December 18, 2020

Supporting Statement for a Generic Information Collection Request (ICR)
Under the Paperwork Reduction Act (PRA)

EXECUTIVE SUMMARY

Identification of the Information Collection – Title and Numbers

Title: Generic Clearance for TSCA Section 4 Test Rules, Test Orders, Enforceable Consent Agreements (ECAs), Voluntary Data Submissions, and Exemptions from Testing Requirements

ICR Numbers: EPA ICR No.: 1139.12, OMB Control No.: 2070-0033

Docket ID No.: EPA-HQ-OPPT-2015-0436

Abstract

This is a revision to the existing ICR approved under OMB Control No. 2070-0033 and entitled "TSCA Section 4 Test Rules, Consent Orders, Enforceable Consent Agreements, Voluntary Testing Agreements, Voluntary Data Submissions, and Exemptions from Testing Requirements (Reinstatement)" (identified as EPA ICR No. 1139.11), which is approved through October 31, 2021.

This generic ICR covers the information collection activities associated with the submission of information to EPA pursuant to TSCA section 4 regulatory actions. (15 U.S.C. 2603).[1] The updates in this generic ICR were conducted to include the authorities provided to EPA under TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (hereinafter the "Lautenberg Act"). Under TSCA, EPA has the authority to issue regulatory actions designed to gather or develop health and safety information and exposure information on chemical substances and mixtures, and to control unreasonable risks associated with new and existing chemical substances. TSCA section 4 authorities allow EPA to require the development of information related to chemicals and the use of prescribed "protocols and methodologies" in order to inform EPA and other federal agencies about chemical risks, which in turn will inform decision makers for purposes of prioritization for risk evaluation, risk evaluation and risk management of those chemicals as necessary.

SUPPORTING STATEMENT

1. Explain the circumstances that make the collection of information necessary.

The information collection activities covered by this ICR and imposed on the respondents as part of the TSCA section 4 testing program, as established by 53 USC 2603,allow EPA to ensure that the necessary information will be developed, that the results meet basic scientific standards of acceptability and adequacy, that unforeseen complications or issues can be addressed, and that any required testing is progressing on schedule. The information collection activities would be required if certain statutory determinations are made that indicate the development of information under TSCA section 4 is necessary. TSCA section 4 requires manufacturers and processors of chemical substances and mixtures to conduct testing if it

[1] See also Attachment 1.

finds that the manufacture, distribution, processing, use or disposal of a chemical substance or a mixture may present an unreasonable risk to human health or the environment [TSCA Sections 4(a)(1)]. The rationale for establishing the necessity for issuing a TSCA section 4 regulatory action would be presented under the findings and/or statement of need, along with an indication of the underlying evidence, in the specific action.

TSCA section 2(b)(1) states that it is the policy of the United States that "adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should be the responsibility of those who manufacture [which is defined by statute to include import] and those who process such chemical substances and mixtures."

The Lautenberg Act expanded EPA's explicit statutory authority to require the development of information under TSCA section 4. In addition to the statutory testing authority previously provided under TSCA section 4, the Lautenberg Act amended TSCA to explicitly provide authority to issue orders. TSCA section 4(a)(2) now explicitly authorizes EPA to promulgate rules, issue orders, or enter into consent agreements to require testing to develop information that is necessary:

- To review a notice submitted under TSCA section 5 or to perform a risk evaluation under TSCA section 6(b);
- To implement a requirement imposed in a rule, order, or consent agreement under TSCA section 5(e) or (f), or in a rule promulgated under section 6(a);
- At the request of a Federal implementing authority under another Federal law, to meet the regulatory testing needs of that authority with regard to toxicity and exposure;
- To determine if a chemical substance or mixture manufactured, processed, or distributed in commerce solely for export presents an unreasonable risk of injury to health or the environment in the U.S., pursuant to TSCA section 12(a)(2); and
- To prioritize a chemical substance under TSCA section 6(b) (subject to certain limitations).

TSCA section 4(a)(3) was also established by the Lautenberg Act. According to TSCA section 4(a)(3), rules, orders, and consent agreements pursuant to TSCA section 4(a)(2) must include a "Statement of Need," which requires EPA to identify the need for the development of new information, describe how information reasonably available to EPA informed the decision to require new information, explain the basis for requiring any testing of vertebrate animals, and, as applicable, explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement.

TSCA section 4(a)(4) established that when requiring the development of new information under TSCA section 4(a), EPA must employ a tiered screening and testing process, under which the results of screening tests or assessments of available information inform the decision whether to require more advanced testing. It is therefore assumed, for the purposes of estimating burden for this three-year period, that testing would consist primarily of screening-level tests. If other types of testing are required in the future, the burden estimates will be modified as needed at that time.

TSCA section 4(h) was also established by the Lautenberg Act and requires EPA to take specified steps to reduce and replace vertebrate animal testing to the extent practicable,

scientifically justified, and consistent with policies of Title I of TSCA. Also, voluntary testing developed for submission under Title 1 of TSCA, and not pursuant to a request or requirement by EPA, must first be attempted by means of an alternative test method or strategy identified by EPA pursuant to TSCA section 4(h)(2)(C) and for the development of such information before conducting new vertebrate animal testing.

EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the chemical. Regarding testing pursuant to TSCA section 4(a)(1), EPA need not limit the scope of testing required to the factual basis for the TSCA section 4(a)(1)(A)(i) or 4(a)(1)(A)(ii) findings, as long as EPA finds that there is insufficient information and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and that testing is necessary to develop the information[2].

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the Agency has made of the information received from the current collection.

EPA's Office of Pollution Prevention and Toxics (OPPT) within the Office of Chemical Safety and Pollution Prevention (OCSPP), other EPA Offices and/or other Federal agencies will be the primary groups for which information will be collected. However, to the extent that reported information is not considered to be CBI, the public may have access to this information.

The information required under TSCA section 4 may be used to provide EPA with the necessary information on health effects, ecological effects, and environmental fate to predict the effects of chemicals on human health or the environment. EPA's statutory authority under TSCA sections 4(a)(1) or 4(a)(2) may be used to ensure the safety of existing chemicals in the marketplace by applying a three-step statutory and regulatory approach that includes prioritizing, evaluating, and managing risks of chemicals under TSCA section 6. EPA may also need to develop information under TSCA section 4 pursuant to other authorities provided under TSCA section 4(a)(2), including pursuant to TSCA section 5. Also, EPA may be required to develop a testing action under TSCA section 4 in response to a recommendation received from the TSCA Interagency Testing Committee (ITC).

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

On December 4, 2013, EPA finalized a rule to require electronic reporting of certain information submitted to the Agency under TSCA sections 4, 5, 8(a) and 8(d).[3] The rule became effective in March 2014. Submitters are now required to use EPA's Central Data Exchange (CDX; https://cdx.epa.gov/), the Agency's electronic reporting site to make submissions in response to TSCA section 4. Submitters must register to use EPA's Agency-

[2] This approach is explained in more detail in EPA's statement of policy for making findings under TSCA section 4(a)(1)(B) in the Federal Register of May 14, 1993 (58 FR 28736, 28738-39; FRL-4059-9). Note that the TSCA sections that were previously enumerated as 4(a)(1)(A) and (B) are now enumerated as 4(a)(1)(A)(i) and 4(a)(1)(A)(ii), respectively.

[3] Docket reference EPA-HQ-OPPT-2011-0519

wide CDX portal for submitting information in a secure manner, select the Chemical Safety and Pesticide Programs (CSPP) portion of the site, access a Web-based TSCA reporting tool called the Chemical Information Submission System (CISS), and select the TSCA section 4 option for transmitting information as exhibited in the CDX/Manage Toxic Substances Section 4 User Guides. (Note: Users who have previously registered with CDX are able to add "Submission for Chemical Safety and Pesticide Program (CSPP)" to their current registration.) This reporting tool is compatible with Windows, Mac, Linux, and UNIX based computers, and uses "Extensible Markup Language" (XML) specifications for efficient data transmission across the Internet. Two test rules that were issued before the electronic reporting rule went into effect in March 2014 are still active. Submissions for these two test rules have been made by using the U.S. Mail and by electronic submission. Any information collection activities pursuant to new test rules, test orders, or consent agreements will be made electronically.

4. Describe efforts to identify duplication.

In general, the activities associated with collecting test information for chemicals subject to TSCA are not duplicated by any other agency or office within EPA. TSCA is the only applicable authority to allow for such information collection, and TSCA specifically assigns that authority to EPA. In addition, EPA takes several steps to ensure that its requests for information do not result in duplicative efforts by those responding, including:

- A single submission of the information will satisfy the request.
- Prior to proposing a test rule, issuing a test order, or entering into a testing agreement, EPA searches the scientific literature, holds public information gathering meetings if deemed appropriate, and has discussions with industry representatives and other government agencies to determine what types of information have already been obtained about the chemical under consideration.
- EPA proposes a test rule, issues a test order, or enters into a consent agreement only after it has determined that necessary tests have not yet been conducted.
- Exemption applicants are not required to supply information that EPA can obtain by other existing processes.
- Where appropriate, equivalence data on a similar chemical may be accepted by EPA in place of conducting new studies.

5. If the collection of information impacts small businesses or other small entities, describe the methods used to minimize burden.

Test rules and orders both offer the options of joining a testing consortium or requesting an exemption. Although these options are available to both large and small entities, they are of particular value to small entities as they relieve the small entity (which often has fewer resources) of the direct responsibility for collecting or submitting the required information.

Some relief associated with reimbursement of testing costs is provided to small entities under TSCA section 4(c)(3)(A), which requires that all relevant factors be considered including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market of the person required to provide reimbursement in relation to the share of such market of the person to be reimbursed. In most cases, this requirement would serve to benefit the small entity.

Decisions relating to how the cost of testing is to be divided among companies are decided by the manufacturers subject to the test rule, test order, or consent agreement. Generally, small businesses are assigned a portion of the costs that is proportionate to their market share. However, if any party believes a particular reimbursement arrangement is unfair, TSCA directs the Administrator of EPA to assist in resolving the conflict and EPA will consider the special needs of small businesses if such action becomes necessary. To date, no party has requested that EPA assist in reimbursement decisions.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

EPA believes that test rules, test orders, and consent agreements require the minimal submissions to assure necessary oversight and tracking of the test information necessary to prioritize, evaluate, and manage chemical risks. Less frequent collection would mean that EPA would not have information sufficient to carry out its statutory mandates. Regulatory actions pursuant to TSCA section 4 may require the test sponsor to submit to EPA: 1) a letter of intent to test that identifies who will be conducting the testing, 2) study plans before beginning testing, and 3) a final report that contains the study results. Each party subject to a test rule or order that wants to request an exemption from testing is required to submit an exemption application to EPA.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

The information retention requirements for test rules, test orders, and consent agreements exceed one of the PRA guidelines contained in 5 CFR 1320.5. Documentation records, raw data, and specimens pertaining to a test rule or consent agreement study are required to be retained for ten years from the effective date of the applicable test rule or publication date of the consent agreement. These recordkeeping requirements are codified in 40 CFR 792.195. These requirements are necessary to permit sufficient time to review results, carry out prioritization efforts, perform appropriate risk evaluations and, when necessary, to institute appropriate risk management actions. Long-term studies may take five years from the effective date of the final test rule, test order, or consent agreement to perform and submit to EPA; assessment of study results may require an additional one to two years of internal and external peer review; institution of risk management regulatory controls and legal challenges may require an additional two to four years before final resolution of issues. All studies, both short and long-term, are relevant to assessing the potential risk of the chemical and therefore must be retained during the ten-year period. In those regulatory cases where either EPA’s action or the information upon which it is based are challenged, it is imperative that all records, raw information, and specimens be available for further review or investigation. Applicable record retention requirements will be prescribed in orders and/or updates to applicable recordkeeping regulations and will likely cover the same ten-year period as set forth in the regulations regarding rules and consent agreements.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken in response to the comments. Specifically address comments received on cost and hour burden. Describe efforts to consult with persons outside EPA to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or report.

a. Direct Consultations.

Under 5 CFR 1320.8(d)(1) OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an original or renewal ICR to OMB for review and approval. Accordingly, EPA submitted questions to nine parties via e-mail. An individual at the following companies were contacted:

American Chemistry Council Inc.
700 2nd Street N.E.
Washington, D.C. 20002

Society of Chemical Manufacturers and Affiliates (SOCMA)
1400 Crystal Drive, Suite 630
Arlington, VA 22202

Household and Commercial Products Association
1667 K Street N.W., Suite 300
Washington, D.C. 20006

American Petroleum Institute
1220 L Street N.W.
Washington, D.C. 20005-4070

Environmental Law Center, Vermont Law School
164 Chelsea St, PO Box 96
South Royalton, VT 05068

Plastics Industry Association
1425 K Street NW., Suite 500
Washington, DC 20005

Environmental Defense Fund
1875 Connecticut Ave, NW
Washington, DC 20009

Environmental Working Group
500 Washington, St.

San Francisco, CA 94111

Natural Resources Defense Council
1152 15th Street, NW
Washington, DC 20005

EPA did not receive any direct responses to its solicitation for consultations. SOCMA, EDF, and ACC, however, did submit comments to the docket during the public comment period. A copy of EPA's consultation e-mail to the above potential respondents is included in Attachment 4.

b. Soliciting Public Review and Comments.

In proposing to revise this ICR, EPA provided a 60-day public notice and comment period that ended on July 31, 2020 (85 FR 33151, June 1, 2020). During the comment period, EPA received comments from the Center for Specialty Chemical Science, LLC (CSCS), a subsidiary of the Society of Chemical Manufacturers & Affiliates (SOCMA); the Environmental Defense Fund (EDF); and the American Chemistry Council. A copy of the comments and of EPA's response to the comments are included as Attachments 5, 6, 7, and 8, respectively.

One major comment expressed concern that EPA's practices for administering exemptions and the reimbursement program were unfair, especially in terms of identifying companies from which reimbursement might be appropriate. EPA generally responded that the new Order authority added by the Lautenberg Act amendments to TSCA Section 4 should largely mitigate these concerns and these comments will be taken into consideration when updating the implementing regulations.

The second major comment asserted that EPA underestimated the cost to respondents, without sufficient detail or supporting information that could inform the estimates. EPA responded that the burden estimate provided is based on data available to EPA at the time which did not include experience with Order activities – since that is a new authority. EPA intends to capture information about the experiences associated with the Orders and will use that in preparing the ICR renewal.

The third major comment expressed concern that EPA's future plans to use the TSCA section 4 authority appear to be inadequate to fulfill the need for data in meeting the needs associated with its risk evaluation obligations under TSCA. EPA responded that its future plans are not limiting and that EPA intends to continue to consider implementation needs and adjust plans as appropriate. Any changes affect the ICR will be properly captured in the ICR, as appropriate.

The fourth major comment claimed the ICR's discussion related to confidential business information does not accurately reflect the requirements of TSCA section 14. EPA responded that the ICR does not make assertions about what information is entitled to confidential treatment under TSCA and instead affirms the EPA will administer TSCA section 4 in accordance with TSCA section 14 and implementing regulations in 40 CFR part 2.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

Not applicable.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

Information submitted to EPA in response to test rules, test orders, and consent agreements, is, in most cases, non-confidential. Respondents may claim all or part of a document submitted to be confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14, 40 CFR part 2, 40 CFR 790, and any specific confidentiality requirements under a particular testing action. TSCA, as amended by the Lautenberg Act, establishes additional requirements for respondents claiming CBI. These requirements include the submitter substantiating a CBI claim as well as certifying the claim, when applicable. TSCA section 14(c)(2) exempts certain types of information claimed CBI from CBI substantiation requirements. Certain information required pursuant to TSCA section 4 that is not exempt under section 14(c)(2) may require substantiation if claimed CBI. Certain information collection activities may require specific substantiation information. However, if there are no requirements to answer specific questions in substantiating confidentiality claims, respondents may refer to EPA's website for sample substantiation questions and guidance at https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

No information of a sensitive or private nature is requested in conjunction with these information collection activities, and these information collection activities comply with the provisions of the Privacy Act of 1974 and OMB Circular A-108.

12. Provide estimates of the hour burden of the collection of information.

Methodology revisions and additional estimates are necessary to incorporate considerations of the Lautenberg Act provisions. The methodology changes in this ICR revision build upon key improvements implemented in the previous ICR that are designed to minimize redundant calculations, thereby avoiding errors, and reducing cost for production and quality control (EPA, 2018a; see also Nielsen & Day, 2018). Additionally, EPA reviewed and considered the workflow of TSCA section 4 actions under TSCA, as amended by Lautenberg Act. EPA's methodology objectives include:

Objective 1: Reflect the nature of the information collection according to action in a transparent manner, with continued attention to efficiency and communication,

Objective 2: Provide ease in future updates based on anticipated load projections for TSCA section 4 actions, and

Objective 3: Enable minimal changes during the ICR period (i.e., via worksheet corrections) by providing burden estimates at sufficiently high levels to cover the three-year period.

For each type of activity covered by this generic ICR, this section of the ICR describes the respondents, the information collection activities, and related estimates for burden and costs associated with those activities. Additional information regarding the overall methodology, as well as specific considerations for particular ICs, are available in Appendix F.

Respondents affected by the collection activity may include, but are not limited to, entities identified by the North American Industrial Classification System (NAICS) codes within the following industry categories:

Type of Entity	NAICS	Example of Potentially Affected Entities
Chemical Manufacturers (including Importers)	325, 324	Persons who manufacture (defined by statute to include import) one or more of the subject chemical substances.
Processors	325, 324	Persons who process one or more of the subject chemical substances.

Prior to transmitting TSCA section 4 reports and other key correspondence, new submitters must register with CDX. In addition, these respondents must complete an Electronic Signature Agreement form, including signature and date, and then submit the form electronically back to EPA.

Respondents may undertake one or more of the following activities:

(a) Review rulemaking [4] or order and/or participate in ECA discussions.
(b) Conduct searches for relevant existing information. If information is found:
    i. Determine whether the information is relevant; and
    ii. Submit information to EPA if equivalent to testing action requirements.
(c) Submit "Letter of Intent" to conduct testing (or, for ECA, a "Request to Negotiate a Consent Agreement" or complete and submit testing exemption application to EPA.
(d) Plan necessary activities, e.g., consortia, arrange for conduct of studies, etc.
(e) Prepare and submit periodic progress reports, if applicable.
(f) Record and prepare information for submission (includes QA/QC reviews).
(g) Prepare, review, and submit final report.
(h) Review submission for CBI and provide substantiation for confidentiality claims.
(i) Maintain information and final report in records.

These activities may vary based on the category under which the activity may occur:

Test Rules and Orders – Test rules and orders require manufacturers (including importers) of the subject chemical to submit a letter identifying who is sponsoring the required testing; a study plan before testing begins; semi-annual progress reports, as applicable, during the conduct of the testing; and a final report of the test results. Since information is typically required on a chemical basis – as opposed to a manufacturer basis, test sponsors typically form consortia to satisfy the testing requirements.

[4] The activity of "compliance determination" is not listed here or included in the burden calculations because it involves a task of negligible burden by which the respondent recognizes whether each chemical of the test rule is a chemical that the company manufactures.

Enforceable Consent Agreement (ECAs) – Signatories to an ECA commit to provide information on the subject chemical, and typically adopt the same approach as that used for test rules. As such, one of the ECA participants would take the lead to submit a letter identifying who is sponsoring the required testing and a study plan before testing begins, semi-annual progress reports during the conduct of the testing, and a final report of the test results.

Voluntary Submissions – This activity is not prompted by any rule or agreement. As a result, it only involves the submission of a test's final reports and may include a Robust Summary of the test results.

Testing Exemption Applications – If an entity determines that they are subject to a testing requirement, but qualify for an exemption, the entity would submit a completed application to EPA requesting to be exempt from conducting the required testing and providing an appropriate rationale. Exemption applicants are not required to supply information that the Agency can obtain by other existing processes. In general, test rules reduce the burden associated with preparing exemption applications to a minimum by restricting the information required to that absolutely necessary to determine if the applicant is eligible for an exemption. The exemption process for test orders is expected to be similar to that for test rules.

The respondent universe for test rules, test orders, ECAs, and Voluntary Data Submissions, Exemption Applications and Robust Summaries are presented in Table 1.

Three-year to one-year scaling considerations for activities associated with Testing Exemption Applications, Voluntary Submissions, and CDR Registrations are handled slightly differently than the scaling for bundled activities, as depicted in Table G-1. With the durations short and the activities themselves separate from the bundle associated with a chemical being tested, EPA assumes no need to apportion the activity over there years in the unit burden, but instead takes one third of the incidence rate to determine the counts in Table 1.

For Testing Exemption Applications, EPA revises the assumption from previous ICRs to a basis that three exemptions (yielding one annually) per chemical undergoing testing occur for Test Rules and Test Orders. The basis for this assumption uses information in the previous ICR (EPA, 2018a) stating that during Testing of Certain High Production Volume Chemicals; Second Group of Chemicals (76 FR 1067), 52 exemption applications were received for 19 chemicals subject to the test rule. Taking the ratio of exemption applications at 52 over 19 yields a factor of 2.8 exemption applications per chemical, rounded up to 3 exemption applications per chemical with each application assumed to involve one chemical. EPA also assumes that all tests are exempted in the exemption application. The newly structured assumption based on chemical testing provides ease of future maintenance as the number of exemptions is expected to vary according to the number of chemicals tested in actions.

Similarly, for Voluntary Data Submissions, EPA revises the assumption from previous ICRs to a basis that one submission (yielding one-third annually) per chemical tested occur for Test Rules and Test Orders. The newly structured assumption based on chemical testing provides ease of future maintenance as the number of exemptions is expected to vary according to number of chemicals tested in actions. The resultant number of submissions totals 24.5 for 77 chemicals tested, compared to a total of 10 for 92 chemicals reflecting HPV conditions (EPA, 2013). The newly structured assumption based on chemical testing provides ease of future maintenance as the number of exemptions is expected to vary according to number of chemicals tested in actions.

For CDX registrations, EPA assumes that 40 percent of sponsors, plus all exemption applicants, will produce new registrations.

In the sections that follow, the total burden of each type of information collection activity is estimated using universe information in Table 1. Additional unit burden information can be found in Appendix G.

Table 1. Universe Information for this ICR Period

Type of Action	Program Input		Annual Number of Responses	Generic Assumptions (Standardized for All Types of TSCA Section 4 Actions)
	New Actions per Year	Associated Number of Chemicals		
Test Rule	0.5	7	3.5	1 sponsor per chemical 2.8 overlap factor 7 tests per chemical undergoing testing 3 years testing duration overall
Test Order	10	7	70	
Enforceable Consent Agreement	0.5	7	3.5	
Inferred Inputs				**Assumptions**
Exemption Application, Test Rule			3.5	3 exemption applications per chemical undergoing testing in Test Rules and Test Orders Duration of 1 year or less but occurs throughout the 3-year period All tests exempted for a chemical exempted 2.8 overlap factor
Exemption Application, Test Order			70.0	Same as above
Voluntary Data Submissions			24.5	1 voluntary data submission involving one chemical per chemical undergoing testing in Test Rules and Test Orders Duration of 1 year or less but occurs throughout the 3-year period
CDX Registration			10.7	40% of sponsors plus exemption applicants produce registrations Duration of 1 year or less but occurs throughout the 3-year period 2.8 overlap factor
General Note: For Inputs with "duration of one year or less" the value per chemical is divided by three because the event can occur anytime in the three year period and does not need to be allocated across the three years, in contrast to activities that are part of the bundle presented in Table G-2.				

Based on the unit burden estimates presented in Table G-3, as well as the estimated number of responses presented in Table 1, the total respondent burden and costs for CDX registration for e-Reporting are presented in Table 2 EPA assumes that some respondents are already registered in CDX, and only 40 percent of respondents would be required to register for CDX under this ICR. These respondents may be employees from sponsor companies that are new to EPA e-reporting or they may be employees new to e-reporting due to turnover within a company that has prior experience with e-reporting.[5]

[5] Note that any voluntary submissions under TSCA section 4 are not required to be submitted electronically, and therefore are not included in the universe of responses for CDX registration under this ICR.

Table 2. CDX Registration for e-Reporting – Annual Total Respondent Burden and Costs (2018$)

Activity	Unit Burden per Registration	Number of Registrations/Registrants[1]	Overlap Factor	Total Burden (Hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
CDX Registration	0.180	10.7	2.8	5.393	$411.65	$0.00	$411.65
CDX Electronic Signature	0.350	10.7	2.8	10.486	$800.23	$0.00	$800.23
Total, Reporting	**0.530**	**10.7**	**2.8**	**15.879**	**$1,211.88**	**$0.00**	**$1,211.88**
Total, Recordkeeping	**0.000**	**0.0**		**0.000**	**$0.00**	**$0.00**	**$0.00**
Total, CDX Registration and e-Reporting and Recordkeeping	**0.530**	**10.7**	**2.8**	**15.879**	**$1,211.88**	**$0.00**	**$1,211.88**

Footnotes:
[1] Number of registrations is assumed to be 40 percent of the total number of sponsors for test rules, test orders, ECAs, and exemption applications assuming one sponsor per chemical.

Based on the unit burden estimates presented in Table G-4, as well as the estimated number of responses in Table 1, the total respondent burden and costs for initial response under test rules are presented below in Table 3.

Table 3. Initial Response, Test Rules – Annual Total Respondent Burden and Costs (2018$)

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors) [1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
Letter of Intent	0.333	3.50	3.50	2.8	3.263	$249.02	$0.00	$249.02
Subtotal, Letter of Intent Total	**0.333**	**3.50**	**3.50**	**2.8**	**3.263**	**$249.02**	**$0.00**	**$249.02**
OR								
Prepare Exemption Application	2.000	3.50	3.50	2.8	19.600	$1,495.87	$0.00	$1,495.87
Corporate Review	6.000	3.50	3.50	2.8	58.800	$4,709.29	$0.00	$4,709.29
Subtotal, Exemption Application Reporting	**8.000**	**3.50**	**3.50**	**2.8**	**78.400**	**$6,205.16**	**$0.00**	**$6,205.16**
Subtotal, Recordkeeping	**0.500**	**3.50**	**3.50**	**2.8**	**4.900**	**$169.05**	**$0.00**	**$169.05**
Subtotal, Exemption Application	**8.5**	**3.50**	**3.50**	**2.8**	**83.300**	**$6,374.21**	**$0.00**	**$6,374.21**
Overall Total, Initial Response including Exemption Applications Reporting	**4.166**	**7.00**	**7.00**	**2.8**	**81.663**	**$6,454.18**	**$0.00**	**$6,454.18**
Overall Recordkeeping	**0.500**	**3.50**	**3.50**	**2.8**	**4.900**	**$169.05**	**$0.00**	**$169.05**
Overall Total, Initial Response	**4.416**	**7.0**	**7.0**	**2.8**	**85.563**	**$6,323.23**	**$0.00**	**$6,623.23**

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors) [1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
including Exemption Applications								
Footnotes: [1] Assumes one sponsor per chemical.								

Based on the unit burden estimates presented in Table G-5, as well as the estimated number of responses in Table 1, the total respondent burden and costs for study plans under test rules are presented below in Table 4.

Table 4. Study Plan, Test Rules – Annual Total Respondent Burden and Costs (2018$)

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors) [1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
Study Plan	12.987	3.50	3.50	2.80	127.27	$9,713.47	$0.00	$9,713.47
CBI Substantiation	1.215	3.50	3.50	2.80	11.91	$923.36	$0.00	$923.36
Total, Reporting	**14.202**	**3.50**	**3.50**	**2.80**	**139.18**	**$10,636.83**	**$0.00**	**$10,636.83**
Total, Recordkeeping	**0.000**	**0.00**	**0.00**		**0.00**	**$0.00**	**$0.00**	**$0.00**
Total, Study Plan, Test Rules	**14.202**	**3.50**	**3.50**	**2.80**	**139.18**	**$10,636.83**	**$0.00**	**$10,636.83**
Footnotes: [1] Assumes one sponsor per chemical.								

Based on the unit burden estimates presented in Table G-6, as well as the estimated number of responses in Table 1, the total respondent burden and costs for test results under test rules are presented below in Table 5.

Table 5. Test Results, Test Rules – Annual Total Respondent Burden and Costs (2018$)

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors) [1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
Study Final Report	93.320	3.50	3.50	2.80	914.54	$69,797.36	$0.00	$69,797.36
Study Corporate Review	13.998	3.50	3.50	2.80	137.18	$10,986.78	$0.00	$10,986.78
Laboratory Review	13.998	3.50	3.50	2.80	137.18	$10,469.63	$0.00	$10,986.78
Total, Reporting	**121.316**	**3.50**	**3.50**	**2.80**	**1,188.90**	**$91,253.77**	**$0.00**	**$91,253.77**
Total, Recordkeeping	**1.167**	**3.50**	**3.50**	**2.80**	**11.44**	**$394.35**	**$0.00**	**$394.35**
Total, Test Results, Test Rules	**122.483**	**3.50**	**3.50**	**2.80**	**1,200.33**	**$91,648.12**	**$0.00**	**$91,648.12**
Footnotes: [1] Assumes one sponsor per chemical.								

Based on the unit burden estimates presented in Table G-7, as well as the estimated number

of responses in Table 1, the total respondent burden and costs for initial response under test orders are presented below in Table 6.

Table 6. Initial Response, Test Orders – Annual Total Respondent Burden and Costs (2018$)

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors) [1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost (2018$)	Total Non-Labor Cost (2018$)	Total Cost (2018$)
Letter of Intent	0.333	70.00	70.00	2.80	65.268	$4,980.36	$0.00	$4,980.36
Subtotal, Letter of Intent Total	**0.333**	**70.00**	**70.00**	**2.80**	**65.268**	**$4,980.36**	**$0.00**	**$4,980.36**
OR								
Prepare Exemption Application	2.000	70.00	70.00	2.80	392.000	$29,917.44	$0.00	$29,917.44
Corporate Review	6.000	70.00	70.00	2.80	1,176.000	$94,185.84	$0.00	$94,185.84
Subtotal, Exemption Application Reporting	**8.000**	**70.00**	**70.00**	**2.80**	**1,568.000**	**$124,103.28**	**$0.00**	**$124,103.28**
Subtotal, Recordkeeping	**0.500**	**70.00**	**70.00**	**2.80**	**98.000**	**$3, 381.00**	**$0.00**	**$3,381.00**
Subtotal, Exemption Application	**8.000**	**70.00**	**70.00**	**2.80**	**1,666.000**	**$127,484.28**	**$0.00**	**$124,103.28**
Overall Total, Initial Response including Exemption Applications Reporting	**4.167**	**140.00**	**140.00**	**2.80**	**1,633.268**	**$129,083.64**	**$0.00**	**$127,484.28**
Overall Recordkeeping	**0.500**	**70.00**	**70.00**	**2.80**	**98.000**	**$3,381.00**	**$0.00**	**$3,381.00**
Overall Total, Initial Response including Exemption Applications	**4.417**	**140.00**	**140.00**	**2.80**	**1,731.268**	**$132,464.64**	**$0.00**	**$132,464.64**

Footnotes:
[1] Assumes one sponsor per chemical.

Based on the unit burden estimates presented in Table G-8, as well as the estimated number of responses in Table 1, the total respondent burden and costs for study plans under test orders are presented below in Table 7.

Table 7. Study Plan, Test Orders – Annual Total Respondent Burden and Costs (2018$)

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors) [1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
Study Plan	12.987	70.00	70.00	2.80	2,545.45	$194,269.32	$0.00	$194,269.32
CBI Substantiation	1.215	70.00	70.00	2.80	238.14	$18,467.12	$0.00	$18,467.12
Total, Reporting	**14.202**	**70.00**	**70.00**	**2.80**	**2,783.59**	**$212,736.44**	**$0.00**	**$212,736.44**
Total, Recordkeeping	**0.000**	**0.00**	**0.00**	**2.80**	**0.00**	**$0.00**	**$0.00**	**$0.00**
Total, Study Plan, Test Orders	**14.202**	**70.00**	**70.00**	**2.80**	**2,783.59**	**$212,736.44**	**$0.00**	**$212,736.44**

Footnotes:
[1] Assumes one sponsor per chemical.

Based on the unit burden estimates presented in Table G-9, as well as the estimated number

of responses in Table 1, the total respondent burden and costs for test results under test orders are presented below in Table 8.

Table 8. Test Results, Test Orders – Annual Total Respondent Burden and Costs (2018$)

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors)[1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
Study Final Report	93.320	70.00	70.00	2.80	18,290.72	$1,395,947.28	$0.00	$1,395,947.28
Study Corporate Review	13.998	70.00	70.00	2.80	2,743.61	$219,735.60	$0.00	$219,735.60
Laboratory Review	13.998	70.00	70.00	2.80	2,743.61	$209,392.68	$0.00	$209,392.68
Total, Reporting	**121.316**	**70.00**	**70.00**	**2.80**	**23,777.94**	**$1,825,075.56**	**$0.00**	**$1,825,075.56**
Total, Recordkeeping	**1.167**	**70.00**	**70.00**	**2.80**	**228.73**	**$7,887.04**	**$0.00**	**$7,887.04**
Total, Test Results, Test Orders	**121.316**	**70.00**	**70.00**	**2.80**	**24,006.67**	**$1,832,962.60**	**$0.00**	**$1,832,962.60**

Footnotes:
[1] Assumes one sponsor per chemical.

Based on the unit burden estimates presented in Table G-10, as well as the estimated number of responses in Table 1, the total respondent burden and costs for voluntary initial contact under ECAs are presented below in Table 9.

Table 9. Voluntary Initial Contact, ECAs – Annual Total Respondent Burden and Costs (2018$)

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors)[1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost (2018$)	Total Non-Labor Cost (2018$)	Total Cost (2018$)
Request to Negotiate	0.333	3.50	3.50	2.80	3.263	$249.02	$0.00	$249.02
Total, Reporting	**0.333**	**3.50**	**3.50**	**2.80**	**3.263**	**$249.02**	**$0.00**	**$249.02**
Total, Recordkeeping	**0.000**	**0.00**	**0.00**	**2.80**	**0.00**	**$0.00**	**$0.00**	**$0.00**
Total, Voluntary Initial Contact, ECAs	**0.333**	**3.50**	**3.50**	**2.80**	**3.263**	**$249.02**	**$0.00**	**$249.02**

Footnotes:
[1] Assumes one sponsor per chemical.

Based on the unit burden estimates presented in Table G-11, as well as the estimated number of responses in Table 1, the total respondent burden and costs for study plans under ECAs are presented below in Table 10.

Table 10. Study Plan, ECAs – Annual Total Respondent Burden and Costs (2018$)

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors)[1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
Study Plan	12.987	3.50	3.50	2.80	127.273	$9,713.47	$0.00	$9,713.47
CBI	1.215	3.50	3.50	2.80	11.907	$923.36	$0.00	$923.36

Substantiation								
Total, Reporting	**14.202**	**3.50**	**3.50**	**2.80**	**139.180**	**$10,636.83**	**$0.00**	**$10,636.83**
Total, Recordkeeping	**0.000**	**0.00**	**0.00**	**2.80**	**0.000**	**$0.00**	**$0.00**	**$0.00**
Total, Study Plan, ECAs	**14.202**	**3.50**	**3.50**	**2.80**	**139.180**	**$10,636.83**	**$0.00**	**$10,636.83**
Footnotes: [1] Assumes one sponsor per chemical.								

Based on the unit burden estimates presented in Table G-12, as well as the estimated number of responses in Table 1, the total respondent burden and costs for test results under ECAs are presented below in Table 11.

Table 11. Test Results, ECAs – Annual Total Respondent Burden and Costs

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors) [1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
Study Final Report	93.320	3.50	3.50	2.80	914.536	$69,797.36	$0.00	$69,797.36
Study Corporate Review	13.998	3.50	3.50	2.80	137.180	$10,986.78	$0.00	$10,986.78
Laboratory Review	13.998	3.50	3.50	2.80	137.180	$10,469.63	$0.00	$10,469.63
Total, Reporting	**121.316**	**3.50**	**3.50**	**2.80**	**1,188.896**	**$91,253.77**	**$0.00**	**$91,253.77**
Total, Recordkeeping	**1.167**	**3.50**	**3.50**	**2.80**	**11.437**	**$394.35**	**$0.00**	**$394.35**
Total, Test Results, ECAs	**122.483**	**3.50**	**3.50**	**2.80**	**1,200.333**	**$91,648.12**	**$0.00**	**$91,648.12**
Footnotes: [1] Assumes one sponsor per chemical.								

Based on the unit burden estimates presented in Table G-13, as well as the estimated number of responses in Table 1, the total respondent burden and costs for robust summaries are presented below in Table 12.

Table 12. Voluntary Robust Summaries for Test Rules, Test Orders, and ECAs – Annual Total Respondent Burden and Costs (2018$)

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors) [1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
Robust Summary	0.400	77.00	77.00	2.80	86.240	$6,575.80	$0.00	$6,575.80
Total, Reporting	**0.400**	**77.00**	**77.00**	**2.80**	**86.240**	**$6,575.80**	**$0.00**	**$6,575.80**
Total, Recordkeeping	**0.000**	**0.00**	**0.00**	**2.80**	**0.000**	**$0.00**	**$0.00**	**$0.00**
Total, Robust Summaries (Voluntary)	**0.400**	**77.00**	**77.00**	**2.80**	**86.240**	**$6,575.80**	**$0.00**	**$6,575.80**
Footnotes: [1] Assumes one sponsor per chemical.								

Based on the unit burden estimates presented in Table G-14, as well as the assumption that there is one voluntary data submission for one chemical each year, the total respondent burden and costs for voluntary data submissions are presented below in Table 13.

Table 13. Voluntary Data Submissions - Annual Total Respondent Burden and Costs (2018$)

Activity	Adjusted Unit Burden (hours)	Number of Respondents	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
Paper Submission of Final Reports	10.000	24.50	24.50	2.80	686.000	$23,667.00	$1,002.93	$24,669.93
Total, Reporting	**10.000**	**24.50**	**24.50**	**2.80**	**686.000**	**$23,667.00**	**$1,002.93**	**$24,669.93**
Total, Recordkeeping	**1.000**	**24.50**	**24.50**	**2.80**	**68.600**	**$2,366.70**	**$0.00**	**$2,366.70**
Total, Voluntary Data Submissions	**11.000**	**24.50**	**24.50**	**2.80**	**754.600**	**$26,033.70**	**$1,002.93**	**$27,036.63**

Footnotes:
[1] Assumes one sponsor per chemical.

Based on the unit non-labor cost estimates presented in Table G-15, as well as the estimated number of responses in Table 1, the total respondent non-labor costs for testing costs are presented below in Table 14.

Table 14. Testing Costs (Non-Labor Costs) – Annual Total Respondent Burden and Costs (2018$)

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors) [1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
Laboratory Costs	0.000	77.00	77.00	2.80	0.0000	$0.00	$4,180,986.35	$4,180,986.35
Consortium Management	0.000	77.00	77.00	2.80	0.0000	$0.00	$627,148.06	$627,148.06
Technical Experts	0.000	77.00	77.00	2.80	0.0000	$0.00	$418,097.99	$418,097.99
Total, Testing Costs (Non-Labor Costs)	**0.000**	**77.00**	**77.00**	**2.80**	**0.0000**	**$0.00**	**$5,226,232.40**	**$5,226,232.40**

Footnotes:
[1] Assumes one sponsor per chemical.

13. Provide an estimate for the total annual cost burden to respondents or recordkeepers resulting from the collection of information.

Table 15 summarizes the estimated total reporting burden and cost according to ICs on an annual basis. Similarly, the total burden and cost according to actions are summarized in Table 16.

With respect to reporting burden and cost, EPA estimates that this ICR will impose a total of 32,147 burden hours annually with an annual average respondent burden for a TSCA Section 4 action estimated at about 137 hours for test rules, test orders, or ECAs (response is on a per-chemical, or submission basis). For CDX registrations, the average annual respondent burden is 0.53 hours per registration.

Section 4 generic ICR will be $90 million dollars. The $90 million dollars was estimated by assuming one batch of Test Orders each year of approximately $30 million dollars each (see Appendix D.)

Table 15. Summary of Annual Total Respondent Burden and Cost (2018$), By Type of Information Collection Activity

Type of Information Collection Activity	Adjusted Unit Burden (Hours)	Number of Respondents (Sponsors)[1]	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Annual Burden (Hours)	Total Annual Labor Costs	Total Annual Non-Labor Costs	Total Annual Costs
CDX Registration	0.530	10.70	10.70	2.8	15.88	$1,211.88	$0.00	$1,211.88
Test Rules								
Initial Response, Test Rules	4.416	7	7	2.8	86.56	$6,623.23	$0.00	$6,623.23
Study Plan, Test Rules	14.202	3.5	3.5	2.8	139.18	$10,636.83	$0.00	$10,636.83
Test Results, Test Rules	122.483	3.5	3.5	2.8	1,200.33	$91,648.12	$0.00	$91,648.12
Test Orders								
Initial Response, Test Orders	4.417	140	140	2.8	1,731.77	$132,464.64	$0.00	$132,464.64
Study Plan, Test Orders	14.202	70	70	2.8	2,783.59	$212,736.44	$0.00	$212,736.44
Test Results, Test Orders	122.483	70	70	2.8	24,006.67	$1,832,962.60	$0.00	$1,832,962.60
Enforceable Consent Agreements (ECAs)								
Voluntary Initial Contact, ECAs	0.333	3.5	3.5	2.8	3.26	$249.02	$0.00	$249.02
Study Plan, ECAs	14.202	3.5	3.5	2.8	139.18	$10,636.83	$0.00	$10,636.83
Test Results, ECAs	122.483	3.5	3.5	2.8	1,200.33	$91,648.12	$0.00	$91,648.12
Voluntary – Other								
Robust Summaries (Voluntary) for Test Rules, Test Orders, and ECAs	0.400	77.0	77.0	2.8	86.24	$6,575.80	$0.00	$6,575.80
Voluntary Data Submission	11.000	24.5	24.5	2.8	754.60	$26,033.70	$1,002.93	$27,036.63
Testing								
Laboratory Costs (Non-Labor Costs)	0.00	77	77	2.8	0.00	$0.00	$5,226,232.40	$5,226,232.40
Total		**175**	**262.7**	**2.8**	**32,147**	**$2,423,427**	**$5,227,235**	**$7,650,663**

Notes: All ICs listed above include recordkeeping costs, where applicable
[1] Assumes one sponsor per chemical.

Table 16. Summary of Annual Total Burden and Costs (2018$), by Action

	Adjusted Unit Burden per Response (Hours)	Number of Respondents	Number of Responses (e.g., Chemicals Tested for an Action)	Overlap Factor	Total Annual Burden (Hours)	Total Annual Labor Costs	Total Annual Non-Labor Costs	Total Annual Costs
Section 4 Test Sponsors								
Test Rules [1]	137.418	3.5	3.5	2.8	1,346.70	$102,832.87	$0.00	$102,832.87
Test Orders [2]	137.418	70.0	70.0	2.8	26,933.93	$2,056,657.40	$0.00	$2,056,657.40
Enforceable Consent Agreements (ECAs) [3]	137,418	3.5	3.5	2.8	1,346.7	$102,832.87	$0.00	$102,832.87

					0			
Voluntary Data Submissions [4]	11.000	24.5	24.5	2.8	754.60	$26,033.70	$1,002.93	$27,036.36
Testing Costs, Non-Labor (Test Rules, Test Orders, ECAs) [5]		77.00	77.0	2.8	0.00	$0.00	$5,226,232.40	$5,226,232.40
Subtotal, Testing		**101.5**	**178.5**	**2.8**	**30,381.93**	**$2,288,356.84**	**$5,227,235.33**	**$7,515,592.17**
Section 4 Exemption Applicants								
Subtotal, Exemption Applications	**8.500**	**73.5**	**73.5**	**2.8**	**1,749.30**	**$133,858.49**	**$0.00**	**$132,858.49**
CDX Registrants								
Subtotal, CDX Registration and e-Signature	**0.530**	**10.7**	**10.7**	**2.8**	**15.88**	**$1,211.88**	**$0.00**	**$1,211.88**
Total [6]		**175.0**	**262.7**	**2.8**	**32,147**	**$2,423,427**	**$5,227,235**	**$7,650,663**

Universe		
Total Number of Respondents	**Total Number of Responses (Test Rules, Test Orders, ECAs, Voluntary Data Submissions, Exemption Applications, CDX)**	**Total Number of Chemicals Newly Tested**
175.0	**262.7**	**101.5**

General Notes:
1. All items listed above include recordkeeping activities, where applicable. Non-labor costs are not included.
2. Contributing sets of activities for each TSCA Section 4 Action are mapped as described in footnotes.

Footnotes:
[1] Includes Initial Response, Study Plan, Test Results, Voluntary Robust Summaries
[2] Includes Initial Response, Study Plan, and Test Results, Voluntary Robust Summaries
[3] Includes Voluntary Initial Contact, Study Plan, and Test Results, Voluntary Robust Summaries
[4] Includes Voluntary Data Submission (final reports)
[5] Testing costs are incurred by the same respondents that are considered in test rules, test orders, and ECAs
[6] Note that the CDX Respondent count is not included in total respondent count because there are non-unique and already counted in other lines above.

14. Provide estimates of annualized cost to the Federal government.

Agency Activities

Information submitted under TSCA section 4 test rules, test orders, consent agreements, or not pursuant to a particular section 4 testing action is received by OPPT, where it is reviewed for completeness and then routed to biologists, chemists, toxicologists, and wildlife scientists within OPPT to determine whether the subject chemicals are likely to present an unreasonable risk to human health or the environment. If the information indicates that potential hazards may exist, then this information – coupled with additional exposure and use information received under the Chemical Data Reporting rule (CDR) and other information sources – will be reviewed by EPA staff. Once reviewed, this information may support prioritization for evaluation efforts, risk evaluations and risk management actions. To date, EPA has collected information that has been used to support such activities as the development of water quality criteria, hazardous waste listings, chemical advisories, and reduction of workplace exposures.

For the TSCA section 4 Chemical Testing Program covered by this ICR, EPA may undertake the following activities:

- Review and process initial response (not including Exemption Applications).
- Review and process study plans;

- Review CBI claims and substantiations, when applicable;
- Review and process progress reports, when applicable;
- Review and process final reports for completeness, accuracy, adherence to testing protocols and methodologies, guidelines, and GLPs;
- Review and process exemption applications, and
- Review and process robust summaries.

EPA may also participate in other activities related to the TSCA Chemical Testing Program, e.g., other voluntary efforts to identify data needs and develop that information, international efforts related to chemical testing and associated testing issues, and other activities that may arise.

Unit Burden for Agency Activities

The estimated unit burden for processing initial response (one hour) study plans (four hours), progress reports (one hour) is the same as from the previous ICRs and is believed to be reflective of current conditions. The estimated unit burden for final reports, including those from testing/studies, and from voluntary submissions is estimated at seven hours, as revised to reflect current conditions. The estimated unit burden for the Agency to process and review each exemption application is estimated at three hours, as revised to reflect current conditions. Agency total unit burden and costs per chemical undergoing testing annually are shown below in Table 17 (see Appendix X for wage rate information).

Table 17. Agency Unit Burden and Cost Estimates (2018$) - Per Document Handled by the Agency

Collection Activity	Unit Burden and Cost per Document Handled by the Agency	
	Activity-Level Unit Burden	Activity-Level Unit Cost
Collection, Processing and Review		
Initial Response (not including Exemption Applications)	1	$74.34
Study Plans	4	$297.36
Final Reports	7	$520.38
Robust Summaries	1	$74.34
Exemption Applications	3	$223.02
Voluntary Data Submissions	7	$520.38
Subtotal; Collection, Processing and Review	**N/A**	**$1,709.82**
Review of Confidentiality Claims		
Chemical Identity[1]	1.5	$126.39
Other[2]	0.2	$16.85
Subtotal; Confidentiality Claims	**N/A**	**$143.24**
Total	**N/A**	**$1,853.06**

Footnotes:
[1] Obtained from proposed rule for chemID CBI claims for active chemicals on the TSCA Inventory (EPA, 2019a)
[2] Drawn from the burden and cost report for the final TSCA Inventory Notification Requirements rule (EPA, 2017a) with adjustments for number of applicable data elements

Total Agency Burden and Cost

Table 18Error: Reference source not found lists the number of responses received per chemical undergoing testing annually based on different categories of information collection activities, to provide context for the types and numbers of responses the Agency anticipates receiving due to TSCA Section 4 actions. The number of responses is based on universe information provided in Table 1.

Table 18. Annual Number of Responses Received by the Agency, by Type of Information Collection

Information Collection	Action			Voluntary Data Submissions	Total Number of Documents in Document Group Received Annually
	Test Rules	Test Orders	ECAs		
Initial Response (Letter of Intent)	3.50	70.00	3.50		25.64
Initial Response (Exemption Application)	3.50	70.00	0.00		73.50
Study Plans (including Review of Confidentiality Claims)	3.50	70.00	3.50		25.64
Final Reports	3.50	70.00	3.50	24.50	179.64
Voluntary Robust Summaries	0.35	7.00	0.35		2.56
Total Number of Responses Received	**17.85**	**357.00**	**14.35**	**24.50**	**312.20**

Based on the unit burden for Agency activities as presented in Table 17Error: Reference source not found, as well as the estimated number of responses in Table 18Error: Reference source not found, the total annual Agency burden and cost estimates are presented in Table 19Error: Reference source not found.

Table 19. Annual Agency Burden and Cost Estimates (2018$)

Collection Activity	Unit Burden (hours)	Total Number of Documents Handled Annually	Overlap Factor	Total Burden (hours)	Average Wage Rate	Unit Cost	Total Costs
Collection, Processing and Review							
Initial Repsonse (not including Exemption Applications)	1	25.64	2.80	72	$74.34	$74.34	$5,352
Study Plans	4	25.64	2.80	287	$74.34	$297.36	$21,336
Final Reports	7	179.64	2.80	3,521	$74.34	$520.38	$261,751
Robust Summaries	1	2.56	2.80	7	$74.34	$74.34	$520
Exemption Applications	3	73.50	2.80	617	$74.34	$223.02	$45,868
Voluntary Data Submissions	7	24.50	2.80	480	$74.34	$520.38	$35,683
Subtotal; Collection, Processing and Review		**331.49**	**2.80**	**4,984**	**$74.34**	**N/A**	**$370,511**
Review of Confidentiality Claims							
Chemical Identity[1]	1.5	25.64	2.80	108	$84.26	$126.39	$9,100
Other[2]	0.200	25.64	2.80	14	$84.26	$16.85	$1,180
Subtotal; Confidentiality Claims		**51.28**	**2.80**	**122**	**$84.26**	**N/A**	**$10,280**

Collection Activity	Unit Burden (hours)	Total Number of Documents Handled Annually	Overlap Factor	Total Burden (hours)	Average Wage Rate	Unit Cost	Total Costs
Total, Agency		**382.77**	**2.80**	**5,106**	**N/A**	**N/A**	**$380,791**

[1] Obtained from previous ICR estimates (EPA, 2018a).
[2] Drawn from the burden and cost report for the final TSCA Inventory Notification Requirements rule (EPA, 2017a) with adjustments for number of applicable data elements.

15. Explain the reasons for any program changes or adjustments reported in Items 13 (or 14) of OMB Form 83-I.

There is an overall **increase of 29,020 hours** in the total respondent burden that is currently approved by OMB for this ICR (from 3,127 to 32,147 hours). The increase shown in Table 20 reflects changes in the number of actions, CBI substantiation requirements, and methodological updates. However, there is a reduction in annual cost estimates due to a change in the assumed battery of tests that may be required for this three-year period under potential testing actions. The assumption is based on statutory changes under the Lautenberg Act, such as the mandated tiered testing approach.

Table 20. Summary of Changes in ICR Estimates

Type of Burden Estimate	Previous ICR		Changes						ICR Renewal	
			Changes in Number of Chemicals Tested within TSCA Section 4 Actions[1]		CBI Substantiation		Methodology[2]			
	Unit	Total	Δ Unit	Δ Total	Δ Unit	Δ Total	Δ Unit	Δ Total	Unit	Total
A. CDX Registration	0.53	4.45	0.00	1.22	0.00	0.00	0.00	10.21	0.53	15.88
B. Test Rules, including Robust Summaries, excluding Exemption Applications	248.66	2,486.60	0.00	-1,616.29	1.22	4.25	-112.46	472.14	137.42	1,346.70
C. Test Orders, including Robust Summaries, excluding Exemption Applications	248.66	0.00	0.00	17,406.20	1.22	85.05	-112.46	9,442.68	137.42	26,933.93
D. ECAs, including Robust Summaries	248.66	497.32	0.00	372.99	1.22	4.25	-112.46	472.14	137.42	1,346.70
E. Voluntary Data Submissions[3]	11.00	122.00	0.00	258.50	0.00	0.00	0.00	347.10	11.00	754.60
F. Exemption Applications	8.50	17.00	0.00	607.75	0.00	0.00	0.00	1,124.55	8.50	1,749.30
TOTAL		3,127.37		17,030.37		93.56		11,895.82		**32,147**

Footnotes:
[1] Calculated according to methodology in previous ICR
[2] This ICR's methodology accounts for overlap and better captures the comprehensive view of the number of chemicals tested per year
[3] Previous ICR reports 122 hours as the unit burden. The corrected number is 11 hours.

16. For collections whose results will be published, outline the plans for tabulation and publication.

This information collection activity does not have a calendar-based schedule. The testing period is defined by the individual test rule, test order, or ECA. The time required to conduct the test, based on testing guidelines, is in accord with the timeline established in the approved test plan, or timing otherwise established by the Agency. Required testing is conducted only once, and each related activity occurs on a one-time basis. For the reasons described above, the collection is considered an "on occasion" collection. Also note that in this ICR revision, the definition of a response (i.e., submission) is changed to include all testing activities associated with a chemical. As in previous ICRs, the typical time period for testing may vary from less than a year to three years, although it can be longer and varies according to the chemical and the testing required.

For each chemical identified for testing within EPA's TSCA Chemical Testing Program, the specific information requested, the testing necessary to generate that information, along with the test protocols, the time frame for completing the testing, and the date by which the requested information is to be submitted to the Agency, are established in the TSCA section 4 test rule, test order, or ECA.

Test information submitted to the Agency under the TSCA Chemical Testing Program is reviewed by scientists to determine whether the information developed is adequate for the purposes for which it was gathered. The non-confidential version of this information deemed adequate by the Agency will be housed in an appropriate EPA TSCA docket and made publicly available in the TSCA online database, ChemView (https://chemview.epa.gov/chemview). The information can be used in conjunction with published material and is a valuable source along with or in the absence of published data. The information is used by federal and state agencies, researchers, toxicologists, risk assessors, the regulated industry, attorneys, trade and professional associations, and non-governmental organizations, as well as the public at large.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

Not applicable.

18. Explain each exception to the certification statement identified in Item 19 of OMB Form 83-I.

EPA does not request an exception to the certification of this information collection.

LIST OF REFERENCES, ATTACHMENTS & APPENDICES

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Attachments

The attachments referenced in this ICR are listed below and are available in the public docket established for this ICR under docket ID number **EPA-HQ-OPPT-2015-0436** are available for online viewing at http://www.regulations.gov unless otherwise noted.

Attachment 1:	Toxic Substances Control Act (TSCA) Section 4 - 15 USC 2603
Attachment 2:	Procedures Governing Testing Consent Agreements and Test Rules, 40 CFR part 790
Attachment 3	TSCA Section 4 e-Reporting Screenshots
Attachment 4	Consultations Message Sent by EPA to Potential Respondents
Attachment 5	Center for Specialty Chemical Science, LLC (CSCS) Comment
Attachment 6	Environmental Defense Fund (EDF) Comment
Attachment 7	American Chemistry Council (ACC) Comment
Attachment 8	EPA's Response to Public Comments
Attachment 9	Example of a Section 4 Test Order

Appendices

The appendices referenced in this ICR are listed below and available as a single file (Appendix to EPA ICR No. 1139.12; OMB Control No. 2070-0033) in the public docket established for this ICR under docket ID number **EPA-HQ-OPPT-2015-0436** at http://www.regulations.gov.

Appendix A	Specific Legacy Assumptions Converted to Standardized Assumptions
Appendix B	Overlap Model
Appendix C	Derivation of Program Input Information
Appendix D	ICs for TSCA Section 4 Actions Under a Generic ICR
Appendix E	Additional Information on Methodology