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, Consent Orders, Enforceable Consent Agreements, Voluntary Testing Agreements, Voluntary Data Submissions, and Exemptions from Testing Requirement

EPA ICR No.: 1139.09 OMB Control No.: 2070-0033

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.

The data 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.

[1] See also attachment #1.

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 consent orders and Voluntary Testing Agreements (VTAs). ECAs and VTAs are usually less burdensome than 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: http://www.epa.gov/oppt/chemtest/index.html.)

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, 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 consent order 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 response to a consent order issued under TSCA

section 4 is only mandatory for participants in the consent order or ECA. 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 consent order 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 (rulemaking, ECA, VTA), 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) (frequently described as 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: http://www.epa.gov/opptintr/itc/.)

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 consent order 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, 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 (MSDSs) 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. To date, EPA has 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 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 section 4 Enforceable Consent Agreements, and Negotiated Testing Agreements. 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.[2]

[2] Go to: http://www.epa.gov/oppt/chemtest/pubs/sumindex.html.

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

3(a). Non-Duplication

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 issuing a consent order, 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 issues a consent order 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

In proposing to renew this ICR, EPA provided a 60-day public notice and comment period that ended on October 11, 2011 (76 FR 49471, August 10, 2011). EPA received one comment during that comment period.[3] The commenter, a "user of the information that EPA makes available" and who "also use[s] the analysis EPA develops from the information," wrote that "[i]t is imperative that EPA continue being able t[o] mandate the collection of this information pursuant to the ICR" and that EPA "needs to be able to collect information at this level of detail to ensure it can be used most effectively" and that "a structured format is essential." EPA considers this comment to be supportive of the information collection activities covered by this ICR.

3(c). Consultations

Under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an ICR to OMB for review and approval. In accordance with this regulation and based on OCSPP Regulatory Coordination Staff guidance, EPA submitted questions by e-mail to potential ICR respondents and data users with respect to the renewal of this ICR. The individuals contacted were as follows:

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[3] See Attachment 3.

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EPA did not receive any direct comments in response to this e-mail but one party did submit a comment to the public docket (see preceding section). A copy of the e-mail soliciting comments is included as Attachment 4.

3(d). Effects of Less Frequent Collection

Test rules and consent orders 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 consent orders, and to grant timely exemptions from test rules.

3(e). General Guidelines under the PRA

The data retention requirements for test rules and consent orders exceed one of the PRA guidelines contained in 5 CFR 1320.6. Documentation records, raw data, and specimens pertaining to a test rule or consent order study are required to be retained for ten years from the effective date of the applicable test rule or publication date of the consent order. 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 consent order 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 consent orders and in exemption applications is, in most cases, non-confidential. If respondents wish to claim information submitted in response to a test rule or consent order 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

EPA recently issued a proposed rule (77 FR 22707, April 17, 2012) that would replace paper submissions with electronic online submissions of the information under TSCA section 4 (including enforceable consent agreements (ECAs) and other voluntary data submissions), as well as other reporting and notice requirements under TSCA, using EPA's Central Data Exchange (CDX), which provides a single portal to enable electronic submission of forms, reports, and other documents to the Agency. After considering comments on the proposed rule, which is expected to be released for comment shortly, EPA hopes to publish the final rule in 2013. The Agency's estimates for burden reduction related to the online reporting will be presented in the supporting documents for the proposed

rule. When the final rule is issued, EPA will prepare corresponding amendments to all of the impacted ICRs.

Currently, electronic submissions of the data occurs frequently with the respondent simply including an electronic version of the information on a CD that is mailed to EPA along with the paper submission. In the context of the voluntary HPV Challenge, participants submitted some data online, using the robust summaries format. EPA did not, however, track the method of submission over the last 3 years, such that the percentage of responses received electronically could be calculated. A rough guess would be that greater than 50% of submissions were submitted electronically.

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 and Importers	325, 32411	Persons who manufacture (defined by statute to include import) one or more of the subject chemical substances.
Processors	325, 32411	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)[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 consent orders, 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.

[4] Also available at http://www.epa.gov/oppt/chemtest/pubs/sct4rule.html.

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.

Consent Orders, ECAs & VTAs – EPA may negotiate a consent order, ECA or VTA under which manufacturers agree to conduct specific testing and submit the data to EPA. The consent order, 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[5] that was previously covered by this ICR 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 consent orders generally require testing of only a single representative chemical substance and all chemicals subject to the consent order, ECA or VTA are assumed to be equivalent to it.

Exemptions for Testing Requirements – 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 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. Should they

[5] 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. Additional information about this program is available at http://www.epa.gov/chemrtk/.

decide to do so, EPA simply asks that they follow the same procedures for preparing their package and completing their submission. 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 will be captured in this information collection request.

4(b)(ii). Respondent Activities

Respondents may undertake one or more of the following activities:

(a) Review rulemaking and/or participate in ECA or VTA discussions.
(b) Conduct searches for relevant existing data. If data are found:
    a. Determine whether the data are relevant;
    b. Prepare and review summary of existing data; and
    c. Submit summary of existing data to EPA.
(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 application for a test exemption, 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 during the conduct of the testing, and a final report of the test results. Since data is typically required on a chemical basis – as opposed to a manufacturer basis, test sponsors typically join forces to satisfy the testing requirements.

Consent Orders, ECAs and VTAs – Signatories to a consent order, 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 final report and Robust Summary of the test results.

Exemptions – 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, the rule 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 a consent order, 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, consent orders, or voluntarily 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 Inventory Rule Update Amendments (IURA) 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 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, TSCA Section 4 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 consent orders, 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 consent order. 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 involve more than one submission per activity. Required testing is conducted only once, and each related submission is a one-time on occasion submission. The testing period is based on the individual rule, consent order, or VTA, the standard time required to conduct the required test according to the testing guidelines, according to the timing established in the approved test plan, or timing otherwise established by the Agency.

The time period for screening level testing, like that conducted under the HPV Initiative, 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.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a). Methodology and Assumptions

The methodology used in this ICR to estimate the annual burden and costs to industry resulting from TSCA section 4 test rules, consent orders and agreements, exemptions, and voluntary submissions over the next three years is consistent with that used in previous ICRs. The burden and cost estimates have been combined with current information concerning the number and type of TSCA section 4 test rules, consent orders, or voluntary agreements issued and under development, 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.

Individual actions covered by this ICR may impact industry over most or all of the three year ICR period, with activities often occurring periodically over the three year period covered by the ICR, but not necessarily scheduled to occur in any given year. In these cases, the impacts of the action have been converted to an annual basis by assuming, for example, that one-third of the chemicals covered by the action would be addressed in each of the three years.

The following sections explain the assumptions and methods that were used to estimate the burden and costs for the different activities covered by this ICR, along with the related cost and burden calculations.

6(a)(i). Methodology

The paperwork burden and cost for this ICR fall into two general categories of activity: technical and administrative.

Technical paperwork burden and cost is derived from the labor time needed to complete the paperwork associated with the initiation of testing, collecting and maintaining data, use of laboratory standards, data analysis, data compiling, data entry, oversight of contractor or employee activities, and decision-making.

Administrative paperwork burden and cost is derived from the labor time spent planning the activities necessary to respond to the data collection. Administrative burden and costs are assumed to comprise of both *reporting* and *non-reporting* activities.

Reporting Costs and Burdens are derived from the following reporting activities that are undertaken by respondents: preparing letters of intent and study plans; preparing progress reports;

preparing test results for submission to EPA; recording test results; conducting laboratory or corporate reviews; performing associated clerical work for final report preparation; record keeping; conducting administrative activities to preparing for and oversee the testing program; and applying for exemptions.

The burden estimates and unit supply costs associated with these activities for a single chemical are reported in Table 1 and are based on estimates provided in the prior ICR. The unit wage rate information is explained in Attachment 5. The unit labor hours are derived from previous information collection requests and are believed to be reflective of the annual amount of time required for each activity over the next three year period.

Table 1: Respondent Per Study Cost and Burden

Collection Activity	Unit Labor				Unit Supply Costs (y)	Total Costs (x+y)
	Type [a]	Hours	Rate	Cost (x)		
TESTING:						
Interim Reports						
Letter of Intent and Study Plans	T	40	$61.71	$2,468.32	$21.91	$2,490.23
Prepare Progress Report	T	8	$61.71	$493.66	$5.48	$499.14
Interim Reports Subtotal (a)		*48*		*$2,961.98*	*$27.39*	*$2,989.38*
Final Reports						
Short-term Studies						
Record and Prepare Test for Submission	T	40	$61.71	$2,468.32	--	$2,468.32
Laboratory Review	T	6	$61.71	$370.25	--	$370.25
Corporate Review	M	6	$69.74	$418.44	--	$418.44
Type and Print Results	S	20	$28.98	$579.62	--	$579.62
Recordkeeping	S	1	$28.98	$28.98	$5.48	$34.46
Short-term Studies Subtotal (b)		*73*		*$3,865.61*	*$5.48*	*$3,871.09*
Long-term Studies						
Record and Prepare Test for Submission	T	80	$61.71	$4,936.65	--	$4,936.65
Corporate Review	M	9	$69.74	$627.65	--	$627.65
Type and Print Results	S	40	$28.98	$1,159.25	--	$1,159.25
Recordkeeping	S	1	$28.98	$28.98	$5.48	$34.46
Long-term Studies Subtotal (c)		*130*		*$6,752.53*	*$5.48*	*$6,758.01*
Robust Summaries (d)	T	12	$61.71	$740.50	--	$740.50
Final Reports Subtotal (e)=(b+c+d)		*215*		*$11,358.64*	--	*$11,358.64*
TOTAL for TESTING: (a+e)		*263*		*$14,320.62*	*$38.35*	*$14,358.97*
VOLUNTARY SUBMISSIONS:						
Robust Summaries	T	12	$61.71	$740.50	--	$740.50
Submission of Final Reports	S	10	$28.98	$289.80	--	$289.80
Recordkeeping	S	1	$28.98	$28.98	$5.48	$34.46
TOTAL for VOLUNTARY SUBMISSIONS:		*23*		*$1,059.28*	*$5.48*	*$1,064.76*
EXEMPTIONS:						
Prepare Exemption Applications	T	2	$61.71	$123.42	--	$123.42
Corporate Review	M	6	$69.71	$418.44	--	$418.44
Recordkeeping	S	1	$28.98	$28.98	$5.48	$34.46
TOTAL for EXEMPTIONS:		*9*		*$570.84*	*$5.48*	*$576.62*
SUMMARY of TOTALs by ACTIVITIES:						
Testing Activities		**263**		**$14,320.62**	**$953,694**	**$968,015**
Reporting		262		$14,291.64	-0-	
Recordkeeping		1		$28.98	$38.35	
Laboratory Work[b]		-0-		-0-	$953,656	
Voluntary Submissions Activities		**23**		**$1,059.28**	**$5.48**	**$1,064.76**
Reporting		22		$1,030.30	-0-	
Recordkeeping		1		$28.98	$5.48	

Collection Activity	Unit Labor				Unit Supply	Total Costs
	Type [a]	Hours	Rate	Cost (x)		
Exemptions		**9**		**$571**	**$5.48**	**$577**
Reporting		8		$542.02	-0-	
Recordkeeping		1		$28.98	$5.48	

[a] Labor Type Codes are as follows: T = Technical; M = Managerial; S =Secretarial
[b] See Table 2, item g.

Non-reporting Administrative Costs and Burdens are derived from the following non-reporting activities associated with the effort of respondents to organize a testing program, obtain and review bids from laboratories that would conduct the testing, and prepare and submit samples to the laboratory for testing. EPA's experience has shown the non-reporting administrative costs associated with testing programs to total approximately 25 percent of the laboratory costs, which is derived as follows. A burden equal to 15 percent of the test cost is used to account 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. An additional 10 percent of the test cost is used to cover the costs of technical 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 test cost used to calculate the burden associated with administering the testing consortium and testing. In some cases, the actual burden of these activities may be undertaken by an organization or individual contracted by the respondent and would be included as a cost. However, because respondents may undertake some or all of these activities themselves, the burden is included in this analysis.

The annual burden and costs incurred by respondents performing laboratory testing are presented in Table 2. Total laboratory costs associated with activities covered by this ICR are estimated to be $7.3 million per year (Table 2, line f), and involve a burden of 29,233 hours.

Table 2: Annual Laboratory Cost and Burden Estimates per Chemical

Activities		**(2010$)**
a	Laboratory cost per chemical [a]	$1,466,084
b	Total laboratory costs	$7,330,422
c	Administrative Reporting costs Administrative non-reporting costs Total Administrative costs [b]	$373,531 $1,832,606 $2,206,136
d	Total laboratory and administrative costs (b + c)	$9,536,559
e	Laboratory costs per study (b ÷ 10)	$733,042
f	Administrative costs per study (c ÷ 10)	$220,613
g	**Total testing costs per study (e + f)**	**$953,656**
h	Administrative Reporting burden [c] Administrative non-reporting burden [d] **Total Administrative Burden**	2,630 32,282 **34,912**

Numbers throughout table have been rounded
[a] The laboratory cost per chemical are derived in Table 3.
[b] Administrative non-reporting costs and burdens are assumed to equal 25% of laboratory costs and burdens.
[c] The reporting burdens per study are derived in Table 1 (263 burden hours x 10 studies).
[d] The non-reporting administrative burden is estimated by dividing the administrative cost by $56.77, which represents the weighted average wage rate. The weighted average wage reflects an assumed 20/60/20 mix of managerial/technical/clerical labor.

6(a)(ii). Assumptions: Standard Testing Costs

For purposes of this ICR, as in past ICRs, EPA assumes that each chemical that will be covered by this ICR is likely to perform the tests specified in a "Standard" testing battery (see Table 3). The test battery includes 10 studies per chemical (7 short term, 3 long term).[6] On occasion, based on a specific need identified, a chemical substance may involve other tests that would be identified in the test rule, ECA or VTA. When that occurs in a test rule, the Agency will address any differential burden and costs estimates in the context of that rulemaking.

EPA generates and maintains a listing of the laboratory cost and burden data for numerous TSCA and OECD test protocols. Test cost estimates were adjusted to end-of-year 2010 dollars using the Bureau of Labor Statistics' Employment Cost Index (ECI) and are shown in Table 3. The mean cost of the "Standard" battery is $1,465,985.[7]

EPA has also included 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. Method development and validation is typically performed to determine the effectiveness of an analytical method to determine the levels of the chemical in the dosing matrix in toxicity studies. Short term and long-term studies are assigned a cost of $3,835 and $9,314 respectively, based on typical costs cited by industry experts (Piccirillo, 2004). Total validation costs for the testing battery are $54,787, resulting in a total laboratory cost of $1,465,985.

Table 3: TSCA Section 4 "Standard" Testing Battery Costs

Test Protocol Name	Protocol Number	Date of Estimate	Mean Cost Estimate (2010$)[1]	Validation Costs (2010$)
Algal Acute Toxicity	797.1050	8/3/1990	$28,986.83	$3,835.11
Daphnid Acute Toxicity	797.1300	4/25/1996	$11,232.48	$3,835.11
Fish Acute Toxicity	797.1400	4/25/1996	$22,806.83	$3,835.11
Gene Mutations in Somatic Cells	798.5300	8/16/1994	$25,160.49	$3,835.11
Subchronic Oral Toxicity	870.3100	9/3/1996	$186,149.49	$3,835.11
Prenatal Developmental Tox. (2 species)	870.3700	8/27/1996	$142,943.18	$9,313.83
Reproduction/Fertility Effects	870.3800	8/27/1996	$737,572.04	$9,313.83
Salmonella Reverse Mutation Assay	870.5265	9/16/1996	$9,256.85	$3,835.11
In vivo Bone Marrow Cytogenetics	870.5395	2/27/1997	$19,376.05	$3,835.11
Developmental Neurotoxicity	870.6300	8/27/1996	$227,713.28	$9,313.83
Subtotal			$1,411,198	$54,787
Total			**$1,465,985**	

[1] 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 test costs updated to 2010 dollars.
Source: U.S. EPA, Office of Pollution Prevention and Toxics, Economic and Policy Analysis Branch.

6(a)(iii). Assumptions: Respondents

In all cases, it is assumed that there will be one primary test sponsor for each chemical substance subject to testing, and that sponsors may address up to 5 chemicals each. 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 EPA's experience, each test sponsor is expected to submit one letter of intent and one

[6] "Short-term studies" are tests that can be concluded in the year they begin; "long-term studies" are concluded within three years.
[7] The laboratory cost is considered part of the sponsor's overall cost.

set of study plans for each chemical; five semi-annual progress reports for each long-term study; and one final report for each study. EPA estimates that 10 percent of the studies completed will be accompanied by a robust summary[8].

Exemption applications are not necessary for chemicals that are not subject to a test rule, so there are no exemption applicants counted for consent orders or voluntary submissions.

The estimated number of respondents is provided in the following sections, along with related cost and burden estimates.

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:

- Existing Testing Requirements
- Consent Orders, ECAs and VTAs
- Voluntary Submissions
- Exemptions from a Testing Requirement

6(b)(i). Existing Testing Requirements

This ICR currently covers only those TSCA section 4 test rules that have been promulgated as of January 1, 2012, and only to the extent that such test rules continue to involve reporting or recordkeeping activities. Although several other TSCA section 4 test rules may be under development, they are not currently covered by this ICR. Until a final TSCA section 4 rule is issued, the proposed data collection activities as identified in the proposed rule - or under consideration prior to proposal - are not authorized. The estimated paperwork burden and costs for a proposed TSCA section 4 rule are provided for public comment at the time of the proposal, and in the context of the proposal. At that time, the Agency connects the proposal to this ICR and indicates that the final rule will present the adjusted estimates - adjusted to reflect public comment received and the content of the final rule. In the context of finalizing a TSCA section 4 rule, the Agency submits an addendum or amendment for this ICR to OMB for review and approval under the PRA. Once approved by OMB, the total authorized burden and costs under this ICR is then adjusted by OMB to include the collection activities in the final rule, thereby authorizing or approving them as required by the PRA. When the Agency prepared the next renewal package for ICR, the approved burden for any such final rules will be incorporated into the Supporting Statement for the Renewal ICR. As indicated in the terms of clearance for this ICR, OMB has told the Agency that no estimated burden or costs for proposed rules will be approved under this ICR until the final rule is issued and OMB specifically approves an amendment to the ICR to capture the approval of the activities in the final rule. This is consistent with OMB's regulations for the PRA.

(1). Final Section 4 Test Rule for Certain High Production Volume Chemicals; Third Group of Chemicals

[8] The stakeholders adopted the use of robust summaries in the voluntary HPV Challenge Initiative as a way to standardize how the technical information was presented and summarized for use in the database they established for sharing the information. Guidance, based on that issued by OECD, was agreed upon in 1999. See http://www.epa.gov/chemrtk/pubs/general/robsumgd.htm. Since then, robust summaries have been adopted voluntarily and used by data submitters outside the voluntary program.

On October 21, 2011[9], EPA promulgated a final test rule under TSCA section 4(a)(1)(B) to require manufacturers, importers, and processors to conduct testing to obtain screening level data for health and environmental effects and chemical fate for 15 high production volume (HPV) chemical substances listed in this final rule. This test data is needed in order to help EPA to determine whether these 15 HPV chemical substances pose a risk to human health and/or environmental safety. In the Economic Analysis[10] prepared for the final rule, EPA estimated that approximately 11 respondents or testing consortium will submit letters of intent and study plans, resulting in 118 final reports. EPA also assumes that it will receive five exemption applications per respondent or testing consortium, resulting in a total of 55 requests pursuant to the final rule. Additionally, it is estimated that 10 percent of final test reports will be accompanied by a robust summary of results. EPA estimated that it takes a respondent 40 hours to prepare a letter of intent and study plan, 73 hours to write a final report for a short-term study, 12 hours to prepare a robust summary, and 2 hours to prepare an exemption application. The unit labor hours are derived from the previous information collection requests and are believed to reflect the burden that will be incurred for the final rule. The total reporting burden generated by the rule is estimated to be approximately 9,308 hours.

In addition, respondents also spend time on other administrative activities including soliciting laboratory bids, selecting laboratories, monitoring tests under progress, developing cost-sharing agreements, and auditing the laboratories for compliance with EPA's GLPs. EPA has calculated the costs and burdens of these activities as 25 percent of the total laboratory testing costs. Based on this calculation, other administrative costs associated with laboratory testing are estimated to amount to $0.70 million ($0.85 million) under the least (average) cost assumption. These costs are translated into burden estimates using an average labor cost of $55.01 per hour, which is based on a labor mix that is 20 percent managerial, 60 percent technical, and 20 percent clerical. The estimated administrative burden based on this approach is 12,659 (15,543) hours under the least (average) cost assumption.

(2). TSCA Existing Chemicals Testing Program

In addition, last updated on January 17, 2012, EPA maintains a Table[11] on its Website that lists, in ascending Chemical Abstract Service (CAS) Registry number order, all chemical substances and mixtures that are and/or have been the subject of final TSCA Section 4 test rules and/or TSCA Section 4 enforceable consent agreements/orders (ECAs) issued by EPA under the TSCA Existing Chemicals Testing Program. This table currently identifies 86 chemical substances for which testing is either still required or is ongoing or pending. Some of these tests are only required in certain circumstances, such as when production exceeds a certain threshold. EPA considered this in determining the estimates to use in this ICR.

The table includes the sunset (termination) date or other status information for each chemical substance or mixture. When a sunset date is indicated on the table, the TSCA Section 4 testing, reimbursement, reporting, and Section 4 related Section 12(b) export notification requirements terminate on that date. The FR and CFR citations in the table refer to the specific TSCA Section 4 final test rule or announcement of a enforceable consent agreement/order which address the particular chemical substance or mixture for which the sunset date/status column in the table applies. Those chemical substances or mixtures that are the subject of two or more TSCA Section 4 final testing actions may have Section 4 requirements and Section 4-triggered TSCA Section 12(b) export notification requirements that have sunset, as well as TSCA Sections 4 and 12(b) requirements that have not sunset.

[9] 76 FR 65285, October 21, 2011, http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0112-0086.
[10] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0112-0081.
[11] http://www.epa.gov/oppt/chemtest/pubs/sunset.html.

It should be noted that the sunset date for TSCA section 12(b) requirements that are associated with a particular TSCA Section 4 action is the same as the sunset date for that TSCA Section 4 action. TSCA Section 4 final test rules and enforceable consent agreements/orders that have sunset will be removed periodically from the CFR; however, the subject chemical substance or mixture will remain in this table for historical as well as informational purposes.

The Agency plans to use the expanded information contained in this table to revise and update the table that is currently found at 40 CFR 799.18 ("Chemicals subject to test rules or consent orders for which the testing reimbursement period has passed"). It is important to note that TSCA Section 12(b) export notification requirements are also triggered by proposed or final actions issued under TSCA Sections 5, 6 or 7 (see 40 CFR 707 Subpart D for further information regarding the specific TSCA Section 12(b) export notification requirements). This table does **not** reflect the status of Section 12(b) export notification requirements that are triggered by such actions.

(3). Estimated Annual Respondent Costs and Burdens – Existing Testing Requirements

For purposes of this ICR, the estimated annual activities for chemicals covered by existing testing requirements are presented in Table 4.

Table 4: Estimating Annual Activities for Chemicals Covered by a Test Rule

Ref.	Description	See discussion in ICR	Factor	Totals [1]
a	Number of Test Rules Issued[2]	Section 6(b)(i)	6	
	1) HPV 3rd Group of Chemicals	Section 6(b)(i)(1)	1	
	2) Existing Testing	Section 6(b)(i)(2)	5	
b	Chemicals per Rule (max is based on last rule issued)	Section 6(b)(i)	15	
	1) HPV 3rd Group of Chemicals	Section 6(b)(i)(1)	15	
	2) Existing Testing	Section 6(b)(i)(2)	15	
c	Total Number of Chemicals (a × b)			90
d	Number of Chemicals per Sponsor	Section 6(a)(iii)	5	
e	Number of Sponsors per rule (b ÷ d)			3
f	Total Number of Sponsors (a × e)			18
g	Number of Letters of Intent/Study Plans per Sponsor	Section 6(a)(iii)	1	
h	Total Letters of Intent/Study Plans (f × g)			18
i	Number of Short-term Studies per Chemical	Section 6(a)(ii)	7	
j	Total Number of Short-term Studies (c × i)			630
k	Number of Long-term Studies per Chemical	Section 6(a)(ii)	3	
l	Total Number of Long-term Studies (c × k)			270
m	Total Number of Studies per Chemical (i + k)		10	
n	Total Number of Studies Under Test Rules (j + l)			900
o	Number of Semi-annual Progress Reports per Short-term Study Number of Semi-annual Progress Reports per Long-term Study	Section 6(a)(iii) Section 6(a)(iii)	0 5	
p	Total Number of Semi-annual Progress Reports			0

Ref.	Description	See discussion in ICR	Factor	Totals [1]
	per Short-term Study (o x j) Total Number of Semi-annual Progress Reports per Long-term Study (o x l)			1350
q	Number of Final Reports per Study	Section 6(a)(iii)	1	
r	Total Number of Final Reports (n × q)			900
s	Total Number of Robust Summaries [3]			90
t	Total Number of Reports (h + p + r + s)			2358
u	Total Number of Reports per Sponsor (t ÷ f)			131
v	Total Number of Reports per Rule (t ÷ a)			393
w	Total Number of Reports per Chemical (t ÷ c)			26.2

[1] Numbers are rounded - calculations may not appear exact.
[2] To account for the 86 chemicals that are still subject to testing, EPA assumed 5 rules with 15 chemicals a rule.
[3] For test rule submissions, only 10 percent of studies are expected to be accompanied by robust summaries because they are optional.

The burden and cost estimates for those chemicals currently subject to testing has been combined and is presented in Table 5.

Table 5: Estimating Respondent Burden and Costs Under Existing Testing Requirements

Collection Activity	Per Activity [a]			Frequency [b]	Totals [c]		
	Hrs.	Costs ($)			Hrs.	Costs ($)	
		Labor	Non-Labor			Labor	Non-Labor
Interim Reports							
Letter of Intent and Study Plans	40	$2,468.32	$21.91	18	720	$44,430	$394
Prepare Progress Report	8	$493.66	$5.48	1350	10800	$666,441	$7,398
Interim Reports Subtotal (w)	*48*	*$2,961.98*	*$27.39*		*11520*	*$710,871*	*$7,792*
Final Reports							
Short-term Studies							
Record and Prepare Test for Submission	40	$2,468.32	--	630	25200	$1,555,042	--
Laboratory Review	6	$370.25	--	630	3780	$233,258	--
Corporate Review	6	$418.44	--	630	3780	$233,258	--
Type and Print Results	20	$579.62	--	630	12600	$365,161	--
Recordkeeping	1	$28.98	$5.48	630	630	$18,257	$3,452
Short-term Studies Subtotal (x)	*73*	*$3,865.61*	*$5.48*		*45990*	*$2,404,976*	*$3,452*
Long-term Studies							
Record and Prepare Test for Submission	80	$4,936.65	--	270	21600	$1,555,048	--
Corporate Review	9	$627.65	--	270	2430	$197,710	--
Type and Print Results	40	$1,159.25	--	270	10800	$365,164	--
Recordkeeping	1	$28.98	$5.48	270	270	$9,129	$1,480
Long-term Studies Subtotal (y)	*130*	*$6,752.53*	*$5.48*	*270*	*35100*	*$2,127,051*	*$1,480*
Final Reports Subtotal	*203*	*$11,359*	--	*900*	*182700*	*$10,223,100*	--
Robust Summaries (z)	12	$740.50	--	90	1080	*$8,886*	--
TOTAL (w+x+y+z)	*263*	*$14,321*	*$38.35*		*126113*	*$5,242,898*	*$12,724*

[a] See Table #1.
[b] See Table #4.
[c] Calculated as hours/costs x frequency.

(4). IC Entry for Existing Testing Requirements

The information presented in Table 4 will be used to complete the IC entry for this group of collection activities under this ICR.

Table 6: IC Entry: Existing Testing Requirements

IC Field:	**EPA's Estimates:**[a]		
1. Responses:			
Total Number of Respondents (Table 4, item f)	18		
Number of Responses per Respondent (Table 4, item u)	131		
Time Period for Each Response	Annual, on occasion		
Annual Frequency (times per year, per respondent)	131		
Annual Number of Responses (Table 4, item n)	**2,358** [b]		
2. Burden Hours:			
Activities	**Time per Response**	**Hour per Response**	**Annual Hour Burden**
Reporting	262	262	617,796
Recordkeeping	1	1	2,358
Third-party Disclosure	-0-	-0-	
Total Burden Hours:	**263**	**263**	**620,154**
3. Capital and O&M Costs (this does NOT include labor costs):			
Activities		**Cost per Response**	**Annual Cost Burden**
Reporting		$27.39	$64,585.62
Recordkeeping		$10.96	$25,843.68
Third-party Disclosure		-0-	-0-
Total Capital and O&M Costs:		**$38.35**	**$90,429.30**
4. Annual Responses and Burdens:			
Annual Totals		**Total Requested**	
Annual Responses		2,358	
Annual Hour Burden		620,154	
Annual Cost (Non-Labor) Burden		90,429	

[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). Consent Orders, Enforceable Consent Agreements (ECAs) and Voluntary Testing Agreements (VTAs)

Based on historical experience with the TSCA testing program and expected consent order activity over the next three year ICR period, EPA assumes that there would be no more than five consent orders, enforceable consent agreements (ECA) or voluntary testing agreements (VTA) issued during the ICR period. Past consent orders/ECAs/VTAs have covered an average of one to five chemicals. For this ICR, EPA assumes four agreements involving one chemical each.

The specific testing required under future consent orders/ECAs/VTAs cannot be predicted at this time because it is determined on a case-by-case basis. For purposes of the ICR, however, EPA retains

the same assumption used in past ICRs, i.e., each chemical will be evaluated by performing the tests specified in the "Standard" testing battery (see Table 2). The test battery includes 10 studies per chemical (7 short-term, 3 long-term).[12] Each test sponsor must submit one letter of intent and one set of study plans for each chemical; five semi-annual progress reports for each long-term study; and one final report for each study. EPA estimates that 10 percent of the studies completed will be accompanied by a robust summary. These assumptions are used to estimate the burden and costs for consent orders/ECAs/VTAs and are recorded in Table 7.

Table 7: Estimating Annual Costs and Burdens for Testing Agreements

Ref.	Description	See discussion in ICR	Factor	Totals [1]
a	Number of agreement Issued[2]	Section 6(b)(i)	2	
b	Chemicals per agreement	Section 6(b)(i)	1	
c	Total Number of Chemicals (a × b)			2
d	Number of Chemicals per Sponsor	Section 6(a)(iii)	2	
e	Number of Sponsors per agreement (b ÷ d)			1
f	Total Number of Sponsors (a × e)			2
g	Number of Letters of Intent/Study Plans per Sponsor	Section 6(a)(iii)	1	
h	Total Letters of Intent/Study Plans (f × g)			2
i	Number of Short-term Studies per Chemical	Section 6(a)(ii)	7	
j	Total Number of Short-term Studies (c × i)			14
k	Number of Long-term Studies per Chemical	Section 6(a)(ii)	3	
l	Total Number of Long-term Studies (c × k)			6
m	Total Number of Studies per Chemical (i + k)		10	
n	Total Number of Studies Under Test Rules (j + l)			20
o	Number of Semi-annual Progress Reports per Short-term Study Number of Semi-annual Progress Reports per Long-term Study	Section 6(a)(iii) Section 6(a)(iii)	0 2	
p	Total Number of Semi-annual Progress Reports per Short-term Study (o x j) Total Number of Semi-annual Progress Reports per Long-term Study (o x l)			0 12
q	Total Number of Final Reports per Study	Section 6(a)(iii)	1	
r	Total Number of Final Reports (n × q)			20
s	Total Number of Robust Summaries [3]			2
t	Total Number of Reports (h + p + r + s)			36
u	Total Number of Reports per Sponsor (t ÷ f)			18
v	Total Number of Reports per agreement (t ÷ a)			18
w	Total Number of Reports per Chemical (t ÷ c)			18

[1] Numbers are rounded - calculations may not appear exact.
[2] EPA assumed 2 agreements, with 1 chemical per agreement.
[3] For data submissions, only 10 percent of studies are expected to be accompanied by robust summaries because they are optional.

[12] "Short-term studies" are tests that can be concluded in the year they begin; "long-term studies" are concluded within three years.

The burden and cost estimates for potential future testing agreements is presented in Table 8.

Table 8: Estimating Respondent Burden and Costs for Testing Agreements

Collection Activity	Per Activity [a]			Frequency [b]	Totals [c]		
	Hrs.	Costs ($)			Hrs.	Costs ($)	
		Labor	Non-Labor			Labor	Non-Labor
Interim Reports							
Letter of Intent and Study Plans	40	$2,468.32	$21.91	2	80	$12,342	$110
Prepare Progress Report	8	$493.66	$5.48	12	96	$123,415	$1,370
Interim Reports Subtotal (w)	*48*	*$2,961.98*	*$27.39*		*176*	*$135,757*	*$1,480*
Final Reports							
Short-term Studies							
Record and Prepare Test for Submission	40	$2,468.32	--	14	560	$34,556	--
Laboratory Review	6	$370.25	--	14	84	$5,184	--
Corporate Review	6	$418.44	--	14	84	$5,858	--
Type and Print Results	20	$579.62	--	14	280	$8,115	--
Recordkeeping	1	$28.98	$5.48	14	14	$406	$77
Short-term Studies Subtotal (x)	*73*	*$3,865.61*	*$5.48*		*1022*	*$53,373*	*$77*
Long-term Studies							
Record and Prepare Test for Submission	80	$4,936.65	--	6	480	$29,620	--
Corporate Review	9	$627.65	--	6	54	$3,766	--
Type and Print Results	40	$1,159.25	--	6	240	$6,956	--
Recordkeeping	1	$28.98	$5.48	6	6	$174	$33
Long-term Studies Subtotal (y)	*130*	*$6,752.53*	*$5.48*	*6*	*780*	*$40,516*	*$33*
Final Reports Subtotal	*142*	*$11,359*	--	*20*	*2840*	*$227,180*	--
Robust Summaries (z)	12	$740.50	--	2	24	*$1,481*	--
TOTAL (w+x+y+z)	*263*	*$14,321*	*$38.35*		*1978*	*$229,646*	*$1,590*

[a] See Table #1.
[b] See Table #7.
[c] Calculated as hours/costs x frequency.

The information presented in Table 9 will be used to complete the IC entry for this group of collection activities under this ICR.

Table 9: IC Entry: Testing Agreements

IC Field:	EPA's Estimates:[a]		
1. Responses:			
Total Number of Respondents (Table 7, item f)	2		
Number of Responses per Respondent (Table 7, item u)	18		
Time Period for Each Response	Annual, on occasion		
Annual Frequency (times per year, per respondent)	18		
Annual Number of Responses	**36** [b]		
2. Burden Hours:			
Activities	**Time per Response**	**Hour per Response**	**Annual Hour Burden**
Reporting	262	262	9432
Recordkeeping	1	1	36
Third-party Disclosure	-0-	-0-	-0-

Total Burden Hours:	**263**	**263**	**9,468**
3. Capital and O&M Costs (this does NOT include labor costs):			
Activities		**Cost per Response**	**Annual Cost Burden**
Reporting		27.39	$986.04
Recordkeeping		$10.96	$394.56
Third-party Disclosure		0	0
Total Capital and O&M Costs:		**$38.35**	**$1,381**
4. Annual Responses and Burdens:			
Annual Totals		**Total Requested**	
Annual Responses		36	
Annual Hour Burden		9468	
Annual Cost (Non-Labor) Burden		$1,381	

[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). Voluntary Submission

There is no way for the Agency to predict potential voluntary submissions. For purposes of this ICR, EPA assumes at least one voluntary submission annually. Since such a submission is unrelated to any agreement or other testing requirement, EPA assumed that these submissions involve the activities related to submitting the final reports and recordkeeping. EPA also assumed that 10 percent of the studies submitted will be accompanied by a robust summary. These assumptions are used to estimate the burden and costs for such voluntary submissions and are recorded in Table 10.

Table 10: Estimating Annual Costs and Burdens for Voluntary Testing Submissions

Ref.	Description	See discussion in ICR	Factor	Totals [1]
a	Number of Voluntary Submissions[2]	Section 6(b)(i)	1	
b	Chemicals per Voluntary Submissions	Section 6(b)(i)	1	
c	Total Number of Chemicals (a × b)			1
d	Number of Chemicals per Sponsor	Section 6(a)(iii)	1	
e	Number of Sponsors per Voluntary Submissions (b ÷ d)			1
f	Total Number of Sponsors (a × e)			1
g	Total Number of Final Reports	Section 6		10
h	Number of Robust Summaries [3]			1
i	Total Number of Reports (g + h)			11

[1] Numbers are rounded - calculations may not appear exact.
[2] EPA assumed 1 chemical per submission.
[3] For data submissions, only 10 percent of studies are expected to be accompanied by robust summaries because they are optional.

The burden and cost estimates for future voluntary submissions are presented in Table 11.

Table 11: Estimating Respondent Burden and Costs for Voluntary Submissions

Collection Activity	Per Activity [a]			Frequency [b]	Totals [c]		
	Hrs.	Costs ($)			Hrs.	Costs ($)	
		Labor	Non-Labor			Labor	Non-Labor
Robust Summaries	12	$740.50	--	1	12	$740.50	--

Collection Activity	Per Activity [a]			Frequency [b]	Totals [c]		
	Hrs.	Costs ($)			Hrs.	Costs ($)	
		Labor	Non-Labor			Labor	Non-Labor
Submission of Final Reports	10	$289.80	--	11	110	$3,187.80	--
Recordkeeping	1	$28.98	$5.48	11	11	$318.78	$60.28
TOTAL	*23*	*$570.84*	*$5.48*		*133*	*$4,247.08*	*$60.28*

[a] See Table #1.
[b] See Table #10.
[c] Calculated as hours/costs x frequency.

The information presented in Table 12 will be used to complete the IC entry for this group of collection activities under this ICR.

Table 12: IC Entry: Voluntary Submissions

IC Field:	**EPA's Estimates:[a]**		
1. Responses:			
Total Number of Respondents (Table 10, item f)	1		
Number of Responses per Respondent (Table 10, item i)	11		
Time Period for Each Response	On occasion		
Annual Frequency (times per year, per respondent)	1		
Annual Number of Responses	11		
2. Burden Hours:			
Activities	**Time per Response**	**Hour per Response**	**Annual Hour Burden**
Reporting	22	22	242
Recordkeeping	1	1	11
Third-party Disclosure	0	0	0
Total Burden Hours:	**23**	**23**	**253**
3. Capital and O&M Costs (this does NOT include labor costs):			
Activities		**Cost per Response**	**Annual Cost Burden**
Reporting		0	0
Recordkeeping		$5.48	$60.28
Third-party Disclosure		0	0
Total Capital and O&M Costs:		**$5.48**	**$60.28**
4. Annual Responses and Burdens:			
Annual Totals		**Total Requested**	
Annual Responses		11	
Annual Hour Burden		253	
Annual Cost (Non-Labor) Burden		$60.28	

[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). 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 to EPA an application to be exempt from a testing requirement imposed by a test rule. The first scenario involves a company who manufacturers the covered chemical for TSCA uses, but will not be submitting the data because, for example, they joined a consortium and the consortium is expected to submit the data. The second scenario involves a company that 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. For purposes of this ICR, EPA has assumed that at least 2 applications would be submitted each year; that each application would involve at least 1 chemical; and that the application would involve a request for an exemption from all of the testing. EPA will evaluate these assumptions with the next renewal, making adjustments warranted by the Agency's experience over the next two years.

These assumptions are used to estimate the burden and costs for an entity subject to a testing requirement to apply for an exemption from that requirement, and are recorded in Table 13.

Table 13: Estimating Annual Costs and Burdens for Testing Exemptions Applications

Ref.	Description	See discussion in ICR	Factor	Totals
a	Number of Exemption Applications[2]	Section 6(b)(i)	2	
b	Chemicals per Exemption Application	Section 6(b)(i)	1	
c	Total Number of Chemicals (a × b)			2
d	Number of Chemicals per Sponsor	Section 6(a)(iii)	1	
e	Number of Sponsors per Application (b ÷ d)			1
f	Total Number of Sponsors (a × e)			2

[1] Although history does not provide an annual estimate, EPA assumed 2 applications, with 1 chemical each.

The burden and cost estimates for potential future testing exemption applicants are presented in Table 14.

Table 14: Estimating Respondent Burden and Costs for Testing Exemptions Applications

Collection Activity	Per Activity [a]			Frequency [b]	Totals [c]		
	Hrs.	Costs ($)			Hrs.	Costs ($)	
		Labor	Non-Labor			Labor	Non-Labor
Exemption Application							
Prepare Exemption Application	2	$123.42	--	2	4	$493.68	--
Corporate Review	6	$418.44	--	2	12	$836.88	--
Recordkeeping	1	$28.98	$5.48	2	2	$57.96	$10.96
TOTAL	*9*	*$570.84*	*$5.48*		*18*	*$1,388.52*	*$10.96*

[a] See Table #1.
[b] See Table #13.
[c] Calculated as hours/costs x frequency.

The information presented in Table 15 will be used to complete the IC entry for this group of collection activities under this ICR.

Table 15: IC Entry: Testing Exemptions Applications

IC Field:	EPA's Estimates:[a]
1. Responses:	
Total Number of Respondents (Table 13, item f)	2

Number of Responses per Respondent (Table 13, item d)	1		
Time Period for Each Response	Annual, on occasion		
Annual Frequency (times per year, per respondent)	1		
Annual Number of Responses	**2** [b]		
2. Burden Hours:			
Activities	**Time per Response**	**Hour per Response**	**Annual Hour Burden**
Reporting	8	8	16
Recordkeeping	1	1	2
Third-party Disclosure	0	0	0
Total Burden Hours:	**9**	**9**	**18**
3. Capital and O&M Costs (this does Not include labor costs):			
Activities		**Cost per Response**	**Annual Cost Burden**
Reporting		0	0
Recordkeeping		$5.48	$10.96
Third-party Disclosure		0	0
Total Capital and O&M Costs:		**$5.48**	**$10.96**
4. Annual Responses and Burdens:			
Annual Totals		**Total Requested**	
Annual Responses		2	
Annual Hour Burden		18	
Annual Cost (Non-Labor) Burden		$11	

[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 section 4 test rules, consent orders and agreements, and voluntary testing programs are discussed below and detailed in Table 1.

The Agency collection procedures are estimated to be accomplished, on average, by a GS-13, Step 1 employee. The annual 2010 loaded cost of a full-time equivalent (FTE) for this level employee is $142,453. This includes a base wage of $89,033 plus 60 percent for overhead and benefits (i.e., $53,420). Dividing this value by 2,080 (i.e., the number of hours in a work year) results in an hourly wage rate of $68.48 (see the Attachment 5 for the derivation of these figures).

AGENCY LABOR CATEGORY	LOADED HOURLY RATE ($2010)
GS-13, Step 1	$68.48

The estimated unit Agency burden of processing letters of intent and study plans (three hours), progress reports (one hour), and final reports (five hours) is derived from the previous ICRs and is believed to be reflective of the time required for each activity. This information is presented in Table 6. It takes approximately one hour for the Agency to process and review each exemption application and 16 hours for the Agency to enter study plans and results into the HPV Information System (HPVIS). The total annual Agency costs and burden for processing letters and reports is $175,298.48 and 2,560 hours,

or approximately 1.2 FTEs per year, where one FTE is equivalent to 2,080 hours per year. There are no exemptions associated with these actions and therefore no associated cost or burden.

Table 16: Annual Agency Cost and Burden Estimates

Collection Activity	Unit Labor			Unit Supply Costs	Total Annual Items	Grand Total	
	Hours	Rate	Cost			Hours	Costs
Letter of Intent and Study Plans	3	$68.48	$205.44	0	1	3	$205.44
Progress Reports	1	$68.48	$68.48	0	100	100	$6,848.00
Final Reports	5	$68.48	$342.4	0	67	103	$22,940.80
HPVIS Data Entry	16	$68.48	$1095.68	0	7	112	$7,669.76
Robust Summary	1	$68.48	$68.48	0	7	7	$458.82
SUBTOTAL					**182**	**557**	**$38,122.82**
Exemptions	1	$68.48	$68.48	0	0	0	$0
TOTAL					**182**	**557**	**$38,122.82**

6(d). Bottom Line Burden Hours and Costs

6(d)(i). TOTAL Respondent Annual Hours and Costs

Table 17 summarizes the estimated annual burden and cost per response. EPA estimates that this ICR will impose a total of 629,893 burden hours on respondents annually, with a per response burden hour between 9 and 263 hours. The total estimated burden hour costs are $13,289,461, with an additional $9,628,441 for non-labor costs related to laboratory test costs, and a per response cost between $571 and $14,321 for burden hour activities, and between $5 and $953,656 for non-labor activities.

Table 17: Estimated Total Annual Respondent Burden Hours & Costs

Collection Activity	Per Activity [a]			Frequency [b]	Totals [c]		
	Hrs.	Costs ($)			Hrs.	Costs ($)	
		Labor	Non-Labor			Labor	Non-Labor
Testing Requirements							
Reporting	262	$14,292	$27.39	2,358	617,796	$12,862,800	$64,585.62
Recordkeeping	1	$28.98	$10.96		2,358	$28.98	$25,843.68
+ Subtotal	**263**	**$14,321**	**$38.35**		**620,154**	**$12,862,828**	**$90,429**
Testing Agreements							
Reporting	262	$14,292	$27.39	36	9432	$285,840	$986.04
Recordkeeping	1	$28.98	$10.96		36	$580	$394.56
+ Subtotal	**263**	**$14,321**	**$38.35**		**9468**	**$286,420**	**$1,381**
Voluntary Testing Submissions							
Reporting	22	$542	-0-	11	242	$131,164	-0-
Recordkeeping	1	$28.98	$5.48		11	$319	$60
+ Subtotal	**23**	**$571**	**$5**		**253**	**$131,483**	**$60**
Exemptions Applications							
Reporting	8	$542	-0-	2	16	$8,672	-0-
Recordkeeping	1	$28.98	$5.48		2	$58	$10.96
+ Subtotal	**9**	**$571**	**$5**		**18**	**$8,730**	**$11**
Laboratory Costs							

Collection Activity	Per Activity [a]			Frequency [b]	Totals [c]		
	Hrs.	Costs ($)			Hrs.	Costs ($)	
		Labor	Non-Labor			Labor	Non-Labor
+ Subtotal	**-0-**	**-0-**	**$953,656**	**10**	**-0-**	**-0-**	**$9,536,560**
TOTALs	***558***	***$29,784***	***$953,743***		***629,893***	***$13,289,461***	***$9,628,441***

[a] See Table #1.
[b] Total # respondents x annual # responses = Annual Number Responses (See Tables # 6, 9, 12, 15).
[c] Calculated as hours/costs x frequency.

6(d)(ii). TOTAL Agency Annual Hours and Costs

The total annual burden hours and costs for the government were derived in Table 16 and are summarized below in Table 18.

Table 18: Summary of Annual Agency Burden and Costs Estimates

Collection Activity	Total Agency Burden and Costs	
	Hours	Cost
Reporting Activities		
Letters of Intent/Study Plans	3	$205
Progress Reports	100	$6,848
Final Reports	335	$22,941
HPVIS Data Entry	112	$7,670
Robust Summary	7	$459
Exemptions	0	$0
TOTAL	**557**	**$38,123**

6(e). Reasons for Change in Burden

This request represents an increase of 477,931 hours from that currently in the OMB inventory (from 151,962 hours to 629,893 hours). This increase reflects several adjustments in the estimates related to a better break-out of the different activities for the covered collection and an adjustment in projected potential future activities. Specifically, the methodology used in this ICR was changed to better reflect the break-out of the different collection activities covered under Section 4 of TSCA, as well as mirror the designated information collections in the system used for submitting the ICRs to OMB for approval. Moreover, this ICR covers TSCA section 4 test rules that were promulgated as of January 1, 2012, including the *Final Section 4 Test Rule for Certain High Production Volume Chemicals; Third Group of Chemicals,* which was promulgated on October 21, 2011.

The methodology and assumptions used in this ICR were modified to more closely reflect the methodology and assumptions used in the final test rule. The previous ICR assumed a total of 3 testing orders and agreements, covering 5, 67 and 9 chemicals, respectively. This ICR divides the discussion into the different categories of information collection activities covered under TSCA section 4 in order to better explain the number of responses expected under existing testing requirements (i.e., test rules – mainly the *Final Section 4 Test Rule for Certain High Production Volume Chemicals; Third Group of Chemicals);* future testing agreements in the form of Consent Orders, ECAs, or VTAs; voluntary submissions; and exemption applications.

The primary reason for the dramatic increase in the number of total responses expected under this ICR is due to the adjustments made by including in this ICR the responses expected to be submitted

to the Agency as a result of the *Final Section 4 Test Rule for Certain High Production Volume Chemicals; Third Group of Chemicals.*

The Agency has also adjusted all unit costs to reflect the latest available labor wage rates and has identified the non-labor costs more clearly.

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 9 and 263 hours per response. Burden is defined in 5 CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a 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-2010-1010, 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.

Submit your comments, referencing Docket ID No. EPA-HQ-OPPT-2010-1010 and OMB Control No. 2070-0033, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Document Control Office (DCO), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Mail Code: 7407T, 1200 Pennsylvania Ave., NW, Washington, D.C. 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

7. 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-2010-1010.** These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described below.

Attachment 1: 15 U.S.C. 2603, Toxic Substances Control Act (TSCA), Section 4
(Also available at http://epw.senate.gov/tsca.pdf.)

Attachment 2: 40 CFR 790, Procedures Governing Testing Consent Agreements and Test Rules
(Also available at
http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title40/40cfr790_main_02.tpl.)

Attachment 3: Copy of Public Comment Received During Public Notice and Comment Period

Attachment 4: Copy of Consultations Message Sent by EPA to Potential Respondents

Attachment 5: Wage Rates Used in this ICR
(This document follows below - at the end of the electronic file for the ICR.)

ATTACHMENT 5

Wage Rates Used in this ICR

Wage Rates Used in this ICR

Table A: Industry Wage Rates (December 2010)						
Labor Category	**Wage ($/hour)[1]**	**Fringe Benefits ($/hour)[1]**	**Fringes as % Wage**	**Overhead % Wage[2]**	**Fringe + Overhead Factor**	**Loaded Wages ($/hour)**
	(a)	**(b)**	**(c) = (b)/(a)**	**(d)**	**(e)=(1)+(c)+(d)**	**(f) = (a) x (e)**
Managerial	$42.82	$19.64	45.87%	17%	1.63	$69.74
Technical	$36.93	$18.50	50.09%	17%	1.67	$61.71
Clerical	$17.36	$8.67	49.94%	17%	1.67	$28. 98
Weighted Average[3]	--	--	--	--	--	$56.77

Notes:
[1]Employer Costs for Employee Compensation Supplementary Tables: December 2010, US Bureau of Labor Statistics, March 9, 2011 (BLS, 2011a)
[2]An overhead rate of 17 percent was estimated based on industry data gathered for the Revised Economic Analysis for the Amended Inventory Update Rule: Final Report (EPA, 2002a)
[3] The weighted average wage reflects an assumed 20/60/20 mix of managerial/technical/clerical labor.

Table A presents the derivation of the industry wages for 2010 used in this ICR.

Table presents the derivation of the Agency wage rates for 2010 used in this ICR.

Table B: Agency Wage Rate for GS-13 Step 1 (January 2010)							
Labor Category	**Data Source for Wage Information**	**Wage ($)**	**Fringe Benefit**	**Fringes as % wage**	**Overhead as % wage**	**Fringe + Overhead Factor**	**Loaded Wage ($)**
		(a)	**(b)**	**(c) = (b) / (a)**	**(d)**	**(e) = (c) + (d) + 1**	**(f) = (a) * (e)**
EPA staff FTE	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-14 Step 5 pay rates [a]	$89,033 (annual)	--	[Included in 60% overhead]	60% [b]	1.6	$142,453 (annual)
		$42.80 (hourly)					$68.48 (hourly)

Notes:
[a]The Agency salary is the unloaded federal GS-13 Step 1 salary ($89,033 for 2010), from the OPM salary table for the Washington-Baltimore-Northern Virginia Locality Pay Area (OPM, 2010). Hourly rates are based on annual salary divided by 2,080 hours.
[b]The 60 percent fringes-and-overhead rate is from an EPA guide, *Instructions for Preparing ICRs* (EPA, 1992).