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

1 IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

Title: TSCA Section 4 Test Rules, Enforceable Consent Agreements (ECAs), Voluntary Testing Agreements (VTAs), Voluntary Data Submissions, and Exemptions from Testing Requirement

EPA ICR No.: 1139.11 OMB Control No.: 2070-0033

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

1(b) Short Characterization/Abstract

This information collection request (ICR) covers the submission of test data to the Environmental Protection Agency (EPA) to support the decision making process for an industrial chemical under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601).[1] Under TSCA, EPA has the 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. EPA's TSCA Inventory currently contains over 70,000 existing chemicals. The TSCA Inventory is a compilation of the names of all existing chemical substances along with their respective Chemical Abstract Service (CAS) Registry numbers, production/importation volume ranges, and specific sites of production/importation. Chemicals produced in annual volumes above 1 million pounds are considered High Production Volume or "HPV" chemicals. This subset of 3,000-4,000 HPV chemicals is the main focus of OPPT's Existing Chemicals Data Collection and Data Development (Testing) activities. Data on chemicals that are collected or developed are made accessible to the public and are intended to provide input for efforts to evaluate potential risk from exposures to these chemicals.

As stated in section 2 of TSCA, "It is the policy of the United States that adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and development of such data be the responsibility of those who manufacture and those who process such chemicals and mixtures."

Section 4 of TSCA gives EPA the authority to require chemical manufacturers and processors to test existing chemicals. Under section 4, EPA can by rule require testing after finding that (1) a chemical may present an unreasonable risk of injury to human health or the environment, and/or the chemical is produced in substantial quantities that could result in significant or substantial human or environmental exposure, (2) the available data to evaluate the chemical are inadequate, and (3) testing is needed to develop the needed data.

[1] See also Attachment 1.

The information collected under this ICR is designed to provide EPA with the necessary data on health effects, ecological effects and environmental fate to predict the probable impacts on human health or the environment of chemicals that may present an unreasonable risk. EPA uses the information collected to assess risks associated with the manufacture, processing, distribution, use or disposal of a chemical, and to support any necessary regulatory action with respect to that chemical.

The Chemical Testing Program in EPA's Office of Pollution Prevention and Toxics (OPPT) also works with members of the U.S. chemical industry and other interested parties to develop needed data via TSCA section 4 enforceable consent agreements (ECAs) and voluntary testing agreements (VTAs). Historically, the uses of ECAs have been varied. In the past, ECAs may have been the outgrowth of a proposed rule that received comments indicating the need for more involvement and negotiation with industry in order to obtain the data needed. However, ECAs have also been established with industry, without the proposal of a test rule, when a specific situation may have needed more initial involvement and negotiation with industry, such as a relatively recent ECA that involved monitoring of facilities not represented by standardized protocol. ECAs and VTAs do not involve formal TSCA rulemaking and allow EPA to consider agreed-upon pollution prevention and other types of product stewardship initiatives by the chemical industry as a possible substitute for or adjunct to certain types of needed testing.

The Chemical Testing Program requires the development of test data that provide critical information on health effects, ecological effects and environmental fate that enables EPA and others to properly assess and manage health and environmental risks that may be posed by existing and new chemicals covered by TSCA. The "universe" of existing chemicals on the TSCA Chemical Substances Inventory that may present the greatest potential health and/or environmental concerns have been and continue to be identified and refined through various existing chemical screening activities within OPPT. EPA also makes the testing data publicly available to help the public understand the risks posed by exposure to chemicals and to facilitate the public's involvement in environmental decision-making. (For more information about the Chemical Testing program, go to: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/data-development-and-information-collection-assess-risks.)

In addition to developing test rules under TSCA section 4 that meet specific needs identified by OPPT, EPA may also develop such actions to meet the information needs of other offices within EPA and other agencies. For example, test data in the past have been developed for EPA's Office of Solid Waste and Emergency Response (OSWER), Office of Air and Radiation (OAR), and Office of Water (OW). EPA has also developed test rules to collect data that would also be used by other agencies, including the Occupational Safety and Health Administration (OSHA), the Agency for Toxic Substances and Disease Registry (ATSDR), and the Organization for Economic Cooperation and Development (OECD), to name a few.

OPPT may also be required to develop a test rule under TSCA section 4 in response to a recommendation received from the TSCA Interagency Testing Committee (ITC). TSCA established the ITC as an independent advisory committee to identify chemicals regulated by TSCA for which there are suspicions of toxicity or exposure and for which there are few, if any, ecological effects, environmental fate or health effects testing data. When the ITC designates

chemicals for testing, EPA is required under TSCA section 4(e)(1)(B) to publish Federal Register notices either to initiate proceeding under TSCA section 4(a) or to provide reasons for not doing so.

In general, when the need for data is identified by EPA, or the ITC, EPA may obtain the needed test data (1) by issuing a test rule through notice and comment rulemaking, (2) through negotiation with industry and issuing an ECA, or (3) through commitments from industry as VTAs.

The testing specified in a rule or ECA issued under TSCA section 4 only needs to be conducted once for each specified chemical. As such, only one of the entities that manufacture, import or process the specified chemical, or a consortia formed by these entities, will conduct the specified testing and report the results of that testing to EPA. An entity subject to a test rule may also apply for an exemption from the testing requirement if that testing will be or has been performed by another party.

Responses to the collection of information specified in a rule issued under TSCA section 4 are mandatory (see 40 CFR part 790, Attachment 2), while responses to an ECA entered into under TSCA section 4 is only mandatory for participants in the ECA. In contrast, participating in a VTA, or otherwise submitting data without a requirement, is completely voluntary.

The export notification provisions of TSCA section 12 apply to any exporter of a chemical subject to a rule or an ECA issued under TSCA section 4, regardless of their participation in the ECA or any related testing consortia.

Respondents may claim all or part of a document 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 and 40 CFR part 2.

EPA maintains an official record for all activities conducted under TSCA section 4 (rulemakings, ECAs, and VTAs). The official record consists of the documents referenced in a specific activity, any public comments received during an applicable comment period, any test data developed (including letters of intent to conduct testing, exemption letters, study plans, progress reports and the final study report), and other information related to the activity, including information claimed as CBI. The official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Office of Pollution Prevention and Toxics (OPPT) Docket, EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, D.C. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

2 NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

> TSCA section 2(b)(1) states that it is the policy of the United States that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data 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."

To implement this policy, TSCA section 4(a)(1) mandates that EPA require manufacturers and processors of chemical substances and mixtures to conduct testing if it finds that:

> "(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,
> (ii) there are insufficient data and experience upon which the effects of such 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 (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or
>
> (B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,
>
> (ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or any combination of such activities on health or the environment can reasonably be determined or predicted, and
>
> (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data [.]"

If EPA makes these findings for a chemical substance or mixture, the Agency must require that testing be conducted on that chemical substance or mixture. The purpose of the testing would be to develop data about the substance or mixture's health and environmental effects where there is an insufficiency of data and experience in order to support a determination that the manufacture, distribution in commerce, processing, use or disposal of the substance or mixture, or any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

Once the Agency has made a finding under TSCA section 4(a)(1), EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the chemical substance. EPA need not limit the scope of testing required to the factual basis for the TSCA section 4(a)(1)(A)(i) or (B)(i) findings, as long as EPA finds that there are insufficient data 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 data. This approach is explained in more detail in EPA's statement of policy for making findings under TSCA section 4(a)(1)(B) (a.k.a. the "B" policy) in the Federal Register of May 14, 1993 (58 FR 28736, 28738-39; FRL-4059-9).

The statute also specifies that EPA should give priority consideration to chemicals that the TSCA ITC places on the TSCA section 4(e) "Priority Testing List." The ITC is an independent advisory committee to the EPA Administrator that includes 14 U.S. Government organizations. The ITC was created under TSCA section 4(e) to: 1) review chemicals regulated by TSCA, 2) determine which chemicals need ecological effects, environmental fate or health effects test data and 3) add those chemicals with test data needs to the Priority Testing List and recommend them for testing or information reporting in May and November Reports to the EPA Administrator. (For more information about the ITC, see: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/interagency-testing-committee.) Currently, there are 109 chemicals and chemical mixtures on the TSCA ITC Priority Testing List, which was last updated in January 2014[2].

Although the Agency may not have yet made the TSCA section 4(a) finding for a particular chemical substance, EPA may still cooperate with industry or others to identify data gaps and develop testing plans to fill some or all of these gaps. These voluntary efforts help provide additional information about the many chemicals on the TSCA Inventory, and can be used to assess the potential risks associated with the manufacture, processing, distribution, use or disposal of the chemical, as well as allowing the Agency to establish a regulatory agenda that focuses on those chemicals of greater concern.

The information collected through the Chemical Testing Program, whether submitted pursuant to a rule or ECA or voluntarily, provides critical information on health effects, ecological effects and environmental fate that enables EPA and others to properly assess and manage health and environmental risks that may be posed by existing and new chemicals covered by TSCA. This information is also made publicly available to help the public understand the risks posed by exposure to chemicals and to facilitate the public's involvement in environmental decision-making.

2(c) Practical Utility/Users of the Data

Data collected under the Chemical Testing Program are used, in conjunction with exposure information, by EPA scientists to determine whether the subject chemicals are likely to present an unreasonable risk to human health or the environment. Furthermore, such information,

[2] The most recent ITC report can be found at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2013-0651-0001

considered in conjunction with toxicological and health effects data, ecological effects data, and environmental fate data, will be used by non-EPA scientists, professional industrial hygienists, other occupational health professionals and workers for hazard communication and right-to-know purposes, including Safety Data Sheets (SDSs) and product labels required under OSHA regulations.

Additionally, data developed for chemicals used or produced in particular work sites will be useful in developing and/or maintaining comprehensive safety and health programs at those facilities. Local, state and county governments rely on the Agency's ability to set health and environmental standards, as do other national governments. The paperwork related requirements imposed on the respondents as part of the Chemical Testing Program allow EPA to ensure that the necessary testing data will be developed, that the results meet basic scientific standards of acceptability and adequacy, that unforeseen complications or issues can be addressed, and that the testing is progressing on schedule.

If the test data submitted indicate that potentially unreasonable risks may exist, the data will be used by EPA and the manufacturer to determine the appropriate action necessary to avoid or mitigate the risks. EPA uses the data it obtains under section 4 authority to support chemical actions under TSCA. For example, hazard and exposure data received under section 4 on an existing chemical that is structurally similar to new chemical can be used to support taking regulatory action on the new chemical. , EPA has also used collected data to perform the necessary assessments that support such activities as the development of water quality criteria, hazardous waste listings, chemical advisories, and reduction of workplace exposures. EPA has also used the resulting assessments to identify chemicals that may not warrant additional regulation or concern, or should otherwise be treated as a low priority for further consideration.

In addition, since EPA is required under TSCA section 4(d) of TSCA to publish a Federal Register notice announcing the receipt of test data developed under a TSCA section 4 rule, the data collected may be used by other agencies and interested parties.

Since 1979, approximately 230 of the 15,000 chemicals on the TSCA Inventory that are, or have been, produced in quantities greater than 10,000 pounds per year have been the subject of testing actions within the OPPT Existing Chemicals Testing Program. Virtually all of the 230 chemicals are "High Production Volume (HPV) chemicals." The testing actions taken to date include a mix of formal TSCA section 4 Test Rules and ECAs. In addition, almost 250 formal TSCA section 4 "Decisions Not to Test" (DNTs) have been issued by EPA to date. EPA maintains a listing on its website that identifies the TSCA chemicals for which testing data has been received by EPA under TSCA section 4, along with basic background information about the chemical, and available summaries of the testing results.[3]

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

3(a) Non-Duplication

[3] Go to: https://chemview.epa.gov/chemview

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

- A single submission of the data will satisfy the request.
- Prior to proposing a test rule or entering into an ECA, EPA searches the scientific literature, holds public information gathering meetings if deemed appropriate, and has discussions with industry representatives in order to determine what types of data have already been obtained about the chemical under consideration. The Agency proposes a test rule or enters into an ECA only after it has determined that necessary tests have not yet been conducted.
- Exemption applicants are not required to supply information that the Agency can obtain by other existing processes. The equivalence information required provides verification that a chemical is the same. Often this information is CBI and only the manufacturer or processor of the chemical has this information.

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

EPA provided a 60-day public notice and comment period that ended on May 16, 2016 (81 FR 13790, March 15, 2016). EPA received one comment, from the American Chemistry Council, during the comment period. A copy of the comment and of EPA's response to the comment are included as Attachments 4 and 5, respectively. In general ACC asks, due to the imminent passing of the "bipartisan legislation to modify TSCA" now known as the Frank R. Lautenberg Chemical Safety for the 21st Century Act, that EPA either (1) withdraw the ICR renewal, after addressing public comments and modifying the ICR appropriately, once the modifications to TSCA are made final, or (2) if the ICR renewal is approved, "resubmit the ICR request following enactment of TSCA reform legislation." As ACC recommends, EPA plans to amend the ICR to reflect the Lautenberg Act amendments to TSCA section 4.

3(c) Consultations

Additionally, 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 ICR to OMB for review and approval. In accordance with this regulation, EPA submitted questions to nine parties via e-mail. The individuals contacted were:

Scott Jensen
Chemical Safety, TSCA, etc.
American Chemistry Council
Scott_Jensen@AmericanChemistry.com

Jenny Gaines, Director
Public Relations & Media
SOCMA
gainesj@socma.com

Dan Turner
Corporate Media Contact
DuPont.com
Daniel.a.Turner@dupont.com

Eric Wohlschlegel, Director
Media Contacts
American Petroleum Institute
wohlschlegele@api.org

Melissa Scanlan, Associate Dean
Environmental Law Program
Director, Environmental Law Center
Vermont Law School
MSCANLAN@vermontlaw.edu

Stacy Cooks
External Affairs Coordinator
Asthma & Allergy Foundation of America
stacy@aafa.org

James Proctor, Director and Professor of Environmental Studies
Lewis & Clark College (Northwestern)
jproctor@lclark.edu

Ken Cook, President
Environmental Working Group
ken@ewg.org

David Goldston, Director,
Government Affairs Program
Natural Resources Defense Council
eheyd@nrdc.org

EPA did not receive any direct responses to its solicitation for consultations. The ACC, however, did submit a comment to the docket during the public comment period described in the preceding section. A copy of EPA's consultation e-mail to the above potential respondents is included in Attachment 6.

3(d) Effects of Less Frequent Collection

Test rules and ECAs require the test sponsor to submit to EPA a letter that identifies who will be conducting the testing, study plans before beginning testing, and a final report that contains the study results. Each exemption applicant is required to submit an exemption application to EPA. In either case, each submission is intended to be a one-time submission to

EPA. Less frequent collection would equate to no collection and could jeopardize EPA's ability to ensure that testing is being conducted in accordance with the rules and ECAs, and to grant timely exemptions from test rules.

3(e) General Guidelines under the PRA

The data retention requirements for test rules and ECAs exceed one of the PRA guidelines contained in 5 CFR 1320.6. Documentation records, raw data, and specimens pertaining to a test rule or ECA study are required to be retained for ten years from the effective date of the applicable test rule or publication date of the ECA. These recordkeeping requirements are codified in 40 CFR 792.195. This requirement is necessary to permit sufficient time to review results, perform appropriate risk assessments and, when necessary, to institute appropriate regulatory control responses. Long-term studies may take five years from the effective date of the final test rule or ECA to perform and submit to the Agency; assessment of study results may require an additional one to two years of internal and external peer review; institution of regulatory controls and legal challenges may require an additional two to three 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 the Agency's action or the data upon which it is based are challenged, it is imperative that all records, raw data, and specimens be available for further review or investigation.

3(f) Confidentiality

Information submitted to EPA in response to test rules and ECAs and in exemption applications is, in most cases, non-confidential. If respondents wish to claim information submitted in response to a test rule or ECA to be confidential, they may do so. These claims will be handled according to the EPA procedures described in 40 CFR part 2 and the TSCA Confidential Business Information Security Manual, which call for careful protection of confidential business information.

3(g) Sensitive Questions

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

3(h) Electronic Submissions

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).[4] The rule became effective in March 2014. Submitters are now required to use EPA's Central Data Exchange (CDX), the Agency's electronic reporting site to make submissions in response to TSCA section 4, including test rules and ECAs. Submitters must register to use EPA's Agency-wide CDX portal for submitting information in a secure manner, select the Chemical Safety and Pesticide

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

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 submitting test rule or ECA data 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 the new requirement of electronic submission. Any new test rules will be made by electronic submission alone.

4 THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

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.

4(b) Information Requested

4(b)(i) Data Items

EPA may require any type of health effects, ecological effects and environmental fate testing necessary to address unanswered questions about the effects of a chemical substance. EPA need not limit the scope of testing required to the factual basis for the TSCA section 4(a)(1)(A)(i) or (B)(i) findings, as long as EPA also finds that there are insufficient data 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 such data. This approach is explained in more detail in EPA's statement of policy for making findings under TSCA section 4(a)(1)(B) (frequently described as the "B" policy) in the Federal Register of May 14, 1993 (58 FR 28736, 28738-39; FRL-4059-9).[5]

[5] Also see https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/industry-testing-requirements-under-tsca-section-4

In addition to submitting the specified test data to EPA, respondents may also need to submit a letter of intent, study plans and progress reports, or an exemption application. Respondents must also maintain certain records related to the testing.

The specific requirements and procedures governing testing ECAs, test rules, and exemption from test rules are found in 40 CFR part 790. The requirements regarding Good Laboratory Practice standards (GLPs) are found in 40 CFR part 792, the various test guidelines that are incorporated into the individual test rules are in 40 CFR parts 795 through 799, and the chemical specific testing requirements are in 40 CFR part 799.

The following is an overview of the specific requirements for each type of activity:

Test Rules – EPA may promulgate a rule describing what type of testing must be performed on the chemical and specifying specific test guidelines that have been published by the EPA or alternative methods proposed by industry and approved by EPA as test methods. In combination with the GLPs requirements, these guidelines or methods provide the TSCA-mandated standards (TSCA section 4(d)) for development of adequate and reliable data. Records concerning data developed according to these standards must be retained for a minimum of ten years, as described in GLP standards. Information collections under TSCA section 4(c) are designed to reduce the burden of duplicative testing under test rules. As such, test rules generally require testing of only a single representative chemical substance and all chemicals subject to the test rule are assumed to be equivalent to it.

Testing Agreements: ECAs and VTAs – EPA may negotiate an ECA or VTA under which manufacturers agree to conduct specific testing and submit the data to EPA. The ECA or VTA describes what type of testing is to be performed on the chemical and which test guidelines need to be followed to generate the data sought. Although EPA is wrapping up the HPV Challenge Program[6] that was covered in previous ICRs and employed the use of VTAs, EPA may still enter into individual VTAs in the future.

As with test rules, the test guidelines have either been published by EPA or another organization (e.g., OECD), or involve alternative methods proposed by industry and approved by EPA as test methods. In combination with the GLPs requirements, these guidelines or methods provide the TSCA-mandated standards (TSCA section 4(d)) for development of adequate and reliable data. Records concerning data developed according to these standards must be retained for a minimum of ten years, as described in GLP standards. Information collections under TSCA section 4(c) are designed to reduce the burden of duplicative testing under test rules. As such, test rules and ECAs generally require testing of only a single representative chemical substance and all chemicals subject to the ECA or VTA are assumed to be equivalent to it.

Testing Exemption Applications – TSCA section 4 allows an entity subject to a test rule to apply for an exemption from the testing requirement if that testing will be, or has been, conducted by another party. Any manufacturer or processor subject to a test rule may submit an

[6] A voluntary initiative under which manufacturers of HPV chemicals volunteered to develop and/or submit certain Organization for Economic Cooperation and Development (OECD) screening level studies for the chemicals they manufacture.

application to EPA for an exemption from performing any or all of the tests required under the test rule. The exemption application process and requirements are set out in 40 CFR Part 790, Subpart E. The exemption application, which generally must be filed within thirty days after the effective date of the test rule, must identify the test rule, the chemical, and the Chemical Abstract Service Registration Number (CASRN) of the test substance on which the application is based, and the specific testing requirement(s) from which an exemption is sought, along with the basis for the exemption request. An exemption application will generally be approved if a letter of intent to conduct the testing has been received from another party; if a study plan submitted by another party has been approved; or if the data needs identified in the test rule have been satisfied by another party. A procedure is provided for the appeal and hearing of the denial of an exemption application. Exemptions are also only relevant for testing requirements in test rules.

Voluntary Data Submissions – Unrelated to any test rule or other testing requirement or agreement, chemical manufacturers may voluntarily submit data to EPA at any time. Historically, voluntary data submissions have been provided as paper submissions. However, these submissions may be provided electronically through CDX, and it is anticipated that such submissions would be provided electronically in the future when applicable. Should submitters decide to do so, EPA simply asks that submitters follow the same procedures for preparing their package and completing their submission as test rule respondents. Since such data submissions are entirely voluntary and based on decisions in which EPA is not a participant, EPA can only provide a general estimate of potential burden and costs associated with such submissions, guided generally by past such submissions, which have been rare. In doing so, EPA believes that the potential costs and burdens for such voluntary submissions are captured in this information collection request.

4(b)(ii) Respondent Activities

(1) Electronic Submission Activities

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.

(2) Document Preparation Activities

Respondents may undertake one or more of the following activities:

(a) Review rulemaking [7] and/or participate in ECA or VTA discussions.
(b) Conduct searches for relevant existing data. If data are found:
    i. Determine whether the data are relevant;
    ii. Prepare and review summary of existing data; and
    iii. Submit summary of existing data to EPA.

[7] 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 firm manufactures.

(c) Submit "Letter of Intent" to EPA.
(d) Plan necessary activities, e.g., consortia, arrange for conduct of studies, etc.
(e) Prepare and submit periodic progress reports.
(f) Record and prepare test data for submission (includes QA/QC reviews).
(g) Prepare and review final report.
(h) Review submission for CBI.
(i) Submit final report with test data to EPA.
(j) Maintain test data and final report in records.
(k) Complete and submit testing exemption application, when applicable

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

Test Rules – Test rules require manufacturers/importers of the subject chemical substance to submit a letter identifying who is sponsoring the required testing and study plans before testing begins, semi-annual progress reports, as applicable, during the conduct of the testing, and a final report of the test results. Since data are typically required on a chemical basis – as opposed to a manufacturer basis – test sponsors typically join forces to satisfy the testing requirements.

Testing Agreements: ECAs and VTAs – Signatories to an ECA or VTA commit to provide data for the subject chemical substance, and typically adopt the same approach as that used for test rules. As such, one of the participants would take the lead to submit a letter identifying who is sponsoring the required testing and study plans 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 final reports and 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, they would submit a completed exemption application to EPA that requested the exemption and provided an appropriate rationale. Exemption applicants are not required to supply information that the Agency can obtain by other existing processes. Equivalence data are often confidential business information (CBI) and only the manufacturer or processor of the chemical has this information. In general, test rules reduces 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. In most cases, the manufacturer is required to give only its identity, address, a technical contact and a list of the tests for which an exemption is being requested. When equivalence data are needed because more than one representative substance is being tested, the Agency will limit the data required by giving minimum chemical specific requirements in the individual test rules. This approach was devised in response to comments by industry that applying the broad equivalence data requirements to all exemptions candidates would, in some cases, result in submission of unnecessary data.

Exemption applications are not necessary for chemicals being tested under an ECA or VTA because of the inherent nature of the related agreement process itself. For the same reason,

an exemption application would not be submitted by someone who is voluntarily submitting data, because an exemption is never necessary when there is no requirement.

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

5(a) Agency Activities

Data submitted under TSCA section 4 test rules, ECAs, or voluntarily agreement are received by OPPT, Chemical Control Division (CCD), Chemical Information and Testing Branch (CITB), where they are 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 data indicate that potential hazards may exist, then these data – coupled with exposure and use information received under the Chemical Information Reporting rule (CDR) and other information sources – will be reviewed by EPA staff. Once reviewed, these data may support possible risk management action. To date, EPA has collected data that have been used to support such activities as the assessment of TSCA new chemicals, development of water quality criteria, hazardous waste listings, chemical advisories, and reduction of workplace exposures.

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

a) Review letters of intent and study plans for completeness;
b) Review progress reports;
c) Review final reports for completeness, accuracy, adherence to test rule guidelines and GLPs;
d) Process and review exemption applications; and
e) Facilitate development of test rules, ECAs and VTAs, as appropriate.

Related to the activities cited in (c) above, the Agency maintains a facility inspection and test data audit program to ensure testing is done in compliance with GLPs. 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 test data, efforts to establish test guidelines or standards that may be used in the TSCA Chemical Testing Program, and international efforts related to chemical testing and associated testing issues.

5(b) Collection Methodology and Management

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

Test data submitted to the Agency under the TSCA Chemical Testing Program are reviewed by scientists to determine whether or not the data developed are adequate for the purposes for which they were gathered and to determine whether or not further regulatory action is necessary. In addition to being housed in an appropriate EPA TSCA docket, references to the data are entered into the TSCA Test Submission Database (TSCATS). TSCATS is a publicly available, online index to unpublished, non-confidential studies covering chemical testing results and other submitted studies on the possible effects of chemicals on health and ecological systems. Submitted studies are indexed in TSCATS under three broad categories: health effects, ecological effects and environmental fate. TSCATS contains information that is pertinent to risk assessment and hazard evaluation processes. 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 data are used by federal and state agencies, researchers, toxicologists, risk assessors, the regulated industry, attorneys, trade and professional associations as well as the public at large. TSCATS was developed by EPA in 1985 to make the results of ongoing and completed chemical testing available to the public and includes chemical exposure studies, epidemiology, environmental fate, monitoring, episodic incidents, such as spills and case reports.

There are four primary types of documents referenced in the TSCATS database: TSCA section 4 chemical testing results, TSCA section 8(d) health and safety studies, TSCA section 8(e) substantial risk of injury to health or the environment notices, and voluntary documents submitted to EPA known as For Your Information (FYI) submissions. TSCATS is available through a number of electronic sources; the studies referenced in TSCATS can be viewed in EPA's public TSCA docket located at EPA's Headquarters in Washington, D.C., or, alternatively, via microfiche copies that are available through the National Technical Information Service (NTIS).

5(c) Small Entity Flexibility

The test rule process minimizes the burden on small businesses by giving them the option of fulfilling their responsibilities under a test rule by either joining a testing consortium or by applying for a test rule exemption. Participation in a testing consortium relieves the small business of direct responsibility for collecting or submitting test information as well as applying for an exemption.

Under ECAs, small businesses are not required to participate, but if they do, they would participate as part of a consortium.

Small businesses are also apportioned a smaller proportion of the cost of testing than their larger counterparts. The decision as to how the cost of testing is to be divided among these firms has, to date, been decided by the manufacturers subject to the rule or ECA. Generally, small businesses are assigned a proportion of the costs that is proportionate to their size and 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 the Agency will certainly consider the special needs of small businesses if such action becomes necessary. To date, no party has requested that the Agency assist in reimbursement decisions.

5(d) Collection Schedule

This information collection activity does not have a calendar-based schedule. The testing period is defined by the individual test rule, ECA, or VTA. 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 submission, the definition of a response (i.e., submission) is changed to include all testing activities associated with a chemical. As in previous ICRs, the time period for screening level testing is usually less than a year. The typical time period for other types of testing is around three years, although it can be longer and varies according to the chemical and the test required. See Section 6(a) for revised methodology and Table 3 for a summary of typical activities per chemical over a three year period, and on average annually.

6 ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a) Methodology and Assumptions

The methodology used to estimate the annual burden and costs to industry resulting from TSCA section 4 test rules, testing agreements, exemption applications, and voluntary submissions over the next three years has been revised starting with this ICR submission. Two key changes are implemented. First, the response definition is changed from "per-activity" to a "per-chemical" metric. A response is now defined as the collection of activities pertaining to the "standard" testing battery of ten tests (seven short-term; three long-term), all of which are performed on one specified chemical. This response definition provides the necessary structure for accurate and transparent scaling according to conditions for "number of chemicals" (e.g., involved in a test rule).[8] Second, for test rules and testing agreements, the annual rate for activities is rigorously calculated (i.e., prorated) to accurately reflect the assumption that long-term studies are three years in duration.[9] The resultant unit burdens are in units of annual responses per chemical and are readily used with revisions to conditions for test rules, testing agreements, voluntary submissions, and exemption applications. Additionally, electronic reporting was implemented during the previous ICR period, requiring unit burden and supply cost revisions.[10]

[8] In previous ICR renewals, the response unit was per activity (e.g., submit robust summary). As activities vary with respect to timing and relative weight (based on burden hours), the new definition provides a more coherent response definition. This was determined to be important under current conditions of very low counts of chemicals subject to TSCA section 4 test rules. However, for future reference the new method is robust to a wide variety of ICR conditions and easily applied to conditions of higher rule and chemical counts.

[9] Under the prior methodology, long-term study activities were being counted every year thereby generating an "over-count" (relative to short-term studies) by a factor of three for the activity-level burdens of long-term studies.

[10] The primary effects of the e-reporting rule on burden estimates involve cutting recordkeeping burden to half its paper-based value, eliminating clerical burden in other activities, and adding an activity to account for electronic registration (see EPA 2013b). Additionally non-labor costs are eliminated due to reductions in paper and postage costs. See Table D in Attachment 3 for a comparison of activity level burdens before and after e-reporting.

The revised unit burden and cost estimates are combined with information on current conditions concerning the number and type (i.e., number of chemicals involved) of TSCA section 4 test rules, testing agreements, and voluntary submissions, all of which may result in industry submitting existing data or conducting new testing to provide EPA with information necessary to evaluate chemicals under its TSCA section 4 mandate. These assumptions are discussed in detail below. For reference, the respondent burdens are organized according to OMB-designated information collection (ICs) as follows:

- CDX Registrations for e-Reporting
- Test Rules
- Testing Agreements: ECAs, and VTAs
- Voluntary Submissions
- Testing Exemption Applications

Methodology

Respondent reporting burden and costs are derived herein. In addition to reporting burden, this analysis provides estimates for testing costs. Note that a response is defined as the collection of related activities involving a battery of ten tests (seven short-term, three long-term), all of which pertain to one specified chemical.

(1) Reporting Burden and Costs

Reporting burden and costs are based on the following activities: CDX registration, preparing letters of intent and study plans; preparing progress reports; preparing test results in final reports; preparing robust summaries; recording test results; conducting laboratory and/or corporate reviews; and recordkeeping.

The burden estimates by activity, and associated supply costs are listed in Table A of Attachment 3. These estimates are based on estimates in the prior ICR, as updated for e-reporting.[11] The wage rate information by type of labor (i.e., managerial, technical, clerical) is presented in Table B of Attachment 3. Detailed calculations provided in Sections 6(b)(i) through 6(b)(v) are based on these tables. The next section presents the estimates for testing burden and costs for use in final summary tables (Section 6(d)(i)). The estimates for reporting burden are presented below in Sections 6(b)(i)-(v) for CDX registration, test rules, testing agreements, voluntary submissions, and testing exemption applications, respectively.

(2) Testing Costs

Testing costs include laboratory costs and administrative costs. For purposes of this ICR, as in past ICRs, EPA assumes that the tests specified in a standard testing battery of ten tests are all likely to be performed on each chemical. As shown in Table 1, seven of these studies are designated as short-term as they are expected to conclude within the year that they are initiated, and three of these studies are designated as long term as they will take three years to conclude.

[11] In this ICR submission, additional minor revisions are made to the activity-level burdens to improve consistency, including the addition of "Laboratory Review" to long-term studies' reports, and the adjustment to recordkeeping for Voluntary Submissions.

The costs presented in Table 1 are drawn from an EPA-maintained listing of the laboratory cost data for numerous TSCA and OECD test protocols (EPA 2013a). Estimates include non-labor costs for analytical chemistry method development and validation where it was judged that such method development would be necessary to conform to good laboratory practices. Short term and long-term studies are assigned costs based on typical costs cited by industry experts (Piccirillo, 2004).[12] Both labor and non-labor test costs were adjusted to end-of-year 2014 dollars using an employment cost index (ECI via US BLS 2014). The overall cost of the "standard" testing battery (per chemical) is estimated at $1,663,397.

Table 1: TSCA Section 4 "Standard" Testing Battery Costs (2014$), Per Chemical

Test Protocol Name	Protocol Number	Date of Estimate	Mean Cost Estimate (2014$)[a]	Validation Costs (2014$)
Algal Acute Toxicity	797.105	8/3/1990	$12,132.58	$4,398.95
Daphnid Acute Toxicity	797.13	4/25/1996	$11,965.05	$4,398.95
Fish Acute Toxicity	797.14	4/25/1996	$18,285.73	$4,398.95
Gene Mutations in Somatic Cells	798.53	8/16/1994	$25,366.24	$4,398.95
Subchronic Oral Toxicity	870.31	9/3/2005	$167,921.14	$4,398.95
Prenatal Developmental Tox. (2 species)[b]	870.37	1/1/2010	$152,450.48	$10,683.16
Reproduction/Fertility Effects[b]	870.38	1/1/2010	$422,689.97	$10,683.16
Salmonella Reverse Mutation Assay	870.5265	9/16/1996	$9,792.46	$4,398.95
In vivo Bone Marrow Cytogenetics	870.5395	2/27/2005	$24,968.83	$4,398.95
Developmental Neurotoxicity[b]	870.63	1/1/2010	$754,982.00	$10,683.16
Subtotal			$1,600,554.48	$62,842.13
Total			**$1,663,397**	

Notes:
[a] Where multiple versions of a test have been assessed by EPA (e.g., covering different species or routes of exposure), the mean cost estimate is used. All testing costs are updated to 2014 dollars.
[b] Designated as "long-term" studies.

Sources:
1. U.S. Bureau of Labor Statistics. July 2014, Employment Cost Index Historical Listing - Volume V. Series: All Private Workers Total Compensation (not seasonally adjusted).
2. U.S. EPA. 2013. Office of Pollution Prevention and Toxics, Economic and Policy Analysis Branch. Filename: Standard Nano Test Costs 9-01-2013.xls.
3. Piccirillo 2004. Vincent Piccirillo, personal communication. September 20, 2004.

Testing administrative costs are based on the following activities: organizing the testing program, obtaining and reviewing bids from laboratories, and submitting samples to the laboratory for testing.

[12] Testing providers typically perform method development and validation in order to determine the effectiveness of an analytical method, as well as to determine the levels of the chemical in the dosing matrix in toxicity studies. Estimates were originally provided in 2004 dollars as $3,835 and $9,314 for short-term and long-term studies, respectively.

Based on experience, EPA assumes that the administrative costs associated with testing programs total approximately 25 percent of the laboratory costs, with the following components:

- **15 percent of the test cost accounts for management of a consortium.** This includes activities such as identifying manufacturers, meetings, organizing payment for testing, developing contracts for testing, and employing toxicologists who may be hired to provide technical expertise for the testing.

- **10 percent of the test cost is used to cover the costs of technical experts.** These experts that may work for the consortium and covers study review and site visits to the laboratory.

This amounts to a total of 25 percent of the laboratory costs to account for administering the testing consortium and the testing. Applying these assumptions to the total reported laboratory costs of $1,663,397 (as presented in Table 1), yields an estimate of $2,079,246 per chemical for the full extent of the testing assumed to be conducted over three years.[13] Based on conditions reported later is this analysis, the resultant testing costs total $27,030,195 over three years, with the annual cost at $9,010,065 (presented in Table 2). The number of responses (discussed in more detail after Table 2) are based on expected minimal levels of activity.

Table 2: TSCA Section 4 Total Laboratory and Non-reporting Administrative Costs (2014$)

Data Submissions	Number of Respondents[a]	Number of Responses, each involving a 10-test study	Administrative and Laboratory Costs[b]
Section 4 Test Rules	10	10	$20,792,458
Testing Agreements (ECAs and VTAs)	2	2	$4,158,491
Voluntary Submissions	1	1	$2,079,246
TOTAL (three years)			**$27,030,195**
TOTAL (annual)			**$9,010,065**

Notes:
[a] See later sections (e.g. 6(b)(ii) for test rules) for discussion of assumptions regarding conditions for this ICR period.
[b] Administrative non-reporting costs are assumed to equal 25% of laboratory costs.

6(a)(ii) Assumptions: Respondents and Activities in the Per-Chemical Response

With the exception of voluntary submissions, electronic submissions are required. Therefore, estimates are made to assess burden and cost for respondents who are setting up first-time e-reporting. Submitters are required to register with CDX and complete the electronic signature agreement.

For purposes of this ICR, and consistent with most recent information on e-reporting (EPA 2015), EPA assumes that 40% of respondents are new CDX submitters, yielding 8.4

[13] In the previous ICR, this estimate also included administrative reporting costs (4% of the total costs). For ease of presentation and separate accounting of testing versus reporting costs, this component is neglected.

responses annually.[14] These respondents may be from firms that are new to EPA e-reporting or they may be employees new to e-reporting due to turnover within a firm that has prior experience with e-reporting.

With respect to test rules and testing agreements, EPA assumes that there will be one test sponsor for each chemical substance subject to testing.[15] In cases where there is more than one manufacturer of the chemical subject to testing, it is assumed that the other manufacturers subject to the request for information will participate in a consortium that is managed by the test sponsor.

Based on experience, EPA retains the same assumption that was used in past ICRs. For a specified chemical, each sponsor is expected to submit:

- one letter of intent and one set of study plans;
- five semi-annual progress reports per long-term study; and
- one final report for each long-term and short-term study.

EPA estimates that 10 percent of the studies completed will be accompanied by a robust summary, yielding one robust summary.[16]

Table 3 summarizes the activities overall for a three year period and derives the average annual frequency to use in ICR estimates. For test rules, EPA assumes that conditions for the next ICR period will amount to the equivalent levels of burden and cost for two rules per year with each involving five chemicals. For testing agreements, EPA assumes that there will be two agreements (one ECA and one VTA) per year involving one chemical. These response rates are based on expected minimal levels of activity.

[14] In the ICR Renewal for section 5 notices, 392 CDX registrations are reported (with one response per respondent) out of a total of 1,000 notices for PMN, SNUN, TME, LVE /LoREX, MCAN, TERA,Tier I and II notices (EPA 2015). EPA assumes that a similar percentage of respondents will register for CDX for purposes of TSCA section 4 submissions at 40%. This assumption is made for simplification purposes. A precise accounting of submitters pertaining to TSCA section 4 CDX registration is implausible due to the fact that companies may have already registered with CDX for purposes of submissions under other EPA programs, e.g., e-PMN, e-CDR, or TRI-ME web.

[15] Under the previous ICR, EPA assumed that a given sponsor would manage chemical testing for five chemicals. In this ICR submission, with much lower counts for rules and chemicals per rule, EPA assumes that a given sponsor will manage chemical testing for one chemical. This change has no effect on estimates for total number of per-chemical responses.

[16] Historically, robust summaries have been developed in order to standardize how the technical information is presented and summarized. Robust summaries have been adopted voluntarily and used by data submitters outside EPA programs.

Table 3: Test Rules and Testing Agreements Activities per Chemical Annually

Activity	Section 4 Test Rule -OR- Testing Agreement (ECA, VTA)				
	Total Counts Three Year Period	Year 1	Year 2	Year 3	Average Per Year
Interim Reports					
Letter of Intent/Study Plans	1	1			0.33
Prepare Progress Report (for long-term studies)	5	2	2	1	1.67
Final Reports					
Short-term Studies	7	2	2	3	2.33
Long-term Studies	3			3	1.00
Robust Summaries	1			1	0.33

Notes:
1. Note that a response is defined as the collection of related activities involving a battery of ten tests (seven short-term; three long-term) all of which pertain to one specified chemical. See Table 1 for additional detail.
2. Additional detail is provided in Attachment 3. Table A lists detailed activities and applicable labor categories (i.e., managerial, technical, clerical); Table B provides wage rates.
3. Long-term studies are completed in three years; short-term studies are completed in one year.
4. Averages per year are rounded for presentation purposes but are not rounded for calculations of total burden.

For voluntary submissions, given that the submission is unrelated to any agreement or other testing requirement, the related activities are more generic, involving final reports and the associated recordkeeping. Although the nature and frequency of such submissions cannot be predicted, EPA conservatively assumes, as in previous ICRs, that there will be one submission per year involving one chemical. Although submitters may use e-reporting, at this time there have been no voluntary submissions and therefore no e-reporting is assumed. Also in the same manner as in previous ICRs, each submission includes:

- ten final reports; and
- one robust summary (10%, as discussed above).

For testing exemption applications, EPA assumes, based on the 52 exemption applications received between 2011 and 2018 for the 19 chemicals subject to the rule, Testing of Certain High Production Volume Chemicals; Second Group of Chemicals (76 FR 1067) that two (1.9 rounded up) exemption applications per year, each involving one chemical will be submitted. Table 4 summarizes the assumptions on respondents and responses, by type of information collection (IC).

Table 4: Respondents and Responses Summary

Information Collection	CDX Registration	Test Rules	Testing Agreements: ETAs, and VCAs	Voluntary Submissions	Testing Exemption Applications
Number of Respondents	8.4	10	2	1	2
Number of Responses per Respondent	1	1	1	1	1
Number of Responses Total	**8.4**	**10**	**2**	**1**	**2**
Note: A response is defined as the collection of related activities pertaining to one specified chemical.					

6(b) Estimating Respondent Burden and Cost

To mirror the designated information collections (ICs) in the system used for submitting the ICRs to OMB for approval, the burden and cost estimates are grouped as follows:

- CDX Registrations for e-Reporting
- Test Rules
- Testing Agreements: COs, ECAs and VTAs
- Voluntary Submissions
- Testing Exemption Applications

The burden and cost estimates, unit labor costs, and unit supply costs[17] are listed according to detailed activity in Table A of Attachment 3. The wage rate information by type of labor (i.e., managerial, technical, clerical) is provided in Table B of Attachment 3. Detailed calculations that are presented in Sections 6(b)(i) through 6(b)(v) draw information from these tables.

6(b)(i) CDX Registration for e-Reporting

As a result of the final electronic reporting rule of 2013, and as of March 2014, respondents incur a small amount of additional burden and costs in carrying out the additional activities associated with e-reporting. Activities that are needed to facilitate electronic submission include: CDX registration and CDX electronic signature. Table A in Attachment 3 provides unit burden and cost estimates based on the most recent on e-reporting information as reported in the Section 5 ICR renewal supporting statement (EPA 2015). For purposes of this ICR, EPA assumes that 8.4 new submitters register annually for purposes of TSCA section 4 e-reporting.[18] These respondents may be from firms that are new to EPA e-reporting or they may be employees new to e-reporting due to turnover within a firm that has prior experience with e-reporting. Table 5 presents unit and total burdens and costs. The information presented in Table 5 is used to complete the IC entry for this group of collection activities under this ICR, as shown in Table 6.

Table 5: CDX Registration for e-Reporting Respondent Unit and Total Burden/Cost

[17] Unit supply costs are only applicable to voluntary submissions as all other submissions require electronic reporting.

[18] See detailed footnote in Section 6(a)(ii).

(2014$)

Respondent Activities	Unit Burden per Registrant (hours)	Total Burden	Unit Cost	Total Costs
CDX Registration	0.180	1.512	$13.00	$109.20
CDX Electronic Signature	0.350	2.940	$25.28	$212.35
CDX Registration and e-Signature total	**0.530**	**4.452**	**$38.28**	**$321.55**

Notes:
1. Additional detail is provided in Attachment 3. Table A lists detailed activities and applicable labor categories (i.e., managerial, technical, clerical); Table B provides wage rates. Costs listed in this table are all labor costs.
2. Totals are obtained for 8.4 new registrations annually.

Table 6: IC Entry: CDX Registration

IC Field:	EPA's Estimates:[a]		
1. Responses:			
Total Number of Respondents			8.4
Number of Responses (chemicals) per Respondent			1.0
Time Period for Each Response			On occasion
Annual Frequency (times per year, per respondent)			1.0
Annual Number of Responses[b]			**8.4**
2. Burden Hours:			
Activities	**Time per Response**	**Hour per Response**	**Annual Hour Burden**
Reporting	0.530	0.530	4.452
Recordkeeping	0.000	0.000	0.000
Third-party Disclosure	-0-	-0-	-
Total Burden Hours:	**0.530**	**0.530**	**4.452**
3. Capital and O&M Costs (this does NOT include labor costs):			
Activities		**Cost per Response**	**Annual Cost**
Reporting		$0.00	$0.00
Recordkeeping		$0.00	$0.00
Third-party Disclosure		-0-	-0-
Total Capital and O&M Costs:		**$0.00**	**$0.00**
4. Annual Responses and Burdens:			
Annual Totals		**Total Requested**	
Annual Responses			8.400
Annual Hour Burden			4.452
Annual Cost (Non-Labor)			$0.00

[a] Based on details provided in the Tables presented earlier in this section.
[b] The system uses this number as a multiplier to calculate the Annual Burden hours and costs.

6(b)(ii) Test Rules

In this ICR TSCA section 4 test rule activity is anticipated from rules promulgated prior to this ICR period. Such test rules are still generating responses from sponsors because testing projects can have protracted timelines and/or can encounter delays. For purposes of estimates for this ICR period, EPA assumes that both effects amount to the equivalent activity of issuing two rules annually with five chemicals per rule. Activities are as described in Section 6(a)(ii), plus recordkeeping. Each chemical is evaluated by performing the tests specified in the "standard"

testing battery with seven short-term and three long-term tests, as portrayed in Table 1. The list of activities is the same for test rules and testing agreements with annual frequencies drawn from Table 3. Activity-level and per-chemical unit burdens reflect updates due to e-reporting (see Tables A and D in Attachment 3 for reference).

(1) Estimated Annual Respondent Burdens and Costs – Test Rules

This section presents test rules unit burdens and costs, followed by total burden and cost. Table 7 presents components of unit burdens and unit costs for test rules (note these are the same for test rules and testing agreements).[19] Given the unit values from Table 7, and applying the conditions of two rules per year and five chemicals per rule, yields total burden and cost results presented in Table 8.

Table 7: Test Rules/Testing Agreements Respondent Annual Unit Burden and Cost, per Chemical (2014$)

Respondent Activities	Average per Year	Burden per Activity (hours)	Unit Burden (hours)	Cost per Activity	Unit Cost per Chemical
Interim Reports					
Letter of Intent/Study Plans	0.33	40.00	13.33	$2,888.80	$962.93
Prepare Progress Report	1.67	8.00	13.33	$577.76	$962.93
Final Reports					
Short-term Studies	2.33	52.00	121.33	$3,803.44	$8,874.69
Recordkeeping	2.33	0.50	1.17	$15.63	$36.47
Long-term Studies	1.00	89.00	95.00	$6,499.58	$6,499.58
Recordkeeping	1.00	0.50	0.50	$15.63	$15.63
Robust Summaries	0.33	12.00	4.00	$866.64	$288.88
Totals			**248.66**		**$18,074.43**

Notes:
1. Costs listed in this table are all labor costs.
2. See Table 3 for derivation of activity "average per year."
3. See Table A of Attachment 3 for detailed activities and applicable labor categories (i.e., managerial, technical, clerical); Table B provides wage rates.

[19] In this ICR submission, the activity “Laboratory Review” was added to long-term studies’ reports in order to provide consistency with short-term studies.

Table 8: Test Rules Respondent Annual Total Burden and Cost (2014$)

Respondent Activities	Unit Burden per Chemical (hours)	Total Burden	Unit Cost per Chemical	Total Costs
Interim Reports				
Letter of Intent/Study Plans	13.33	133.30	$962.93	$9,629.30
Prepare Progress Report	13.33	133.30	$962.93	$9,629.30
Final Reports				
Short-term Studies	121.33	1,213.30	$8,874.69	$88,746.90
Recordkeeping	1.17	11.70	$36.47	$364.70
Long-term Studies	95.00	950.00	$6,932.90	$69,329.00
Recordkeeping	0.50	5.00	$15.63	$156.30
Robust Summaries	4.00	40.00	$288.88	$2,888.80
Totals	248.66	**2,486.60**	$18,074.43	$**180,744.30**

Notes:
1. Costs listed in this table are all labor costs.
2. See Table A of Attachment 3 for detailed activities and applicable labor categories (i.e., managerial, technical, clerical); Table B provides wage rates.
3. Totals are obtained for two rules involving five chemicals each annually.

(2) IC Entry for Test Rules

The information presented in Table 8 is used to complete the IC entry for this group of collection activities under this ICR, as shown in Table 9.

Table 9 IC Entry: Test Rules

IC Field:	EPA's Estimates:[a]		
1. Responses:			
Total Number of Respondents			10
Number of Responses (chemicals) per Respondent			1
Time Period for Each Response			On occasion
Annual Frequency (times per year, per respondent)			1
Annual Number of Responses[b]			**10**
2. Burden Hours:			
Activities	**Time per Response**	**Hour per Response**	**Annual Hour Burden**
Reporting	240.99	240.99	2409.90
Recordkeeping	1.67	1.67	16.70
Third-party Disclosure	-0-	-0-	-
Total Burden Hours:	**248.66**	**248.66**	**2486.60**
3. Capital and O&M Costs (this does NOT include labor costs):			
Activities		**Cost per Response**	**Annual Cost**
Reporting		$0.00	$0.00
Recordkeeping		$0.00	$0.00
Third-party Disclosure		-0-	-0-
Total Capital and O&M Costs:		**$0.00**	**$0.00**
4. Annual Responses and Burdens:			
Annual Totals		**Total Requested**	
Annual Responses			10
Annual Hour Burden			2,487
Annual Cost (Non-Labor)			$0.00

[a] Based on details provided in the Tables presented earlier in this section.
[b] The system uses this number as a multiplier to calculate the Annual Burden hours and costs.

6(b)(iii) Enforceable Consent Agreements (ECAs) and Voluntary Testing Agreements (VTAs)

The specific testing required under future ECAs/VTAs cannot be predicted at this time because it is determined on a case-by-case basis. EPA assumes, as in previous ICRs, that there will be two agreements per year (one ECA and one VTA), each involving one chemical. Activities are as described in Section 6(a)(ii), including recordkeeping. Each chemical is evaluated by performing the tests specified in the "standard" testing battery in Table 1. The test battery includes 10 studies per chemical (7 short-term, 3 long-term). The list of activities is the same for test rules and testing agreements with annual frequencies drawn from Table 3.

(1) Estimated Annual Respondent Burdens and Costs – Testing Agreements

This section presents testing agreement total burden and cost (see Table 7 for components of unit burdens and unit costs). Given the unit values from Table 7, and applying the conditions of two testing agreements per year and one chemicals per agreement yields total burden and cost results presented in Table 10.

Table 10: Testing Agreements (ECAs and VTAs) Respondent Annual Total Burden and Costs (2014$)

Respondent Activities	Unit Burden per Chemical (hours)	Total Burden	Unit Cost per Chemical	Total Costs
Interim Reports				
Letter of Intent/Study Plans	13.33	26.66	$962.93	$1,925.86
Prepare Progress Report	13.33	26.66	$962.93	$1,925.86
Final Reports				
Short-term Studies	121.33	242.66	$8,874.69	$17,749.38
Recordkeeping	1.17	2.34	$36.47	$72.94
Long-term Studies	95.00	190.00	$6,932.90	$13,865.80
Recordkeeping	0.50	1.00	$15.63	$31.26
Robust Summaries	4.00	8.00	$288.88	$577.76
Totals	248.66	**497.32**	$18,074.43	**$36,148.86**

Notes:
1. Costs listed in this table are all labor costs.
2. See Table A of Attachment 3 for detailed activities and applicable labor categories (i.e., managerial, technical, clerical); Table B provides wage rates.
3. Totals are obtained for two testing agreements involving one chemical each annually.

(2) IC Entry for Testing Agreements (ECAs and VTAs)

The information presented in Table 10 is used to complete the IC entry for this group of collection activities under this ICR, as shown in Table 11.

Table 11: IC Entry: Testing Agreements (ECAs and VTAs)

IC Field:	EPA's Estimates:[a]		
1. Responses:			
Total Number of Respondents			2
Number of Responses (chemicals) per Respondent			1
Time Period for Each Response			On occasion
Annual Frequency (times per year, per respondent)			1
Annual Number of Responses[b]			**2**
2. Burden Hours:			
Activities	**Time per Response**	**Hour per Response**	**Annual Hour Burden**
Reporting	246.99	246.99	493.98
Recordkeeping	1.67	1.67	3.34
Third-party Disclosure	-0-	-0-	-0-
Total Burden Hours:	**248.66**	**248.66**	**497.32**
3. Capital and O&M Costs (this does NOT include labor costs):			
Activities		**Cost per Response**	**Annual Cost Burden**
Reporting		$0.00	$0.00
Recordkeeping		$0.00	$0.00
Third-party Disclosure		0	$0.00
Total Capital and O&M Costs:		**$0.00**	**$0.00**
4. Annual Responses and Burdens:			
Annual Totals		**Total Requested**	
Annual Responses			2
Annual Hour Burden			497
Annual Cost (Non-Labor) Burden			$0.00

[a] Based on details provided in the Tables presented earlier in this section.
[b] The system uses this number as a multiplier to calculate the Annual Burden hours and costs.

6(b)(iv) Voluntary Submission

EPA is unable to predict potential voluntary submissions, given none have been received to date. EPA conservatively assumes, as in previous ICRs, that there will be one voluntary submission for one chemical annually. Activities are as listed in Section 6(a)(ii) plus associated recordkeeping.[20]

[20] In this ICR submission, recordkeeping was reduced from two hours to one hour per chemical to make the estimate consistent with the test rule/testing agreement recordkeeping estimate.

(1) Estimated Annual Respondent Burdens and Costs – Voluntary Submissions

This section presents voluntary submission unit burdens and costs, followed by total burden and cost. Table 12 presents components of unit burdens and unit costs for voluntary submissions. Given the unit values from Table 12, and applying the conditions of two agreements per year each involving one chemical, yields total burden and cost results presented in Table 13.

Table 12: Voluntary Submission Respondent Unit Burden and Cost (2014$), per Chemical

Respondent Activities	Average per Year	Burden per Activity (hours)	Unit Burden (hours)	Cost per Activity		Unit Cost per Chemical		
				Labor Cost	Unit Supply Cost	Labor Cost	Unit Supply Cost	Cost
Robust Summaries	1	12	12	$866.64	$0.00	$866.64	$0.00	$866.64
Voluntary Submission Final Reports	10	10	100	$312.60	$8.41	$3,126.00	$84.10	$3,210.10
Recordkeeping	10	1	10	$31.26	$0.00	$312.60	$0.00	$312.60
Totals			**122**			$4,305.24	$84.10	**$4,389.34**

Note: See Table A of Attachment 3 for detailed activities and applicable labor categories (i.e., managerial, technical, clerical); Table B provides wage rates

Table 13: Voluntary Submission Respondent Total Burden and Cost (2014$)

Respondent Activities	Unit Burden per Chemical (hours)	Total Burden	Unit Cost per Chemical		Total Costs		
			Labor Cost	Unit Supply Cost	Labor Cost	Unit Supply Cost	Total
Robust Summaries	12	12	$866.64	$0.00	$866.64	$0.00	$866.64
Voluntary Submission Final Reports	100	100	$3,126.00	$84.10	$3,126.00	$84.10	$3,210.10
Recordkeeping	10	10	$312.60	$0.00	$312.60	$0.00	$312.60
Totals	122	**122**	$4,305.24	$84.10	$4,305.24	$84.10	**$4,389.34**

Notes:
1. See Table A of Attachment 3 for detailed activities and applicable labor categories (i.e., managerial, technical, clerical); Table B provides wage rates.
2. Totals are obtained for one voluntary submission involving one chemical annually.

(2) IC Entry for Voluntary Submissions

The information presented in Table 13 is used to complete the IC entry for this group of collection activities under this ICR, as shown in Table 14.

Table 14: IC Entry: Voluntary Submissions

IC Field:	EPA's Estimates:[a]		
1. Responses:			
Total Number of Respondents			1
Number of Responses (chemicals) per Respondent			1
Time Period for Each Response			On occasion
Annual Frequency (times per year, per respondent)			1
Annual Number of Responses[b]			1
2. Burden Hours:			
Activities	**Time per Response**	**Hour per Response**	**Annual Hour Burden**
Reporting	112	112	112
Recordkeeping	10	10	10
Third-party Disclosure	0	0	0
Total Burden Hours:	**122**	**122**	**122**
3. Capital and O&M Costs (this does NOT include labor costs):			
Activities		**Cost per Response**	**Annual Cost Burden**
Reporting		84.10	84.10
Recordkeeping		$0.00	$0.00
Third-party Disclosure		0	0
= Total Capital and O&M Costs:		**$84.10**	**$84.10**
4. Annual Responses and Burdens:			
Annual Totals		**Total Requested**	
Annual Responses			1
Annual Hour Burden			122
Annual Cost (Non-Labor) Burden			$84.10

[a] Based on details provided in the Tables presented earlier in this section.
[b] The system uses this number as a multiplier to calculate the Annual Burden hours and costs.

6(b)(v) Testing Exemption Applications

As indicated previously, an entity subject to a test rule may apply for an exemption from one or all of the testing requirements imposed in a test rule if that testing will be, or has been performed by another party. There are basically two different scenarios under which a chemical manufacturer might prepare and submit an application to be exempt from a testing requirement imposed by a test rule. The first scenario involves a company who manufacturers the specified chemical for TSCA uses, but who will not be submitting the data because, for example, they joined a consortium that is expected to submit the data. The second scenario involves a company who manufacturers the covered chemical, but only for uses that are not covered by TSCA.

In either case, it is difficult to predict how many exemption applications might be submitted to EPA in any one year. EPA assumes, based on the 52 exemption applications received between 2011 and 2018 for the 19 chemicals subject to the rule, Testing of Certain High Production Volume Chemicals; Second Group of Chemicals (76 FR 1067)that there will be two (1.9 rounded up) exemption applications annually, each involving one chemical. EPA also assumes that each application would request the exemption from all of the testing. Activities related to an exemption application are as listed in Section 6(a)(ii) plus associated recordkeeping.

(1) Estimated Annual Respondent Burdens and Costs – Testing Exemption Applications

This section presents exemption application unit burdens and costs, followed by total burden and cost. Table 15 presents components of unit burdens and unit costs for testing exemption applications. Given the unit values from Table 15, and applying the conditions of two exemption applications per year, each involving one chemical, yields total burden and cost results presented in Table 16.

Table 15: Testing Exemption Application Respondent Unit Burden and Cost (2014$), per Chemical

Respondent Activities	Average per Year	Burden per Activity (hours)	Unit Burden per Chemical (hours)	Cost per Activity	Unit Cost per Chemical
Exemption Application	1.00	8.00	8.00	$625.76	$625.76
Recordkeeping	1.00	0.50	0.50	$15.63	$15.63
Totals			**8.50**		**$641.39**

Notes
1. Costs listed in this table are all labor costs.
2. See Table A of Attachment 3 for detailed activities and applicable labor categories (i.e., managerial, technical, clerical); Table B provides wage rates.

Table 16: Testing Exemption Application Respondent Total Burden and Cost (2014$)

Respondent Activities	Unit Burden per Chemical (hours)	Total Burden	Unit Cost per Chemical	Total Costs
Exemption Application	8.00	16.00	$625.76	$1,251.52
Recordkeeping	0.50	1.00	$15.63	$31.26
Totals	8.50	**17.00**	$641.39	**$1,282.78**

Notes:
1. See Table A of Attachment 3 for detailed activities and applicable labor categories (i.e., managerial, technical, clerical); Table B provides wage rates.
2. Totals are obtained for two testing exemption applications involving one chemical annually.

(2) IC Entry for Testing Exemption Applications

The information presented in Table 16 is used to complete the IC entry for this group of collection activities under this ICR, as shown in Table 17.

Table 17: IC Entry: Testing Exemptions Applications

IC Field:	**EPA's Estimates:[a]**		
1. Responses:			
Total Number of Respondents			2
Number of Responses (chemicals) per Respondent			1
Time Period for Each Response			On occasion
Annual Frequency (times per year, per respondent)			1
Annual Number of Responses[b]			**2**
2. Burden Hours:			
Activities	**Time per Response**	**Hour per Response**	**Annual Burden**
Reporting	8.00	8.00	16.00
Recordkeeping	0.50	0.50	1.00
Third-party Disclosure	0.00	0.00	0.00
Total Burden Hours:	**8.50**	**8.50**	**17.00**
3. Capital and O&M Costs (this does Not include labor costs):			
Activities		**Cost per Response**	**Annual Cost**
Reporting		$0.00	$0.00
Recordkeeping		$0.00	$0.00
Third-party Disclosure		$0.00	$0.00
Total Capital and O&M Costs:		**$0.00**	**$0.00**
4. Annual Responses and Burdens:			
Annual Totals		**Total Requested**	
Annual Responses		2	
Annual Hour Burden		17	
Annual Cost (Non-Labor) Burden		$0.00	

[a] Based on details provided in the Tables presented earlier in this section.
[b] The system uses this number as a multiplier to calculate the Annual Burden hours and costs.

6(c) Estimating Agency Burden and Cost

The cost and burden to the Agency to process, review, and analyze the information collected under TSCA section 4 test rules, testing agreements, voluntary testing programs, and testing exemption applications are discussed below and detailed in Tables 18 and 19. Table 18 lists the documents submitted to the agency (same counts as provided earlier in industry respondent burden and cost sections). Table 19 derives unit and total Agency burden and costs. Costs are based on the assumption that the Agency collection procedures are accomplished, on average, by a GS-13, Step 1 employee (see Table C in Attachment 3 for wage rate information).

The estimated unit burden for processing letters of intent and study plans (three 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 short-term studies, long-term studies, and from voluntary submissions is estimated at ten hours, as revised to reflect current conditions. The estimated unit burden for the Agency to process and review each exemption application is estimated at six hours, as revised to reflect current conditions. The total annual Agency burden and costs is estimated at 554 hours and $38,553.

Table 18: Summary of Reports and Exemption Applications Received by the Agency Annually

Information Collection	Test Rules	Testing Agreements: COs, ETAs, and VCAs	Voluntary Submissions	Testing Exemption Applications	Total Number of Reports
Industry Number of Respondents	10	2	1	2	
Industry Number of Responses per Respondent	1	1	1	1	
Industry Number of Responses Total	**10**	**2**	**1**	**2**	
Interim Reports					
Letter of Intent and Study Plans	3.33	0.67			4
Prepare Progress Report	16.67	3.33			20
Final Reports					
Short-term Studies Final Report	23.33	4.67			28
Long-term Studies Final Report	10.00	2.00			12
Robust Summaries	3.33	3.33	1.00		8
Voluntary Submission Final Reports			10.00		10
Testing Exemption Applications				2.00	2
Total Number of Reports to the Agency					**84**

Notes
1. See Table 3 for further explanation on test rule and testing agreement per-chemical reporting activities, year-by-year for a three-year period. Averages per year are rounded for presentation purposes but are not rounded for calculations of total reports per year received by the Agency.
2. Number of reports for test rules and testing agreements is obtained by separately multiplying the number of rules/agreements times the number of chemicals involved. A similar approach is taken for voluntary submissions and exemption applications.

Table 19: Annual Agency Burden and Cost Estimates (2015$)

Collection Activity	Unit Burden and Cost per Document			Total Burden and Cost		
	Unit Burden (hours)	Rate	Cost	Total Number of Documents	Total Burden (hours)	Total Costs
Letter of Intent and Study Plans	5	$69.63	$348.16	4	20	$1,392.64
Progress Reports	1	$69.63	$69.63	20	20	$1,392.60
Final Reports	10	$69.63	$696.32	50	500	$34,816.00
Robust Summaries	1	$69.63	$69.63	8	8	$533.83
SUBTOTAL				**82**	**548**	**$38,135.07**
Exemption Applications	3	$69.63	$208.90	2	6	$417.79
TOTAL				**84**	**554**	**$38,552.86**

6(d) Bottom Line Burden Hours and Costs

Total Respondent Annual Hours and Costs

Table 20 summarizes the estimated annual reporting burden and cost according to OMB-designated information collections, along with testing costs. With respect to reporting burden and cost, EPA estimates that this ICR will impose a total of 3,127 burden hours annually with a per response burden hour ranging from 8.5 for exemption applications to 249 hours for test rules/testing agreements (a response is on a per chemical basis). The associated per response reporting costs range from $641-$18,074 per chemical, respectively. For CDX registrations, per response burden is 0.53 hours or about 32 minutes per registration with an associated cost of $322. The total reporting costs are estimated at $222,887, with an additional $9 million in testing costs, yielding $9.2 million in total cost.

Table 20: Estimated Total Annual Respondent Burden Hours and Costs (2014$)

	Total Burden (hours)	Costs		
		Labor	Non-Labor	Total
Test Rules				
Reporting	2,469.90	$180,223.30	$0.00	$180,223.30
Recordkeeping	16.70	$521.00	$0.00	$521.00
+ Subtotal	**2,486.60**	**$180,744.30**	**$0.00**	**$180,744.30**
Testing Agreements				
Reporting	493.98	$36,096.76	$0.00	$36,096.76
Recordkeeping	3.34	$52.10	$0.00	$52.10
+ Subtotal	**497.32**	**$36,148.86**	**$0.00**	**$36,148.86**
Voluntary Testing Submissions				
Reporting	112.00	$3,992.64	$84.10	$4,076.74
Recordkeeping	10.00	$312.60	$0.00	$312.60
+ Subtotal	**122.00**	**$4,305.24**	**$84.10**	**$4,389.34**
Testing Exemptions Applications				
Reporting	16.00	$1,251.52	$0.00	$1,251.52
Recordkeeping	1.00	$31.26	$0.00	$31.26
+ Subtotal	**17.00**	**$1,282.78**	**$0.00**	**$1,282.78**
CDX Registration				
Registration	**4.452**	**$321.55**	**$0.00**	**$321.55**
Total Burden/Cost	**3,127.00**			**$222,886.83**
Testing Costs				**$9,010,064.97**
OVERALL TOTAL COSTS				**$9,232,952**

Total Agency Annual Hours and Costs

The total annual burden hours and costs for the government as detailed in Table 19, is estimated at 554 hours and $38,553.

6(e) Reasons for Change in Burden

This request represents a decrease of 626,766 hours from that currently in the OMB inventory (from 629,893 to 3,127 hours). As shown in Table 21, this decrease is due mainly to corrections to the estimates (-534,060 hours). Additional decreases are due to reduced levels of activity in test rules given the decrease from 90 responses to 10 responses (-82,960 hours). Also, e-reporting produced burden reductions (-2,577 hours). Last, methodological corrections and updates produced newly defined unit burdens and adjustments to total burden (-7,169 hours). The decrease associated with e-reporting is a program change; the rest of the decreases are adjustments. The discussions below provide additional detail for the corrections to the estimates and methodology updates.

6(e)(1). Error Correction

During the preparation of this ICR Reinstatement request, EPA discovered that the previously approved burden estimates presented in the expired ICR were significantly miscalculated due to an administrative error. Although the underlying estimates presented in the ICR burden analysis were correct, EPA erroneously applied a constant, rather than variable, number of annual responses to activities covered under the Testing Requirements IC that were otherwise demonstrated to have very different annual response estimates on an activity-by-activity basis (see Table 22). EPA believes that a footnote in the supporting statement for the expired ICR which explained that the total number of responses to the various activities covered under the IC would be used "as a multiplier to calculate the Annual Burden hours and costs" was misinterpreted and misapplied when reporting the IC burden to OMB. This error caused EPA to overcount the estimated burden hours associated with testing requirements by 526,464 hours. In addition, EPA believes that a minor discrepancy between the miscalculated Testing Requirements IC burden in presented in the expired ICR (620,154 hours) and the miscalculated Testing IC burden reported to and approved by OMB (620,191 hours) is the result of rounding. EPA's correction of these errors in this reinstatement request is an adjustment.

EPA repeated this administrative error when calculating the burden for the Testing Agreements and Voluntary Submissions ICs in the supporting statement for the expired ICR and reporting to OMB. This error cause EPA to similarly overcount the reported burden hours for these ICs by 7,466 hours and 130 hours respectively (see Table 23 and Table 24). Minor discrepancies between the miscalculated burden figures for the Testing Agreements IC in presented in the expired ICR (9,468 hours) and the miscalculated Testing Agreements burden reported to and approved by OMB (9,431 hours) are the result of rounding. EPA's correction of these errors in this reinstatement request is also an adjustment.

6(e)(2). Methodology Change

Regarding methodology updates, estimated at -7,169 hours, as presented in Section 6(a) and in the details in footnote "e" of Table 21, these changes incorporate the revised response unit of "per chemical," and the prorated unit burdens for test rules and testing agreements. Such changes are in-house strategies by which errors such as the one described above are made less likely to occur (see Nielsen and Day, 2018). In changing from a "per activity" to a "per-chemical" basis, the transparency of the estimate is improved and errors are prevented. The number of chemicals, as an organizing unit, is a more intuitive basis with which to scale from unit burdens to totals. Furthermore, the associated implementation of a roll-up strategy by which related activities are combined in an appropriately weighted average unit burden (i.e., prorated unit burdens), and subsequently comprehensively scaled according to universe information (i.e., number chemicals tested) avoids voluminous repetitive parallel calculations, or even erroneous redundant calculations. Although these methodology changes theoretically have no impact on total burden results, as the previous and new methods are algebraically equivalent, some relatively minor corrections were still required after the conversion in order to reconcile the new

estimates in comparison to the old estimates. EPA's estimate attributed to methodology changes in Table 21 is due to these minor corrections, and for this reinstatement request, is an adjustment.

Table 21: Reasons for the Change in Burden

Information Collection (IC)	Previous ICR (as reported in Notice of OMB Action 8/28/13)[a]		Calculation Corrections to Previous ICR		Previous ICR Corrected Estimates[b]		Changes						Revised ICR	
							1) Reduction in Section 4 Test Rules[c]		2) Program Change of e-Reporting[d]		3) Methodology Correction and Updates[e]			
	Unit	Total	Unit	Total	Unit	Total	Unit	Total	Unit	Total	Unit	Total	Unit	Total
CDX Registration									0.53	4.45	0.00	0.00	0.53	4.45
Test Rules	263	620,191	0	-526,501	263	93,690	0	-82,960	-31.00	-2,050.00	16.66	-6,193.40	248.66	2,486.60
Testing Agreements: ECAs, and VTAs	263	9,431	0	-7,429	263	2,002	0	0	-31.00	-530.00	16.66	-974.68	248.66	497.32
Voluntary Submissions	23	253	0	-130	23	123	0	0	0.00	0.00	99.00	-1.00	122.00	122.00
Testing Exemption Applications	9	18	0	0	9	18	0	0	-0.50	-1.00	0.00	0.00	8.50	17.00
TOTAL		629,893		-534,060		95,833		-82,960		-2,577		-7,169		**3,127**

Note: All unit and total burden estimates are reported in hours.

Footnotes:

[a] The breakdown according to IC is approximate, based on Supporting Statement posted on reginfo.gov, as adjusted by the final Notice of OMB Action, assuming the difference of 2,395 hours is entirely due to updates to the Test Rules burden estimate.

[b] Verification of totals from detailed calculations versus totals in IC Entry Tables confirmed that calculation errors occurred (US EPA 2013c).

[c] In the previous ICR, the conditions include six rules annually, each involving an average of 15 chemicals (90 responses). In this ICR submission, conditions include two rules annually, each involving an average of 5 chemicals.

[d] The primary effects of the e-reporting rule on burden estimates involve cutting recordkeeping burden to half its paper-based value, eliminating clerical burden in other activities, and adding an activity to account for electronic registration. Additionally non-labor costs are eliminated due to reductions in paper and postage costs. See Table D of Attachment 3.

[e] Two key changes are implemented in the methodology update. First, the response definition is changed from a per-activity to a per-chemical metric. A response is now defined as the collection of activities pertaining to the "standard" testing battery of 10 tests (seven short-term; three long term), all of which are performed on one specified chemical. Second, for test rules and testing agreements, the annual rate for activities is calculated (i.e., prorated) to accurately reflect the assumption that long term studies are three years in duration. Additionally, minor changes were made to activity-level burdens to improve consistency, including the addition of "Laboratory Review" to long-term studies' reports, and the adjustment to recordkeeping for Voluntary Submissions.

Table 22. Erroneously-reported Testing Requirements Burden

Collection Activity	2012 Estimate [a]			2012 Reported [b]			Reporting Error: Overcounted Burden Hours
	Hrs. per Response	Annual Responses	Annual Burden	Hrs. per Response	Annual Responses	Annual Burden	
Interim Reports							
Letter of Intent and Study Plans	40	18	720	40	*2,358*	94,320	93,600
Prepare Progress Report	8	1350	10,800	8	*2,358*	18,864	8,064
Final Reports - Short-term Studies (includes the following)	73	630	45,990	73	*2,358*	172,134	126,144
Record and Prepare Test for Submission	*40*			*40*			
Laboratory Review	*6*			*6*			
Corporate Review	*6*			*6*			
Type and Print Results	*20*			*20*			
Recordkeeping	*1*			*1*			
Final Reports - Long-term Studies (includes the following)	130	270	35,100	130	*2,358*	306,540	271,440
Record and Prepare Test for Submission	*80*			*80*			
Corporate Review	*9*			*9*			
Type and Print Results	*40*			*40*			
Recordkeeping	*1*			*1*			
Robust Summaries	12	90	1,080	12	*2,358*	28,296	27,216
TOTAL	*263*	*2,358*	*93,960*	***263 x***	***2,358 =***	***620,154***	*526,464*

[a] (EPA, 2013c) Table 5
[b] (EPA, 2013c) Table 6

Table 23. Erroneously-reported Testing Agreements Burden

Collection Activity	2012 Estimate [a]			2012 Reported [b]			Reporting Error: Overcounted Burden Hours
	Hrs. per Response	Annual Responses	Annual Burden	Hrs. per Response	Annual Responses	Annual Burden	
Interim Reports							
Letter of Intent and Study Plans	40	2	80	40	*36*	1,440	1,360
Prepare Progress Report	8	12	96	8	*36*	288	192
Final Reports - Short-term Studies (includes the following)	73	14	1,022	73	*36*	2,628	1,606
Record and Prepare Test for Submission	*40*			*40*			
Laboratory Review	*6*			*6*			
Corporate Review	*6*			*6*			
Type and Print Results	*20*			*20*			
Recordkeeping	*1*			*1*			

Collection Activity	2012 Estimate [a]			2012 Reported [b]			Reporting Error: Overcounted Burden
	Hrs. per Response	Annual Responses	Annual Burden	Hrs. per Response	Annual Responses	Annual Burden	
Final Reports - Long-term Studies (includes the following)	130	6	780	130	*36*	4,680	3,900
Record and Prepare Test for Submission	*80*			*80*			
Corporate Review	*9*			*9*			
Type and Print Results	*40*			*40*			
Recordkeeping	*1*			*1*			
Robust Summaries	12	2	24	12	*36*	432	408
TOTAL	*263*	*36*	*2,002*	***263 x***	***36 =***	***9,468***	*7,466*
[a] (EPA, 2013c) Table 8 [b] (EPA, 2013c) Table 9							

Table 24. Erroneously-reported Voluntary Submissions Burden

Collection Activity	2012 Estimate [a]			2012 Reported [b]			Reporting Error: Overcounted Burden Hours
	Hrs. per Response	Annual Responses	Annual Burden	Hrs. per Response	Annual Responses	Annual Burden	
Robust Summaries	12	1	12	12	*11*	132	130
Submission of Final Reports	10	11	110	10	*11*	110	0
Recordkeeping	1	11	11	1	*11*	11	0
TOTAL	*23*	*11*	*133*	***23 x***	***11 =***	***253***	*130*
[a] (EPA, 2013c) Table 11 [b] (EPA, 2013c) Table 12							

6(f) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0033, is estimated to range between 8.5 and 243 hours per response, not including CDX registration, and 0.53 hours per CDX registration. 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 current and 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-2015-0436, which is available for online viewing at 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.

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-2015-0436 and OMB Control No. 2070-0033, to both EPA and OMB as follows:

- To EPA online using http://www.regulations.gov (our preferred method), or by mail to: Pollution Prevention and Toxics Docket, Environmental Protection Agency Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and

- To OMB by e-mail to: oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under Docket ID No. EPA-HQ-OPPT-2015-0436. These attachments are available for online viewing at http://www.regulations.gov.

Attachment 1: 15 U.S.C. 2603, Toxic Substances Control Act (TSCA), Section 4

Attachment 2: 40 CFR 790, Procedures Governing Testing Consent Agreements and Test Rules

Attachment 3: Economic Analysis Tables

Attachment 4: Public Comment Received from the American Chemistry Council

Attachment 5: EPA's Response to the Public Comment

Attachment 6: Consultations Message Sent by EPA to Potential Respondents

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