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

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Numbers

Title: Expanded Access to TSCA Confidential Business Information

EPA ICR No.: 2570.01; OMB Control No. 2070-[new]

Docket ID No.: EPA-HQ-OPPT-2017-0652

1(b) Short Characterization

The Toxic Substances Control Act of 1976 (TSCA) amendments of June 22, 2016, known as the Frank R. Lautenberg Chemical Safety for the 21st Century Act, expanded the categories of people to whom EPA may disclose TSCA confidential business information (CBI). The amendments authorize EPA to disclose TSCA CBI to state, tribal, and local governments; environmental, health, and medical professionals; and emergency responders, under certain conditions, including consistency with guidance that EPA is required to develop. Three guidance documents have been developed, corresponding to the new authorities in TSCA section 14(d)(4), (5), and (6).

The conditions for access vary under each of the new provisions, but generally include the following: requesters must show that they have a need for the information related to their employment, professional, or legal duties; recipients of TSCA CBI are prohibited from disclosing or permitting further disclosure of the information to individuals not authorized to receive it (physicians/nurses may disclose the information to their patient); and except in emergency situations EPA must notify the entity that made the CBI claim at least 15 days prior to disclosing the CBI. In addition, under these new provisions, requesters (except in some emergency situations) are required to sign an agreement and may be required to submit a statement of need to EPA.

In accordance with the requirements of TSCA section 14(c)(4)(B), the guidance documents cover the content and form of the agreements and statements required under each provision, and include information on where and how to submit requests to EPA.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Section 14(c)(4)(B) of TSCA requires that EPA develop guidance concerning the content and form of the agreements and statements required under TSCA section 14(d)(4), (5), and (6).

2(b) Use/Users of the Data

EPA will review requests for information under section 14(d)(4), (5), and (6), as well as the required agreements and statements of need, to determine whether a given request for TSCA CBI complies with statutory requirements and may be granted. The information (agreements, statements of need, requests for access, and EPA's determinations of whether access may be granted) will be maintained within the Office of Pollution Prevention and Toxics (OPPT) and the Office of General Counsel (OGC).

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

3(a) Non-Duplication

No other Federal agency or department could provide the information necessary for EPA to determine whether a given request for access to TSCA CBI may be granted. The data being collected are not available from any other sources and can only be collected from individuals and/or other governments (e.g., states) themselves.

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

Prior to submission to the Office of Management and Budget (OMB), this ICR was made available to the public for comment. In the **Federal Register** on March 12, 2018 (83 FR 10719) (FRL-9975-24), EPA announced the availability of and solicited comment on the draft ICR. The comment period closed on May 11, 2018. No comments were received.

3(c) Consultations

Under 5 CFR 1320.8(d)(1), OMB requires Federal 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. In accordance with this regulation, EPA will pursue consultations with interested parties during the development of this collection.

3(d) Effects of Less Frequent Collection

This collection is made when a requester decides to submit a request for TSCA CBI information to EPA. Such request is not required, and occurs at a frequency corresponding to the needs of the requester.

3(e) General Guidelines

This information collection complies with the general guidelines found at 5 CFR 1320.5.

3(f) Confidentiality

The information collected will be stored at EPA Headquarters in paper files and in a secured local area network, the Chemical Information System (CIS) module. Any hard-copy information that is discarded from the system is shredded. Any personal information or CBI

included in a request would be treated in accordance with the Privacy Act, section 14 of TSCA, and the Freedom of Information Act.

3(g) Sensitive Questions

There are no sensitive questions contained in this information collection.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) **Respondents and NAICS Codes**

Respondents affected by this activity are mainly government employees (federal, state, local, tribal), as well as medical professionals, such as doctors and nurses. The NAICS code for health care and social assistance is 62.

4(b) Information Requested

(i) Data Items

There are currently no specific forms used to make a request under these new provisions. The guidance includes text for the statutorily-required statements and agreements, and suggests the submission of several narrative statements, as elaborated in the next paragraph. These statements will help EPA to verify the requestor and circumstances meet the criteria for access to the TSCA CBI information, in accordance with TSCA section 14(d).

(ii) Respondent Activities

The process that CBI requestors follow in order to request and maintain access to TSCA CBI involves the following:

For access under TSCA section 14(d)(4) (state, tribal, and local governments), requesters—

- (1) Review the Guidance Document.
- (2) Complete and sign an agreement regarding protection of CBI.
- (3) Develop statement of legal authority.
- (4) Develop statement of CBI safeguarding procedures.
- (5) Write request for information.
- (6) Management review and preparation of submission.
- (7) Manage CBI information.
- (8) Keep records (store, file, or maintain copy of agreements for in-house reference)

For access under TSCA section 14(*d*)(5) (health and environmental professionals, non- emergency), requesters—

- (1) Review the Guidance Document.
- (2) Gather required information and complete statement of need (selecting statement of need, providing eligibility information, describing circumstance of request).

- (3) Read and sign confidentiality agreement.
- (4) Review and prepare submission.
- (5) Manage CBI information
- (6) Keep records (store, file, or maintain copy of agreements for in-house reference).

For access under TSCA section 14(d)(6) (emergencies), requesters—

- (1) Review the Guidance Document.
- (2) Review and prepare submission.
- (3) Manage CBI information.
- (4) May be required to prepare a statement of need.
- (5) May be required to sign a confidentiality agreement.
- (6) Keep records (store, file, or maintain copy of agreements, if any, for inhouse reference).

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

5(a) Agency Activities

Upon receipt of a request for CBI access, EPA (principally OPPT and OGC staff and management) will evaluate the information provided by the requestor to determine whether access to the information requested may be granted pursuant to TSCA section 14(d). EPA may ask the requestor clarifying questions, and will notify the requestor of the decision to grant or deny the request. When a request is granted, EPA will advise the requestor on how to access the information, or where practical, simply provide the information orally. Prior to release (in the case of the non-emergency access provisions) or shortly after release (in the case of emergencies), EPA is required by TSCA section 14(g)(2) to notify the person who made the CBI claim of the release.

5(b) Collection Methodology and Management

Requests may be made on paper, electronically (e.g., via email—an electronic request system may be developed in the future), or (at least in emergency situations) orally. Documents relating to the request will be stored by OPPT, most likely in OPPT's Chemical Information System (CIS). CIS is housed on a secured Local Area Network with OPPT internal access only. The system is available to CBI-cleared users exclusively.

5(c) Small Entity Flexibility

All requesters are treated in the same manner, in accordance with each statutory provision.

5(d) Collection Schedule

The information is not collected on any particular schedule—it is collected only when a requestor chooses to make a request for access to CBI information, which is voluntary, and according to the requestor's needs.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

State, local, or tribal governments; health and environmental professionals in nonemergency situations; and emergency responders choosing to request access to TSCA CBI will undertake a number of actions associated with TSCA sections 14(d)(4), (5), and (6), respectively. Because this ICR presents new requirements, EPA has used its best professional judgement and experience from previous ICRs with similar activities to determine the amount of time that would be required to complete the tasks outlined in section 4 (b) of this ICR. It is estimated that in the next three years the total number of submissions under TSCA section 14(d)(4), (5), and (6) will be 18 (six per year, under TSCA section 14(d)(4), (5), and (6) combined).

The state, local, or tribal government annual burden is given in Table 6.1. The annual burden for health and environmental professionals in non-emergency situations is given in Table 6.2. The annual burden for emergency requesters is provided in Table 6.3. The total annual burden for all state, local, or tribal governments is estimated to be **42** hours. The total annual burden for health or environmental professionals in non-emergency situations is **37** hours. For emergency requests, the total annual burden is **10** hours. Therefore, the total annual burden associated with TSCA section 14(d) requests is **89** hours.

	Managerial	Technical	Clerical	Request	Annual	Annual
Activity	Hours \$88.08	Hours \$65.34	Hours \$27.87	per Year	Burden Hours	Costs (\$)
Rul	e Familiarization	(one-time bure	den)			
Review of the guidance	0.27	0.55	0	2	1.64	\$119.43
	Reque	st Submission				
Filling in the model agreement	0	0	2	2	4	\$111.48
Developing statement of legal authority	0	4	0	2	8	\$522.72
Developing statement of CBI safeguarding procedures	0	3	0	2	6	\$392.04
Written request for information	0	2	0	2	4	\$261.36
Management review and preparation of submission	3	0	0	2	6	\$528.48
Management of CBI information	0	2	2	2	8	\$372.84
Recordkeeping						
Recordkeeping (store, file, or maintain copy of agreements for in- house reference)	0	0	2	2	4	\$111.48
TOTAL	3.27	11.55	6		41.64	\$2,419.83

Table 6.1: Total Annual Respondent Burden and Costs Associated with a TSCA Section14(d)(4) request. State, Local, or Tribal government.

Activity	Managerial Hours \$88.08	Technical Hours \$65.34	Clerical Hours \$27.87	Reques t per Year	Annual Burden Hours	Annual Costs
Ru	ıle Familiarizat	ion (one-time	burden)			
Review the Guidance	0	0.55	0	3	1.65	\$107.81
	Request	Submissions	_			-
Gather required information and complete statement of need (selecting statement of need, providing eligibility information, describing circumstance of request)	0	4	0	3	12	\$784.08
Read and sign the confidentiality agreement	0	0.75	0	3	2.25	\$147.01
Review and preparation of submission	0	3	0	3	9	\$588.06
Management of CBI information	0	2	0	3	6	\$392.04
Recordkeeping						
Recordkeeping (store, file, or maintain copy of agreements for in-house reference)	0	0	2	3	6	\$167.22
TOTAL	0	10.3	2		36.9	\$2186.22

Table 6.2: Total Annual Respondent Burden and Costs Associated with a TSCA Section 14(d)(5) request. (Health or environmental professional – non-emergency)

Table 6.3: Total Annual Respondent Burden and Costs Associated with a TSCA Section 14(d)(6)request. (Health or environmental professional - emergency)

Activity	Managerial Hours \$88.08	Technical Hours \$65.34	Clerical Hours \$27.87	Request per Year	Annual Burden Hours	Annual Costs
		Rule Familia	rization (on	e-time burd	en)	
Review of the guidance	0	0.55	0	1	0.55	\$35.94
	Reque	st Submission				
Gather required information and complete statement of need (selecting statement of need, providing eligibility information, describing circumstance of request) (*)(**)	0	2	0	1	2	\$130.68
Read and sign the confidentiality agreement (**)	0	0.75	0	1	0.75	\$49.00
Review and Preparation of submission (*) (**)	0	3	0	1	3	\$196.02
Management of CBI information	0	2	0	1	2	\$130.68
	Rec	ordkeeping				
Recordkeeping ((store, file, or maintain copy of agreements for in- house reference)	0	0	2	1	2	\$55.74
TOTAL	0	8.3	2		10.3	\$598.06
(*) Requests may be made over the pho personal identification information. (**) Some requesters may not ultimatel		Ū				

-this is only required where the person who made the CBI claim so requests.

6(b) Estimating Respondent Costs

Respondent hourly costs in this ICR have been calculated using the Bureau of Labor Statistics' *Employer Costs for Employee Compensation Supplementary Tables: September 2017*, US Bureau of Labor Statistics, December 15 (BLS 2017, accessed January 8, 2018). Hourly costs were calculated for workers in professional and business services industries.¹ Total hourly cost estimates include wages, fringe benefits, and overhead. The wage and fringe benefit numbers are from the BLS data, and the overhead allowance is calculated at 17% of the hourly wage.

Category ²	Hourly wage	Fringe benefits	Overhead	Total hourly cost
Managerial	\$ 52.29	\$26.90	\$8.89	\$88.08
Technical	\$40.72	\$ 15.73	\$6.92	\$65.34
Clerical	\$18.03	\$6.78	\$3.06	\$27.87

Estimated total annual costs to the respondents (under TSCA 14(d)(4), (5), and (6)) are equal to **\$ 5,204.11** and are presented in Table 6.4. There are no capital costs for the contractors associated with this collection.

tuble 0.11 A minuti Respondent Costs estimated associated with 15 CAT I ((a)(1)), (b)), and (b)						
	Hours	per Labor Category		Number of	Annual	Annual Costs
	Managerial	Technical	Clerical	Requests	Burden	
	(\$88.08)	(\$65.34)	(\$27.87)	-	Hours	
TSCA 14(d) (4)	3.27	11.55	6	2	41.64	\$2.419.83
TSCA 14(d) (5)	0	10.3	2	3	36.9	\$2,186.22
TSCA 14(d) (6)	0	8.3	2	1	10.3	\$598.06
Totals	3.27	30.15	10	6	88.9	\$5,204.11

6(c) Estimating Agency Burden and Cost

The costs and hours to the Federal Government are presented in the Table 6.5. The Office of Pollution Prevention and Toxics bases its hour estimates on prior experience processing requests and eligibility determination with other information collections. The activities associated with Agency responses to TSCA section 14(d)(4), (5), and (6) requests are assumed to be accomplished by two GS 13, step 5 federal employees (technical and attorney). The 2018 hourly wage rate for this level of employee in the Washington, D.C., locality is \$52.66 per hour. The hourly rates were taken from the U.S. Office of Personnel Management's 2018 General Schedule for workers with the Washington, D.C., locality payment table (Table 2018-DCB). These hourly estimates were then multiplied by 1.6 to account for benefits (ICR Handbook: EPA's Guide to Writing Information Collection Requests under the Paperwork Reduction Act of 1995, 2009). The hourly cost estimates adjusted for benefits are \$ 84.26. The total cost to the Agency to maintain the collection system is \$4,550.04 per annum and the total Agency burden is estimated at 54 hours.

¹ Specifically, EPA used Supplementary Table 10. "Employer costs per hour worked for employee compensation and costs as a percent of total compensation: private industry workers in professional and business service industries, by occupation group and establishment size, September 2017."

² The Managerial category corresponds to "Management, business, and financial" in Supplementary Table 10. Likewise, the Technical category corresponds to "Professional and related" in that table and Clerical corresponds to "Office and administrative support."

Collection Activity	Weighted Average Hours per request	Total number of requests (14(d) 4, 5 and 6)	Total Number of hours	Total Annual Cost
Request processing and eligibility determination	6	6	36	\$3,033.36
Notify the requestor and provide instructions to access the CBI data	2	6	12	\$1,011.12
Notify companies and store or file request for in-house reference	1	6	6	\$505.56
TOTALS	9		54	\$4,550.04
Source: OPM 2018 hourly rate table for the Washington-Baltimore-Northern Virginia Locality Pay Area, with 60% for benefits and overhead added.				

Table 6.5. Agency Annual Cost Estimates

6(d) Total Burden Estimates

Table 6.6 displays the annual burdens and costs borne by requesters and EPA, respectively, associated with this information collection.

	Annual Burden Hours	Annual Costs
Requesters	89	\$5,204.11
Agency	54	\$4,550.04

6(e) Burden Statement

The annual public burden for this collection of information is estimated to average 14.8 hours per request and cost about \$868 per request. 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 number for this information collection appears on page 1 of this document. 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 docket for this ICR under Docket ID No. **EPA-HQ-OPPT-2017-0652**, which is available for online viewing at http://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., N.W., 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.

For 30-calendar days after announced in the **Federal Register**, 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-2017-0652** and OMB Control No. 2070-[new], to both EPA and OMB as follows:

• To EPA online using http://www.regulations.gov (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW,

Washington, DC 20460, and

• To OMB via email to oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive your ICR-related comments no later than 30 days after the date of publication in the **Federal Register**.

7. REFERENCES/ATTACHMENTS TO THE SUPPORTING STATEMENT

The following information is available in the public docket established for this ICR under docket identification number EPA-HQ-OPPT-2017-0652. These documents are available for online viewing at <u>www.regulations.gov</u> as described in section 6(f) of the supporting statement, or through the links provided.

A. Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613); available at: <u>https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act</u>.

B. EPA Guidance documents outlining the circumstances under which TSCA allows the Agency to disclose CBI and how representatives of the three groups listed above can request disclosure. Available at <u>https://www.epa.gov/tsca-cbi/requesting-access-cbi-under-tsca</u>.