented in the preceding tables, the total estimated number of annual responses is 572, which include: initial and follow-up/supplemental section 8(e) submissions; initial and follow-up voluntary FYI submissions; and CDX registrations. The industry reporting burden totals 21,412 hours (See also Table 5).

6(b) Estimating Submitter Costs

EPA estimates submitter costs using burden estimates above along with labor rates obtained from the Bureau of Labor Statistics (BLS). Table 4 presents the derivation of the loaded industry wage rates used in this analysis. The wages and fringe benefits for the Managerial,

Technical, and Clerical labor categories are drawn from the BLS "Employer Costs for Employee Compensation Supplementary Tables Historical Data" for December 2015 (BLS, 2016). For each labor category, wages are loaded using fringe benefit rate from BLS plus a 17 percent overhead rate.

In Table 5, the unit burden estimates from the previous sections are combined with the wage rates in Table 4 to compute unit costs (per response) and total costs. Overall, the submissions costs associated with the burden of 21,412 hours totals $1,650,068.

Table 4: Industry Wage Rates (2015$)

Labor Category	Data Sources [a]	Date	Wage	Fringe Benefit	Fringes as % Wage	Over-head % wage [b]	Fringe + Overhead Factor [c]	Hourly Loaded Wages [d]
			(a)	*(b)*	*(c) =(b)/(a)*	*(d)*	*(e)=(c)+(d)+1*	*(f)=(a)×(e)*
Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial"	Dec-15	$45.90	$24.30	53%	17%	1.70	$78.00
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional and related"	Dec-15	$44.06	$24.33	55%	17%	1.72	$75.88
Clerical	BLS ECEC, Private Manufacturing industries, "Office and Administrative Support"	Dec-15	$19.91	$10.37	52%	17%	1.69	$33.66

Footnotes

[a] Source: *Employer Costs for Employee Compensation Supplementary Tables: December 2006 – December 2015* (U.S. Bureau of Labor Statistics, 2016).

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

[c] The inflation factor of "1" in the formula for calculating the fringe + overhead factor means wage data are not escalated to reflect inflation.

[d] Wage data are rounded to the closest cent in this analysis.

Table 5: Industry Annual Reporting Costs (2015$)

Activity	Unit Burden (hours)	Weighted Average Wage Rate	Unit Cost (per response)	Number of Responses	Number of Respondents	Annual Cost
Section 8(e) – Initial	50.06	$77.06	$3,858	408	59	$1,575,219
Section 8(e) – Follow-up/Supplemental	4.06	$77.34	$314	86	19	$26,901
Subtotal 8(e) Submissions				**494**	**59**	**$1,602,120**
FYI Submission – Initial	50.06	$77.06	$3,858	12	9	$45,006
FYI Submission – Follow-up	4.06	$77.34	$314	1	1	$314
Subtotal FYI Submissions				**13**	**9**	**$45,320**
CDX Registration	0.18	$75.88	$14	65	65	$892
CDX E-Signature	0.35	$75.88	$27			$1,735
Subtotal CDX Submissions				**65**	**65**	**$2,627**
Total hours and cost		21,412	hours	572	65	**$1,650,068**

6(c) Estimating EPA Burden and Costs

For this ICR, EPA estimates that a GS-13, Step 5, staff member spends 7.1 hours to initially review, process, and/or answer questions on each submission. The Agency wage rate is

presented in Table 6. Given 494 Section 8(e) submissions and 13 FYI submissions, yielding 507 total submissions, with each requiring 7.1 hours of EPA staff time, annual agency burden totals 3,600 hours. Applying the agency wage rate in Table 6 yields annual agency costs at $284,052 (see also Table 7).

Table 6: Agency Wage Rate (2015$)

Labor Category	Data Source for Wage Information	Wage ($/hour)	Fringe Benefit	Fringes as % wage	Overhead as % wage	Fringe + Overhead Factor	Loaded Wage ($/hr)
		(a)	(b)	(c) = (b) / (a)	(d)	(e) = (c) + (d) + 1	(f) = (a) * (e)
EPA staff	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-13 Step 5 pay rates [a]	$49.32	Included in 60% overhead	N/A	60% [b]	1.6	$78.91

Footnotes:

[a] Source: U.S. Office of Personnel Management. (2015). Salary Table 2015-DCB. Retrieved March 19, 2015 from Pay & Leave: Salaries & Wages: www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/15Tables/html/DCB_h.aspx.

[b] The 60 percent fringes-and-overhead rate is from an EPA guide, *Instructions for Preparing ICRs* (US EPA, 2009).

6(d) Bottom Line Burden Hours and Costs

Table 7 below summarizes the burden and costs estimates presented in previous sections.

Table 7. Bottom Line Annual Burden Hours and Costs

Activity	Annual Responses	Respondents	Annual Burden	Annual Cost
INDUSTRY				
Section 8(e) Initial and Follow-up	*494*	*59*	*20,789*	*$1,602,120*
FYI Initial and Follow-up	*13*	*9*	*588*	*$45,320*
CDX Registration and e-Signature	*65*	*65*	*35*	*$2,627*
INDUSTRY TOTAL	**572**	**65**	**21,412**	**$1,650,068**
AGENCY TOTAL	**N/A**	**N/A**	**3,600**	**$284,052**

6(e) Change in Burden

This request represents a net increase of 2,894 hours from that currently in the OMB inventory (from 18,518 to 21,412 hours). This reflects an overall increase in the number of section 8(e) initial submissions, which increased from 299 to 408 submissions. Offsetting that increase are slight decreases in certain other areas, as well as the transition from 90% to 100% e-reporting.

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 be 50.06 hours per initial section 8(e) submission and 4.06 hours per follow-up/supplemental section 8(e) submission. The same estimates apply to FYI initial and follow-up submissions. For CDX registrations, burden per registration is estimated at 0.53 hours. 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-2015-0744, 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-2015-0744 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.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under Docket ID No. EPA-HQ-OPPT-2015-0744. These attachments are available for online viewing at http://www.regulations.gov.

Attachment 1: 15 U.S.C. 2603, Toxic Substances Control Act (TSCA), Section 4

Attachment 2: Public Comments Received from the American Chemistry Council (ACC) and the Environmental Working Group (EWG); copy of EPA's Response to the Public Comments

Attachment 3: Consultations Message Sent by EPA to Potential Respondents

REFERENCES

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