

**1 Supporting Statement for a Request for OMB Review under
the Paperwork Reduction Act**

1. IDENTIFICATION OF THE INFORMATION COLLECTION

l(a) Title and Numbers of the Information Collection

**TITLE: Correction of Misreported Chemical Substances on the Toxic
Substances Control Act (TSCA) Chemical Substance Inventory**

EPA ICR No.: 1741.08 OMB Control No.: 2070-0145

Docket ID No.: EPA-HQ-OPPT-2017-0320

l(b) Short Characterization

Section 8(b) of the Toxic Substances Control Act (TSCA), requires the Environmental Protection Agency (EPA) to compile and keep current an Inventory of Chemical Substances in Commerce (hereinafter “the Inventory”), which is a listing of chemical substances manufactured, imported and processed for commercial purposes in the United States. Individual plant or factory sites producing chemicals submit the required information.

This information collection request pertains to the use of the TSCA Chemical Substance Inventory Reporting Form C (EPA Form 7710-3C; see Attachment 4 below), which the chemical industry uses exclusively in submitting requests to EPA’s Office of Pollution Prevention and Toxics (OPPT) for correcting misreported chemical identities of substances listed on the Inventory. Such requests pertain only to errors discovered in the original submissions to the Inventory when the Inventory was first established in 1979.

Each year, OPPT receives a small number of such correction requests from chemical companies or their legal representatives. In almost all cases, a submitter who wishes to correct the chemical identity of a substance that was previously misreported for the Inventory initiates these requests for correction. The correction mechanism allows the submitter to add the correct substance to the Inventory without having to file a Premanufacture Notice (PMN) under TSCA section 5.

In submitting a request for correction, the submitter provides certain basic information to EPA on Form C. This information is stored in one of EPA’s mainframe computers. This information allows OPPT to establish a correct chemical identity that accurately reflects the substance the submitter manufactures. Since the Inventory performs a regulatory function by distinguishing between an existing chemical and a new chemical, it is imperative that the Inventory be accurate. A correct Inventory also ensures the accuracy of EPA’s chemical screening and risk assessment activities.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

TSCA requires EPA to identify, assess and control risks of injury to human health and the environment posed by commercial chemicals. TSCA section 8(b) requires EPA to compile and keep current a complete list of chemical substances manufactured or processed in, or imported into, the United States. Under TSCA section 8(a) the Administrator of EPA promulgates rules to provide for the maintenance and collection of records from manufacturers, importers and processors of commercial chemicals. The Inventory Update Rule (IUR), which EPA uses periodically to update the TSCA section 8(b) Inventory, is codified at 40 CFR 710. Copies of the relevant sections of TSCA and of the Code of Federal Regulations are attached below (see Attachments 1 and 2, respectively).

The purpose of the Inventory is to define, for the purpose of TSCA, what chemical substances exist in U.S. commerce. Substances not included on the Inventory are considered to be new substances that are subject to the Premanufacture Notification (PMN) requirements stipulated under section 5(a) of TSCA.

The need for correcting chemical identities listed on the Inventory arose following the initial Inventory reporting period, when both EPA and the chemical industry recognized that substances submitted for inclusion in the initial Inventory could be, for various reasons, incorrectly described by reporting companies. EPA determined that reported substances may have been unintentionally misidentified as a result of simple typographical errors, the misidentification of substances, or the lack of sufficient technical or analytical capabilities fully to characterize the exact chemical substances. Although not required to do so under TSCA, EPA developed guidelines, at the request of industry, under which industry could correct the chemical identities of incorrectly described substances listed in the Inventory. EPA published these guidelines in the Federal Register on July 29, 1980 (45 FR 50544); see Attachment 3.

For the Inventory to perform its regulatory function, it must accurately identify those substances that exist in U.S. commerce. Otherwise the Inventory will not be able to provide reliable information that EPA needs in performing chemical screening and risk assessment activities under TSCA. The submitter, on the other hand, must be certain that the substance he/she manufactures or imports is correctly identified on the Inventory, so that he/she will be in full compliance with TSCA reporting requirements. The correction mechanism ensures the accuracy of the Inventory without imposing an unreasonable burden on the chemical industry. Without the Inventory correction mechanism, a submitter would have to file a PMN to place the correct chemical substance on the Inventory whenever finding that the previously reported substance was misidentified. This would impose a much greater burden on both EPA and the submitter than the existing correction mechanism.

2(b) Practical Utility/Users of the Data

OPPT will use the data contained in the correction request to alter the incorrect chemical identities in the Inventory so that the information is complete and accurate. Many branches of the

Agency rely on the Inventory when making regulatory decisions. Within OPPT, the Chemical Control Division (CCD) and the Interagency Testing Committee (ITC) frequently use the Inventory. Both CCD and the ITC rely on the accuracy of the Inventory for screening chemical substances for further attention or testing. If the Inventory data were inaccurate, CCD or the ITC could inadvertently screen a fictitious chemical, i.e., a misreported substance not yet corrected on the Inventory.

As well as providing vital government service, the Inventory provides information necessary to members of industry. Correspondence between the private and public sectors of the U.S. concerning the Inventory is ceaseless. OPPT receives hundreds of inquiries regarding the Inventory each year. These letters are primarily requests for Chemical Abstracts Service (CAS) Registry Numbers or Accession Numbers assigned to a substance, although the Agency also receives a variety of other requests regarding TSCA.

One such request expresses a bona fide intent to manufacture a chemical substance. A “bona fide” letter requests a formal search of the Inventory for a particular chemical substance. If the substance is included on the Inventory, the potential manufacturer need not submit a PMN. Since failure to submit a PMN for a substance not included on the Inventory, i.e., a new chemical, would constitute a violation of TSCA, the Inventory must be correct to ensure that only substances that are actually manufactured are included. An Inventory correction letter requests a change in the Inventory to correct a previously misreported substance. This correction mechanism allows the Inventory to be kept accurately, thus ensuring that the Agency’s responses to industry inquiries, e.g., bona fide, Accession Number and CAS Registry Number requests, are accurate. Furthermore, an accurate Inventory also ensures that the Agency performs risk assessments on the correct chemical substance and that industry will not need to submit unnecessary PMNs.

3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

Not applicable: the required data can only be provided by the submitter and no other government agency collects such information.

3(b) Public Notice Required Prior to ICR Submission to OMB

Prior to submission to OMB, this ICR was made available to the public for comment through a Federal Register notice ([83 FR 5257, February 6, 2018 \(FRL-9970-37\)](#)). The public had 60 days to provide comments. No comments were received.

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 original or

renewal ICR to OMB for review and approval. Although consultations were not completed for this renewal, EPA will pursue additional consultations with interested parties during the development of the next renewal of this collection.

3(d) Effects of Less Frequent Collection

Not applicable, since the frequency of correction depends wholly on industry.

3(e) General Guidelines

To the best of EPA's knowledge, this collection does not exceed any of the Paperwork Reduction Act guidelines at 5 CFR 1320.6.

3(f) Confidentiality

Respondents may claim information submitted to EPA on the correction form as confidential if release of such information would reveal the submitter's trade secrets or proprietary information, as defined by TSCA section 14. A respondent may claim as confidential any information submitted on the reporting form, except the identity of a chemical substance that the respondent has not claimed as confidential in the existing Inventory data base. Respondents must assert claims of confidentiality at the time they submit the information to EPA and only in the manner specified by EPA.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act made several substantive amendments to TSCA. The 2016 amendments include new provisions that impact procedures for how confidential business information (CBI) claims can be made and the Agency's obligations to review and make determinations concerning the validity of the claims. Persons submitting correction requests that claim reported information CBI must follow the general requirements of TSCA section 14 for making such claims, as modified by the specific provisions under TSCA section 8(b). TSCA section 14(c) requires that submitters claiming CBI must provide a specific statement attesting to the basis for the CBI claims. TSCA also requires that all submissions containing information claimed as CBI must also include substantiations in support of the CBI claims.

Based on its experience, EPA expects that some information included in correction requests, specifically submitter information (company name and contact information), may be claimed as CBI. EPA has established elaborate procedures for handling, storing, processing, and disposing of CBI, in accordance with stipulations set forth at 40 CFR Part 2, subpart B. In general, EPA houses confidential information in secured areas and only persons specifically authorized by EPA may access such information. EPA further restricts access to computer systems containing TSCA CBI to those who have a need for access. Such systems may be accessed only via special computer terminals in restricted areas. Furthermore, the procedures set forth in 40 CFR Part 2, subpart B, strictly govern any transfer of TSCA CBI from EPA to another agency, and the Agency receiving such information must agree to comply fully with EPA procedures.

Furthermore, this information collection fully complies with the requirements of the Privacy Act of 1974 and OMB Circular A-108.

3(g) Sensitive Questions

Not applicable; this information collection does not include questions of a sensitive nature.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

The respondent community consists of persons manufacturing or importing chemicals listed on the Inventory and regulated under TSCA section 8. In general, the industry segments that compose the respondent community for this information collection are those that produce or import organic chemicals, who have already reported to the initial Inventory effort, and who need to make a correction to that submission. Using North American Industry Classification System (NAICS) codes, these persons are typically classified under Chemical Manufacturing (NAICS 325) and Petroleum and Coal Product Manufacturing (NAICS 324).

4(b) Information Requested

(i) Data Items

The correction request form requires the submitter to include information concerning the chemical substance's identity, plant site where it is produced, production volume, site limitations, and imports/exports of the substance, if applicable. Additionally, the submitter must provide substantiation of any confidentiality claims.

(ii) Respondent Activities

Most of the information contained on the Form C reporting form is readily accessible to the submitter as "customary business practices," such as production and site-limitation data. The remaining information is equally apparent, e.g., plant site location and whether the submitter imports or manufactures.

With regard to the chemical substance identity requirement, such data should be predetermined before the time of an Inventory correction submission. Since industry almost exclusively initiates corrections to the Inventory, the submitter presumably has already determined the new chemical substance identity before he/she is able to conclude that the substance was previously misidentified. Therefore, the information required to submit a correction request is readily available to the submitter, who needs only to transpose the data to the form the Agency provides.

Furthermore, if, for whatever reason, the submitter is unable to produce a suitable technical name for the corrected substance, he/she need only provide the Agency with

information concerning the reaction mechanism, including all reactants. In such a case, EPA will devise an appropriate name for the chemical substance.

It is significant to note that in almost all cases it is industry, not EPA, that initiates correction requests. The Agency does not require industry to provide correction information nor does EPA have an obligation to provide a correction mechanism or to specify a reporting format. The correction mechanism exists at the request of industry and the EPA form is used because it reduces the burden on both the Agency and industry by providing a clear format for the data. Because the Form C has been in use since the initial Inventory reporting period, submitters are generally familiar with the format and with the information needed to complete the form, as well as the process for submitting a hard-copy form to the Document Control Officer in EPA's Office of Pollution Prevention and Toxics. Furthermore, use of the form guards against delays due to incomplete submissions, as the form clearly outlines the required information.

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

5(a) Agency Activities

As a result of the correction mechanism, the Agency must review the original submissions to determine whether a correction is needed. Once EPA confirms the validity of the correction, the Agency will process the correction information. EPA will maintain the confidentiality of the information at the request of the submitter, and will forward the results to the Chemical Abstracts Service (CAS) where the data are stored. EPA will add the corrected chemical substance to the Inventory while the incorrectly reported substance will become a candidate for deletion from the Inventory, if no other person has reported the same substance, through notice and comment rulemaking. Additionally, EPA will analyze submissions for confidentiality, review CBI substantiation claims, and provide appropriate protection for confidential data

5(b) Collection Methodology and Management

EPA sends all of the submitted information, after processing, to an EPA contractor, Chemical Abstracts Service (CAS), whereupon the contractor enters the information to a computerized system. The public is able to access non-confidential data through commercial on-line systems, or on compact discs (CDs) available from the National Technical Information Service (NTIS).

5(c) Small Entity Flexibility

No small entity exemption exists. A small entity exemption would be meaningless or counterproductive to the interests of small entities who may wish to submit corrections. In addition, the amount of information required to complete a correction request is minimal. Furthermore, the correction cannot be processed without each piece of information requested, as only essential data are solicited. Any small entity simplification of the correction process would fail to provide the Agency with the pertinent information needed to make a correction.

5(d) Collection Schedule

Not applicable since industry, not EPA, initiates corrections as necessary.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION**6(a) Estimating Respondent Burden**

This ICR addresses an information collection effort that has been undertaken in the same manner since 1980. Over time, the need for correcting the initial Inventory entries has diminished, given that most of the necessary corrections presumably have been discovered and made by now, after over 30 years and several Chemical Data Reporting (CDR) cycles.¹ With the passage of the Frank R Lautenberg Chemical Safety Act for the 21st Century, additional burden per submission is incurred to meet CBI substantiation requirements for Chemical Identity and for other (non-chem ID) data elements. A base set of substantiation questions apply to the confidentiality claims for all data elements, with an additional set of questions that apply to the confidentiality claims for chemical substance identity. However, as stated in the previous ICR, EPA still estimates the number of respondents to be no more than nine per year, based on recent experience, with resulting total burden and cost at minimal levels.

6(b) Estimating Respondent Burden and Cost

Table 1 presents unit burden per submission involving one chemical substance. Table 2 provides wage rates according to labor category. Table 3 provides unit cost per submission. Table 4 summarizes unit burdens and costs and provides total burden/cost for nine submissions. Burden estimates for form completion and recordkeeping (items 1 and 4) are the same as in the previous ICR. Burden estimates for CBI substantiation are obtained from the recent ICR supporting statement associated with the EPA Inventory (Active-Inactive) Notification rule (EPA 2017). Annual total respondent burden/cost are estimated at 39 hours / \$3,030 per year.

¹ Previously named Inventory Update Rule (IUR) reporting cycle.

Table 1: Respondent Unit Burden per Form C

Respondent Activity	Managerial Hours	Technical Hours	Clerical Hours	Overall Unit Burden
Certification Statement, Plant Site Information, Technical Contact, Production Range: by Activity (M/I), and Site-Limited, Chemical Substance Identity (Number, Name, Class), CBI Designations	0.50	1.50		2.00
Chemical Identity CBI Substantiation	0.38	0.77		1.15
Non-Chemical ID CBI Substantiation	0.32	0.64		0.96
Recordkeeping			0.25	0.25
TOTAL				4.36

Source for CBI Substantiation Estimates: *Supporting Statement: TSCA Section 8(b) Reporting Requirements for TSCA Inventory Notification* (US EPA June, 2017).

Table 2: Industry Wage Rates (2016\$)

Labor Category	Data Series ^a	Date	Wage	Fringe Benefit	Fringes as % Wage	Overhead % 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-16	\$50.09	\$24.65	49%	17%	1.66	\$83.26
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional and related"	Dec-16	\$45.66	\$24.98	55%	17%	1.72	\$78.40
Clerical	BLS ECEC, Private Manufacturing industries, "Office and Administrative Support"	Dec-16	\$20.29	\$10.52	52%	17%	1.69	\$34.26

Footnotes:

^a Source: *Employer Costs for Employee Compensation Supplementary Tables: December 2006 – December 2016* (U.S. Bureau of Labor Statistics, 2017).

^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 3: Respondent Unit Cost per Form C

Respondent Activity	Hours	Activity Average Wage Rate	Overall Unit Cost
Certification Statement, Plant Site Information, Technical Contact, Production Range: by Activity (M/I), and Site-Limited, Chemical Substance Identity (Number, Name, Class), CBI Designations	2.00	\$79.62	\$159.24
Chemical Identity CBI Substantiation	1.15	\$80.01	\$92.01
Non-Chemical ID CBI Substantiation	0.96	\$80.02	\$76.82
Recordkeeping	0.25	\$34.26	\$8.57
TOTAL	4.36		\$336.64

Table 4: Respondent Total Burden and Cost

Respondent Activity	Overall Unit Burden	Total Burden	Activity Average Wage Rate	Overall Unit Cost	Total Cost
Certification Statement, Plant Site Information, Technical Contact, Production Range: by Activity (M/I), and Site-Limited, Chemical Substance Identity (Number, Name, Class), CBI Designations	2.00	18.00	\$79.62	\$159.24	\$1,433.16
Chemical Identity CBI Substantiation	1.15	10.35	\$80.01	\$92.01	\$828.10
Non-Chemical ID CBI Substantiation	0.96	8.64	\$80.02	\$76.82	\$691.37
Recordkeeping	0.25	2.25	\$34.26	\$8.57	\$77.09
TOTAL		39.24			\$3,029.72

6(c) Estimating Agency Burden and Cost

Costs associated with this collection include the printing and distributing of reporting forms, providing reporting assistance, reviewing and processing of the report forms and entry of data into the Inventory databases. Table 5 provides the Loaded Wage Rate for Agency staff and Table 6 details Agency activities, burdens, and cost. Annual total Agency cost is estimated at \$3,574 per year.

Table 5: Agency Wage Rate (2016\$)

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-12 Step 1 pay rates ^a	\$37.13	Included in 60% overhead	N/A	60% ^b	1.6	\$59.41

Footnotes:
^a Source: U.S. Office of Personnel Management. (2016). Salary Table 2016-DCB. Retrieved March 21, 2016, from Pay & Leave: Salaries & Wages: www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/16Tables/html/DCB_h.aspx.
^b The 60 percent fringes-and-overhead rate is from an EPA guide, *Instructions for Preparing ICRs* (US EPA, 2009).

Table 6. Agency Burden and Cost for Corrections to the TSCA Inventory

Activity	Burden	IC Burden (Hours)	Labor Cost ^a	Non-Labor Cost		Total Cost (2016\$)
Staff review of correction requests	2 hours x 9 submissions	18	\$1,069.38			\$1,069.38
Submission processing and data entry	2 hours x 9 submissions	18	Included in non-labor estimate	\$275.25 x 9 submissions	\$2,504.25	\$2,504.25
Total		36				\$3,573.63

Footnotes:
^a All FTE hours are associated with a labor cost based on wage rate for GS-12 Step 1 of \$37.13/hour (OPM, 2016)
^b Based on contractor's fee plus an estimate of 2 hour EPA time (0.50 non-exempt and 1.5 exempt).

6(d) Bottom Line Burden Hours and Cost

(i) Respondent Burden

Burden: 39 hours
 Cost: \$3,030

(ii) Agency Burden

Burden: 36 hours
 Cost: \$3,574

(iii) The complex collection - Not applicable.

(iv) Variations in the annual bottom line - Not applicable.

6(e) Reasons for Change in Burden

This request represents a net increase of about 19 hours from that currently in the OMB inventory (from 20 to 39 hours). This increase reflects program changes in CBI substantiation requirements, as enacted in the Frank R Lautenberg Chemical Safety Act for the 21st Century.

6(f) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0145, is estimated to be 2.25 hour per response. 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-2017-0320, 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-2017-0320 and OMB Control No. 2070-0145, 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-2017-0320. These attachments are available for online viewing at <http://www.regulations.gov>.

- Attachment 1:** Toxic Substances Control Act Section 8 (15 USC 2607)
- Attachment 2:** Inventory Reporting Regulations (40 CFR 710)
- Attachment 3:** Availability of TSCA Revised Inventory (45 FR 50544)
- Attachment 4:** TSCA Chemical Substance Inventory Reporting Form C (EPA Form 7710-3C)

References

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