

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

1 IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Number of the Information Collection

Title: TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR)

EPA ICR No.: 0586.14 OMB Control No.: 2070-0054

Docket ID No.: EPA-HQ-OPPT-2018-0516

1(b) Short Characterization

EPA promulgated the generic section 8(a) Preliminary Assessment Information Rule (PAIR) (40 CFR part 712) under the Toxic Substances Control Act (TSCA). EPA uses PAIR to collect information to help identify, assess, and manage human health and environmental risks from chemical substances, mixtures and categories. PAIR requires chemical manufacturers and importers to complete and submit standardized information about production, use, or exposure-related data to help evaluate the potential for human health and environmental risks caused by the manufacture or importation of identified chemical substances, mixtures or categories.

EPA or other federal agencies (e.g., the agencies that are part of the Interagency Testing Committee (ITC) as authorized under TSCA section 4(e)) can identify chemicals for a TSCA section 8(a) PAIR expediated rulemaking that have a justifiable need for production, use, or exposure-related data. PAIR is also available to the EPA for the purpose of informing the prioritization and risk evaluation activities required under the 2016 amendments to TSCA enacted when the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) was signed into law on June 22, 2016.

This information collection activity also covers certain specific chemical testing and reporting requirements under Subpart B of 40 CFR part 766 (see Attachment C) that are very similar to the PAIR requirements. The Agency rarely receives submissions of the information required by 40 CFR 766. EPA received less than five submissions over the course of the last OMB approval for this aspect of the information collection. However, collection of this information is covered under the PAIR ICR because the requirements are similar and because the Paperwork Reduction Act requires that recordkeeping and reporting activities contained in any regulation be approved by OMB even if they involve less than ten respondents or would otherwise not require approval (see 5 CFR 1320.3(c)(4)(i)).

The dibenzo-para-dioxin/dibenzofuran regulations at 40 CFR part 766 require that any person who manufactures, imports, or processes a chemical substance listed at 40 CFR 766.25 test that chemical substance and submit appropriate information to EPA according to the schedules described at 40 CFR 766.35. Persons who commence manufacture, import, or processing of a chemical substance listed at 40 CFR 766.25 must submit a letter of intent to test

or an exemption application within 60-days of starting any of those activities. Each person who is manufacturing or processing a chemical listed in 40 CFR 766.25, must submit a protocol for testing according to the schedule at 40 CFR 766.35(a)(2). Persons who manufacture or import a chemical substance listed under 40 CFR 766.25 must report positive test results, using the Dioxin/Furan Report Form (EPA Form 7710-51; see Attachment D), of all existing test data that show that chemical substance has been tested for the presence of halogenated dibenzodioxins/halogenated dibenzofurans (HDDs/HDFs), as well as any health and safety studies for the chemical substance, as defined in the regulation, no later than 90 days after the date of submission of the positive test result. Additionally, any manufacturer or importer of a chemical substance listed in 40 CFR 766.25 in possession of unpublished health and safety studies on HDDs/HDFs is required to submit copies of such studies to EPA, in accordance with various provisions of 40 CFR 716, no later than 90 days after the person first manufactures or imports the chemical substance.

2 NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Under TSCA, which covers the production, distribution, use, and disposal of chemical substances, EPA's Office of Pollution Prevention and Toxics (OPPT) is charged with the responsibility for assuring that chemicals made available for sale and use in the United States do not pose any unreasonable adverse risks to human health or to the environment. To carry out this mandate, EPA has broad authority to issue regulations designed to gather health/safety and exposure information on, require testing of, and control exposure to chemical substances and mixtures. Drugs, cosmetics, foods, food additives, pesticides, and nuclear materials are exempt from TSCA and are subject to control under other U.S. Government statutes (e.g., foods, food additives, drugs and cosmetics are under the purview of the Federal Food, Drug, and Cosmetic Act (FFDCA)).

Specifically, TSCA section 8(a) can also be used to support the activities required in Section 6 of TSCA, as amended by LCSA, which outlines procedures and timelines for risk-based prioritizing and evaluating the risk of the chemicals on the TSCA Inventory. EPA intends to resolve any concerns it may have about the sufficiency of information about a given chemical substance for purposes of prioritization before subjecting that chemical substance to the prioritization process. To address these concerns, the Agency plans to use the authorities under TSCA sections 4, 8, and 11 to gather information and request data to fill data gaps after internal audits and voluntary calls for information have been exhausted first.

TSCA section 8(a) gives EPA the authority to promulgate rules under which manufacturers (which by statute includes importers) and processors of chemical substances must maintain records and/or report such data as EPA may reasonably require to in order to carry out the TSCA mandates. Examples of information that can be required to be reported under TSCA section 8(a) include:

- chemical or mixture identity;
- categories of use;

- quantity manufactured or processed;
- by-product description;
- health and environmental effects information;
- number of individuals exposed; and
- method(s) of disposal

Section 8(a) regulations can be tailored to meet unique information needs (e.g., via chemical-specific rules, which are covered under EPA ICR #1198, OMB Control #2070-0067) or information can be obtained via the use of “model” or standardized reporting rules. The subject of this ICR, the TSCA section 8(a) PAIR rule, is one example of a model TSCA section 8(a) reporting rule. Under PAIR, producers and importers of a listed chemical are required to report the following site-specific information (described in more detail in section 4 of this Supporting Statement):

- Quantity of chemical produced and/or imported;
- Amount of chemical lost to the environment during production or importation;
- Quantity of enclosed, controlled and open releases of the chemical; and
- Per release, the number of workers exposed and the number of hours exposed.

Exemptions for such reporting are as follows:

- Production or importation for the sole purpose of research and development (R&D);
- Production or importation of less than 500 kilograms during the reporting period at single plant site;
- Companies whose total annual sales from all sites owned by the domestic or foreign parent company are below \$30 million for the reporting period and who produced or imported less than 45,400 kilograms of the chemical; and
- Production or importation of the listed chemical solely as an impurity, a non-isolated intermediate, and under certain circumstances as a by-product.

This Supporting Statement addresses the information collection activities associated with PAIR, which establishes procedures for chemical manufacturers and processors to report production, use, and exposure-related information on listed chemical substances. Subpart A establishes requirements that apply to all reporting under PAIR, and Subpart B covers manufacturers’ and importers’ reporting. Processors are not required to report PAIR information under this information collection.

In addition, as described in the previous section, this Supporting Statement addresses information collection activities associated with the reporting and recordkeeping requirements contained in 40 CFR 766.

2(b) Use/Users of the Data

EPA uses PAIR and subpart B of 40 CFR 766 data to (1) monitor domestic manufacture and/or importation of chemical substances, mixtures and categories, (2) identify possible routes of human or environmental exposure, (3) support regulations designed to prevent possible

adverse health effects and (4) support EPA programs. The information provided by PAIR and subpart B of 40 CFR 766 is needed to complete assessments of chemicals of interest and to assist in the development of regulations to control hazardous chemicals. In particular, PAIR can be used to support the activities under TSCA section 6 for risk-based prioritization and risk evaluation of TSCA chemicals.

All EPA program offices are potential users of the PAIR and subpart B of 40 CFR 766. The information helps EPA prioritize and evaluate the potential for adverse human health or environmental effects caused by the manufacture and importation of the identified chemical substance, mixture or category.

Other federal agencies, which require data on the human health and environmental effects of a chemical, use PAIR information. States also have access to public portions of PAIR and subpart B of 40 CFR 766 information. Public interest groups use information reported under the public portions of PAIR and subpart B of 40 CFR 766.

3 NON-DUPLICATION, CONSULTATION AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

PAIR and subpart B of 40 CFR 766 reporting data assist EPA in identifying, evaluating and managing the human health and environmental effects of chemical substances, mixtures and categories.

EPA has developed procedures that must be met to ensure that the chemicals added to the rule and the information requested on these chemicals does not duplicate other activities or impose a burden on industry that outweighs the need for the data. These procedures are for rule promulgation and implementation:

- (1) A continuous evaluation of the information collection and management activities;
- (2) The management of the collected information;
- (3) A chemical nomination, screening and selection process; and
- (4) Technical assistance for persons subject to the rule.

It is unlikely that the information to be reported is duplicative because (1) EPA estimates that each rule will generate only a few reports, (2) the information required by the PAIR and subpart B of 40 CFR 766 is unique to the manufacturer or importer, and (3) efforts are made to ensure that the information requested is not currently in the possession of EPA or easily obtained by EPA from other public sources. The following databases and sources of information are checked to ensure non-duplication:

- The Chemical Data Reporting (CDR) database for production and use information of chemicals in commerce.
- ChemView, a publicly available web portal, and internal EPA data repositories containing information on data received by EPA under TSCA;

- The Toxic Substances Control Act Test Submissions (TSCATS) database, an online index of the compiled, unpublished health and safety studies submitted to EPA;
- The Registry of Toxic Effects of Chemical Substances (RTECS), a file containing chemical toxicity data;
- LexisNexis, a data network with a wide range of fields including information published in the *Code of Federal Regulations* (CFR) and BNA's *Environmental Reporter and Chemical Regulation Reporter*;
- The Toxicology Data Network (TOXNET), run by the National Library of Medicine; and

Similar searches are conducted for each list of chemical substances, mixtures or categories added to the PAIR.

Some chemicals in PAIR are referred to EPA by other federal agencies. These agencies conduct searches of their own databases for existing chemical information before they refer any chemical to EPA. Referrals are made to EPA only after a decision has been made that an agency's existing chemical information is inadequate to meet its needs.

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

In proposing to renew this ICR, EPA provided a 60-day public notice and comment period that ended on October 29, 2018 (83 FR 44045, August 29, 2018). EPA received no public comments in response to this notice.

3(c) Consultations

Additionally, under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and information users about specific aspects of ICRs before submitting an ICR to OMB for review and approval. In accordance with this regulation, EPA submitted questions to several interested parties via e-mail. The individuals contacted were:

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EPA received no responses to its consultation correspondence.

3(d) Effects of Less Frequent Collection

Under PAIR or subpart B of 40 CFR 766, persons are required to report only once for a chemical listed in the PAIR or subpart B of 40 CFR 766. However, for PAIR, if information received from the initial report indicates human health and environmental risks, then the Agency may require that additional information be submitted at some future date to monitor any changes pertaining to that chemical. As such, the reporting frequency for PAIR and subpart B of 40 CFR 766 cannot be reduced without effectively suspending the information collection requirement.

3(e) General Guidelines

This collection does not exceed any of the Paperwork Reduction Act guidelines at 5 CFR 1320.6.

3(f) Confidentiality

Submitters may designate information reported under PAIR and subpart B of 40 CFR 766 as confidential business information (CBI). EPA has implemented procedures to protect any confidential, trade secret or proprietary information from disclosure. These procedures comply with EPA's confidentiality regulations at 40 CFR part 2, subpart B, and TSCA section 14.

3(g) Sensitive Questions

This information collection does not include questions of a sensitive nature.

4 THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondent NAICS Codes

PAIR and subpart B of 40 CFR 766 respondents are manufacturers and importers of chemical substances, mixtures or categories. Respondents affected by this collection are included primarily in the following NAICS codes:

3251 Basic Chemical Manufacturing

3252 Resin, Synthetic Rubber, and Artificial Synthetic Fibers and Filaments
Manufacturing
3255 Paint, Coating, and Adhesive Manufacturing
3253 Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing
3259 Other Chemical Product and Preparation Manufacturing
32411 Petroleum Refineries

4(b) Information Requested

(i) Data Items

PAIR requires manufacturers or importers of the listed chemical substances, mixtures or categories to report to EPA information such as the substances' chemical identification, quantity produced or imported, chemical processes, employee exposure, environmental releases, uses and products. Respondents are only required to report information that is known or reasonably ascertainable by them. As described in the previous section, extensive file searches are not required. The PAIR reporting requirements are included in the PAIR form (EPA Form 7710-35) and instructions (see Attachment H).

In addition, each person who is manufacturing or processing a chemical listed in 40 CFR 766.25, must submit a protocol for testing according to the schedule at 40 CFR 766.35(a)(2). Persons who manufacture or import a chemical substance listed under 40 CFR 766.25 must report positive test results, using the Dioxin/Furan Report Form (EPA Form 7710-51; see Attachment D), of all existing test data that show that chemical substance has been tested for the presence of halogenated dibenzodioxins/halogenated dibenzofurans (HDDs/HDFs), as well as any health and safety studies for the chemical substance, as defined in the regulation. Additionally, any manufacturer or importer of a chemical substance listed in 40 CFR 766.25 in possession of unpublished health and safety studies on HDDs/HDFs is required to submit copies of such studies to EPA.

(ii) Respondent Activities

A representative respondent would engage in the following activities:

- Conduct an initial review of the rule to determine if their company must report;
- Familiarize themselves with the PAIR and subpart B of 40 CFR 766 requirements;
- Complete the PAIR and subpart B of 40 CFR 766 reporting via the Agency's Central Data Exchange (CDX);
- Provide trade name notification;
- Indicate CBI status if so desired; and
- Keep a copy for recordkeeping requirements.

The PAIR (40 CFR part 712) and subpart B of 40 CFR 766 generally requires one-time reporting and establishes the reporting period for the listed chemical substances, mixtures or categories. Therefore, a reporting schedule is not required.

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

5(a) Agency Activities

The activities routinely conducted by EPA related to the rule development, processing, analysis and storage of the information collected under a PAIR rule (40 CFR part 712) and subpart B of 40 CFR 766 are as follows:

- Chemical nomination, review and selection;
- Rule development;
- Evaluation of the rule (including impact assessments);
- Industry/public assistance;
- Compliance monitoring; and
- Processing of data received for listed chemicals (includes receipt, dissemination, evaluation, etc.).

5(b) Collection Methodology and Management

The PAIR (40 CFR part 712) and subpart B of 40 CFR 766 requires respondents to submit information electronically via CDX. Information collected under PAIR and subpart B of 40 CFR 766 is catalogued, distributed to appropriate EPA personnel for further processing, review and analysis. The information is maintained by OPPT's Information Management Division.

Electronic submission of TSCA section 8(a) PAIR and subpart B of 40 CFR 766 information is required and to address the CBI substantiation changes under amended TSCA the Agency has updated the interface in CDX. (See also Attachments D and H).

5(c) Small Entity Flexibility

In accordance with TSCA section 8(a)(1)(B), PAIR contains a small business exemption. A manufacturer or importer is considered a small business if (1) the firm's total annual sales when combined with those of its parent company (if any) are less than \$30 million for the reporting period and (2) its total production and/or importation of the chemical substances, mixture or category, for the reporting period, does not exceed 100,000 pounds (45,400 kilograms) at an individual site owned and controlled by the firm. In accordance with amended TSCA the EPA consulted with the Administrator of the Small Business Administration to review the adequacy of the standards for determining which entities are considered small for the purposes of TSCA section 8(a). The agency determined that a revision of the standard is warranted (82 FR 56824, November 30, 2017) and initiated rulemaking to update the standard.

The small manufacturer/importer exemptions apply to PAIR, regardless of which office or agency nominates a chemical. In some instances, the EPA Administrator can remove these exemptions on a chemical-specific basis, provided notice and comment rulemaking is utilized.

EPA expects that those offices that have a critical need for reporting from small businesses usually exempt from PAIR reporting will use other mechanisms to gather the data. EPA does not expect to issue a PAIR rule during the next 3 years that would impact small businesses.

5(d) Collection Schedule

Information collection under PAIR occurs after publication of a *Federal Register* notice establishing the reporting period for the listed chemical substances, mixtures or categories. Respondents are asked to respond once, within 30 days of the effective date of the final PAIR rule (which is usually 30 days after publication of the rule in the *Federal Register*).

Persons who manufacture or import a chemical substance listed under 40 CFR 766.25 must report no later than October 5, 1987 or 90 days after the person first manufactures or imports the chemical substance, the information as detailed at 40 CFR 766.35(b).

The Agency has no plans to publish the data collected by PAIR and subpart B of 40 CFR 766, although non-CBI information may be made available to the public upon request.

6 ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

This section presents the Agency's estimates of the burden associated with the reporting and recordkeeping requirements under the TSCA section 8(a) PAIR and subpart B of 40 CFR 766. The total annual industry burden for both reporting and recordkeeping is estimated to be 33.0 hours. These estimates are based on the level of PAIR and subpart B of 40 CFR 766 reporting activity expected during the ICR period of FY 2019 through 2021. In conducting any study that will be submitted to EPA under TSCA, the respondent must comply with the Good Laboratory Practice Standards (GLPS) at 40 CFR part 792 (see Attachment F). Since the GLPS represent basic standard practices used by laboratories, any burden and costs related to the GLPS are fully captured in the cost and burden estimates provided below.

The PAIR (40 CFR part 712) and subpart B of 40 CFR 766 information is submitted electronically via CDX, (<https://cdx.epa.gov/>) and requests basic identifying information, such as the identity of the chemical (CAS number), the physical location of the plant and mailing address of the responding entity as well as general information on the quantities of the chemical used and number of workers exposed and some additional information on the categories of products (e.g., industrial and consumer) associated with manufacture or processing of the reported substance. In addition, as described in the characterization section, the estimation of burden and cost of collection addresses information collection activities associated with the reporting and recordkeeping requirements contained in 40 CFR 766. See also the forms and instructions in Attachments D and H.

Much of the information requested under this ICR is routinely collected by manufacturers and processors for the maintenance and upkeep of health and safety information but has not previously been made available to the Agency. This information should be readily available to

the firm as it is generated and maintained as part of their normal business practices. In fact, the regulations specifically state that the respondent is not required to conduct an exhaustive search of their files (see 40 CFR 712.7). The EPA has reviewed the average per-report burden estimate in light of the Agency's experience and feedback received from actual submitters. Our average estimate of 33.0 hours per response is consistent with that information.

The methodology used to develop these cost estimates follows principles that have been used in previous ICRs. The methodology and calculations used in this analysis assume the employee responsible for filling out the form has a reasonable level of familiarity with the company and knowledge of the operation at the site. The analysis deals with the marginal costs of complying with this specific request and not the total costs to the company of initial employee training and costs associated with collecting and storing records or of file maintenance that enable a company to comply with a range of other federal and state environmental, health and safety regulations or accounting requirements that rely on this type of information. Based on conversations with respondents, gathering information for an 8(a) PAIR request is similar to other efforts they perform which require familiarity with EPA, state and other federal agency requests for chemical information and does not involve additional familiarization or training to comply with information requested under this ICR.

The Agency is not asserting an exact measurement of the burden and costs that all potential respondents will incur while complying with this information collection activity. The Agency's burden and cost estimates are based on averages. Some respondents may require more time to respond to the information collection than the Agency's estimated average of 33 hours per report; however, the Agency believes some respondents will be able to complete their response activities in less time. The Agency also intends to continue to provide rule-specific estimates of burden and costs, presenting them in the preamble to the PAIR rule. Should the Agency determine in that context that this average estimate is insufficient, it will adjust the ICR accordingly. Upon renewal, EPA will reassess its burden estimate based on the next three-year approval period and adjust as appropriate.

Based on information provided by EPA's Information Management Division (IMD), an average of 14.8 sites submitted a total of 33 reports per year (an average of 2.23 reports per site per year) during the period of FY 2006 through FY 2010. The rate at which new PAIR rule chemicals are added is sporadic and not entirely predictable; between FY 2012 and FY 2017, EPA received no PAIR submissions. In general, the analysis uses data and methodological assumptions from previous economic analyses of PAIR rules, other government data sources, and assumptions as described. A detailed description of the methodology used to derive the estimates follows.

Number of Sites and Reports per Site

The burden hour estimates in this analysis are based on an estimate of the level of PAIR and subpart B of 40 CFR 766 reporting activity during the next three-year ICR approval period (FY 2019 to FY 2021). This, in turn, is related to the number of expected PAIR and subpart B of 40 CFR 766 chemical reports and reporting sites. During fiscal years 2012 to 2017, EPA received no PAIR submissions. Some PAIR reports submitted during a given fiscal year may be

for chemicals added to the PAIR during previous years. EPA received less than five submissions over the course of the last OMB approval for subpart B of 40 CFR 766. For the purposes of this analysis, EPA assumes an annual average of 1 site (respondent) submitting 1 report (form), for an average of 1 report per respondent.

Error: Reference source not found presents the historic submission statistics for section 8(a) PAIR reporting.

Fiscal Year	Sites Reporting
2006	3
2007	68
2008	1
2009	0
2010	2
2011	1
2012	0
2013	0
2014	0
2015	0
2016	0
2017	0
Totals	75

Unit Burden Estimates

To estimate the burden and costs to industry respondents, several reporting activities (or burden factors) are analyzed. These burden items include: form familiarization; report preparation; trade name notification; CBI substantiation; recordkeeping; CDX registration; and report submission. Each of these activities requires the skills of various labor categories. The section below details each separate activity and presents the estimated labor hours required by each task, by labor category (clerical, technical and managerial).

All burden estimates are taken from the *Economic Impact and Small Business Definition Analysis for the Final TSCA Section 8(a) Preliminary Assessment Information Rule, Final Report* (EPA, 1981), previous TSCA Section 8(a) PAIR ICRs updates, and the *Economic Analysis for the Electronic Reporting under the Toxic Substances Control Act (TSCA) Final Rule* (EPA, 2012), unless otherwise noted. The 2012 EA estimates the burden associated with electronic PAIR and subpart B of 40 CFR 766 submissions, including the burden associated with CDX registration, the reduction in recordkeeping burden, and the reduction of the clerical burden associated with report submission. This ICR follows the practice of the last ICR update where EPA removed the clerical burden associated with all other PAIR and subpart B of 40 CFR 766 submission activities. This change was made to be consistent with the burden estimates provided for the electronic reporting of TSCA Section 5 Notices in *The Economic Analysis of the*

Premanufacture Notification Electronic Reporting Rule (EPA, 2009) and the electronic submission of TSCA 8(b) Chemical Data Reporting (CDR) submissions in the *Economic Analysis for the Final Inventory Update Reporting (IUR) Modifications Rule* (EPA, 2011).

Form Familiarization

In the 1981 PAIR economic analysis¹, it was estimated that form familiarization would require 3 hours of effort from managerial personnel and 4 hours from technical personnel for a total of 7 hours per site. The estimate includes efforts for rule familiarization and to determine if reporting is required. Because EPA only expects one report from one site in the next ICR cycle, the per-report burden is estimated to be 7 hours.

Activity	Clerical	Technical	Managerial	Total
Form Familiarization	0.00	4.00	3.00	7.00

Report Preparation

The 1981 PAIR economic analysis estimated that direct reporting activities would require a total of 16 hours of effort per report. This consists of the burden related to the completion of the PAIR (EPA Form No. 7710-35) or subpart B of 40 CFR 766 form (EPA Form No. 7710-51). As indicated previously, the respondents are not expected to conduct an exhaustive search of their files. Respondents are only required to report what is known or reasonably ascertainable to them (see 40 CFR 712.7). The relative distribution of reporting burden between managerial, technical and clerical personnel was developed for the 1992 PAIR ICR update. For this ICR update, EPA assumes that per-report burden for report preparation is the same as in the prior ICR update, for a total burden estimate of 14.75 hours.

Activity	Clerical	Technical	Managerial	Total
Reporting	0	9.25	5.5	14.75

Given that each site produces an average of 1 report, the per-site burden for report preparation is 1 x 14.75 hours, or 14.75 hours.

Trade Name Notification

Some companies may report their customers' uses as "unknown" for more than twenty percent of their volume. These companies must list under Item 10 of the PAIR reporting form the market (trade) name(s) under which they distribute the chemical. This reporting is referred to as trade name notification.²

¹ Economic Impact and Small Business Definition Analysis for the Final TSCA Section 8(a) Preliminary Assessment Information Rule, Final Report, prepared for the EPA by ICF, Inc., Washington, D.C., 1981.

² 40 CFR 712.28 (July 1, 1993).

All commercial manufacturing, importing and processing sites that distribute any of the chemicals subjected to a PAIR reporting rule under a trade name must take steps to ensure that information about the downstream processors is submitted to EPA. Firms may choose among several options to meet trade name notification requirements, including:

- 1) Submit trade name data to EPA for listing in the *Federal Register*;
- 2) Notify all customers of the need to report; or
- 3) Complete the reporting requirements for each customer.

This ICR assumes that companies will adopt the least-costly reporting alternative of providing a trade name list to EPA for inclusion in the *Federal Register*. However, trade name notification is not relevant if processor reporting is not required.

Furthermore, this ICR also assumes that all manufacturers and importers will incur trade name notification costs, but does not address processors due to the lack of data on processor reporting. In the 1994 EPA PAIR ICR,³ the unit burden of trade name notification was given as 3.2 hours (i.e., 2.2 hours managerial and 1.0 hours clerical), for this analysis the 1.0 hours of clerical burden is removed to adjust for electronic submissions, for a total burden of 2.2 hours per report.

Activity	Clerical	Technical	Managerial	Total
Trade Name Notification	0.00	0.00	2.20	2.20

Given that each site produces an average of 1 report, the trade name notification per-site burden for trade name notification is 1 x 2.2 hours, or 2.2 hours.

CBI Substantiation

A company may make claims of confidentiality for any data element contained in its submission. For each CBI (confidential business information) claim, generic information must be supplied for a non-CBI copy of the submission (i.e., a sanitized version must also be submitted). It is assumed that most of the time required for CBI substantiation involves managerial staff discussion of whether or not to make a CBI claim. Furthermore, it is assumed that all firms will review their submissions for CBI content.

The Lautenberg Act, passed in 2016 reformed TSCA and increased requirements for TSCA CBI substantiation claims. These changes significantly change the CBI substantiation burden from prior ICR updates. The previous ICR assumed that all CBI substantiation burden was a managerial decision. The Lautenberg Act changed TSCA to require a statement that the submitter has (1) taken reasonable measures to protect the confidentiality of the information, (2) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law, (3) has a reasonable basis to conclude that disclosure of the

³ Burden Hour and Cost Estimates for PAIR Section 8(a) Reporting (1994 Update), internal U.S. EPA memorandum from Carol Rawie, Economics, Exposure, and Technology Division to Karen Boswell, Chemical Testing and Information Branch, May 16, 1994.

information is likely to cause substantial harm to the competitive position of the person; and (4) has a reasonable basis to believe that the information is not readily discoverable through reverse engineering.⁴ These additional questions make CBI substantiation more a technical than a managerial decision. The previous ICR update assumed 4 hours of managerial time per report; this update estimates 1.270 hours of managerial time and 4.075 hours of technical time per report for a total of 5.345 hours per report.

Activity	Clerical	Technical	Managerial	Total
CBI Substantiation	0.00	4.075	1.27	5.345

Based on an analysis of CBI claims for reporting to the TSCA Inventory (discussed in the 1986 CAIR economic analysis), only 75 percent of reports are expected to make CBI claims. The burden distributed across all reports is 5.345 hours x 0.75, or 4.01 hours. Multiplying the adjusted report burden and cost by 1, in turn, provides the per-site burden for CBI substantiations of 4.01 hours.

Recordkeeping

Pursuant to TSCA section 8(a), the manufacturer/importer or processors of the chemical substances identified under PAIR must also maintain records of the information submitted to EPA. In addition, since manufacturer/importer or processors that submit data to EPA must comply with the GLPS in 40 CFR 792, this ICR also generally covers the burden associated with maintaining records as required under the GLPS. These records are used for compliance monitoring and enforcement purposes.

EPA estimates that the recordkeeping burden associated with this ICR involves about half an hour of time for both the clerical and the technical labor category, based on the *Economic Analysis for the Electronic Reporting under the Toxic Substances Control Act (TSCA) Final Rule* (EPA, 2012). This burden estimate represents the time necessary for the individuals to identify the information, determine the appropriate location for the record to be kept, and placing the record in such a location. The per-report recordkeeping burden is therefore estimated to be 1.00 hour.

Activity	Clerical	Technical	Managerial	Total
Recordkeeping	0.5	0.5	0	1.00

The per-site burden for recordkeeping is 1 report x 1.0 hours, or 1 hours.

CDX Registration

As part of EPA's electronic reporting requirements, submitters of PAIR and subpart B of 40 CFR 766 reports are required to register and submit information electronically with EPA's CDX system. EPA estimates that companies registering with CDX for the first time would incur a one-time burden to complete CDX registration activities, obtain a CDX electronic signature,

⁴ TSCA, Sec. 14(c)(1)(B), (C)

and familiarize themselves with electronic reporting requirements. The total burden associated with CDX registration is taken from the *Economic Analysis for the Electronic Reporting under the Toxic Substances Control Act (TSCA) Final Rule* (EPA, 2012) and is estimated to be 3.48 hours per company, including 0.91 hours for CDX Registration, 1.75 hours for completing electronic signature agreements, and 0.82 hours for rule familiarization.

Activity	Clerical	Technical	Managerial	Total
CDX Registration	0.00	0.73	0.18	0.91
CDX Electronic Signature	0.00	1.00	0.75	1.75
Rule Familiarization	0.00	0.27	0.55	0.82
Total	0.00	2.00	1.48	3.48

For the purposes of this analysis EPA assumes that the one site submitting PAIR or subpart B of 40 CFR 766 data will register with CDX, for a total per-site burden of 3.48 hours.

Report Submission

Report submission consists of the preparation, review and electronic submission of a report in accordance with 40 CFR Part 712, Subpart B, as amended by 78 FR 72818 (December 4, 2013), which required electronic submission.

EPA estimates that the per-report submission will require 0.05 hours of clerical time and 0.5 hours of managerial time for a total of 0.55 hours. The clerical burden is taken from the *Economic Analysis for the Electronic Reporting under the Toxic Substances Control Act (TSCA) Final Rule* (EPA, 2012) and includes time to prepare and submit a report electronically. The managerial time assumes an involvement in the preparation of the transmittal letter and review of the report package before it is submitted to EPA.

Activity	Clerical	Technical	Managerial	Total
Report Submission	0.05	0.00	0.5	0.55

Given that each site produces an average of one (1) report, the per-site burden for report submission is 1 x 0.55 hours, or 0.55 hours.

Total Industry Burden Estimates

Table 9 presents the compilation of the annual burden hour estimates for respondents.

Burden Item	Hours Per Report	Total Number of Reports per Site	Hours Per Site	Total Number of Sites	Total Annual Hours
Form Familiarization	7.00	1	7.00	1.00	7.00
Reporting	14.75	1	14.75	1.00	14.75
Trade Name Notification	2.20	1	2.20	1.00	2.20
CBI Substantiation	4.01	1	4.01	1.00	4.01
Recordkeeping	1.00	1	1.00	1.00	1.00
CDX Registration	-	-	3.48	1.00	3.48
Report Submission	0.55	1	0.55	1.00	0.55
Totals	29.51		32.99		32.99

In summary, an average of one (1) respondent per year would be required to spend an estimated total of 32.99 hours each year to respond to PAIR and subpart B of 40 CFR 766 rules during the period of FY 2019 through FY 2021, resulting in an average burden of 32.99 hours per response.

6(b) Estimating Respondent Costs

This section presents estimates of the cost expected to be incurred due to reporting under the TSCA section 8(a) PAIR and subpart B of 40 CFR 766. The total annual industry cost for both reporting and recordkeeping is estimated to be \$2,533. This estimate is based on the cost of the burden estimate provided above, and includes other costs associated with this ICR.

Labor costs in this report have been updated using the most recently available, revised wage rates and information on benefits costs. These wage rates are taken from the Bureau of Labor Statistics (BLS) Employer Costs for Employee Compensation Supplemental Tables, December 2017 (released in March 2018), with the information extracted from Table 2, *Private industry workers in manufacturing industries, by occupational group*. The clerical wages are taken from the BLS data for “office and administrative support.” The technical wages are taken from the BLS data for “professional and related.” The managerial wages are taken from the BLS data for “management, business and financial.” Labor wage rates and hourly benefit costs taken from those sources have been used to calculate the labor cost to respondents, as shown below. The hourly overhead is calculated as 17 percent of the base wage. This approach is used for consistency with Office of Pollution Prevention and Toxics economics practices, and is based on the analysis in *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*, Cody Rice, U.S. EPA, Office of Pollution Prevention and Toxics, Economic and Policy Analysis Branch, June 10, 2002. This approach, which is now standard practice in this office, produces wage and cost estimates that are somewhat lower than the data and methods used in the most recent previous 8(a) PAIR ICR renewal analysis. Table 10 presents 2017\$ hourly industry wages.

Table 10: Industry Hourly Labor Costs (2017\$)			
Wage Component	Clerical	Technical	Managerial
Hourly Wage Rate	\$20.49	\$45.82	\$46.59
Benefit Costs	\$11.02	\$24.33	\$22.16
Fringe and Overhead Factor	1.71	1.70	1.65
Total Hourly Cost	\$34.99	\$77.94	\$76.67

These labor costs are multiplied by the estimated burden hours per activity and added to any non-labor costs to develop total unit costs per report (See Table 11). It is estimated that only the CDX registration task will require expenditures other than labor.

Total non-burden costs per report are estimated to be \$2.30 associated with mailing CDX electronic signature forms to EPA. With an annual estimate of 1 report expected, the total annual non-burden cost for this ICR is \$2.30. These non-burden hour costs are not included in the Agency's annual burden estimate, but are included in the total costs here. Finally, unit costs per report are multiplied by the number of reports per site per year to arrive at unit costs per site (respondent costs), and are summarized in Table 11.

Table 11: Reporting Costs by Labor Category and Reporting Activity

Cost Element	Clerical		Technical		Managerial		Total Labor Costs	Other Direct Costs	Total Cost Per Report	Total Number of Reports	Total Cost Per Site	Total Number of Sites	Total Annual Industry Cost
Form Familiarization	\$34.99	0.00	\$77.94	4.00	\$76.67	3.00	\$542	\$0.00	\$542	1	\$542	1	\$542
Reporting	\$34.99	0.00	\$77.94	9.25	\$76.67	5.50	\$1,143	\$0.00	\$1,143	1	\$1,143	1	\$1,143
Trade Name Notification	\$34.99	0.00	\$77.94	0.00	\$76.67	2.20	\$169	\$0.00	\$169	1	\$169	1	\$169
CBI Substantiation	\$34.99	0.00	\$77.94	3.06	\$76.67	0.95	\$311	\$0.00	\$311	1	\$311	1	\$311
Recordkeeping	\$34.99	0.50	\$77.94	0.50	\$76.67	0.50	\$56	\$0.00	\$56	1	\$56	1	\$56
CDX Registration	\$34.99	0.00	\$77.94	2	\$76.67	1.48	\$269	\$2.30	\$272	1	\$272	1	\$272
Report Submission	\$34.99	0.05	\$77.94	0.00	\$76.67	0.50	\$40	\$0.00	\$40	1	\$40	1	\$40
TOTAL							\$2,530	\$2.30	\$2,533	1	\$2,533	1	\$2,533

The average respondent is assumed to spend \$2,533 per report, or \$2,533 in total per respondent per year. As noted earlier, the Agency is estimating an average of 1 reporting sites and 1 reports per year. As a result, total industry cost for complying with PAIR and subpart B of 40 CFR 766 rules is estimated to be \$2,533 per year during the period of FY 2019 through FY 2021.

6(c) Estimating Agency Burden and Cost

The FY 2018 cost to EPA of a full-time equivalent employee (FTE), Grade 12, Step 1 in the Baltimore-Washington pay area is \$81,548 (U.S. Office of Personnel Management Internet site at <http://www.opm.gov>). One FTE is equivalent to 2,080 hours per year. The fully loaded FTE cost is \$130,477. The annual costs per FTE are derived by multiplying the annual pay rate by 1.6 (the benefits multiplication factor). The multiplication factor used is recommended in EPA's Office of Policy, Planning, and Evaluation's Instructions for Preparing Information Collection Requests (ICRs), (June 1, 1992).

Data processing costs have been updated from 2014 to average 2017 dollars using the GDP implicit price deflator from the Bureau of Economic Analysis (BEA). The BEA GDP price index series with a base of 2009 = 100 has the 2014 index at 108.832 and the 2017 index at 113.422 so the adjustment factor from 2014 to 2017 is 1.0422 ($113.422/108.832 = 1.0422$). Data processing costs for the 2014 PAIR ICR update were estimated to be approximately \$283.06 per report. Adjusting this number to 2017 with the GDP implicit price deflator yields an adjusted data processing cost of \$295.01 per report (i.e., $\$283.06 \times 1.0422 = \295.01).

This analysis assumes that an annual average of 1 report will be submitted over the three-year period of the ICR. Personnel burden and costs associated with industry/public assistance and data processing activities have been adjusted based on that estimate. From the 1989 PAIR ICR update it has been derived that industry/public assistance required approximately 1.5 hours per report or 0.0007 FTE. Similarly, the 1989 PAIR ICR update estimated that about 3.75 hours, or 0.002 FTE, of data processing/system support personnel time would be required per report.

Table 12 summarizes the government's activities in developing and administrating the PAIR and subpart B of 40 CFR 766. The required FTEs per activity are retained from the 1996 PAIR ICR update and from the previous 8(a) PAIR ICR renewal analyses, for all activities except for the recalculation of the burden associated with industry/public assistance and data processing/system support personnel time.

Activity	Annual Burden
Chemical nomination, review, and selection	0.25
Rule development	0.90
Evaluation of rule	0.05
Industry/public assistance	0.0007
Compliance monitoring	0.10
Data processing and system support personnel	0.002
Total FTE	1.3

It is estimated that the annual cost to the federal government will be \$295 in data processing costs plus 1.3 FTEs. At an estimated loaded annual salary of \$130,477 per FTE, the total of 1.3 FTEs will cost EPA \$157,597 in fully loaded labor cost (salaries, benefits, and overhead). This brings the total costs to the federal government to \$157,880 annually (i.e., \$283 + \$157,597).

Table 13 presents a summary of the costs to the federal government for this information collection.

Total FTEs	1.3
Loaded Cost per FTE	\$130,477
Government Labor Cost	\$169,620
Government Data Processing Cost	\$295
Total Annual Government Cost	\$169,915

6(d) Bottom Line Burden Hours and Costs

Respondent Burden and Costs:

Total respondent annual burden hours = 32.99 hours
Total respondent annual costs = \$2,533

Agency Burden and Costs:

Agency burden hours: 1.3 FTEs = 2,709.3 hours
Agency annual costs = \$169,915

6(e) Reason for Change in Burden

This request reflects a slight increase in the estimated annual burden of 1 hour (from 32 hours to 33 hours) from that currently in the OMB inventory. In the previous ICR update, EPA assumed 4 hours of managerial time per report related to the submitter's decision whether to make a CBI claim; whereas this update estimates a total of 5.345 hours per report. EPA continues to attribute burden to CBI substantiation while also estimating an increased burden due to the revised CBI substantiation requirements in the 2016 amendments to TSCA.

Table 14: Annual Burden Hour Change	
Starting Burden	31.98
Program Changes	
<i>Changes due to statutory requirement for upfront CBI substantiation</i>	<i>1.01</i>
Total Change	1.01
Total Annual Burden	32.99

6(f) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0054, is estimated to average 33.0 hours 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-2018-0516, which is available for online viewing at <http://www.regulations.gov>, or in person viewing at the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., 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 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-2018-0516 and OMB Control No. 2070-0054, to

- (1) 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
- (2) OMB via email to oir_submission@omb.eop.gov. Address comments to the OMB Desk Officer for EPA.

Attachments to the Supporting Statement

- Attachment A** Chemical Information Rules – 40 CFR 712
- Attachment B** Section 8(a) of the Toxic Substances Control Act (15 U.S.C. 2607a)
- Attachment C** Dibenzopara-dioxins/dibenzofurans – 40 CFR 766
- Attachment D** Dioxin/Furan Report Form (EPA Form 7710-51) and instructions.
Available electronically at <https://www.epa.gov/sites/production/files/2015-08/documents/7710-51.pdf>.
- Attachment E** Screenshot of changes to be made to CDX for TSCA section 8(a) PAIR reporting
- Attachment F** Good Laboratory Practice Standards – 40 CFR 792
- Attachment G** CDX Section 8(a) PAIR User Guide
- Attachment H** Manufacturer’s Report Preliminary Assessment Information Form (EPA Form 7710-35) and instructions.
Available electronically at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information>.