

SUPPORTING STATEMENT

1. Identification of the Information Collection

1(a) Title of the Information Collection

Confidentiality Rules (Renewal) EPA ICR No. 1665.14, OMB Control No 2020-0003.

1(b) Short Characterization (Abstract)

The U.S. Environmental Protection Agency (EPA or Agency) established the requirements set forth in 40 C.F.R. § 2.201 et seq. “Confidentiality of Business Information” to establish rules to govern claims of confidential business information (CBI), i.e., the rules governing 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 (FOIA) 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 collecting information the Agency requires to make final determinations regarding whether information claimed as confidential is entitled to confidential treatment under EPA’s CBI regulations 40 C.F.R. § 2.201 et seq., which 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.

The Agency collects such information from businesses asserting CBI claims, which may include state or local governments.

OMB Terms of Clearance

In a 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."

In Fall 2016, EPA responded to OMB’s terms of clearance by obtaining burden information from firms that prepare responses to the Agency’s requests for information to substantiate CBI claims. To update EPA’s 2016 analysis and obtain current burden estimates, in Fall 2019, EPA contacted

additional firms that, on behalf of their clients, prepare responses to the Agency's requests for information to substantiate CBI claims. The burden estimates contained herein are predicated on the recent input from the firms 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 (TSCA), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Resource Conservation and Recovery Act and the Comprehensive Environmental Response, Compensation, and Liability Act. Environmental information is 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 claimed as CBI by the submitter.

Substantiation of Confidentiality Claims

In accordance with 40 C.F.R. § 2.201 et seq. 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 may provide the affected business written notice that EPA is determining whether the information claimed as CBI is entitled to confidential treatment and afford the business an opportunity to comment [i.e., substantiate its confidential filing(s)]. See 40 C.F.R. §§ 2.204, 2.205. 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.

The procedures laid out in 40 C.F.R. § 2.201 et seq. derive their authority from the 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:

- Sections 114, 206, 208, 301, and 307, Clean Air Act, as amended (42 U.S.C. §§ 7414, 7525, 7542, 7601, 7607)
- Sections 308, 501, and 509(a), Clean Water Act, as amended (33 U.S.C. §§ 1318, 1361, 1369(a))
- Section 13, Noise Control Act of 1972, as amended (42 U.S.C. § 4912)
- Sections 1445 and 1450, Safe Drinking Water Act, as amended (42 U.S.C. §§ 300j-4, 300j-9)
- Sections 2002, 3001, 3007, and 9005, Resource Conservation and Recovery Act, as amended (42 U.S.C. §§ 6912, 6921, 6927, 6991d)

- Sections 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)
- Sections 10, 12, and 25, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, (7 U.S.C. §§ 136h, 136j, 136w)
- Section 408(i), Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. § 346a(i))
- Sections 104(f) and 108, Marine Protection Research and Sanctuaries Act of 1972, as amended (33 U.S.C. §§ 1414(f), 1418)
- Sections 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 information provided to substantiate CBI claims by industry to inform the Agency's determination as to whether the information claimed as CBI 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 collected elsewhere from businesses.

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

EPA published a notice of the renewal of the existing ICR for confidentiality rules in the *Federal Register* on January 23, 2020 (85 FR 3910) and invited public comment. No comments were received.

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 CBI substantiations had changed since the issuance of the last ICR.

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3(d) Effects of Less Frequent Collection

These information collection requests are one-time collections regarding individual claims of CBI. The one-time collection of information related to individual claims of CBI ensures that the Agency meets statutory and regulatory requirements to protect confidential information under statutes listed in Section 2(a) of this document, including the FOIA, while also enabling EPA to release to the public information not entitled to confidential treatment. If EPA does not collect such information, then EPA will not have all information that EPA needs to complete confidentiality determinations, such as information regarding actions the submitter takes to protect the information that is claimed to be CBI.

3(e) General Guidelines

Only one provision of this collection exceeds the Paperwork Reduction Act guidelines at 5 C.F.R. § 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 C.F.R. § 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 (Sept. 1, 1976). EPA has found through experience in the years since these regulations were promulgated (40 C.F.R. § 2.204(e)) 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 C.F.R. § 2.201 et seq., respondents may claim substantiations submitted to EPA as CBI.

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 that submitted to EPA information that may be claimed as CBI. Respondents can be entities in both the manufacturing (SIC codes 20-39) and non-manufacturing sectors (no SIC codes identified).

4(b) Information Requested

A. Substantiation of business confidentiality claims

Whenever EPA finds it necessary to determine whether information is entitled to confidential treatment (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 C.F.R. §§ 2.204(a), (c) and (d), 2.206), it may notify affected businesses orally and in writing and provide them with an opportunity to comment (40 C.F.R. § 2.204(e)).

With this ICR renewal, EPA is proposing to use the five attached "Request for Substantiation" letters. The letters address different situations which, under 40 C.F.R. § 2.203(a), require or allow EPA to determine the confidentiality of information claimed CBI: Letter A addresses the situation where information claimed as CBI in EPA possession is responsive to a FOIA request. Letter B requests a generic substantiation for other contexts in which EPA may need to determine whether information is entitled to confidential treatment or foresees the likelihood that the Agency will be requested to disclose the information at some future date. 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 C.F.R. §§ 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 reasons why the information should be protected as confidential;
- (iv) Whether EPA, another federal agency, or court has made any determination as to the confidentiality of the information;
- (v) Whether measures have been 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) Whether the business has customarily kept the information private or closely held;
- (viii) Whether, at the time the information was submitted, EPA provided any express or implied assurance of confidentiality;
- (ix) Whether EPA provided any expressed or implied indications at the time the information was submitted that EPA would publicly disclose the information;
- (x) The reasons for any belief that submitted information is a trade secret;
- (xi) Whether there are means by which a member of the public could obtain access to the information or readily discover the information; and
- (ix) Whether the information is data or information that is prohibited from protection under a regulation or statute.

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
- Respond in one of two ways:
 - Justify the CBI claim by substantiating the CBI claims to EPA; or
 - Waive the CBI claim by deciding not to submit the substantiation to EPA.

B. Designation by Business of Addressee for Notices and Inquiries

Pursuant to 40 C.F.R. § 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.

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

5(a) **Agency Activities**

1. Review and identify whether business information may be claimed as CBI. This review is completed by the affected program office, and it may 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 C.F.R. § 2.205. Not all businesses choose to substantiate their CBI claims.

5(b) **Collection Methodology and Management**

The types of information that are requested are described under Section 4(b) above. EPA may notify affected businesses 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 C.F.R. § 2.205(b) (2)).

Information claimed as CBI that is submitted to EPA is protected in accordance with the policies and procedures discussed in (1) Interim Records Management Policy, CIO 2155.4 (Aug. 22, 2018); (2) Information Security Policy, CIO 2150.5 (Aug. 27, 2019); and (3) information security procedures issued by EPA organizations with statutory authority for the information

[e.g., EPA's Office of Chemical Safety and Pollution Prevention developed specific procedures for protecting the confidentiality of information obtained under the TSCA and 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 the FOIA, unless the information is specifically exempt; (2) if EPA discloses information that is entitled to confidential treatment, the Federal government could potentially 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

6(a) Estimating Respondent Burden

The burden estimates were developed after consultations with the firms identified under Section 3(c), above and adjusted based on changes EPA is making in the information that will be requested, as described more fully in Section 6(d) below.

A. Substantiation of confidentiality claims

Although EPA receives numerous FOIA requests for information that is claimed as CBI each year, many of the requests do not require EPA to request a full substantiation from 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; or, after consulting with an individual who requested information under the 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 C.F.R. § 2.201 et seq. 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

In EPA's previous analysis, EPA noted that only approximately 21% of the businesses submitted comments in response to EPA's requests for substantiation. As explained in Section 6(d) below, EPA anticipates that the response rate will increase based on recent annual submissions in the past reporting period. EPA estimates that approximately 66% or 198 of the 300 businesses will submit comments to EPA in response to EPA's requests for substantiation. In the past, on average, each respondent spent approximately 5.6 hours on responding to each substantiation request. As explained in Section 6(d) below, EPA expects that each respondent will spend approximately 2 hours less time, or a total of 3.8 hours, on responding to each substantiation request using EPA's revised form.

Burden hours for 198 respondents = 752.4 hours

EPA estimates the cost per substantiation to be approximately **\$855.00**, which includes reviewing the information, preparing the response, and mailing the response back to the Agency at the average rate of \$225/hr. The average rate is based on the survey responses received from the firms listed in Section 2(c) and includes the cost multiplier or overhead.

Burden cost for respondents = **\$169,290**.

6(c) Estimating Agency Burden and Cost

The burden on EPA to evaluate CBI 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 CBI. 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 300 letters mailed to businesses, approximately 198 businesses will respond.)

Initial Activities

Burden hours: Based on experience, EPA estimates that on average, it requires approximately **3 hours** (2 attorney 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 **\$262.54** per letter (\$65.88 attorney hr. @ GS-14, Step 5, multiplied by the standard government benefits multiplication factor of 1.6.; and \$32.33 clerical hr. @ GS-9, Step 5, multiplied by the standard government benefits multiplication factor of 1.6).

Total burden to review the subject information and prepare 300 substantiation requests annually = **900 hours** at a total labor cost of **\$78,763.20**.

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 each response is estimated to be **\$810.85** (\$65.88 attorney hr. @ GS-14, Step 5, multiplied by the standard government benefits multiplication factor of 1.6; and \$55.75 technical hr. @ GS-13, Step 5, multiplied by the standard government benefits multiplication factor of 1.6).

Total burden to review and to make final confidentiality determinations on 198 substantiations = **1,584 hours** at a total labor cost of **\$160,547.90**.

The total Agency burden to perform initial activities with substantiation requests submitted to 300 businesses and to make final confidentiality determinations on 198 responses = **2,484 hours** at a total labor cost of **\$239,311.10** annually.

6(d) 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 300 substantiation letters	3 hours per letter	900	\$262.54 per letter	\$78,763.20
Make final confidentiality determinations	Review comments and make final confidentiality determination on 198 responses	8 hours per letter	1,584	\$810.85 per response	\$160,547.90
Overall Agency Burden			2,484		\$239,311.10
RESPONDENTS					
Respond to request from EPA	198	3.8 hours per substantiation	752.4 (3.8 hrs x 198 respondents)	\$855.00 per substantiation	\$169,290.00 (\$855.00 x 198)
Overall Respondent Burden			752.4		\$169,290.00

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; or
- the number of times that affected businesses decide to submit CBI claims and substantiations.

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

6(e) Changes in Burden Estimate

The revised requests for substantiation will decrease the estimated burden hours for each response, although it increases the total estimated respondent burden compared with the ICR currently approved by OMB. The decrease is 2 hours for each business response; the increase is based on an expected higher response rate under the new form, producing an increase from 488 hours to 752.4 hours total. This decrease of hours spent are due to the removal of a question that required a company to describe, with specificity, the “substantial competitive harm” that would occur as a direct result of disclosing the information.

EPA modified its substantiation questions because of the U.S. Supreme Court’s decision in Food Marketing Institute v. Argus Leader Media (Argus), 139 S. Ct. 2356 (2019), which evaluated the definition of “confidential” as used in Exemption 4 of the FOIA. 5 U.S.C. § 552(b)(4). In the Argus decision, the Court held that at least where “[1] commercial or financial information is both customarily and actually treated as private by its owner and [2] provided to the government under an assurance of privacy, the information is ‘confidential’ within the meaning of Exemption 4.” Argus, 139 S. Ct. at 2366. EPA has reduced burdens to business submitters by removing the requirement to explain with specificity whatever “substantial competitive harm” a submitter claims would ensue from release of each CBI claim. The evaluation of “substantial competitive harm” had required businesses to analyze and describe the potential impacts of release. EPA has replaced that question with modified questions that require a factual description of the submitter’s handling and treatment of the CBI-claimed information, as well as a description of any assurances provided by EPA at the time of submission. This replacement will reduce the burden on companies since evaluation and analysis of “substantial competitive harm” is no longer required. Further, EPA reframed preexisting questions to solicit “yes” or “no” responses, which further reduces burdens on submitters. These modifications will result in greater clarity to business submitters and improved responses as the Agency completes its confidentiality determinations.

The Agency anticipates that this lower burden on each response will increase the response rate from 21% in the prior analysis to 66% in the present analysis. EPA has already experienced an

increase in response rate because of the Supreme Court's decision and expects this change to continue under the new form. EPA also made other adjustments in its analysis including adjustments in the hourly costs for both the Agency and responding companies as well as removing a category of burden that was not relevant to EPA's information request.

6(f) **Burden Statement**

The annual public reporting and recordkeeping burden for this collection of information is estimated to average about 3.8 hours 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; adjusting approaches 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 C.F.R. part 9 and 48 C.F.R. 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-OGC-2020-0020, which is available for online viewing 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. Please include the EPA Docket ID No. (EPA-HQ-OGC-2020-0020) and OMB control number (2020-0003) in any correspondence.