

SUPPORTING STATEMENT
Renewal of Existing Information Collection Request for Confidentiality Rules

1. Identification of the Information Collection

1(a) Title of the Information Collection

Confidentiality Rules (Renewal) EPA ICR No. 1665.13, OMB Control No 2020-0003.

1(b) Short Characterization (Abstract)

The U.S. Environmental Protection Agency (EPA) established the requirements set forth in 40 CFR, Part 2, Subpart B, "Confidentiality of Business Information" to establish rules to govern business confidentiality claims, i.e., the handling by the Agency of business information which is or may be entitled to confidential treatment, determining whether such information is entitled to confidential treatment for reasons of business confidentiality and responding to Freedom of Information Act requests pursuant to 5 U.S.C. §552 for this information.

This request to renew an existing information collection request (ICR) allows the Agency to continue obtaining the information it requires from submitters of confidential business information (CBI) to make final administrative determinations regarding whether or not the business information covered by a confidentiality claim is entitled to confidential treatment under Subpart B. Subpart B sets forth:

- ◆ the procedures industry must follow to assert and justify confidentiality claims;
- ◆ the procedures EPA must follow in reviewing business information claimed as confidential; notifying and providing affected businesses with an opportunity to comment; reviewing industry substantiations; making final confidentiality determinations; and
- ◆ the requirement for signing and maintaining confidentiality agreements by all contractor/subcontractor employees who are given access to confidential information in the course of performing work for EPA.

OMB Terms of Clearance

In the previous ICR renewal, OMB had these terms of clearance, "Prior to resubmission of this request for extension, the Agency should reassess burden taking into account recent experience of respondents and changes in EPA's reporting programs. In addition, the Agency should describe its method for estimating burden."

Agency Response: To obtain current burden estimates, EPA contacted organizations during the fall of 2016 that prepare responses to substantiation requests on behalf of clients. The burden estimates contained herein are predicated on the recent input from the organizations identified in

Section 3(c) of this document and input from EPA staff involved in the substantiation process. The Agency's method for estimating burden is discussed in Section 6, page 9.

2. Need For and Use of the Collection

2(a) Need/Authority for the Collection

EPA administers several environmental protection statutes, e.g., the Clean Water Act, the Clean Air Act, the Toxic Substances Control Act, the Federal Insecticide, Fungicide and Rodenticide Act, the Resource Conservation and Recovery Act and the Comprehensive Environmental Response, Compensation, and Liability Act. Environmental information and data are submitted by the regulated industry to EPA in accordance with the requirements of regulations issued under these statutes. Information is also submitted to the Agency voluntarily by the regulated industry. In many instances, the information received by the Agency is designated by the submitter as confidential business information (CBI).

Substantiation of Confidentiality Claims

In accordance with 40 CFR Part 2, subpart B, when EPA finds it necessary to make a final confidentiality determination (e.g., to respond to a FOIA request or in the course of rulemaking or litigation), it must provide the affected business written notice of that EPA is determining whether the information is entitled to confidential treatment, and is affording the business an opportunity to comment [(i.e., substantiate its confidential filing(s))]. The notice is furnished by certified mail (return receipt requested), by personal delivery, or by other means which allows verification of the delivery and date of receipt. The business must comment on the items detailed under Section 4(b) of this supporting statement within 15 days of receipt.

Confidentiality Agreements

When EPA utilizes contractor/subcontractor services for activities involving CBI, the contractor/subcontractor must ensure that all its employees who will be given access to CBI have signed confidentiality agreements. These agreements state that employees shall use the confidential information only for the work in the contract/subcontract, shall refrain from disclosing the information, and shall return all copies of the information to EPA upon request or completion of the project. The contractor/subcontractor company must also maintain a file of these confidentiality agreements.

The procedures laid out in 40 CFR, Part 2, subpart B, derive their authority from FOIA, as amended, 5 U.S.C. 552, the Trade Secrets Act, as amended, 18 U.S.C. 1905, the Federal housekeeping statute, as amended, 5 U.S.C. 301, the Administrative Procedure Act, as amended, 5 U.S.C. 551, et seq., and the confidentiality provisions of environmental statutes administered by EPA, as follows:

- §114, 206, 208, 301, and 307, Clean Air Act, as amended (42 U.S.C. 7414, 7525, 7542, 7601, 7607)

- §§308, 501, and 509(a), Clean Water Act, as amended (33 U.S.C. 1318, 1361, 1369(a))
- §13, Noise Control Act of 1972, as amended (42 U.S.C. 4912)
- §§1445 and 1450, Safe Drinking Water Act, as amended (42 U.S.C. 300j-4, 300j-9)
- §§2002, 3001, 3007, and 9005, Resource Conservation and Recovery Act, as amended (42 U.S.C. 6912, 6921, 6927, 6991d)
- §§8(c), 11, 12(b), and 14, Toxic Substances Control Act (TSCA), as amended (15 U.S.C. 2601, 2607(c), 2610, 2611(b), 2613)
- §§10, 12, and 25, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, (7 U.S.C. 136h, 136j, 136w)
- §408(i), Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 346a(i))
- §§104(f) and 108, Marine Protection Research and Sanctuaries Act of 1972, as amended (33 U.S.C. 1414(f), 1418)
- §§104 and 115, Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (42 U.S.C. 9604, 9615)

2(b) **Use/Users of the Data**

EPA will use the information received from industry to inform its decision for determining whether or not the subject information is entitled to confidential treatment; whether the Agency needs to make a formal confidentiality determination; and/or whether the information in question can be withheld pursuant to Exemption 4 of FOIA when a FOIA request has been filed for the information.

3. **Non-Duplication, Consultations and Other Collection Criteria**

3(a) **Non-Duplication**

This information is not elsewhere collected from businesses.

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

EPA published a notice of the renewal of the existing information collection request for confidentiality rules in the *Federal Register* on September 13, 2016 (81 FR 62883) and invited public comment.

EPA received one comment which stated that the Agency is using outdated information. EPA consulted with six businesses and the revised information is included in Section 6.

3(c) **Consultations**

To update its burden estimates, EPA consulted with the following businesses. These businesses are subject to the environmental statutes administered by EPA and prepare CBI substantiations. Input from the firms below (and the named individuals) was used to determine whether the burden to businesses who must prepare preparing CBI substantiations had changed since the issuance of the last ICR. The Agency determined that the burden calculations required updating according to the information provided when the organizations below were contacted:

Guy J. Musto
ExxonMobile Company
52 Beacham Street
Everett, Massachusetts 02149
(617) 381-2802

Sid Trant
Brandley Arant Boulton Cummings
One Federal Plaza
Birmingham, Alabama 35207
(205) 521-8479

Marcia Levinson
Covestro
(412) 413-2172

Adam Bickel
BASF
(734) 324-6593

Jonathan Gerber
3M
(651) 733-0226

Richard Glaze
Blach & Bingham
30 Ivan Allen Jr. Boulevard, Suite 700
Atlanta, Georgia 30308
(404) 962-3566

3(d) Effects of Less Frequent Collection

Not applicable.

3(e) General Guidelines

Only one provision of this collection exceeds the Paperwork Reduction Act guidelines at 5 CFR 1320.5(d) (2). This collection calls for responses to be furnished to EPA within 15 working days after the business receives the letter requesting substantiation. Under 5 CFR 1320.5(d) (2) (ii), EPA must justify why the response needs to be prepared within a period shorter than 30 days after receipt of the collection. In the context of addressing the time frame for determinations under the FOIA, EPA “tentatively” determined that 15 days is “a reasonable period for the business to furnish comments and substantiating data concerning its claim.” 40 FR 21987, 21988, 21989 (May 20, 1975) and 41 FR 36902, 36908 (September 1, 1976). EPA has found through experience in the years since these regulations were promulgated (40 CFR Part 2) that 15 days fits well with the general timetable of FOIA responses.

3(f) **Confidentiality and Sensitive Questions**

1. Confidentiality

Under EPA’s current CBI regulations (40 CFR Part 2, subpart B), respondents may claim substantiations submitted to EPA as confidential.

2. Sensitive Questions

Not applicable. This information collection does not include questions of a sensitive nature. Only the information returned by the respondents may be of a sensitive nature.

4. **The Respondents and the Information Requested**

4(a) **Respondents/SIC Codes**

Respondents can potentially include any business submitting a document to EPA that it claims as CBI. EPA receives such information from both the manufacturing (SIC codes 20-39) and non-manufacturing sectors (no SIC codes identified).

4(b) **Information Requested**

A. *Substantiation of confidentiality claim*

Whenever EPA finds it necessary to determine the confidentiality of information that has been claimed as CBI (e.g., in response to a FOIA request or in connection with rulemaking or litigation, or with regard to an advance confidentiality determination under 40 CFR 2.204 (a), (c) and (d), 2.206), it must notify affected businesses orally and in writing and provide them with an opportunity to comment (40 CFR 2.204(e)).

With this renewal ICR, EPA is proposing to use the five attached “Request for Substantiation” letters. The letters address different situations which require EPA to determine the confidentiality of information claimed CBI: Letter A addresses the situation where confidential business information in EPA possession is responsive to a Freedom of Information Act (FOIA) request. Letter B requests a generic substantiation. Letter C covers FOIA requests for FIFRA records. Letter D is for FIFRA not related to a FOIA request. Letter E is related to TSCA.

1. Data Items

The written notice from EPA (40 CFR 2.204(e) (1) and (4)) invites the business’s comments (substantiation) on the following:

- (i) The portions of the information which are alleged to be entitled to confidential treatment;
- (ii) The period of time for which confidential treatment is desired by the business (e.g., until a certain date, until the occurrence of a specified event, or permanently);
- (iii) The purpose for which the information was furnished to EPA and the approximate date of submission, if known;
- (iv) Whether a business confidentiality claim accompanied the information when it was received by EPA;
- (v) Measures taken by the business to guard against undesired disclosure of the information to others;
- (vi) The extent to which the information has been disclosed to others, and the precautions taken in connection therewith;
- (vii) Pertinent confidentiality determinations, if any, by EPA or other Federal agencies; and a copy of any such determination, or reference to it, if available;
- (viii) Whether the business asserts that disclosure of the information would be likely to result in substantial harmful effects on the business's competitive position, and if so, what those harmful effects would be, why they should be viewed as substantial, and an explanation of the causal relationship between disclosure and such harmful effects; and
- (ix) Whether the business asserts that the information is voluntarily submitted information as defined in 40 CFR §2.201(i), and if so, whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

2. Respondent Activities

To respond to the written notice, the respondent must:

- Read EPA’s request for comments;
- Review the information it claimed as confidential; and
- Prepare and submit the substantiation to EPA

or

- Read EPA's request for comments;
- Review the information it claimed as confidential; and
- Decide not to submit the substantiation to EPA

B. Designation by Business of Addressee for Notices and Inquiries

Pursuant to 40 CFR 2.213, a business may elect to designate an official contact for inquiries and notices concerning confidentiality claims.

1. Data Items

Name and address of the business making the designation, and the name and address of the designated person or office.

2. Respondent Activities

To review subject materials and decide whether to respond to EPA's request for comments.

C. Confidentiality agreements

When EPA utilizes the services of contractors/subcontractors, all contractor/subcontractor employees who may be given access to confidential information must first sign confidentiality agreements stating that they will honor the terms of the contract/subcontract which requires protection of CBI. See 40 CFR 2.301(h) (2) (ii).

1. Data Items

Signed confidentiality agreements.

2. Respondent activities

The contractor must:

- a. Require each employee given access to CBI to read and sign a confidentiality agreement; and
- b. Maintain a file of such agreements. See 40 CFR 2.301(h) (2) (IV).

In addition to the information collections discussed above, when EPA intends to disclose CBI to contractors/subcontractors, other federal agencies or Congress, EPA generally notifies affected businesses. During a specified period of time prior to disclosure, businesses may submit comments. Industry has rarely submitted comments to EPA under these circumstances.

5. The Information Collected – Agency Activities, Collection Methodology, and Information Management

5(a) Agency Activities

1. Review and make a preliminary determination of whether business information may be entitled to confidential treatment. This review would be undertaken in response to a FOIA request or when EPA desires to determine the confidentiality of information within its possession for other purposes (e.g., rulemaking, litigation or an advance confidentiality determination). It would involve determining whether a business confidentiality claim exists or whether a Federal court or an EPA legal office has previously determined that the information in question is entitled to treatment as CBI.
2. Notify the affected business orally and in writing that the Agency is determining the confidentiality of the information and provide the business with an opportunity to comment.
3. Review the substantiation received (if any) and make a final determination whether the business information in question is entitled to confidential treatment. This determination will be made by the appropriate EPA legal office as described in 40 CFR 2.205. Not all business choose to submit substantiation to the Agency.

5(b) Collection Methodology and Management

The types of information that are requested are described under 4(b) above. EPA notifies affected businesses orally and in writing that it is determining the confidentiality of information they have submitted and affords them the opportunity to comment. Affected businesses may submit comments by the date specified in the notice (i.e., postmarked or hand delivered no later than the specified date); or if a request for an extension of the comment period is made by the business and approved by the EPA legal office before the comments are due, the comment period may be extended (40 CFR 2.205(b) (2)).

Confidential information that is submitted to EPA is protected in accordance with the policies and procedures discussed in (1) Chapter 8, “Information Security,” of EPA’s *Information Resources Management (IRM) Policy Manual*, Directive 2100, revised December 20, 1999; (2) the *EPA Information Security Manual*, Directive 2195A1, December 20, 1999; and (3) information security procedures issued by EPA organizations with statutory authority for the information [e.g., EPA’s Office of Prevention, Pesticides, and Toxic Substances has developed specific procedures for protecting the confidentiality of information obtained under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)].

5(c) **Small Entity Flexibility**

EPA does not have the flexibility to waive the need for substantiations from small entities for several reasons: (1) EPA is required to disclose information that is requested under FOIA, unless the information is specifically exempt; (2) if EPA discloses information that is entitled to confidential treatment, the Federal government could be held liable under the Federal Tort Claims Act and individual Federal employees could be subject to criminal liability under the Trade Secrets Act and other statutes, and (3) the submitter of the information is in the best position to explain why particular information should be entitled to confidential treatment.

5(d) **Collection Schedule**

The request for substantiations occurs on a case-by-case basis, as needed.

6. **Estimating the Burden and Cost of the Collection**

Annual public reporting and recordkeeping burden: 5.6 hours per response

Estimated Number of Respondents: 6

Frequency of Response: 1 response per respondent annually

Estimated Total Annual Hour Burden: 14.6 hours

Estimated Total Annual Cost: \$876.00 includes \$0 annualized capital or O&M costs.

6(a) **Estimating Respondent Burden**

The burden estimates were developed after consultations with the firms identified under Section 3(c), above.

A. *Substantiation of confidentiality claim*

EPA receives approximately 300 FOIA requests for information that is claimed as CBI each year. However, many of the requests do not require EPA to contact the affected business (es). EPA may find that a federal court or EPA legal office has previously determined that the information in question is entitled to confidential treatment, and further examination of the information may not be required; or, after consulting with an individual who requested information under FOIA, the Agency may be able to provide the information that is of most interest to the requester without disclosing any CBI. In these cases, no request for substantiation is issued.

In accordance with the procedures outlined in 40 CFR Part 2, subpart B, the Agency notifies approximately 300 businesses annually that it is making a final confidentiality determination on information the business has previously claimed as CBI (or which could be expected to be CBI) is being made, and provide them with an opportunity to submit comments explaining why previously submitted information should be treated as confidential. Each affected business has an opportunity to submit comments explaining why the information should be protected.

6(b) Estimating Respondents Cost

Over the past year, approximately 21% or 64 of the 304 businesses submitted comments to EPA and spent approximately 6 hours on each substantiation type reviewing the information, preparing the response and mailing the response back to the Agency (3.00 attorney hrs. + 3.00 manager hrs.)

Burden for 64 respondents = 358 hours

EPA estimates the cost per substantiation (64) to be approximately **\$17,063.42**, which includes reviewing the information, preparing the response and mailing the response back to the Agency (\$60.00 attorney hr. + \$35.22 manager hr.).

Burden cost for respondents = **\$17,063.42**.

B. Confidentiality agreements

When EPA utilizes the services of contractors/subcontractors in implementing 40 CFR, Part 2, subpart B, all contractor/subcontractor employees who may be given access to confidential information must first sign confidentiality agreements stating that they will honor the terms of the contract which requires the protection of CBI. In addition, the contractor/subcontractor businesses must maintain a file of all such agreements. EPA estimates that there are approximately 130 businesses that have contracts with the Agency that require CBI access. These businesses are estimated to employ approximately 650 employees who must sign confidentiality agreements each year.

Signing Confidentiality Agreements

Burden hours: Each of the 650 employees is estimated to require 0.10 hours to review and sign the agreement. The total burden to review and sign confidentiality agreements = 65.00 hours annually.

Burden costs: EPA estimates the cost incurred to review and sign the agreement per employee to be \$3.50 in labor (0.10 time @ \$35.00/hr.). The total costs for 650 employees to review and sign agreements = **\$2,275** annually.

Performing Recordkeeping Requirements

Each of the 130 businesses is required to maintain records of all confidentiality agreements.

Burden hours: EPA estimates that it requires 0.50 hours annually for 130 businesses to maintain confidentiality agreement files for 650 employees. The total burden for the 130 businesses to maintain records for the 650 employees = **65.00** hours annually.

Burden costs: It is estimated that burden costs for the 130 businesses to maintain records for the 650 employees to be \$8.53 (0.50 clerical time @ \$17.05 clerical hr.) = **\$1,108.90** annually.

C. *Overall Respondent Burden*

Annual respondent burden is anticipated to be 844 respondents, 488 hours, at a labor cost of \$20,447.

6(b) **Estimating Agency Burden and Cost**

The burden on EPA to evaluate confidentiality claims, notify affected businesses, and make final confidentiality determinations varies depending on the complexity of the claim. In some cases, the information that industry claims as confidential is specific and easily identified; yet in other cases, entire reports may be claimed as confidential. In the latter case, a significant amount of time may be required to review the information in question. In other cases, EPA may be able to satisfy a FOIA request without going through the entire substantiation process, if after conferring with a requestor, the Agency is able to provide the information of interest without releasing CBI.

(EPA estimates that of the 304 letters mailed to businesses, approximately 64 businesses will respond.)

Initial Activities

Burden hours: Based on past experience, EPA estimates that on average, it requires approximately **9 hours** (6 attorney hrs. + 2 technical hrs. + 1 clerical hr.) to conduct an initial review of a confidentiality claim and prepare and mail a substantiation to a submitter.

Burden costs: Burden costs are estimated to be **\$387.84** per letter (\$47.39 attorney hr. @ GS-14, Step 5 + \$40.10 technical hr. @ GS-13, Step 5; and \$23.25 clerical hr. @ GS-9, Step 5).

Total burden to review the subject information and prepare 304 substantiation requests annually = **2736 hours** at a total labor cost of **\$117,903.36**.

Making Confidentiality Determinations

Burden hours: After industry comments are received, approximately **8 hours** (6 attorney hrs. and 2 technical hrs.) are required to review the comments and determine whether the information that is claimed as confidential is indeed entitled to confidential treatment.

Burden costs: Burden costs to review and make final confidentiality determinations on 64 responses are estimated to be **\$364.59**(\$47.39 attorney hr. @ GS-14, Step 5 + \$40.10 technical hr. @ GS-13, Step 5).

Total burden to review and make final confidentiality determinations on 64 substantiations = **512 hours** at a total labor cost of **\$2,916.54**.

The total Agency burden to perform initial activities and make final confidentiality determinations on 304 responses = **3,48 hours** at a total labor cost of **\$120,819.90** annually.

6(c) Bottom Line Burden Hours and Costs

Task	Activity	Burden Hours	Total Annual Burden Hours	Burden Costs	Total Annual Burden Costs
AGENCY					
Perform Initial activities	Review, preliminary determination & mail 304 substantiation letters	9 hours per letter	2,736	\$387.84 per letter	\$117,903.36
Make final confidentiality determinations	Review comments and make final confidentiality determination on 64 letters	8 hours per letter	512	\$364.59 per letter	\$2,916.72
Overall Agency Burden			3,248		\$120,820.08
RESPONDENTS					
Respond to request from EPA	64	5.6 hours per substantiation	358.4 (5.6 hrs x 64 respondents)	\$266.62 per substantiation	\$17,063.42 (\$266.62 x 64)
Sign Confidentiality Agreements	650	.10 hour	65.00 (.10 hrs x 650 respondents)	\$3.50 per employee	\$2,275.00 (\$3.50 x 650)
Recordkeeping	130 businesses maintain records	.50 hours	65.00 (.50 hrs x 130)	\$8.53	\$1,108.90 (8.53 x 130 respondents)
Overall Respondent Burden			488.40		\$20,447.32
Annual	844 respondents		488 hours		\$20,447

5. *Variations in the Annual Bottom Line*

Variations in the annual burden on EPA and respondents could potentially occur due to changes in:

- the number of FOIA requests that EPA receives for information that has been claimed as confidential;
- the number of times that EPA determines that a formal confidentiality determination is necessary and notifies affected businesses, providing them with an opportunity to comment; and
- the number of times that affected businesses decide to submit substantiations.

At this time, EPA does not foresee any significant changes in the annual burdens outlined above.

6(d) **Reasons for Change in Burden**

The estimated burden decreased by 1,045 hours based upon consultations with the submitter community identified in Section 3(c). The number of respondents increased by 616, which was due to accounting for the 650 individual employees who sign confidentiality agreements.

6(e) **Burden Statement**

The annual public reporting and recordkeeping burden for this collection of information are estimated to average about half an hour per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop; acquire, install, and utilize technology and systems for the purposes of collecting; validating, and verifying information; processing and maintaining information; and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; training personnel to be able to respond to a collection of information; searching data sources; completing and reviewing the collection of information; and transmitting or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-OEI-2013-0565, which is available for online viewing at www.regulations.gov, or in person viewing at the OEI Docket in the EPA Docket Center (EPA/DC), EPA WJC, Room 3334, 1301 Constitution Avenue,

NW, Washington, DC. The EPA Docket Center 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 OEI Docket and the Reading Room is (202) 566-1744. An electronic version of the public docket is available at www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select “search,” then key in the docket ID number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Please include the EPA Docket ID No. (EPA-HQ-OEI-2013-0565) and OMB control number (2020-0003) in any correspondence.