Supporting Statement for a Request for OMB Review
Under the Paperwork Reduction Act

1 IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Number of the Information Collection

Title: TSCA Section 4 Test Rules, Consent Orders, Test Rule Exemptions, and Voluntary Data Submission

EPA ICR No.: 1139.08 OMB Control No.: 2070-0033

1(b) Short Characterization

This data collection program is designed to provide the Environmental Protection Agency (EPA) with necessary test 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. Section 4 of the Toxic Substances Control Act (TSCA)(see Attachment 1) provides the authority for collecting these test data, and is intended to ensure that chemicals that may pose serious risks to human health or the environment undergo testing by manufacturers or processors, and that the results of such testing are made available to EPA. EPA uses the information collected to assess risks associated with the manufacture, processing, distribution, use or disposal of a chemical, and to support any necessary regulatory action with respect to that chemical.

The Chemical Testing Program in EPA's Office of Pollution Prevention and Toxics (OPPT) also works with members of the U.S. chemical industry and other interested parties to develop needed data via TSCA Section 4 Enforceable Consent Agreements (ECAs) and consent orders and Voluntary Testing Agreements (VTAs). ECAs and VTAs are usually less resource intensive than formal TSCA rulemaking and allows 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/opptintr/chemtest/index.htm.)

In addition to developing actions 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). At the present time, EPA anticipates that data gathered by activities conducted during this ICR renewal period will be used, in addition to those above, by other agencies, including the Occupational Safety and Health Administration (OSHA) and the Organization for Economic Cooperation and Development (OECD).

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, or any testing identified in the voluntary High Production Volume (HPV) Challenge Program, 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)(see Attachment 2), while response to a consent order issued under TSCA section 4 is only mandatory for participants in the ECA. Participating in a VTA is 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) mandates that EPA require manufacturers and processors of chemical substances and mixtures to conduct testing if it finds that:

> "(1)(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 Interagency Testing Committee (ITC) places on the TSCA §4(e) "Priority Testing List." The ITC is an independent advisory committee to the EPA Administrator that includes 16 U.S. Government organizations. The ITC was created under TSCA §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(b) Use/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 scientists, professional industrial hygienists, other occupational health professionals and workers for hazard communication and right-to-know purposes, including Material Safety Data Sheets (MSDSs), and product labels.

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 "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. Screening efforts to identify priorities and determine testing needs for other chemicals are currently underway in OPPT.

3 NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

3(a)(1) Test Rules and Consent Orders

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.

3(a)(2) Exemptions

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(a)(3) HPV Voluntary Challenge Programs

EPA has searched the publicly-available scientific data bases for screening-level hazard and fate test data for those chemicals included in the HPV Voluntary Challenge Program and held meetings with public interest groups and industry.

Industry sponsors of chemicals in the Program also search publicly-available data bases as well as unpublished sources for the screening-level hazard and fate test data that are the subject of the Program. Consequently, any new test data that are developed and/or submitted as a result of the Program are unlikely to be duplicative.

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 January 14, 2008 (72 FR 64075, November 14, 2008). EPA received two non-substantive comments, one from the American Chemistry Council (ACC) and the other from an anonymous individual. The comments appear as Attachment 4 to this Supporting Statement.

3(c) Consultations

The Agency has issued two procedural rules on the test rule development and exemption process (October 1984 and May 1985) and one procedural rule on the consent order process (June 1986) that describe the information collection requirements for test rules and consent orders. Of particular note, the Agency held a series of public meetings at the request of the ACC (formerly the Chemical Manufacturers Association) and Environmental Defense (ED) (formerly the Environmental Defense Fund) during the spring and summer of 1985 to develop the consent order process. In addition to the procedural rules, each individual test rule solicits comment on the information collection requirements.

Previous commenters on EPA's information gathering requirements under test rules, consent orders, and the exemption process have included numerous representatives of the chemical industry, environmental groups and the public at large. A number of issues were discussed including the schedule for the test rule and consent order process, what constitutes confidential information, how EPA should provide guidance for submission of equivalence data, how the Agency will provide standards for development of test data, enforceability of consent orders, and how to make consent orders equivalent to test rules.

In addition to the public notice and comment period required by the Paperwork Reduction Act (PRA), OMB regulations at 5 CFR 1320.8(d)(1) also require agencies to consult

with potential ICR respondents and data users about specific aspects of an ICR before the agency submits the ICR to OMB for review and approval. In accordance with this regulation, EPA solicited comments from the following potential respondents and data users with respect to the renewal of this ICR:

Kathleen Roberts
American Chemistry Council
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Susan Hearn
Dow Chemical
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Jessine Monaghan
General Electric
jessine.monaghan@ge.com

Derek Swick
API
swickd@api.org

Richard Denison
Environmental Defense
rdenison@environmentaldefense.org

Douglas Fratz
Consumer Specialty Products Association
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Tom Neltner
Improving Kids' Environment
neltner@ikecoalition.org

Jennifer Sass
National Resources Defense Council
jsass@nrdc.org

Bill Almond
Synthetic Organic Chemical Manufacturers Association
info@socma.com

EPA received no responses from this solicitation for comments. A copy of EPA's outgoing communication appears as Attachment 5 to this Supporting Statement.

3(d) Effects of Less Frequent Collection

Test rules and consent orders require the test sponsor to submit a letter notifying EPA who will be conducting the testing, study plans before beginning testing, and a final report of the study results. Each exemption applicant is required to submit an exemption application. Less frequent information collection would jeopardize EPA's ability to ensure that testing is being conducted in accordance with the rules and consent orders, and to grant exemptions from test rules.

3(e) General Guidelines

The data retention requirements for test rules and consent orders exceed one of the PRA guidelines established at 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. 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 the Agency's action may be challenged, it is imperative that all records, raw data, and specimens be available to support the Agency's decision.

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. EPA, for purposes of the HPV Challenge Program, has also discouraged the submission of CBI material. If respondents wish to claim information submitted in response to a test rule or consent order 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

The information requested does not include information of a sensitive nature other than CBI, which is discussed above.

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:

Type of Entity	NAICS	Examples 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).

In addition to submitting specified test data to EPA, respondents may also need to submit letters of intent, study plans and progress reports, or exemption applications. Respondents must also maintain certain records related to testing activities.

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.

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

Test Rules And Consent Orders - EPA promulgates a rule or consent order 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 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.

Exemptions - Information collection authorized by section 4(c) of TSCA is designed to reduce the burden of duplicative testing under test rules. Test rules generally require testing of only a single representative chemical substance and all chemicals subject to the test rule are assumed equivalent to it. Exemption applicants are required to submit only that information necessary to establish the identity of the applicant and the test requirements from which the exemption is being requested. In those few cases in which more than one representative substance is to be tested under a test rule, exemption applicants will also be required to submit data showing to which of these representative substances their chemical is equivalent. The type of data needed may vary with the chemical being tested, and will be described in detail in each individual test rule.

HPV Voluntary Challenge Program - The HPV Challenge Program is a voluntary initiative under which manufacturers of HPV chemicals voluntarily develop and submit certain OECD screening level studies for the chemicals they manufacture. Although the data submissions are voluntary, EPA believes that the development and/or submission of such data represent costs and burdens not captured in existing information collections.

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:

- Determine whether the data are relevant;
- Prepare and review summary of existing data; and
- Submit summary of existing data to EPA.

(c) Submit "Letter of Intent" to EPA or an application for an exemption.
(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.

These response activities may vary based on the type of testing activity:

Test Rules and Consent Orders - Test rules and consent orders require test sponsors 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.

Exemptions - *Test Rules*. 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.

Consent Orders. Exemption applications are not necessary for chemicals being tested under consent orders because the consent order process inherently eliminates duplicative testing.

HPV Voluntary Challenge Program. Exemption applications are not necessary for chemicals being tested under the HPV Voluntary Challenge Programs. However, companies may submit relevant information pertaining to the production volume for chemicals that EPA believes are produced or imported in substantial amounts. Based on this information, EPA may de-list a chemical. That is to say, companies may submit information that indicates that specific chemicals are not produced in substantial quantities and, therefore, testing of these chemicals is not necessary for purposes of this Program. Based on a review of the information submitted, EPA may remove a chemical from the list of HPV chemicals according to guidance on the HPV website at www.epa.gov/chemrtk.

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

5(a) Agency Activities

Data collected under TSCA section 4 test rules and consent orders are received by the Office of Pollution Prevention and Toxics (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. Similarly, data received under the HPV Voluntary Challenge Program will be reviewed as described above for purposes of developing preliminary hazard characterizations for those chemicals. If the HPV 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.

In order to sustain this Program, the EPA must undertake the following applicable 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 ECAs and VTAs.

In addition to the activities cited above the Agency maintains a facility inspection and test data audit program to ensure testing is done in compliance with GLPs, and may also participate in other activities related to this program, e.g., other voluntary efforts to identify data gaps and develop test data, efforts to establish test guidelines or standards that may be used in the 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. Information about the data collection/management activities specifically regarding the HPV Chemical Challenge Program is presented at the end of this discussion

It is also important to note that the TSCA Chemical Testing Program is an integral component of OPPT's TSCA existing and new chemicals programs. These programs are

responsible for assessing and managing 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.

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).

HPV Challenge Program

Public access to hazard data is integral to the HPV Challenge Program. Test plan and data summary submissions, sponsor commitment information, chemical lists, guidance documents, and other materials can be found at the HPV Challenge Program web site (http://www.epa.gov/hpv). EPA continues to enter sponsor-submitted HPV Challenge Program data into the HPV Information System (HPVIS), which is a comprehensive, online, data-searchable application for HPV chemical information (http://www.epa.gov/hpvis/index.html). This system allows users to thoroughly search across all test-plan and data summary materials – including the data presented within and among data summaries. Once HPVIS is fully populated with HPV Challenge Program data, then the system can be used for producing endpoint statistics and prioritizing chemicals for review.

The HPV Challenge Program has nearly completed its sponsor-submitted data collection effort. The Agency has received data submissions for 1,357 (98%) of the 1,385 chemicals that were sponsored directly in the Program as of May 2007, and expects to receive data for the

remaining 28 (2%) chemicals. EPA also continues to receive revised submissions from sponsors, in an effort to eliminate data gaps.

Other current HPV Challenge Program efforts focus on reviewing submitted HPV chemical data for quality and completeness, and preparing summary reports for the public that will outline any hazards associated with HPV chemicals. Based upon review findings, EPA will determine whether Agency actions are required to protect human health and the environment from risks posed by HPV chemicals.

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

Overview

The methodology used in estimating the annual burden and costs to industry resulting from TSCA section 4 test rules, consent orders and agreements, and voluntary submissions over the next three years is based on EPA's most recent cost and burden estimates. These have been combined with current information concerning the number and type of TSCA section 4 test rules under development, estimates of the potential number of consent orders and agreements, and the current and anticipated level of industry participation in the voluntary HPV Challenge Program, 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. 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.

Additional data collection efforts beyond those identified in this ICR may be conducted during the three year ICR period, but the extent of such activities cannot be projected at this time. For example, although the Agency anticipates the need to issue test rules for HPV chemical data needs that remain unaddressed by the voluntary HPV Challenge Program, this ICR assumes that most of the HPV chemicals will be captured by the voluntary program. If, in the context of a rulemaking, the Agency determines that the total annual burden covered by this ICR needs to be increased, it will submit a revision to the ultimately approved collection in order to account for any increase in the total annual burden in the OMB inventory.

The following sections explain the assumptions and methods that were used to estimate the burden and costs for this ICR, along with a summary of the cost and burden calculations.

6(a) Respondent Cost and Burden

Consent Orders and Enforceable Consent Agreements

Based on historical experience with the TSCA testing program and expected consent order activity over the three year ICR period, EPA assumes that one consent order or enforceable consent agreement (ECA) will be issued per year for a total of three consent orders/agreements issued during the ICR period. Past consent orders and agreements have covered an average of one to five chemicals. For this ICR, EPA assumes five chemicals will be covered by each order/agreement.

The testing required under future consent orders or agreements cannot be predicted and will be determined on a case by case basis. For purposes of the ICR, EPA assumes as in past ICRs that each chemical will be evaluated by performing the tests specified in a "Standard" testing battery (see Table 1). The test battery includes 10 studies per chemical (7 short term, 3 long term).[1] 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% of the studies completed will be accompanied by a robust summary. These assumptions are used to estimate the costs and are recorded in Table 3.

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 2006 dollars using the Bureau of Labor Statistics' Employment Cost Index (ECI) and are shown in Table 1. The mean cost of the "Standard" battery is $1,287,890.[2]

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 $3,500 and $8,500 respectively, based on typical costs cited by industry experts (Piccirillo, 2004). Total validation costs for the testing battery are $50,000, resulting in a total laboratory cost of $1,337,890.

Exemption applications are not necessary for chemicals being tested under consent orders because the consent order process inherently eliminates duplicative testing.

Table 1. TSCA Section 4 "Standard" Testing Battery Costs

	Test Protocol Name	Protocol Number	Date of Estimate	Mean Cost Estimate ($2006)a	Validation Costs ($2006)
1	Algal Acute Toxicity	797.1050	8/3/1990	$26,454	$3,500
2	Daphnid Acute Toxicity	797.1300	4/25/1996	$10,251	$3,500
3	Fish Acute Toxicity	797.1400	4/25/1996	$20,814	$3,500
4	Gene Mutations in Somatic Cells	798.5300	8/16/1994	$22,962	$3,500
5	Subchronic Oral Toxicity	870.3100	9/3/1996	$169,884	$3,500
6	Prenatal Developmental Tox. (2 species)	870.3700	8/27/1996	$130,453	$8,500
7	Reproduction/Fertility Effects	870.3800	8/27/1996	$673,124	$8,500
8	Salmonella Reverse Mutation Assay	870.5265	9/16/1996	$8,448	$3,500
9	In vivo Bone Marrow Cytogenetics	870.5395	2/27/1997	$17,683	$3,500

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

[2] The laboratory cost is considered part of the sponsor's overall cost.

Table 1. TSCA Section 4 "Standard" Testing Battery Costs

	Test Protocol Name	Protocol Number	Date of Estimate	Mean Cost Estimate ($2006)a	Validation Costs ($2006)
10	Developmental Neurotoxicity	870.6300	8/27/1996	$207,816	$8,500
	Subtotal			$1,287,890	$50,000
	TOTAL			**$1,337,890**	

a Where multiple versions of a test have been costed by EPA (e.g., covering different species or routes of exposure), the mean cost estimate is used. All test costs updated to 2006 dollars.

Source: U.S. EPA, Office of Pollution Prevention and Toxics, Economic and Policy Analysis Branch.

Voluntary Programs

This ICR also incorporates estimates of the burdens and costs associated with the voluntary component of the HPV chemicals testing program launched in 1998.[3] Under the HPV Challenge Program manufacturers of chemicals targeted for testing agree voluntarily to submit data on certain hazard, physical/chemical property, and environmental fate endpoints. EPA would exclude any chemicals enrolled in the Program from its planned section 4 test rules and would provide recognition to Program participants for their voluntary actions.

Table 2 shows the full set of endpoints to be submitted under the HPV Challenge Program. The testing suite is based on the Tier I tests from the OECD Screening Information Data Set (SIDS). The Tier I battery includes 16 endpoints. Following the approach used in the previous ICR, EPA assumes that industry participation in the voluntary HPV Challenge Program will result in new testing to satisfy an average of one additional endpoint per sponsored chemical during the first year of this ICR for those chemicals for which a test plan has been submitted. The cost per endpoint is recorded in Table 2 and ranges from $129 for the transportation/distribution endpoint (which is modeled) to $125,861 for the repeated-dose test with reproductive and developmental toxicity.

[3] HPV chemicals are those manufactured in, or imported to, the United States in annual quantities of one million pounds or more. The HPV Challenge Program covered 2,782 chemicals at its launch in 1998.

Table 2. TSCA Section 4 ICR SIDS Tier I (HPV) Testing

	Test Protocol Name	Protocol Number	Mean Cost Estimate ($2006)a	Validation Costs
1	Melting Point	OECD 102	$1,547	$0
2	Boiling Point	OECD 103	$1,580	$0
3	Vapor Pressure	OECD 104	$9,434	$0
4	Water Solubility	OECD 105	$6,594	$0
5	Partition Coefficient (shake flask)	OECD 107	$6,730	$0
	SUBTOTAL		**$25,885**	**$0**
6	Photo-degradation	OECD 113	$9,785	$0
7	Inherent Biodegradation	OECD 302	$14,160	$0
8	Stability in Water	OECD 111	$59,589	$0
9	Transportation/Distribution	EQC Model	$129	$0
	SUBTOTAL		**$83,664**	**$0**
10	Acute Toxicity to Aquatic Plants	OECD 201	$9,845	$3,500
11	Acute Toxicity to Fish	OECD 203	$10,910	$3,500
12	Acute Toxicity to Daphnia OR	OECD 202(I)	$5,419	$3,500
	Chronic Toxicity to Daphnia	850.1300	$38,961	$8,500
	SUBTOTAL (AVERAGE)		**$42,945**	**$13,000**
13	Acute Oral Toxicity OR	OECD 401	$3,799	$3,500
	Acute Dermal Toxicity OR	OECD 402	$5,127	$3,500
	Acute Inhalation Toxicity	OECD 403	$13,290	$3,500
	SUBTOTAL		**$7,405**	**$3,500**
14	Genetic Toxicity (Salmonella)	OECD 471	$7,932	$3,500
15	Chromosomal Aberration, in vitro OR	OECD 473	$22,378	$3,500
	Chromosomal Aberration, in vivo	OECD 474	$17,479	$3,500
	SUBTOTAL		**$27,860**	**$7,000**
16	Combined Repeated Dose with Repro./Devel. Toxicity Screen OR	OECD 422	$125,861	$8,500
	Repeated Dose Oral Toxicity AND	OECD 407	$60,200	$8,500
	Repro./Devel. Toxicity Screening Test	OECD 421	$124,277	$8,500
	SUBTOTAL (AVERAGE)		**$155,169**	**$12,750**
	TOTAL		**$342,928**	**$36,250**
	"SIDS TIER I" - GRAND TOTAL		**$379,178**	

For each of SIDS Tier 1 toxicity tests shown in Table 2, EPA assigned an analytical methodology development and validation cost of $3,500 for short term studies and $8,500 for long-term studies, based on typical costs cited by industry experts (Piccirillo 2004). Analytical

methodology validation is not expected to be necessary for physical, chemical and other non-toxicological testing. For chemicals undergoing the complete suite of SIDS tests, analytical chemistry method development and validation adds $36,250 to the $342,928 in testing costs, for a total laboratory cost of $379,178.

During the previous ICR period, many of the HPV Challenge Program participants undertook a search for any existing chemical testing studies and submitted "robust summaries" of such studies to EPA. For those endpoints not adequately covered by existing studies, sponsors also prepared test plans and submitted these to EPA. Based on the studies and test plans received by May 2007, EPA estimates that the current sponsorship program encompasses 1,385 chemicals. This includes 1,357 chemicals for which sponsors have already submitted test plans and robust summaries. Given that data for these 1,357 chemicals are mostly submitted, or expected to be submitted, prior to the effective date of this ICR, estimates of the burden and costs associated with testing and provision of test results for those chemicals are not included. Test plans and testing are estimated still pending for 28 sponsored chemicals (1,385 - 1,357 = 28). On an annual basis, this implies that approximately 9 chemicals per year (28 / 3 = 9) will be addressed through test plans and necessary testing (see Table 3, line b). EPA estimates that five endpoints will be addressed through testing for each chemical and the remainders consist of existing data. Ten percent of the existing studies are estimated to be accompanied by robust summaries.

This ICR also provides estimates of cost and burden for the test result submissions for about 200 sponsored HPV Challenge "Class 2 Substances." These Class 2 Substances are complicated process stream and mixture chemicals that pose extra difficulties in testing and describing, and therefore, test results are not expected prior to this ICR taking effect. The substances have been referenced in category test plan submissions, and EPA therefore considers test plans for these chemicals as submitted, but the actual data for the endpoints are lacking until the sponsors of such chemicals submit the associated data summaries. On an annual basis, this implies that sponsors will submit test plans and robust summaries for approximately 67 chemicals per year (200 / 3 = 67) (Table 3, line b). EPA estimates that five endpoints will be addressed through testing for each chemical and the remainders consist of existing data. Ten percent of the existing studies are estimated to be accompanied by robust summaries.

Based upon the assumptions and testing batteries discussed above, various factors can be derived that are employed to estimate total costs and burdens for the respondents. These factors are summarized below in Table 3.

Table 3. Assumptions Used in Estimating Annual Costs and Burdens

	TSCA Section 4 ICR Assumptions	Consent Orders & Agreements	HPV Challenge w/ Test Plans	HPV Challenge No Test Plans	Total
a	No. of orders/agreements issued	1	1	1	3

b	Chemicals per order/agreement	5	67	9	--
c	Total no. of chemicals (a × b)	5	67	9	81
d	No. of chemicals per sponsor	5	1.34	1.34	--
e	No. of sponsors per rule or order (b ÷ d)	1	50	7	--
f	Total no. of sponsors (a × e)	1	50	7	58
g	Letters of intent/study plans per sponsor	5	0	1	--
h	Total letters of intent/study plans (f × g)	5	0	7	12
i	No. of short-term studies per chemical	7	5	5	--
j	Total no. of short-term studies (c × i)	35	385	45	465
k	No. of long-term studies per chemical	3	0	0	--
l	Total no. of long-term studies (c × k)	15	0	0	15
m	Total no. of studies per chemical (i + k)	10	5	5	-
n	Total no. of studies (j + l)	50	385	45	480
o	No. of semi-annual progress reports per				
	Short-term study	0	0	0	--
	Long-term study	5	0	0	--
p	Total no. of semi-annual progress reports				
	Short-term studies (o x j)	0	0	0	0
	Long-term study (o x l)	75	0	0	75
q	No. of final reports per study	1	1	1	--
r	Total no. of final reports (n × q)	50	385	45	480
s	No. of robust summaries[1]	5	73	10	88
t	Total no. of reports (h + p + r + s)	135	458	62	655
u	Total reports per sponsor (t ÷ f)	135	9	9	--
v	Total reports per rule/order (t ÷ a)	135	458	62	--
w	Total reports per chemical (t ÷ c)	27	7	7	--
x	No of exemptions per sponsor	0	0	0	--
y	No. of exemptions per rule/order	0	0	0	--
z	Total no. of exemptions	0	0	0	0
aa	Total no. of responses (t + z)	135	458	62	655
bb	No. of responses per rule/order (e + y)	1	50	7	--
cc	Total no. of respondents (f + z)	1	50	7	58

[1] For consent orders, only 10% of studies are expected to be accompanied by robust summaries. For the HPV challenge chemicals, EPA estimates the 10% of the endpoints where data exist will be accompanied by robust summaries.

The number of sponsors was determined based on a review of HPV chemical sponsorship patterns (Table 3, line f). Currently, there are 105 consortia participating in the Program and these consortia account for approximately one-third of the HPV Challenge chemicals for which data are currently or expected to be submitted, or 457 chemicals (1,385 x 0.33). The remaining 928 chemicals are sponsored individually. The total number of sponsors participating is thus 1,033 (928 + 105), and the ratio of chemicals to sponsors is approximately 1.34:1. Applying the same ratio of one sponsor per 1.34 chemicals to the 200 chemicals for which test plans have been submitted, EPA estimates there are a total of approximately 150 sponsors covering these chemicals over the three year ICR period, or 50 sponsors per year. For the 28 chemicals with test plans outstanding, EPA estimates there will be 21 sponsors (28 ÷ 1.34) over the three year ICR period, or 7 sponsors per year.

Total Number of Respondents

The Agency's estimates assume that on an annual basis there will be one respondent to an enforceable consent order or agreement and 50 sponsors of HPV Challenge chemicals covered by test plans already submitted to the Agency, and seven sponsors of HPV Challenge chemicals for which test plans have yet to be submitted to the Agency (Table 3, line f), for a total of 58 respondents annually. These respondents are all expected to provide reporting and there are no third party disclosures associated with these activities. Exemption applications are not necessary for chemicals being tested under the HPV Voluntary Challenge Programs so there are no exemption applicants counted among the respondents (Table 3, line y).

Total Number of Reports

Over the course of the testing period, a total of 655 reports will be submitted (Table 3, line t). Therefore, on average, each test sponsor, or a common representative of the test sponsors, will submit 11.3 reports per year (i.e., 655 total reports ÷ 58 sponsors = 11.3). This may include, but is not limited to: letter of intent and set of study plans, semi-annual progress reports for long-term studies, and the final reports for each study.

Types of Costs and Burdens

The following discussion presents estimates of the costs and burdens of each of the main categories of collection activities covered in this ICR. Table 4 presents estimates of the laboratory and administrative costs, and administrative burdens, and is discussed in detail below.

Laboratory Costs

The costs incurred by sponsors performing laboratory testing are presented in Table 4.

For the approximately 9 chemicals (28 over 3 years) for which EPA has not received test plans, EPA assumes sponsors will submit test plans during the three year ICR period and conduct all necessary testing. For purposes of estimating testing needs for these chemicals, EPA analyzed the number of tests proposed for chemicals with test plans submitted and found that approximately 70 percent of chemicals had no testing proposed and more than 90 percent proposed fewer than five. EPA assumed that each test plan still to be submitted will cover five endpoints at the average test cost of $23,699 for a total of $118,493 (Table 4, line e). (This is probably a conservative estimate since the median number of tests proposed is 1.25). The cost of submitting the test plan is estimated at two hours of technical time using a loaded labor rate of $54.72, or a total cost of $109.44.

For the 200 Class 2 substances for which EPA has received test plans, EPA maintains the assumption that tests will be performed to cover 5 test endpoints. Because these chemicals are

mixtures or other complicated substances, EPA has assumed that costs for analytical method development and validation costs will be higher than for other chemicals. Therefore, those validation costs are estimated to be 50% higher for those chemicals for a total of $54,375 for the entire testing battery. The average laboratory cost per test for these chemicals is $24,831 (($342,928 + 54,375)/16). The total laboratory cost for testing is estimated to be $124,155 ($24,831*5) for these chemicals.

Total laboratory costs associated with activities covered by this ICR are estimated to be approximately $16.1 million per year (Table 4, line f). These costs include $6.7 million for consent orders and agreements; $8.3 million for testing related to HPV Challenge chemicals covered by test plans; and $1.1 million for HPV Challenge chemicals not yet covered by test plans. With a projected total of 480 studies to be conducted (Table 4, line d), the average laboratory cost is $33,488 per study[4] (Table 4, line i).

Administrative Costs

Administrative costs are assumed to comprise both *reporting* and *non-reporting* activities and are explained in detail below. The average administrative cost is calculated based on the average lab cost per study of $33,488 (Table 4, line i), and is equal to $12,179 (Table 4, line j). The average administrative cost is divided by the weighted average hourly labor rate of $51.28 per hour to result in an average burden of 317 hours per chemical (Table 4, line n). The weighted average hourly labor rate is based on a labor mix that is 20 percent managerial, 60 percent technical, and 20 percent clerical. The total administrative cost is estimated to be $5.8 million annually (Table 4, line g).

Reporting Costs and Burdens

Part of the administrative costs associated with this ICR is derived from reporting activities undertaken by respondents. These activities include: 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. Reporting estimates also include the data search and reviews conducted for the voluntary HPV Challenge Program. The burden estimates and unit supply costs associated with these activities are reported in Table 5 and are based on estimates provided in the prior ICR.

Table 4. Annual Laboratory Cost and Burden Estimates

	TSCA Section 4 ICR Factors	Consent Orders/ Agreements	HPV Challenge w/ Test Plans	HPV Challenge No Test Plans	TOTALS
a	Total no. of rules/orders	1	1	1	3

[4] Some long-term tests assumed to be conducted under consent order may take more than a year to complete. For purposes of the ICR EPA assumes the full cost and burden of completing the testing is incurred during each year.

b	Total no. of chemicals	5	67	9	81
c	Total no. of sponsors	1	50	7	58
d	Total no. of studies	50	385	45	480
e	Lab. cost per chemical	$1,337,890	$124,155	$118,493	$198,448
f	Total lab. costs (b × e)	$6,689,450	$8,318,385	$1,066,437	$16,074,272
g	Admin. reporting costs	$260,500	$1,387,921	$178,650	$1,827,071
	Admin. non-reporting costs	$1,672,363	$2,079,596	$266,609	$4,018,568
	Total admin. costs [a]	$1,932,863	$3,467,517	$445,259	$5,845,639
h	Total lab. & admin. costs (f + g)	$8,622,313	$11,785,902	$1,511,696	$21,919,911
i	Lab. costs per study (f ÷ d)	$133,789	$21,606	$23,699	$33,488
j	Admin. costs per study (g ÷ d)	$38,657	$9,007	$9,895	$12,179
k	Total testing costs per study (i + j)	$172,446	$30,613	$33,594	$45,667
l	Total testing costs per sponsor (h ÷ c)	$8,622,313	$235,718	$215,957	$377,930
m	Admin. reporting burden [b]	5,365	28,981	3,685	38,031
	Admin. non-reporting burden [c]	37,629	67,619	8,683	113,931
	Total admin. burden	42,994	96,600	12,368	151,962
n	Admin. burden per study (m ÷ d)	860	251	275	317
o	Total admin. burden per sponsor (m ÷ c)	42,994	1,932	1,767	2,620

Numbers throughout table have been rounded

[a] Administrative non-reporting costs and burdens are assumed to equal 25% of laboratory costs and burdens.

[b] The reporting burdens are derived in Table 5.

[c] The non-reporting administrative burden is estimated by dividing the administrative cost by $51.28, which represents the weighted average wage rate. The weighted average wage reflects an assumed 20/60/20 mix of managerial/technical/clerical labor.

Estimates of the respondents' annual reporting costs and the burden associated with each reporting activity are detailed in Table 5. The unit wage rate information is explained in Attachment 3. 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.

For the seven sponsors who have not yet submitted test plans and the one sponsor for the consent order, EPA assumes that there is a 40-hour administrative burden assigned for submission of the test plans, and letter of intent in the case of the consent order. The total annual respondent cost and burden for reporting activities is $1.8 million and 38,031 hours (for reporting costs see Table 4, line g; for reporting burdens see Table 4, line m; for total reporting costs and burdens see Table 5).

Non-reporting Administrative Costs and Burdens

EPA's experience in test rule development has shown the non-reporting administrative costs associated with testing programs to total approximately 25 percent of the laboratory costs, and is divided as follows. Non-reporting administrative activities include 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 has included a burden equal to 15 percent of the test cost to account for management of the 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 testing cost will be added 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 for 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

Based on these assumptions, non-reporting activities associated with laboratory testing are estimated to cost $4.0 million annually (Table 4, line g). These costs are translated into burden estimates using a weighted average labor cost of $51.28 per hour, which is based on a labor mix that is 20 percent managerial, 60 percent technical, and 20 percent clerical. The estimated non-reporting administrative burden based on this approach is 113,931 hours annually (Table 4, line m).

Table 5. Total Annual Respondent Cost and Burden for Reporting Activities

COLLECTION ACTIVITY	UNIT LABOR				UNIT SUPPLY COSTS	TOTAL ANNUAL ITEMS	GRAND TOTAL	
	TYPE [a]	HOURS	RATE	COST			HOURS	COSTS
INTERIM REPORTS								
Letter of Intent and Study Plans	T	40	$54.72	$2,188.80	$20.00	12	480	$26,506
Prepare Progress Report	T	8	$54.72	$437.76	$5.00	75	600	$33,207
INTERIM REPORTS SUBTOTAL				*$2,626.56*		87	*1,080*	*$59,713*
FINAL REPORTS								
Short-term Studies								
Record and Prepare Test for Submission	T	40	$54.72	$2,188.80	$0.00	465	18,600	$1,017,792
Laboratory Review	T	6	$54.72	$328.32	$0.00	465	2,790	$152,669
Corporate Review	M	6	$65.22	$391.32	$0.00	465	2,790	$181,964
Type and Print Results	S	20	$27.00	$540.04	$0.00	465	9,300	$251,119
Record Keeping	S	1	$27.00	$27.00	$5.00	465	465	$14,880
Short-term Subtotal				*$3,475.48*			*33,945*	*$1,618,424*
Long-term Studies								
Record and Prepare Test for Submission	T	80	$54.72	$4,377.60	$0.00	15	1,200	$65,664
Corporate Review	M	9	$65.22	$586.98	$0.00	15	135	$8,805
Type and Print Results	S	40	$27.00	$1,080.08	$0.00	15	600	$16,201
Record Keeping	S	1	$27.00	$27.00	$5.00	15	15	$480
Long-term Subtotal				*$6,071.66*			*1,950*	*$91,150*
Robust Summaries	T	12	$54.72	$656.64	$0.00	88	1,056	$57,784
FINAL REPORTS SUBTOTAL						568	36,081	$1,767,358
EXEMPTION REQUESTS	T	2	$54.72	$109.44	$0.00	0	0	$0
TOTALS						655	38,031	$1,827,071

[a] Labor Type Codes are as follows: T = Technical; M = Managerial; S = Secretarial

Table 5-1. Annual Burden and Cost by Reporting Type

Activity Type	Consent Orders & Agreements				HPV Challenge with Test Plans				HPV Challenge without Test Plans			
	No. of Responses	Burden/ Response	Burden Subtotals	Cost ($) Subtotals[a]	No. of Responses	Burden/ Response	Burden Subtotals	Cost ($) Subtotals[a]	No. of Responses	Burden/ Response	Burden Subtotals	Cost ($) Subtotals[a]
Interim Reports												
Letters of Intent and Study Plans	5	40	200	11,044	0	40	0	0	7	40	280	15,462
Progress Reports	75	8	600	33,207	0	8	0	0	0	8	0	0
Short Term Studies												
Record and Prepare Test for Submission	35	40	1,400	76,608	385	40	15,400	842,688	45	40	1,800	98,496
Laboratory Review	35	6	210	11,491	385	6	2,310	126,404	45	6	270	14,774
Corporate Review	35	6	210	13,696	385	6	2,310	150,658	45	6	270	17,610
Type and Print Results	35	20	700	18,901	385	20	7,700	207,916	45	20	900	24,302
Record Keeping	35	1	35	1,120	385	1	385	12,320	45	1	45	1,440
Long Term Studies												
Record and Prepare Test for Submission	15	80	1,200	65,664	0	80	0	0	0	80	0	0
Corporate Review	15	9	135	8,805	0	9	0	0	0	9	0	0
Type and Print Results	15	40	600	16,201	0	40	0	0	0	40	0	0
Record Keeping	15	1	15	480	0	1	0	0	0	1	0	0
Robust Summaries												
Robust Summaries	5	12	60	3,283	73	12	876	47,935	10	12	120	6,566
Exemption Requests												
Exemption Requests	0	2	0	0	0	2	0	0	0	2	0	0
SUBTOTALS			5,365	260,500			28,981	1,387,921			3,685	178,650

OVERALL ANNUAL REPORTING BURDEN AND COST:	Burden	Cost ($)
Consent Orders & Agreements:	5,365	260,500
HPV Challenge with Test Plans:	28,981	1,387,921
HPV Challenge without Test Plans	3,685	178,650
TOTAL:	38,031	1,827,071

[a] Based on labor rates and unit supply costs cited in Table 5.

6(b) Agency Cost and Burden

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 6.

The Agency collection procedures are estimated to be accomplished, on average, by a GS-13, Step 1 employee. The annual 2007 loaded cost of a full-time equivalent (FTE) for this level employee is $127,035. This includes a base wage of $79,397 plus 60 percent for overhead and benefits (i.e., $47,638). Dividing this value by 2,080 (i.e., the number of hours in a work year) results in an hourly wage rate of $60.86 (see Attachment 3 for derivation of these figures).

AGENCY LABOR CATEGORY	LOADED HOURLY RATE ($2007)
GS-13, Step 1	$60.86

The estimated unit Agency burden of processing letters of intent and study plans (3 hours), progress reports (1 hour), and final reports (5 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 $164,992 and 2,711 hours, or approximately 1.3 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 6. Annual Agency Cost and Burden Estimates

COLLECTION ACTIVITY	UNIT LABOR			UNIT SUPPLY COSTS	ANNUAL ITEMS	GRAND TOTAL	
	HOURS	RATE	COST			HOURS	COSTS
Letter of Intent and Study Plans	3	$60.86	$182.58	0	12	36	$2,191
Progress Reports	1	$60.86	$60.86	0	75	75	$4,565
Final Reports	5	$60.86	$304.30	0	480	2,400	$146,064
HPVIS Data Entry	16	$60.86	$973.76	0	7	112	$6,816
Robust Summary	1	$60.86	$60.86	0	88	88	$5,356
SUBTOTAL					**662**	**2,711**	**$164,992**
Exemptions	1	$60.86	$60.86	0	0	0	$0
GRAND TOTAL					**662**	**2,711**	**$164,992**

6(c) Annual Burden Hours and Costs

6(c)(i) Respondent Tally

Table 7 summarizes the average annual burden per response. EPA estimates that this ICR will impose 151,962 burden hours on respondents annually with an average of 232 hours per response.

Table 7. Average Annual Respondent Burden Hours Per Response

COLLECTION ACTIVITY	RESPONDENT BURDEN PER RESPONSE		
	TOTAL HOURS	**TOTAL ITEMS**	**HOURS PER RESPONSE**
Reporting Activities			
Letters of Intent/Study Plans	480	12	40
Progress reports	600	75	8
Final Reports	36,951	568	65
Exemption Requests	0	0	0
Subtotal (all responses)	38,031	655	58 (avg. hrs. per response)
Non-reporting activities	113,931	655	174 (avg. hrs. per response)
Total	**151,962**	**655**	**232 (avg. hrs. per response)**

The total annual burden hours and costs for respondents were derived in Table 5, above, and are summarized below in Table 8.

Table 8. Summary of Respondents' Estimated Annual Burden and Costs

COLLECTION ACTIVITY	Total	
	Hours	**Cost**
Reporting activities		
Letters of Intent and Study Plans	480	$26,506
Progress Reports	600	$33,207
Final Reports	36,951	$1,767,358
Exemption Requests	0	$0
Subtotal	38,031	$1,827,071
Non-reporting activities	113,931	$4,018,568
TOTAL (all responses)	**151,962**	**$5,845,639**

6(c)(ii) Agency Tally

The total annual burden hours and costs for the government were derived in Table 6, above, and are summarized below in Table 9.

Table 9. Summary of Annual Agency Burden and Costs Estimates		
COLLECTION ACTIVITY	**TOTAL AGENCY BURDEN AND COSTS**	
	BURDEN (Hours)	**COSTS**
Letter of Intent and Study Plans	36	$2,191
Progress Reports	75	$4,565
Final Reports	2,400	$146,064
HPVIS Data Entry	112	$6,816
Robust Summaries	88	$5,356
Exemptions	0	$0
TOTAL	**2,711**	**$164,992**

6(d) Reasons for Changes in Burden

This request reflects a decrease in the total estimated burden of 51,052 hours (from 203,014 hours to 151,962 hours) from that currently in the OMB inventory. This request also represents a decrease in total respondent administrative cost from $8.66 million to $5.8 million, or a decrease of about $3 million.

In the previous ICR, the EPA's estimated burden was based on the assumption that the Agency would issue one test rule, one ECA or consent order, and included estimates of testing needs to be completed under the voluntary HPV Challenge for 508 chemicals. For this ICR, the burden is based on the Agency's expectation that it will issue three ECAs and does not include any estimates for test rules. In addition, the Agency's estimate of the expected level of testing remaining to be done under the HPV Challenge Program covers only 228 chemicals, or less than half those included in the previous ICR. Therefore, total annual burden has decreased. However, burden per respondent has increased. This is because this ICR has estimated that up to five studies may be conducted for each of the HPV chemicals, whereas, the previous ICR estimated one. This ICR has used a number closer to the upper end of the range for numbers of studies submitted, rather than the median for all types of HPV chemicals (those with and without test plans already submitted). Additionally, this analysis includes additional non-reporting administrative burden that was not included in the previous analysis and has added an estimated for burden hours associated with completing robust summaries for both the HPV Challenge Program and voluntarily under consent orders.

In addition to these changes, the Agency has adjusted all costs to reflect an update in the labor rates, and more recent laboratory testing costs.

6(e) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0033, is estimated to average 232 hours per response (Table 7). According to the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a 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-2007-0716, 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-2007-0716 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, Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

References

Moore 2004. Jack Moore, Memo to National Pollution Prevention and Toxics Advisory Committee, part of minutes from May 13, 2004 meeting, available at www.epa.gov/oppt/npptac/meetings/summarymay2004.pdf.

Piccirillo 2004. Vincent Piccirillo, personal communication. September 20, 2004.

USEPA 2004. Economic Impact Analysis and Small Entity Impact Analysis of the TSCA Section 4(a) Test Rule for 34 Chemicals Targeted for *in Vitro* Dermal Absorption Rate Testing. Economic and Policy Analysis Branch, Economics, Exposure and Technology Division, Office of Pollution Prevention and Toxics. February 3, 2004.

USEPA 2002. "Wage Rates for Economic Analysis of the Toxics Release Inventory Program." Memorandum from Cody Rice, Analytical Support Branch, Environmental Analysis Division, Office of Environmental Information, U.S. EPA. April 11, 2002.

USEPA 1989. "Administrative costs and burden hours for test rule." Note from Dan Axelrad to Bob Lee and Libby Parker, Regulatory Impacts Branch, Office of Pollution Prevention and Toxics, U.S. EPA. October 26, 1989.

ATTACHMENTS TO THE SUPPORTING STATEMENT

The attachments to the supporting statement are available in the public docket established for this ICR under docket identification number EPA-HQ-OPPT-2007-0716. These appendices are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(f) of the supporting statement.

Attachment 1: **15 USC 2603) - Section 4 of the Toxic Substances Control Act**. Also available at online at the US House of Representatives' US Code website

Attachment 2: **40 CFR part 790 - Procedures Governing Testing Consent Agreements and Test Rules.** Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment 3: **Wage Rates Estimation**

Attachment 4: **Copy of Public Comments Received by EPA**

Attachment 5: **Copy of Consultations Message Sent by EPA to Potential Respondents**

Attachment 6: **Display Related to OMB Control #2070-0033 -Listings of Related Regulations in 40 CFR 9.1**