

**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: Data Submissions for the Voluntary Children's Chemical Evaluation Program (VCCEP)**

**ICR Nos.: EPA ICR # 2055.01; OMB Control # 2070-[tbd]**

**1(b) Short Characterization**

This voluntary data collection program is designed to provide the Environmental Protection Agency (EPA) with information under the Toxic Substances Control Act (TSCA) on health effects, exposure, risk, and additional data needed to evaluate the safety of chemicals to which children have a high likelihood of exposure. This Information Collection Request (ICR) covers the submission of these types of data as well as the commitment letters from companies volunteering to sponsor their chemical(s) at each of three tiers in the Voluntary Children's Chemical Evaluation Program (VCCEP). Although this ICR is submitted as a new information collection request, it is important to note that EPA's ICR #1139.06, approved under OMB #2070-0033, included estimated burden associated with the anticipated industry participation in the initial phases of the VCCEP. To present a complete picture of the estimated burden for the VCCEP, however, that burden has been reassessed and is included in this ICR. Upon approval of this ICR by OMB, EPA will submit an Information Correction Worksheet (ICW) to reduce the total approved burden under OMB #2070-0033 by \$2,484,534 and 52,295 hours, which represents the removal of the estimated burden associated with the VCCEP that was included in that ICR, and that will be covered by this ICR.

The VCCEP was developed by EPA's Office of Pollution Prevention and Toxics (OPPT) after considering various comments and concerns voiced by a number of individuals through an extensive stakeholder involvement process that included individuals from the chemical industry, various government agencies, child health groups, environmental groups, animal welfare groups, as well as the general public. Participation in VCCEP and submission of data is voluntary. EPA and others will use the information collected on risks of certain chemical exposures to children to support any necessary risk management or regulatory action with respect to that chemical.

The VCCEP is designed to provide data to enable EPA and the public to better understand the potential health risks to children associated with certain chemical exposures. EPA will obtain needed chemical evaluation data from voluntary commitments by chemical sponsors. The commitment will be initiated by a letter to EPA identifying the chemical and tier

of information that a company commits to sponsor. Industry will have the opportunity to make a separate commitment for each of three tiers. The Program is also designed to ensure that health effects, exposure, and risk information on these chemicals are made available to allow EPA and others to pursue appropriate mitigation measures.

The VCCEP requires the development of test data that provide critical information on health effects, exposure, risk, and additional data needs that enable EPA and others to assess and manage health risks that may be posed by certain chemicals to which children are likely to be exposed. EPA will use a publicly conducted Peer Consultation Process to help assess whether data developed are adequate to fully characterize risk to children and, if not, what additional data are needed. EPA will also make the collected data publicly available to help the public understand the risks posed to children by exposure to certain chemicals and to facilitate the public's involvement in environmental decision-making. (For more information about the VCCEP go to: <http://www.epa.gov/chemrtk/childhlt.htm>.)

The data that a sponsor commits to develop under the VCCEP need to be collected only once for each specified chemical. As such, only one of the entities that manufactures or imports the specified chemical, or a consortium formed by these entities, will develop the specified data and report the results to EPA.

EPA has established an official record under docket number OPPTS-00274 for all activities conducted under the VCCEP. The official record consists of the documents referenced in the notice announcing the VCCEP (65 FR 81700, December 26, 2000), letters of commitment to sponsor a chemical, the Peer Consultation Documents (containing hazard, exposure, risk, and data needs assessments for each chemical assessed), the third party's report on the results of the Peer Consultation, EPA's Data Needs Decisions, any public comments received during an applicable comment period, and other information related to the Stakeholder Involvement Process, including information claimed as confidential business information (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 any comment period, is available for inspection in the TSCA Nonconfidential Information Center (NCIC), Rm. NE B-67, 401 M St., SW., Washington, D.C. The Center is open from noon - 4:00 p.m., Monday through Friday, excluding legal holidays.

## **2 NEED FOR AND USE OF THE COLLECTION**

### **2(a) Need/Authority for the Collection**

Section 2(b)(1) of TSCA, 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, EPA may rely on TSCA section 4(a), which authorizes EPA to require manufacturers and processors of chemical substances and mixtures to conduct testing if findings for hazard or exposure were made. With the VCCEP, however, EPA is working with manufacturers and other stakeholders to voluntarily develop needed data.

In general, chemicals were selected for the VCCEP pilot if there were data indicating that exposure to humans had likely occurred and that the chemicals are present in the environment. The biomonitoring data sets used for selection of the VCCEP pilot chemicals included samples from human blood, breast milk, and exhaled breath. Presence in the environment was established by monitoring data indicating presence in indoor air or presence in drinking water as an unregulated contaminant.

Chemicals were screened from the VCCEP pilot if they were being adequately addressed by another risk management program, were being phased out, or were not manufactured or imported in the United States. Other chemicals were deferred because of ongoing assessments that are similar in scope to VCCEP.

### **2(b) Use/Users of the Data**

The information collected through the VCCEP will provide critical information on health effects, exposure, risk, and data needs that will enable EPA and others to properly assess and manage health risks to children that may be posed by exposure to the 23 pilot VCCEP chemicals covered by TSCA. This information will also be made publically available to help the public understand the risks posed by exposure to certain chemicals and to facilitate the public's involvement in environmental decision-making.

Data collected under the VCCEP, along with a report of a Peer Consultation's discussion of the data, will be used by EPA scientists to determine whether the subject chemicals are likely to present an unreasonable risk to children's health. If the hazard, exposure, and risk data submitted by the sponsor indicate that potentially unreasonable risks to children may exist, the data will be used by EPA and the manufacturer to determine the appropriate action necessary to avoid or mitigate the risks. Furthermore, such information, considered in conjunction with exposure data, can be used for risk management, hazard communication and right-to-know purposes, and product labels. EPA may also use the

assessments to identify chemicals that may not warrant additional regulation or concern, or should otherwise be treated as a low priority for further consideration. The data may also be used by other Federal agencies such as the Consumer Product Safety Commission (CPSC), the Occupational Safety and Health Administration (OSHA), and the National Institute for Occupational Safety and Health (NIOSH).

Additionally, data developed for chemicals used or produced in particular work sites will be useful in developing 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 sponsors as part of the VCCEP allow EPA to ensure that the necessary data will be developed, that the results meet basic scientific standards of acceptability and adequacy, and that the testing is progressing on schedule. To date, EPA has used collected data from other test programs 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.

Since 1979, approximately 540 of the 15,000 chemical sub-set of the TSCA Inventory have been the subject of testing actions within the OPPT Existing Chemicals Testing Program. Virtually all of the 540 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 Voluntary Testing Agreements. More than 50% of these testing actions have been taken in the last several years and have focused on chemicals with clearly identified data "needs" (as opposed to simply data gaps). 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) Testing and assessments**

Prior to announcing the VCCEP, EPA held three public meeting with stakeholders (industry, other government agencies, children's health groups, environmental groups, animal welfare groups) to discuss the appropriate test battery to evaluate chemicals of concern for children health. This was done to ensure that only the tests that could contribute to the understanding of a chemical's effect on children's health would be conducted under the VCCEP. The stakeholder involvement process and recommendations from the Science Advisory Panel (SAP) identified such a test battery. The stakeholder involvement process also identified a tiering process that would stage when the sponsor would be asked to submit

the data specified by the test battery.

Under the VCCEP, the sponsor(s) will only be asked to submit the data specified by the test battery in accordance with a tiering process that allows the sponsor(s) to make a separate commitment for each tier. Before conducting any new testing, it is the VCCEP sponsor's responsibility to review available data and existing studies so the duplication of testing can be avoided. Because a sponsor's use of adequate, existing data to evaluate a chemical under the VCCEP will provide a substantial cost savings over developing data through new testing, EPA believes the data developed as a result of the VCCEP will not be duplicative. EPA also believes that duplication of the required assessments (hazard, exposure, risk, and data needs) will not be done in implementing the VCCEP, because only one submission is necessary for each chemical. As a result, each chemical is sponsored by either a single company or a single consortium of companies, usually consisting of the manufacturers of the chemical in question. In addition, information regarding the voluntary commitments under VCCEP will be posted on the EPA website, where they will be available to the public (go to: <http://www.epa.gov/chemrtk/childhlt.htm>).

### 3(a)(2) Exemptions

Exemptions are not required or necessary for this program because it is a voluntary program.

### 3(a)(3) Equivalence information

Equivalence information will provide verification that a chemical tested is the same as the chemical in the VCCEP. Often this information is CBI and only the manufacturer or processor of the chemical has this information. As such, the collection of this information under the VCCEP is not duplicative.

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

Prior to submission to OMB, this ICR will be made available to the public for comment through a Federal Register notice. The public will have 60 days to provide comments. Any comments received will be given consideration when completing the supporting statement that is submitted to OMB.

### **3(c) Consultations**

A number of issues applicable to the implementation of the VCCEP, including the time allowed for completing testing, what constitutes confidential information, how EPA should provide guidance for submission of equivalence data, and how the Agency will provide standards for development of test data, were developed over the past 25 years as part of the Agency's overall TSCA chemical testing program and involved an extensive public process

involving both notice and comment rulemakings and many public meetings.

In developing the details of the VCCEP, EPA considered advice from the SAP and individual input from the stakeholders concerning the appropriate test battery for this program. EPA also considered stakeholder comments in a public meeting setting on the need for exposure and risk assessments in addition to the hazard assessment. The initial interest in exposure and risk assessments came from industry representatives at the meetings. EPA described what each assessment should contain in a document provided prior to or at each public meeting. Hazard assessments were to follow the format of “robust summaries.” The format for an Exposure Assessment was to be discussed and developed at a workshop with EPA and industry participation. Risk assessments were to be an integration of the information in the hazard and exposure assessments. Guidance documents were also identified to guide the sponsor in developing information for the assessments. The submission of all the assessments in a single document for review by a Peer Consultation was also discussed at the public meetings. EPA also considered input on how the Peer Consultation should be run and how the pilot program should be evaluated. At three and six years after the initiation of the pilot, EPA expects to evaluate the pilot program to consider what modifications might be made that would make the VCCEP run more efficiently. Representatives of the stakeholders and the third party scientific organization will be consulted in this evaluation.

### **3(d) Effects of Less Frequent Collection**

As designed, this program minimizes overall burden by allowing companies to join together to sponsor a chemical, limiting submissions per chemical to the bare minimum (only one response per sponsor, per chemical, per occasion), and by utilizing a tiering process for submissions. The VCCEP requires the sponsor to submit a letter notifying EPA that it is volunteering to sponsor a particular chemical and include the anticipated start date and completion date for any testing conducted under that tier of the program. There are three separate tiers, but the sponsor for each tier may vary from tier to tier. The sponsor is also required to submit all four assessments (hazard, exposure, risk, and data needs) in a single document. EPA believes this is the absolute minimum frequency for collecting the information under such a chemical evaluation program.

### **3(e) Compliance with General OMB Guidelines**

The data retention requirements for test rules and consent orders exceeds one of OMB’s general guidelines contained in 5 CFR 1320.5(d)(2). Documentation records, raw data, and specimens pertaining to a test rule or consent order study are required by Good Laboratory Practices (GLPs) 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.

These same considerations apply to the data generated for the VCCEP. The time necessary to develop the data required by the VCCEP should closely reflect the time needs previously calculated for a test rule and consent order because the VCCEP, test rules, and consent orders follow the same guidance concerning time allowed per test. However, in the VCCEP, additional time is needed to develop exposure, risk, and data needs assessments at each tier. The notice announcing the VCCEP specified that four months could be requested for this purpose. The four months would be in addition to the time necessary to develop the health effects data. If four months is requested at each of 3 tiers, an additional 12 months would be added to the time requirement for the program. Also, the VCCEP is a tiered testing program and for some pilot chemicals, Tier 3 testing might not begin until 8 years into the program.

Additional time may be necessary for review in the VCCEP compared to what is necessary for test rules and consent orders. The VCCEP has features not present in most test rules and consent orders, namely a Peer Consultation (approx. 2 months), the third party's report preparation (approx. 1 month), EPA's announcement of its Data Needs Decision (approx. 1 month), 60 days public comment on EPA's Data Needs Decision if it differs substantially from the third party report, EPA's Final Data Needs Decision (approx. 1 month), and 4 months for the sponsor to commit to the next tier of testing. This additional time of 11 months would be required for both Tier 1 and Tier 2, while Tier 3 would require only 3 additional months since it does not have a Data Needs Decision. Therefore, the VCCEP may require an additional 2 years to implement, but a significant amount of this time may be matched by the test rule/consent order review time that requires a complete review of studies in house, the development of an exposure assessment in house, and the development of an EPA risk assessment document. A final consideration that would add to the VCCEP implementation time is the likelihood of scheduling problems in arranging the Peer Consultation meetings due to the time demands on the scientific experts whose participation will be sought.

For the above reasons, the records retention time for the VCCEP pilot will be 10 years from the date that the studies/information are submitted to EPA. Ten years is also the records retention time specified by GLPs. Thus, the PRA guidelines specifying that data other than health, medical, or tax records not be required to be retained for more than three years will be exceeded in this program.

### **3(f) Confidentiality**

EPA expects that information submitted to EPA in response to the VCCEP is, in most cases, non-confidential. If respondents wish to claim information submitted in response to the VCCEP as CBI, they may do so. Respondents may claim all or part of a document confidential if there is a legitimate need to do so as described in 40 CFR part 2. 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. 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.

### **3(g) Sensitive Questions**

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

### **3(h) Electronic Reporting**

In a process that began in 1996, OPPT has been working with representatives from various offices within EPA, OMB, Department of Justice (DOJ), General Services Administration (GSA), and the regulated community to develop a user-friendly electronic reporting process for the information that is submitted to EPA under sections 4, 5, 8, and 12(b) of TSCA. EPA is expected to announce the availability of the electronic reporting option for these submissions under TSCA by the end of 2001.

Although the TSCA electronic submission project has not been implemented yet, participants in the VCCEP will submit some information electronically to allow EPA to respond to public requests for information more efficiently. The VCCEP requests one electronic copy, in addition to the 3 hard copies, of the Peer Consultation Document for each chemical at each tier. If a Peer Consultation Document were developed for each of the 23 chemicals for each of the 3 tiers there could be as many as 69 electronic submissions for 3 tiers of the pilot program.

## 4 THE RESPONDENTS AND THE INFORMATION REQUESTED

### 4(a) Respondents/SIC Codes

Respondents affected by the collection activity may include, but are not limited to:

<u>Type of Entity</u>	<u>NAICS</u>	<u>Examples of Potentially Affected Entities</u>
Chemical Manufacturers and Importers	325, 32552 32551 313 42272	Persons who manufacture (defined by statute to include import) one or more of the subject chemical substances.

The North American Industrial Classification System (NAICS) codes have been provided to indicate which entities might be affected by this information collection activity. This listing is not intended to be exhaustive and other types of entities not listed in this table could also be affected.

### 4(b) Information Requested

#### 4(b)(i) Data Items

The VCCEP is a voluntary initiative under which manufacturers and importers of chemicals to which children have a high likelihood of exposure agree to submit available data, develop data, and/or conduct any needed testing for the chemicals they manufacture or import. Although the data submissions are voluntary, EPA believes that the development and/or submission of such data represents costs and burdens not captured in existing information collections. Please note, however, that the estimated burden and costs associated with the anticipated industry participation in the initial phases of the VCCEP were captured in EPA's ICR #1139.06, approved under OMB #2070-0033. That burden has been reassessed and is included in this ICR for completeness. Upon approval of this ICR by OMB, EPA will revise the total burden approved under OMB #2070-0033 as appropriate.

In general, Sponsors will be asked to submit a letter of commitment to sponsor a chemical in a specific tier; submit a Peer Consultation Document for each tier and each chemical committed to which will contain four assessments; and retain the required records related to the assessments for 10 years after the date they are submitted to EPA. If the sponsor wishes, he may submit comments on EPA's Data Needs Decision for Tier 2 and Tier 3 data.

Following is a list of information that the Sponsor will submit:

1. Letter of commitment for each chemical and tier sponsored.
2. Peer Consultation Document for each chemical and tier sponsored. Each Peer Consultation Document will contain four assessments:
  - Hazard Assessment.
  - Exposure Assessment.
  - Risk Assessment.
  - Data Needs Assessment.
3. Comments on EPA's Data Needs Decision for Tier 2 and Tier 3. This is optional.

EPA has specified four assessments as necessary to address unanswered questions about the effects on children from exposure to a chemical substance. The four assessments will address hazard, exposure, risk, and data needs. The assessments will be submitted in a single document, the Peer Consultation Document, and prepared for each tier to which a company or consortium commits. For the VCCEP, EPA will limit the scope of testing/data development for each chemical to the tier for which a commitment to sponsor has been received, and to the tests/data specified for that tier. However, if there are existing studies, even though they address an endpoint in an upper tier not committed to, the sponsor must include that study in the relevant assessment. Because the availability of data on the pilot VCCEP chemicals has yet to be determined by the sponsor and decisions on additional data needs have yet to be made by EPA, it is not possible at this time to predict with certainty how many of the 23 chemicals in the pilot VCCEP will have completed all three tiers during the effective period of the ICR. At this time, however, it is known that a full set of Tier 1 hazard data is available on 15 pilot VCCEP chemicals that have been evaluated in the Screening Information Data Set (SIDS) program. Also, an analysis of 44 similar HPV chemicals targeted for a Children's Health Test Rule (now set aside due to the VCCEP) indicated that many of the chemicals had been tested for endpoints addressed by Tier 2 and Tier 3 tests in the VCCEP. The percentages of those chemicals that had available Tier 2 and Tier 3 tests was determined for each test. The results of that analysis were used by EPA in its analysis for this ICR to give some indication of how many of the 23 pilot VCCEP chemicals may already have some Tier 2 and Tier 3 tests completed. This analysis is further discussed in section 6(a).

The Hazard Assessment to be prepared by the sponsor will primarily be based on the toxicity tests specified for the tier committed to, but must also include existing studies even though they address endpoints in an upper tier not committed to. The three tiers of toxicity tests specified by the VCCEP are listed in Table 1.

**Table 1.--Three Tiers of VCCEP Tests**

<b>Tier</b>	<b>Test</b>	<b>Test Guideline</b>
1 <sup>1</sup>	Acute oral toxicity (up/down) OR Acute inhalation toxicity	OECD 425 or ASTM E1163-98 OECD 403 or 40 CFR 799.9130
	<i>In vitro</i> gene mutation: Bacterial reverse mutation assay	OECD 471, 870.5100, or 40 CFR 799.9510
	Combined repeated dose toxicity with reproductive and developmental toxicity screens OR Repeated dose oral toxicity AND Reproductive toxicity (1-generation)	OECD 422  OECD 407 OECD 415/421
	<i>In vitro</i> chromosomal aberrations OR <i>In vivo</i> chromosomal aberrations OR <i>In vivo</i> mammalian erythrocyte micronucleus	OECD 473, 870.5375, or 40 CFR 799.9537 OECD 475, 870.5385, or 40 CFR 799.9538 OECD 474, 870.5395, or 40 CFR 799.9539
	90-Day subchronic toxicity in rodents	870.3100 (oral), or 870.3250 (dermal), or 870.3465 (inhalation) or 40 CFR 799.9346 (inhalation)
2	Reproduction and fertility effects	870.3800 or 40 CFR 799.9380
	Prenatal developmental toxicity (two species)	870.3700 or 40 CFR 799.9370
	<i>In vivo</i> mammalian bone marrow chromosomal aberrations, OR <i>In vivo</i> mammalian erythrocyte micronucleus Triggered off results from <i>in vitro</i> mammalian chromosomal aberration test if conducted in Tier 1)	OECD 475, 870.5385, or 40 CFR 799.9538  OECD 474, 870.5395, or 40 CFR 799.9539
	Immunotoxicity	870.7800 or 40 CFR 799.9780
	Metabolism and pharmacokinetics	870.7485 or 40 CFR 799.9748
	Carcinogenicity OR chronic toxicity/carcinogenicity	870.4200 or 40 CFR 799.9420 870.4300
3	Neurotoxicity screening battery	870.6200 or 40 CFR 799.9620
	Developmental neurotoxicity	870.6300 or 40 CFR 799.9630

The various guidelines that are appropriate to use when conducting each test are the TSCA guidelines in 40 CFR part 799, the OECD guidelines, or the OPPTS harmonized guidelines in the 870 series.

The Exposure Assessment to be prepared by the sponsor should contain information to answer the following questions for a particular chemical:

- Who and how many people are exposed?
- What are the sources of exposure, i.e., environmental releases, consumer products, etc.?
- Does the exposure occur through breathing air, drinking water, eating food, contact with skin, or any other routes?
- How intense is the exposure, i.e., what is the potential dose level?
- How often and for how long does exposure occur, that is, what is its frequency and duration?

The populations of concern to this program are children and, in certain situations, prospective parents. Exposures that can affect children are those that occur prior to conception (to either parent), during prenatal development, and postnatally to the age of sexual maturation, which is completed around 18-21 years of age. Although adult exposures are not intended to be a major focus of the VCCEP, certain risks to children cannot be assessed without evaluating parental exposures. Specifically, prospective parents' exposure is relevant to an evaluation of risks due to fertility and reproductive effects, as well as developmental effects from in utero exposures. Children can be exposed to chemicals through food and drinking water, through indoor and outdoor air, through ingestion of dust and soil, and through direct contact with products they use and products used in their immediate vicinity. Prospective parents can be exposed to chemicals through these pathways as well as through occupational activities.

The information in a complete Exposure Assessment should be representative and encompass manufacturing, processing, and use. If existing data are submitted, they may include non-TSCA uses, but if new data are developed they should focus on exposure data from TSCA uses. Following are the specific types of information that should be submitted in an Exposure Assessment:

- Identification of all potential manufacturing and processing activities associated with the chemical that can lead to exposure to children or, where relevant, prospective parents. It is appropriate to evaluate a prospective parent's exposure if it is relevant to determining the need for higher tier developmental and reproductive toxicity studies.
- Identification of all potential uses (industrial, commercial, consumer) of the chemical and activities associated with these uses that may lead to exposure to children or, if appropriate, prospective parents.
- Measures or estimates of exposure to children (including significant subpopulations) or, where relevant, prospective parents.

- Measures or estimates of environmental releases from all activities and exposures resulting from these releases.
- Identification of relevant activity patterns, age ranges and subpopulations associated with activities that can lead to exposures.
- Physical/chemical properties and environmental fate characteristics.
- Review and analysis of relevant existing environmental and biological monitoring data.
- Documentation of all measured data, scenarios, assumptions, and estimation techniques.

Exposure Assessments should be developed using EPA's Exposure Assessment Guidelines as well as other existing exposure assessment procedures and guidance. EPA's National Center for Environmental Assessment (NCEA) is preparing a document entitled "Child-Specific Exposure Factors Handbook" that consolidates all child exposure factors and related data in one document. A draft copy is available on the NCEA website (<http://www.epa.gov/ncea/csefh2.htm>) and the final document should be available in the near future. The exposure information that is provided for the VCCEP must be transparent and must address the completeness of the assessment, i.e., how complete is the assessment in terms of addressing sources, populations, pathways and routes of exposure to children.

#### 4(b)(ii) Respondent (Sponsor) Activities

Sponsors in the pilot VCCEP may undertake a number of activities during the effective period of this ICR. The actual number and type of activities a sponsor will undertake will depend on the tier(s) committed to, the amount of currently available data on the health effects, exposure, and risk to children of their chemical(s), and EPA's decision on the need for additional data on their chemical(s). Because the availability of data on the pilot VCCEP chemicals has yet to be determined by the sponsor and decisions on additional data needs have yet to be made by EPA, the likely number of sponsor activities cannot be predicted with certainty at this time. The maximum number and type of activities that a sponsor in the pilot VCCEP can be anticipated to undertake per tier commitment is listed below for all three tiers, even though many of the chemicals may not complete all three tiers of evaluation during the effective period of this ICR.

#### **Tier 1:**

- (1) Review notice announcing VCCEP.
- (2) Submit "Letter of Commitment" to EPA volunteering to sponsor a chemical in Tier 1.
- (3) Conduct file search for relevant existing data on toxicity and exposure. If existing data are found:
  - Prepare and review summaries of existing data.
  - Add summaries to Hazard and Exposure Assessments.

- (4) Plan necessary activities, e.g., consortia, arrange for conduct of studies, etc..
- (5) Prepare "Hazard Assessment," "Exposure Assessment," "Risk Assessment," and "Data Needs Assessment" for Tier 1 for each chemical committed to.
- (6) Prepare "Peer Consultation Document" for Tier 1.
- (7) Review Peer Consultation Document for CBI.
- (8) Submit 3 copies and one electronic copy of the Peer Consultation Document for Tier 1 to EPA.
- (9) Present the assessments to the Peer Consultation Group at the public meeting.
- (10) May Submit comments to EPA on EPA's "Data Needs Decision."
- (11) Maintain test data records and Peer Consultation Documents for 10 years.

**Tier 2:**

- (1) Submit "Letter of Commitment" to EPA volunteering to sponsor a chemical in Tier 2. It is anticipated that all 23 chemicals will reach this stage during the effective period of the ICR.
- (2) Conduct file search for relevant existing data on toxicity and exposure. If existing data are found:
  - Prepare and review summaries of existing data.
  - Add summaries to Hazard and Exposure Assessments.
- (3) Plan necessary activities, e.g., consortia, arrange for conduct of studies, etc.
- (4) Prepare "Hazard Assessment," "Exposure Assessment," "Risk Assessment," and "Data Needs Assessment" for Tier 2 for each chemical committed to.
- (5) Prepare "Peer Consultation Document" for Tier 2 for each chemical committed to.
- (6) Review Peer Consultation Document for CBI.
- (7) Submit 3 copies and one electronic copy of the Peer Consultation Document to EPA.
- (8) Present the assessments to the Peer Consultation Group at the public meeting.
- (9) May Submit comments to EPA on EPA's "Data Needs Decision."
- (10) Maintain test data records and Peer Consultation Documents for 10 years.

**Tier 3:**

- (1) Submit "Letter of Commitment" to EPA volunteering to sponsor a chemical in Tier 3. It is anticipated that 15 chemicals will reach this stage during the effective period of the ICR.
- (2) Conduct file search for relevant existing data on toxicity and exposure. If existing data are found:
  - Prepare and review summaries of existing data.
  - Add summaries to Hazard and Exposure Assessments.
- (3) Plan necessary activities, e.g., consortia, arrange for conduct of studies, etc.
- (4) Prepare "Hazard Assessment," "Exposure Assessment," and "Risk Assessment," for Tier 3 for each chemical committed to.
- (5) Prepare "Peer Consultation Document" for Tier 3 for each chemical committed to.
- (6) Review Peer Consultation Document for CBI.

- (7) Submit 3 copies and one electronic copy of the Peer Consultation Document to EPA.
- (8) Present the assessments to the Peer Consultation Group at the public meeting.
- (9) Maintain test data records and Peer Consultation Documents for 10 years.

Additional information describing the products of the above activities is provided below:

(a) Letter of Commitment: A company wishing to volunteer to sponsor its chemical in Tier 1 of the VCCEP must send a letter to EPA committing to do so by June 25, 2001. (ICR # 1139.06 covers this request for information, but it is also included in this ICR so that all VCCEP information requests can be contained in one ICR to facilitate future renewals). The letter must identify the company, technical contact (name, address, e-mail address, telephone, and fax number), the chemical name and its CAS number, the tier committed to, the anticipated start date, the anticipated submission date to EPA, and a commitment to start testing by December 26, 2001. Letters of commitment for Tiers 2 and 3 are due 4 months after the announcement of EPA's Data Needs Decision.

(b) Hazard Assessment: A separate Hazard Assessment must be prepared for each tier for each chemical to which a sponsor commits. (ICR # 1139.06 covers this request for information, but it is also included in this ICR so that all VCCEP information requests can be contained in one ICR to facilitate future renewals). The Hazard Assessment should be a "robust summary" of the studies conducted for a particular tier and also any existing relevant studies, even though they may address an endpoint in an upper tier not committed to. A robust summary must include an objective, discussion of methods, results, and conclusions. From a practical standpoint, it is not reasonable to attempt to create an electronic version of full study reports. Instead electronic summaries of full study reports should be prepared that contain the appropriate technical information for that particular endpoint. Robust Summaries should provide sufficient information to allow a technically qualified person to make an independent assessment of a given study report without having to go back to the full study report. Any additional information, such as mechanistic information or SAR, that may influence decisions on further testing needs should also be included.

For a Tier 2 commitment, the sponsor should develop a Hazard Assessment that includes summaries of those Tier 2 studies that EPA has announced in its Data Needs Decision. In addition to the new hazard data developed for Tier 2, the Tier 2 Hazard Assessment should also contain all the information from the Tier 1 Hazard Assessment, which should be revised as appropriate to reflect new insights provided by the new hazard data developed for Tier 2.

For a Tier 3 commitment, the sponsor should develop a Hazard Assessment that includes summaries of those Tier 3 studies that EPA has announced in its Data

Needs Decision. In addition to the new hazard data developed for Tier 3, the Tier 3 Hazard Assessment should also contain all the information from the Tier 2 Hazard Assessment, which should be revised as appropriate to reflect new insights provided by the new hazard data developed for Tier 3.

(c) Exposure Assessment: The Exposure Assessment should be a “robust summary” of existing exposure information and any exposure studies conducted by the sponsor. The Exposure Assessment for Tier 1 should consist primarily of screening level (or, if available, better) information on exposure from manufacturing supplemented with relevant screening level data on downstream processing and use activities and specific information on children’s exposures, if available. A screening level exposure assessment should generate conservative, quantitative estimates of exposure. The screening approach generally involves using readily available measured data, existing release and exposure estimates and other exposure-related information. Where actual measures of exposure are not available, the use of models may be necessary. For example, a screening-level model for ambient air exposure that uses the assumption that the exposed populations live near the chemical release locations is often used in EPA screening level assessments. An appropriately conservative screening level assessment can also help to rule out certain exposure concerns and set priorities for more detailed evaluation of the remaining concerns. A Tier 2 Exposure Assessment will be more advanced assessments that develop more accurate estimates of exposure and will generally focus on the higher priority exposures identified in the Tier 1 screening assessment. An advanced Exposure Assessment should quantify central tendency (e.g. median, geometric mean) and high end (i.e., greater than 90<sup>th</sup> percentile) exposures. Representative, well designed monitoring studies of known quality are the ideal. Higher tier exposure models may also be used in advanced assessments when appropriate measured data are unavailable. When higher tier models are used, every effort should be made to obtain accurate input data. For example, a higher tier model for ambient air exposure may use facility-specific parameters for emission rates, such as stack height and the exact size and location of the exposed population. Tier 2 assessments should also more specifically address exposures relevant to Tier 2 health testing endpoints. Similarly, Tier 3 Exposure Assessments would further develop Tier 1 and 2 exposure data and more specifically address exposures relevant to Tier 3 health testing endpoints. The format for the Exposure Assessment will be discussed and defined at a workshop in 2001 with EPA and industry participation.

(d) Risk Assessment: The Risk Assessment should integrate information presented in the Hazard Assessment and the Exposure Assessment for the purpose of characterizing the risk to children’s health from exposure to the chemical in question.

(e) Data Needs Assessment: The Data Needs Assessment is the sponsor’s opinion of what additional studies or data are needed from the next tier of the VCCEP so that

a thorough assessment of the risk to children from exposure to a chemical can be developed.

(f) Peer Consultation Document: The Peer Consultation Document is the compilation of the Hazard Assessment, Exposure Assessment, Risk Assessment, and Data Needs Assessment into a single document that will be submitted to EPA (3 copies and one electronic copy). EPA will provide one copy to the third party scientific organization who will provide copies to the Peer Consultation members. EPA will also put one copy in the TSCA NCIC docket.

(g) Data Needs Decision: The Data Needs Decision is made by EPA and is a decision concerning which tests in the next tier of the VCCEP are needed. EPA makes this decision after reviewing third party's report of the Peer Consultation.

As a voluntary program, it is unnecessary for anyone to request an exemption under the VCCEP. However, companies may submit relevant information that indicates that specific chemicals included in the VCCEP based on production volume, are not currently produced in substantial quantities and therefore, testing of these chemicals is not necessary. Based on a review of the information submitted, EPA may remove a chemical from the list of HPV chemicals or list of children's health chemicals. This ICR does not separately account for submitting such production information, although it could reasonably be submitted in lieu of a commitment letter.

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

### **5(a) Agency Activities**

In order to sustain three tiers of the pilot VCCEP, the EPA must undertake the following applicable activities:

- a) review letters of commitment for Tiers 1, 2, and 3 (separate letter for each tier) for completeness;
- b) develop a system to track commitments and progress of program on VCCEP website and update monthly;
- c) issue a grant to a third party to: arrange public meetings of the Peer Consultation, solicit recommendations from EPA and stakeholder for experts to serve as Peer Consultation members, identify and invite scientific experts to serve as Peer Consultation members, distribute Peer Consultation Documents and other guidance to Peer Consultation members, act as facilitator at the public meeting, summarize results of the Peer Consultation, and send report to EPA and the sponsor.
- d) review Peer Consultation Documents and third party reports, make data needs decisions;

- e) announce the Data Needs Decisions for Tiers 1 and 2 on VCCEP website and in letters to relevant sponsors;
- f) provide explanation of Data Needs Decisions if they differ substantially from the third party report. Take comments and make final Data Needs Decisions at Tiers 1 and 2;
- g) announce the final Data Needs Decision at Tiers 1 and 2 on VCCEP website and in letters to relevant sponsors;
- h) make the Peer Consultation Documents available to public in the TSCA NCIC; make third party reports and Data Needs Decisions available to the public in the TSCA NCIC and on the VCCEP website.

In addition to the activities cited above the Agency may also participate in other activities related to this program, e.g., an Exposure Workshop, other voluntary efforts to identify data gaps and develop test data, efforts to establish test guidelines or standards that may be used in the VCCEP, and international efforts related to chemical testing and associated testing issues.

### **5(b) Collection Methodology and Management**

Data collected under the VCCEP will be received by the TSCA Nonconfidential Information Center (NCIC), which will place a copy in OPPTS docket no. 00274. The NCIC will then transfer the data to the program manager in the Office of Pollution Prevention and Toxics, Chemical Control Division, Chemical Testing and Information Branch, where they will be reviewed for completeness and then, depending on the data received, routed as follows:

- Letters of Commitment will be routed to the person in CITB assigned to track the progress of the VCCEP and update the VCCEP website.
- Peer Consultation Documents will be routed to the third party scientific organization (one copy), to the person in CITB maintaining the VCCEP files (one copy and the electronic copy), and to the RAD/EETD group that makes the data needs decision (one copy).
- Third party reports on Peer Consultation will be routed to the person in CITB maintaining the VCCEP files (one copy) and to the RAD/EETD/CCD group that makes the data needs decision (one copy).
- Comments on EPA's Data Needs Decision will be routed to the person in CITB maintaining the VCCEP files (one copy), and to the RAD/EETD/CCD group that makes the data needs decision (one copy).

The Peer Consultation Document prepared by the sponsor for Tier 1 will contain hazard, exposure, risk, and data needs assessments. The sponsor will present his assessments to the Peer Consultation that will then discuss the assessments with emphasis on the data needs assessment. A third party scientific organization that has arranged and facilitated the meeting will summarize the results of the Peer Consultation and send a report to EPA and the sponsor. EPA, specifically representatives from RAD, EETD, and CCD will review the third party report and the Peer Consultation Document and decide if any

information from the next tier is needed to assess the risk to children of the chemical in question. If the decision is that additional data are needed, EPA announces this on the VCCEP website and in a letter to the sponsor. If EPA's decision differs substantially from the third party report, EPA will provide an explanation for its decision and allow the sponsor and the public 60 days to comment. EPA will consider the comments and make a final data needs decision. There is a 4-month period for the sponsor or others to volunteer to provide the data needed in Tier 2. The steps in Tier 1 are repeated for Tier 2; the steps in Tier 1 are repeated in Tier 3 up to but not including a Data Needs Decision. At the end of Tier 3 or if EPA decides that sufficient data have been provided at the end of Tier 1 or Tier 2 to evaluate risk to children, EPA and the sponsor may use the data in risk management activities if necessary. To date, EPA has collected data in other testing programs 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 chemicals identified for evaluation as part of the VCCEP pilot, the specific data requested at Tier 1, the data that might be requested at Tiers 2 and 3 (which will not be known with certainty until EPA issues its final Data Needs Decisions), the guideline requirements for conducting any needed tests, the time frame for completing the testing/data collection, and the time frame for submitting a Peer Consultation Document to the Agency were established in the notice announcing the VCCEP (65 FR 81700, December 26, 2000).

#### **5(c) Small Entity Flexibility**

Under the VCCEP, no company, including small businesses, is required to participate. Any small businesses that do participate will likely do so as part of a consortium. Participation in a testing consortium relieves the small business of direct responsibility for collecting or submitting test information, while still allowing the small business to participate in the program.

## 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 time allowed to complete each tier of testing/data collection is based on the test in that tier that requires the longest time to complete. An additional four months can be requested to complete the Exposure Assessment, Risk Assessment, and Data Needs Assessment for each tier. Following in Table 2 are the times that EPA believes are reasonable to complete each test in the VCCEP. It is assumed that tests in the same tier will be conducted simultaneously.









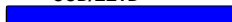








**Table 2.--Time Allowed to Conduct Toxicology Test and Prepare Final Report**

Test	Months
Acute oral toxicity (up/down) OR Acute inhalation toxicity	18
In vitro gene mutation: Bacterial reverse mutation assay	18
In vitro chromosomal aberrations	18
90 Day subchronic in rodents	18
Reproduction and fertility effects	29
Prenatal developmental toxicity (two species)	12
In vivo mammalian bone marrow chromosomal aberrations, OR in vivo mammalian erythrocyte micronucleus	16
Immunotoxicity	12 <sup>1</sup>
Metabolism and pharmacokinetics	12
Carcinogenicity OR chronic toxicity/carcinogenicity	60
Neurotoxicity screening battery	21
Developmental neurotoxicity	21

1. If the test for immunotoxicity is run as a satellite of another study, the final report would be due on the reporting date of the other study.

A likely timeline for the VCCEP pilot that indicates anticipated collections of commitment letters and sponsor assessments is presented below.

## VCCEP Pilot Tier 1 Timeline

ID	Task Name	Start Date	End Date	2001				2002				2003				2004			
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2		
1	Letter to sponsor IUR/HPV contacts from AA	2/21/01	3/26/01	<b>CCD/EAD</b> 															
2	Letter to sponsor CEOs from Administrator	3/21/01	4/20/01	<b>CCD/EAD</b> 															
3	Sponsor commitments to EPA	2/21/01	6/25/01	<b>Sponsors</b> 															
4	Sponsors develop hazard data	2/21/01	12/25/02	<b>Sponsors</b> 															
5	Sponsors prepare hazard, exposure, risk and data needs assessments	2/21/01	4/25/03	<b>Sponsors</b>  <div style="display: flex; justify-content: space-between; align-items: center; margin-top: 5px;"> <div style="text-align: center;">  <p>Due date for chemicals with complete Tier 1 hazard data sets at project onset (eg. SIDS chemicals)</p> </div> <div style="text-align: center;">  <p>Due date for all remaining chemicals</p> </div> </div>															
6	Commitment tracking and website development and maintenance	2/21/01	12/25/03	<b>CCD</b> 															
7	Information Collection Request development	2/21/01	10/25/01	<b>CCD/EETD</b> 															
8	Exposure Robust Summary development leading to July 2001 Workshop	2/21/01	10/25/01	<b>EETD</b>  <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 5px;"> <div style="text-align: center;">  </div> <div style="text-align: center;">  <p>Exposure Workshops</p> </div> </div>															
9	Peer Consultation Preparation and Contracting	2/21/01	10/25/01	<b>RAD</b> 															
10	Tier 1 Peer Consultations	10/25/01	12/25/03	<b>RAD</b>  <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 5px;"> <div style="text-align: center;">  <p>1st Peer Consultation</p> </div> </div>															
11	Development Information Management Plan	2/21/01	7/25/01	<b>IMD</b> 															
12	Construct Information Management Systems	7/26/01	7/26/02	<b>IMD</b> 															

## 6 ESTIMATING THE BURDEN AND COST OF THE COLLECTION

### Overview

This section presents 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. If, in the context of implementing the VCCEP, the Agency determines that the total annual burden covered by this ICR needs to be revised, it will submit an Information Correction Worksheet (ICW) to amend the total annual burden for this ICR in the OMB inventory.

### Assumptions

The estimated burden and costs to the Federal Government and to the respondents is based on the following assumptions. These assumptions are based on historical experience with the TSCA testing program, as well as projections for the VCCEP pilot over the next three years. These assumptions are reflected in the estimated burden and costs that are presented:

- 1) EPA assumes that 23 chemicals will be enrolled in the VCCEP pilot. To date, 20 chemicals have been sponsored by 34 companies acting through 11 consortia. Additionally, EPA assumes that the entire three-tier process for each chemical will be completed within the three year ICR approval period for 12 of the 23 chemicals, and that the remaining 11 will only complete Tier 2 (i.e., 23 chemicals will complete Tiers 1 and 2, and 12 chemicals will complete all three Tiers). This assumption is optimistic (see section 3(e) for a possible VCCEP timeline), but allows for quick action on the part of EPA and its industry partners. These assumptions provide a conservative estimate of the cost and burden associated with the VCCEP pilot. In the event that fewer than 23 chemicals are enrolled in the program, or some of the chemicals do not participate to the degree assumed, then the total cost and burden will be less than estimated here. Additionally, if, as is likely, the process for any of the enrolled chemicals lasts longer than three years, then the total burden and cost will be extended over a longer time frame, thus reducing the annual burden and cost of the program.
- 2) One or several chemicals may be sponsored by one company or a consortium representing several companies.<sup>1</sup> For purposes of this ICR, however, EPA assumes that the VCCEP program will have one respondent per chemical. That one respondent will represent a company or consortium of companies that

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<sup>1</sup> In most instances, test sponsors will form a "Consortium", through a common trade organization (e.g., American Chemistry Council [formerly the Chemical Manufacturers Association], Synthetic Organic Chemical Manufacturers Association), to coordinate testing and preparation of assessments.

manufacture the chemical. Thus, the total number of respondents for the VCCEP will be 23.

- 3) The 3 tiers of tests listed in Table 1 of this ICR allow sponsors to choose among a number of test guidelines. EPA has assumed that, as a default, sponsors will conduct tests defined at 40 CFR 799 (i.e., the 799 series). In cases where sponsors have a choice between more than one 799 series test, EPA assumes that sponsors will choose the lower cost test. In cases where EPA did not have cost and burden estimates for a 799 series test, EPA assumes that sponsors will choose the least cost test from among the alternative test guidelines for which cost and burden data are available. Details on the default testing assumptions can be found in Table 3.
- 4) For the 90-Day subchronic toxicity test in Tier 2, three routes of exposure are possible (inhalation, oral, dermal). Although many VCCEP chemicals have multiple potential routes of exposure relevant to total dose, EPA expects that sponsors will conduct the test using the one route most relevant to expected exposure. Considering that the VCCEP chemicals are expected to be present in indoor air, drinking water, or breast milk, EPA assumes that 75% of the subchronic tests will be conducted by inhalation (guideline 799.9346), and 25% will be conducted by the oral route of administration(870.3100). (EPA made no such assumption about route for the acute toxicity test in Tier 1 because the testing is assumed to have already been completed.)
- 5) Each respondent must submit one letter of commitment, and one Peer Consultation Document for each chemical they have committed to for each Tier. The Peer Consultation Document (PCD) contains a Hazard Assessment, an Exposure Assessment, and a Risk Assessment. The PCDs for Tiers 1 and 2 also contain Data Needs Assessments.
- 6) In conducting any test that will be submitted to EPA under TSCA, the respondent must comply with Good Laboratory Practices (GLPs). Since the GLPs represent basic standard practices used by laboratories, any burden and costs related to GLPs are fully captured in the laboratory cost and burden estimates provided in Table 3.
- 7) EPA assumes that some of the 23 chemicals have already been subject to some of the tests identified in Table 1 of this ICR. EPA used a baseline testing rate to estimate the number of chemicals needing specific tests (see "Laboratory Costs and Burdens" in Section 6(a)). EPA does not calculate test costs for chemicals assumed to have already been tested.

- 8) EPA assumes that all of the chemicals have Tier 1 test data available through either the EPA High Production Volume (HPV) Challenge program or the SIDS program.
- 9) For estimating the burden and costs for conducting the testing, EPA used available information regarding the price that a laboratory would charge for conducting the test. Many respondents, however, are likely to use their own facilities to conduct the testing.
- 10) The programs established for the VCCEP and HPV Challenge chemicals are voluntary initiatives under which manufacturers of chemicals targeted for testing will voluntarily submit data on hazard endpoints; the VCCEP also includes exposure, risk, and data needs information. EPA would exclude any chemicals enrolled in these voluntary programs from its planned section 4 test rules and would provide recognition to program participants for their voluntary actions.
- 11) For purposes of this ICR, EPA estimates that participants conducting tests for the VCCEP would incur roughly the same costs and burdens that they would incur if the chemicals were subject to a section 4 rule, but would not submit study plans or progress reports, and would not submit full study reports to EPA unless specifically requested to do so. Instead, study results would be submitted in the “robust summary” format. In addition, to determine which endpoints need to be tested, VCCEP participants would most likely undertake a search for any existing studies for each chemical, and include them in the robust summaries.<sup>2</sup> The costs and burden associated with these data searches are included as reporting costs and are described below under “Reporting Costs and Burdens.”

#### **6(a) Respondent Cost and Burden**

For purposes of calculating the PRA paperwork-related burden and costs for this ICR, the Agency assumed that the respondents will incur both laboratory testing costs and administrative costs and burden when participating in the program. For the laboratory testing costs, only a portion of the total cost may be attributed to the paperwork related requirements that EPA imposes on the participants. To calculate the potential paperwork burden and costs under this ICR, EPA used the laboratory testing costs to calculate the potential paperwork burden and costs associated with conducting the testing (i.e., generating the data to be submitted), and the potential paperwork burden and costs associated with participation in the VCCEP. These are described in more detail later in this section.

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<sup>2</sup> Guidance on Searching for Chemical Information and Data, May 1999 (<http://www.epa.gov/opptintr/chemrtk/srchguid.htm>).

The unit burden for each activity is based upon previous section 4 ICRs and EPA's best estimates of the burdens that will be incurred under TSCA section 4 test rules over the next three year period. The unit wage rates used to monetize these burdens are derived in Attachment 1 and are summarized as follows:

<b>INDUSTRY LABOR CATEGORY</b>	<b>LOADED HOURLY RATE (\$2001)</b>
Managerial	\$97.51
Technical	\$71.96
Secretarial	\$28.85

Based upon the assumptions and default testing assumptions discussed above, various factors can be derived that are employed to estimate total costs and burdens for the respondents. These factors are presented in the sub-sections that follow.

#### Number of Respondents

The Agency assumes that each chemical will have one respondent: a company or consortium of companies that manufacture the chemical. Thus, there will be 23 total respondents for the VCCEP. EPA recognizes, however, that more than one entity may participate in the VCCEP, and that the participation of these "non-respondents" may not be reflected in the burden and cost estimates for the respondent. For example, whenever more than one entity form a consortium to provide the requested data, only one entity may experience the full burden of data gathering and submission as estimated here, but the other entities still experience what can be described as "initial" burden and costs related to their participation in the consortium. Although the Agency does not have sufficient information at this time to assess this additional burden and costs, the Agency has attempted to account for it by including an additional burden estimate that assumes a total of 45 entities (34 companies and 11 consortia, some of which are trade associations) participating in the VCCEP.

#### Types of Costs and Burdens

The following discussion presents estimates of the costs and burdens of each of the main categories of collection activities that will be undertaken in response to the VCCEP: laboratory cost and burdens (hazard assessments), administrative costs and burdens, exposure assessments, risk assessments, data needs assessments, preparing the peer consultation document, presenting the assessments at public meetings, and submitting comments on EPA's data needs decision. EPA's estimated costs and burdens for each of these respondent activities is discussed below.

### *Laboratory Costs and Burdens (Hazard Assessments)*

Each chemical that is sponsored in the VCCEP must be evaluated by performing the tests specified for each tier, unless there are adequate existing data for one or more of the endpoints addressed by tests in that Tier. Table 1 of this ICR provides the list of possible tests. As can be seen in Table 1, sponsors have some choice in the tests that are conducted. As noted above, EPA assumes that sponsors will choose the least-costly test among the alternatives listed in Table 1. In preparing the estimates for this ICR, EPA used the costs of the testing alternative based on 799 series as a default, and has not attempted to develop costs for all of the alternatives. Assumptions about routes of administration are discussed under Assumption 4 above. Table 3 summarizes EPA's assumptions regarding which test protocol will be chosen for each testing requirement in Table 1, as well as the cost and burden estimate for those protocols.

EPA generates and maintains a listing of the laboratory cost and burden data for numerous TSCA and OECD test protocols. Any test protocols listed in Table 3 for which cost and burden data were estimated prior to 1994 were adjusted to end-of-year 2000 dollars using the Bureau of Labor Statistics' Employment Cost Indices (ECIs) (see Attachment 1).

EPA expects that at least some of these chemicals will already have been subject to a number of these tests. EPA used information gathered in preparing the draft Children's Health Proposed Test Rule to determine the number of chemicals that will require each specific test. Table 3 presents EPA's estimate of the percentage of chemicals that have undergone each test from the draft Children's Health Proposed Test Rule analysis (i.e., the baseline testing rate in Table 3). EPA assumes that these percentages can be applied in this analysis. Using this information, the number of chemicals requiring a specific test is calculated by multiplying the baseline testing rate by 23 chemicals and then subtracting the result from 23 (the total number of chemicals for each tier).<sup>3</sup> As noted above, EPA has assumed that all chemicals have Tier 1 testing data.

For each protocol, the total testing cost is calculated by multiplying the cost per test by the number of chemicals for that protocol. Total laboratory costs of the ICR are estimated to be \$23.9 million and 282,070 hours of labor over the three-year ICR period. EPA estimates that a total of 78 studies (equal to the total number of chemical tests conducted under all tiers) will be conducted over the three-year ICR period. The average laboratory cost is \$306,846 per study (\$23.9 million/78 studies).

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<sup>3</sup> For the 90-day subchronic toxicity in rodents study under Tier 2, however, the number of chemicals requiring testing was divided among those that would receive oral route testing (25 percent) and those that would receive inhalation route testing (75 percent). This is explained in more detail in assumption number 4 above and in the notes to Table 3.

**Table 3. The VCCEP Test Battery**

Protocol Name		Protocol Number	Cost Estimate Per Test	Lab Burden Per Test (Hours)	Baseline Testing Rate	Number of Chemicals Needing Test [a] [b]	Total Testing Cost	Total Testing Burden (Hours)
<b>Tier 1</b>								
1	Acute inhalation toxicity	OECD 403	\$14,735	184	100%	0	\$0	0
2	<i>In vitro</i> gene mutation: Bacterial reverse mutation assay	799.9510	\$7,389	61	100%	0	\$0	0
3	Repeated dose oral toxicity	OECD 407	\$40,630	328	100%	0	\$0	0
4	<i>In vivo</i> mammalian erythrocyte micronucleus	799.9539	\$15,158	132	100%	0	\$0	0
<i>TOTAL FOR TIER 1</i>			<i>\$77,912</i>	<i>705</i>	<i>-</i>	<i>0</i>	<i>\$0</i>	<i>0</i>
<b>Tier 2</b>								
1	90-Day subchronic toxicity in rodents	870.3100	\$105,214	757	81.8%	1 [c]	\$105,214	757
		799.9346	\$305,507	2,458	81.8%	3 [d]	\$916,521	7,374
2	Reproduction and fertility effects	799.9380	\$826,676	9,449	29.5%	16	\$13,226,816	151,184
3	Prenatal developmental toxicity (two species)	799.9370	\$88,448	1,079	38.6%	14	\$1,238,272	15,106
4	<i>In vivo</i> mammalian erythrocyte micronucleus	799.9539	\$15,158	132	81.8%	4	\$60,632	528
5	Immunotoxicity	799.9780	\$45,887	550	31.8%	16	\$734,192	8,800
6	Metabolism and pharmacokinetics	870.7485	\$31,650	330	90.9%	2	\$63,300	660
<i>TOTAL FOR TIER 2</i>			<i>\$1,418,540</i>	<i>14,755</i>	<i>-</i>	<i>56</i>	<i>\$16,344,947</i>	<i>184,409</i>
<b>Tier 3</b>								
1	Carcinogenicity	799.9420	\$1,259,677	17,953	68.2%	4	\$5,038,708	71,812
2	Neurotoxicity screening battery	799.9620	\$100,001	883	45.5%	7	\$700,007	6,181
3	Developmental neurotoxicity	870.6300	\$168,212	1,788	4.5%	11	\$1,850,332	19,668
<i>TOTAL FOR TIER 3</i>			<i>\$1,527,890</i>	<i>20,624</i>	<i>-</i>	<i>22</i>	<i>\$7,589,047</i>	<i>97,661</i>
<b>GRAND TOTALS</b>		-	-	-	-	78	\$23,933,994	282,070

[a] These numbers also represent the number of studies that would be conducted.

[b] To calculate the number of tests for Tiers 1 and 2, EPA multiplied the baseline testing rate by 23 chemicals and then subtracted the result from 23. To calculate the number of tests for Tier 3, EPA multiplied the baseline testing rate by 12 chemicals and then subtracted the result from 12.

[c] To calculate the number of tests performed by the oral route, EPA multiplied the number of chemicals needing testing (4), by 25 percent per Assumption 4.

[d] To calculate the number of tests performed by inhalation, EPA multiplied the number of chemicals needing testing (4), by 75 percent per Assumption 4.

Once a study is complete, sponsors are required to develop a robust summary of the results. A robust summary must also be developed for each available, adequate study that addresses endpoints in any of the 3 tiers, but EPA assumes that robust summaries have already been developed for Tier 1 tests. Therefore, the number of robust summaries to be developed will equal the number of tests in Tier 2 multiplied by 23 chemicals (6 tests x 23 chemicals = 138) plus the number of tests in Tier 3 multiplied by 12 chemicals (3 tests x 12 chemicals = 36), for a total of 174 robust summaries. EPA assumes that the robust summaries will require 15 hours of technical time and 5 hours of clerical time. Based on this assumption, EPA estimates that robust summaries will impose a burden of 3,480 hours and \$212,915 over the same period.<sup>4</sup>

#### *Administrative Costs and Burdens Associated with Laboratory Costs and Burdens*

EPA's experience in test rule development has shown that administrative costs and burdens (i.e., related to the paperwork burden and costs) associated with testing programs to be approximately 25 percent of the laboratory costs. EPA applied this assumption to the Tier 2 and 3 estimates, but did not do the same for Tier 1 since all Tier 1 testing is assumed to be complete. Under EPA's standard 25 percent assumption, the cost estimate per test is used to calculate the cost of the paperwork or administrative burden associated with conducting that test by using our 25 % assumption. EPA typically states that this is the **data generation paperwork costs** and calculates the burden by dividing the loaded hourly rate for the technical person into it. For example, if the test cost is \$100,000, then the paperwork/administrative costs are \$25,000, and the paperwork burden is 347.42 hours (technical). EPA then calculates separately the rest of the burden and costs for the ICR, i.e., burden and costs for all the other activities.

Because EPA has assumed that all testing is complete for Tier 1, EPA assumes that total administrative costs and burdens for Tier 1 only need to include the costs and burdens for submitting the data under Tier 1, i.e., that the burden and costs for generating the data under Tier 1 is "0." Based on this method, EPA presents estimates for administrative reporting activities, and then for non-reporting administrative activities in the following two sections.

#### *Administrative Reporting Costs and Burdens*

Part of the administrative costs and burdens associated with this ICR are derived from reporting activities undertaken by respondents. These activities include preparing letters of commitment and performing data searches and reviews. EPA has summarized its estimates for these categories in Table 4, and discusses each below.

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<sup>4</sup> The costs for this requirement are estimated as:  $(174 \text{ studies}) \times [(15 \text{ hours technical time}) \times (\$71.96) + (5 \text{ hours clerical time}) \times (\$28.85)]$ .

For letters of commitment, EPA assumed that each sponsor would submit one letter for each tier. Thus, a total of 58 letters would be received over the three-year ICR period (23 each in Tiers 1 and 2, plus 12 in Tier 3). Following previous ICRs, EPA assumed that submitting these letters would impose a burden of four hours of technical labor for each submission. This implies a total burden of 232 hours and \$16,694 over the three-year ICR period. These costs and burden hours are considered reporting burdens by EPA.

**Table 4. Administrative Reporting Cost and Burden**

<b>Category</b>	<b>Letters of Commitment</b>	<b>Data Searches</b>	<b>TOTAL</b>
<i>Tier 1</i>			
Number	23	69	<b>92</b>
Burden	92	2,220	<b>2,312</b>
Cost	\$6,620	\$160,322	<b>\$166,942</b>
<i>Tier 2</i>			
Number	23	69	<b>92</b>
Burden	92	2,220	<b>2,312</b>
Cost	\$6,620	\$160,322	<b>\$166,942</b>
<i>Tier 3</i>			
Number	12	36	<b>48</b>
Burden	48	1,158	<b>1,206</b>
Cost	\$3,454	\$83,646	<b>\$87,100</b>
<b>TOTALS</b>			
<b>Number</b>	<b>58</b>	<b>174</b>	<b>232</b>
<b>Burden</b>	<b>232</b>	<b>5,598</b>	<b>5,830</b>
<b>Cost</b>	<b>\$16,694</b>	<b>\$404,290</b>	<b>\$420,984</b>

To estimate the cost and burden of performing data searches, EPA assumes that two firms per chemical would search their internal records and one sponsor per chemical would perform an external search of the literature (i.e., a total of three searches per chemical per Tier). The assumption of two firms per chemical is based on the fact that 34 companies are currently involved in sponsoring 20 chemicals; with the possibility that more could join, rounding up to two seems prudent. Based on this, EPA estimates that 69 searches will occur for each Tier 1 and 2 and 36 searches will occur under Tier 3. This results in a total of 174

data searches over the three-year ICR period. Following previous testing ICRs, EPA assumes that firm's searches require 17.75 burden hours per search. This includes 3 hours of managerial time for corporate review, 9 hours of technical time for a file search, one hour of clerical time for a summary sheet, 1.75 hours of clerical time for reproduction, and 3 hours of managerial time for a CBI review. The sponsor-level searches require 61 hours: 60 hours of technical time for an external records search and one hour of clerical time for a summary sheet. Based on these assumptions, EPA estimates that data searches will impose a burden of 5,598 hours and \$404,290 over the three-year ICR period.

### *Non-reporting Administrative Costs and Burdens*

Non-reporting administrative activities include the effort of respondents to organize a testing program, obtain and review bids from laboratories who would conduct the testing, and prepare and submit samples to the laboratory for testing. For this ICR, EPA has calculated the costs and burdens of these activities as the difference between the total administrative costs and burdens and the reporting costs and burdens derived above for Tiers 2 and 3. Additionally, EPA has assumed that no non-reporting administrative costs are incurred for Tier 1. From Table 3, Tiers 2 and 3 testing involve a total cost of \$23.9 million and 282,070 hours.

To calculate total administrative costs (reporting plus non-reporting administrative) for Tiers 2 and 3, we multiply each estimate by 25 percent to get \$6.0 million and 70,518 hours. Next, we subtract off the total administrative reporting for Tiers 2 and 3 from Table 4. These estimates are \$254,043 (\$166,942 + \$87,100) and 3,518 hours (2,312 + 1,206). Thus, non-reporting activities associated with laboratory testing are estimated to cost \$5.7 million (\$6.0 million - \$254,043) over the three-year ICR period and impose a burden of 67,000 hours (70,518 - 3,518) over the three-year period.<sup>5</sup> Since these activities are only undertaken at the discretion of the individual respondent and are not part of the Agency's testing program, these estimates are only being provided for completeness, and are not attributable as burden and costs for the purposes of this ICR. Additionally, the Exposure Assessment and Risk Assessment (see below) also impose some non-reporting administrative costs and burdens. In the summary tables below, EPA combines the non-reporting administrative costs and burdens estimated here with those that are estimated for the Exposure Assessment and Risk Assessment.

In addition, to account for general participation burden for non-respondents, EPA estimated that the level of effort for the typical activities associated with initial participation in a consortium might be reasonably represented by an estimate of 21 hours, representing 4 hours for management (\$390.04), 16 hours for technical (\$1,151.36) and 1 hour for clerical (\$28.85). With 45 entities currently participating in the program, the total burden for this activity would be 945 hours (21 x 45), with a cost of \$70,661.25 (\$1,570.25 x 45).

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<sup>5</sup> Final estimates incorporate some rounding error from previous calculations.

## *Exposure Assessments*

EPA has estimated the labor hours and costs associated with exposure assessments by soliciting information from within the Agency and from several of its contractors that have experience in performing exposure assessments that are similar in scope and complexity to the requirement defined in the Federal Register notice for the VCCEP. Based on this information, EPA has estimated that a Tier 1 exposure assessment would require 500 labor hours, a Tier 2 assessment would require 1,000 labor hours, and a Tier 3 assessment would require 1,200 labor hours. Furthermore, EPA has assumed that 85 percent of those hours are for technical labor, 10 percent are for clerical labor, and 5 percent are for managerial labor. EPA assumes that all 23 chemicals will be subject to the exposure assessment requirement of the VCCEP, regardless of the level of previous testing. Thus, over the three-year ICR period, 58 exposure assessments will take place (23 each in Tiers 1 and 2, plus 12 in Tier 3). Table 5 summarizes EPA's estimates for exposure assessments for the VCCEP rule. Based on EPA's information, the exposure assessment for the VCCEP will result in a three-year burden of 48,900 hours and \$3.4 million. Because a sponsor typically hires a contractor to conduct an exposure assessment, EPA does not attribute the total cost of the assessment to paperwork burden and costs, but instead only 25%.

In addition to these costs, EPA has assumed that the Exposure Assessment will impose some non-reporting administrative costs and burdens. EPA assumes that these costs and burdens will represent 25 percent of the estimated cost for performing the Exposure Assessment, or 12,225 hours and \$842,626 over the three-year ICR period. In the summary tables below, EPA includes these estimates in the non-reporting administrative costs category with similar costs for the hazard assessment and risk assessment.

**Table 5. Burden and Cost Estimates for Exposure Assessments and Risk Assessments**

Requirement/ Tier	Burden Per Chemical				Total Burden [a]	Total Cost [b]
	Technical Labor	Clerical Labor	Management Labor	TOTAL		
<b><i>Exposure Assessment</i></b>						
Tier 1	425	50	25	500	11,500	\$792,655
Tier 2	850	100	50	1,000	23,000	\$1,585,310
Tier 3	1,020	120	60	1,200	14,400	\$992,542
<b>Total</b>					<b>48,900</b>	<b>\$3,370,507</b>
<b><i>Risk Assessment</i></b>						
Tier 1	255	30	15	300	6,900	\$475,593
Tier 2	425	50	25	500	11,500	\$792,655
Tier 3	510	60	30	600	7,200	\$496,271
<b>Total</b>					<b>25,600</b>	<b>\$1,764,519</b>

[a] Total burden is calculated by multiplying the total burden per chemical by 23 chemicals for Tiers 1 and 2 and 12 chemicals for Tier 3.

[b] Total cost is calculated by multiplying the burden per chemical for each labor category (technical labor, clerical labor, and managerial labor) by the category's loaded hourly rate (\$71.96 for technical labor, \$28,85 for clerical labor, and \$97.51 for managerial labor), adding, and then multiplying by 23 chemicals for Tiers 1 and 2 and 12 chemicals for Tier 3.

### *Risk Assessments*

EPA has also estimated the labor hours and costs associated with risk assessments by soliciting information from within the Agency and from several of its contractors that have experience in performing risk assessments that are similar in scope and complexity to the requirement defined in the Federal Register notice for the VCCEP. Based on this information, EPA has estimated that a Tier 1 risk assessment would require 300 labor hours, a Tier 2 assessment would require 500 labor hours, and a Tier 3 assessment would require 600 labor hours. As with the exposure assessment, EPA has assumed that 85 percent of those hours are for technical labor, 10 percent are for clerical labor, and 5 percent are for managerial labor. EPA assumes that all 23 chemicals will be subject to the risk assessment requirement of the VCCEP, regardless of the level of previous testing. Thus, over the three-year ICR period, 58 risk assessments will take place (23 each in Tiers 1 and 2, plus 12 in Tier 3). Table 5 also summarizes EPA's estimates for risk assessments for the VCCEP rule. Based on EPA's information, the risk assessment for the VCCEP will result in a three-year burden of 25,600 hours and \$1.8 million.

In addition to these costs, EPA has assumed that the Risk Assessment will impose some non-reporting administrative costs and burdens. EPA assumes that these costs and burdens will represent 25 percent of the estimated cost for performing the Risk Assessment, or 6,400 hours and \$441,130 over the three-year ICR period. In the summary tables below, EPA includes these estimates in the non-reporting administrative costs category with similar costs for the Hazard Assessment and Exposure Assessment.

#### *Data Needs Assessment*

The data needs assessment for the VCCEP program requires sponsors to identify the additional hazard and/or exposure information that is needed to adequately assess the potential risks to children and, where appropriate, parents. The data needs assessment is required to be submitted with Tiers 1 and 2, but not with Tier 3. Thus, a total of 46 data needs assessments will be required under the ICR (23 chemicals × 2 tiers).

To estimate the costs associated with this requirement, EPA assumed that the burden for this requirement would be proportional to the time that sponsors spend on the hazard, exposure, and risk assessments since the data needs assessment is derived from these three other assessments. EPA further expects that the time for this requirement would represent only a small proportion of the total time for the three other assessments. EPA bases this assumption on the fact that the skilled technical professionals who will conduct the hazard, exposure, and risk assessments should be able to spot data gaps for each chemical. Thus, EPA assumes that the data needs assessment will represent two percent of the total hours spent on the three other assessments and that all of the hours will be for technical labor. From Tables 3 and 4, Hazard Assessments, Exposure Assessments, and Risk Assessments are estimated to impose 237,309 hours for Tiers 1 and 2.<sup>6</sup> Based on the two percent assumption, the data needs assessment will impose a burden of 4,746 hours over the three-year ICR period. Assuming all of this labor is technical labor results in a three-year cost of \$341,522 (4,746 × \$71.96).

#### *Peer Consultation Document*

EPA assumes that the Peer Consultation Document (PCD) will not require any significant additional time. The PCD is a compilation of the hazard assessment, exposure assessment, risk assessment, and data needs assessment. EPA expects that respondents will develop each of these components in a manner that can be readily combined into the Peer Consultation Document.

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<sup>6</sup> From Table 3, the Hazard Assessment imposes 0 hours for Tier 1 and 184,409 hours for Tier 2. From Table 5, the Exposure Assessment imposes 11,500 hours for Tier 1 and 23,000 hours for Tier 2. Also from Table 5, the Risk Assessment imposes 6,900 hours for Tier 1 and 11,500 hours for Tier 2. The total of these six estimates is 237,309 hours.

### *Present Assessments at Public Meetings*

EPA has assumed that at each Tier, a sponsor will incur 50 burden hours per chemical to complete this task. To derive this estimate, EPA has assumed that at least two persons per chemical will attend the public meeting for each sponsor and that the meeting will require three days of time (including preparation, travel, and attendance) from each person (2 persons × 3 days × 8 hours per day = 48 total hours). EPA rounded the estimate up to 50 hours. Based on this assumption, this task will impose a three-year burden of 2,900 hours (50 hours per chemical per Tier × 23 chemicals each for Tiers 1 and 2 , plus 50 hours x 12 chemicals in Tier 3). Assuming all labor is technical labor results in a three-year cost of \$208,684.

### *Submit Comments On EPA's Data Needs Decision*

EPA assumed that the level of effort for submitting comments on EPA's data needs decision would be identical to that of presenting the assessment at public meetings. That is, EPA assumed that respondents would require 50 hours of technical labor to submit comments. Based on this assumption, this task will impose a three-year burden of 2,900 hours (50 hours per chemical per Tier × 23 chemicals each for Tiers 1 and 2, plus 50 hours x 12 chemicals in Tier 3) and a three-year cost \$208,684.

### Total Cost and Burden

Table 6 summarizes the total and annual number of responses, costs, and reporting burdens associated with the VCCEP. To derive the annual estimates, EPA divided the relevant numbers by three years. EPA estimates that the VCCEP will result in paperwork burdens of 81,112 hours and \$5,573,317 over the three-year ICR period. The estimated annual reporting burdens for the VCCEP are 27,037 hours and \$1,857,773.

EPA has also estimated that respondents will incur other non-reporting burdens related to the paperwork activities for testing, data searches, attending public meetings, exposure assessments, risk assessments, the data needs assessment, and non-reporting administrative tasks. EPA estimates that these non-reporting burdens will total 381,884 hours and \$31.9 million over the three-year ICR period, or 127,295 hours and \$10,657,454 annually.

Therefore, the total annual burden and costs associated with this information collection are estimated to be 154,332 hours and \$12,515,227.

### Number of Responses

EPA estimates that the total number of responses for the VCCEP will be 897 over the three-year ICR period, or 297 responses annually. This implies an average of 39.0 responses per respondent (897÷23) over the three-year period (13.0 responses annually). Additionally,

the average response will take 519.6 hours (154,332 hours / 297) at a cost of \$42,139 (\$12,515,227 / 297).

**Table 6. Summary of Respondent Cost and Burden Estimates**

ACTIVITY	THREE-YEAR TOTALS			ANNUAL TOTALS		
	Number	Burden Hours	Costs	Number	Burden Hours	Costs
<b>REPORTING BURDENS</b>						
Letters of commitment	58	232	\$16,694	19	77	\$5,565
Robust Summaries for Hazard Assessments	174	3,480	\$212,915	58	1,160	\$70,972
Exposure Assessments	58	48,900	\$3,370,506	19	16,300	\$1,123,502
Risk Assessments	58	25,600	\$1,764,518	19	8,533	\$588,173
Comments on Data Needs Decision	58	2,900	\$208,684	19	967	\$69,561
<b>REPORTING TOTALS</b>	<b>406</b>	<b>81,112</b>	<b>\$5,573,317</b>	<b>134</b>	<b>27,037</b>	<b>\$1,857,773</b>
<b>NON-REPORTING BURDENS</b>						
Initial Burden	45	945	\$70,661	15	315	\$23,554
Hazard Assessments	78	282,070	\$23,933,994	26	94,023	\$7,977,998
File Searches	174	5,598	\$404,290	58	1,866	\$134,763
Non-Reporting Administrative [a]	78	85,625	\$7,013,212	26	28,542	\$2,337,737
Data Needs Assessment	58	4,746	\$341,522	19	1,582	\$113,841
Public meetings	58	2,900	\$208,684	19	967	\$69,561
<b>NON-REPORTING TOTALS</b>	<b>491</b>	<b>381,884</b>	<b>\$31,972,363</b>	<b>163</b>	<b>127,295</b>	<b>\$10,657,454</b>
<b>TOTAL BURDEN AND COSTS</b>	<b>897</b>	<b>462,996</b>	<b>\$37,545,680</b>	<b>297</b>	<b>154,332</b>	<b>\$12,515,227</b>

Note: totals may not add due to rounding.

[a] Includes non-reporting administrative costs and burdens for Hazard Assessments, Exposure Assessments, and Risk Assessments.

## 6(b) Agency Cost and Burden

The cost and burden to the Agency to process, review, and analyze the information collected under the VCCEP are discussed below and detailed in Table 7.

EPA is assuming that the Agency collection activities will be performed by a GS-14, Step 1, employee and a GS-11, Step 1, employee. The U.S. Office of Personnel Management reports that these labor categories have base hourly rates of \$35.79 and \$21.25, respectively, for 2001 in the Washington, DC area. EPA added 60 percent to these hourly rates to account for benefits. Thus, the 2001 loaded hourly rate for a GS-14, Step 1,

employee is \$57.26 and for a GS-11, Step 1, employee is \$34.00. In addition, the final review and final decision-making activities will be performed by GS-15, Step 1 employees. The Office of Personnel Management reports that the hourly labor rate for these employees is \$42.10 per hour for 2001 in the Washington, DC area. Adding 60 percent to that labor rate results in a loaded hourly rate of \$67.36 for the GS-15, Step 1 labor category.

AGENCY LABOR CATEGORY	LOADED HOURLY RATE (\$2001)
GS-15, Step 1	\$67.36
GS-14, Step 1	\$57.26
GS-11, Step 1	\$34.00

EPA employees will perform a number of activities under the VCCEP program, including: reviewing letters of commitment (GS-14), developing and maintaining a system to track commitments (GS-14), responding to sponsor's questions/problems (GS-14), receiving and forwarding the PCDs (GS-11), reviewing peer consultation reports (GS-14 and GS-15), making final data needs decisions (GS-15), communicating program results/status to public on website (GS-14 and GS-11), and overall program management (GS-14). These activities will account for approximately 60% of the GS-14 employee's time and 20% of the GS-11 employee's time over the period of the ICR, or annually 1200 and 400 hours respectively. The final review and decision-making process will require roughly 500 hours annually from the GS-15 employees.

In addition to the activities performed by EPA personnel, the Agency expects to spend \$500,000 annually on a third-party scientific organization that will arrange peer consultations by relevant experts who will review submissions by sponsors. It is important to note that while this figure represent funds that the Agency expects to expend on cooperative agreements with contractors, EPA will not have direct control over these contractors as it would for a typical contract effort. These cooperative agreements, while paid for by EPA, will provide independent support for the VCCEP.

Table 7 summarizes EPA's estimate. Based on EPA's assumptions, the Agency activities will result in 6,300 labor hours over the three-year ICR period and \$1.8 million. Of the total dollar amount, \$1.5 million represents costs associated with the Peer Consultation process, for which no labor hours are estimated.

**Table 7. Total Agency Cost and Burden Estimates, Three-Year ICR Period**

COLLECTION ACTIVITY	GS-15, Step 1		GS-14, Step 1		GS-11, Step 1		GRAND TOTAL	
	HOURS	COST	HOURS	COST	HOURS	COST	HOURS	COST
Receive PCDs								
Review Letters of Commitment								
Track commitments								
Respond to sponsors								
Communicate results on website	1,500	\$101,040	3,600	\$206,136	1,200	\$40,800	6,300	\$347,976
Manage program								
Review Peer Consultation reports								
Make data needs decision								
Arrange Peer Consultations			NA	NA	NA	NA	NA	\$1,500,000
<b>GRAND TOTAL</b>			<b>3,600</b>	<b>\$206,136</b>	<b>1,200</b>	<b>\$40,800</b>	<b>6,300</b>	<b>\$1,847,976</b>

**6(c) Bottom Line Annual Burden Hours and Costs – Master Tables**

6(c)(i) Respondent Tally

Table 8 summarizes the average annual burden per response. EPA estimates that this ICR will impose paperwork burden hours on respondents over the three-year ICR period. This total burden covers 297 responses annually for an average of 519.6 hours per response.

**Table 8. Average Annual Burden Hours Per Response**

COLLECTION ACTIVITY	ANNUAL RESPONDENT BURDEN PER RESPONSE		
	TOTAL HOURS	TOTAL RESPONSES	HOURS PER RESPONSE [a]
<b>REPORTING BURDENS</b>			
Letters of Commitment	77	19	4.1
Robust Summaries for Hazard Assessments	1,160	58	20.0
Exposure Assessments	16,300	19	857.9
Risk Assessments	8,533	19	449.1
Comments on Data Needs Decision	967	19	50.9
<b>REPORTING TOTALS</b>	<b>27,037</b>	<b>134</b>	<b>201.8</b>
<b>NON-REPORTING BURDENS</b>			
Initial Burden	315	15	21.0
Hazard Assessments	94,023	26	3,616.3
File Searches	1,866	58	32.2
Non-Reporting Administrative	28,542	26	1,097.8
Data Needs Assessment	1,582	19	83.3
Public meetings	967	19	50.9
<b>NON-REPORTING TOTALS</b>	<b>127,295</b>	<b>163</b>	<b>780.9</b>
<b>TOTAL BURDEN HOURS</b>	<b>154,332</b>	<b>297</b>	<b>519.6</b>

Note: Totals may contain some rounding error from previous tables.

[a] = Total hours / Total responses

The total burden hours and costs for respondents have been summarized above in Section 6(a). Table 9 summarizes these estimated annual burden hours and costs.

**Table 9. Summary of Annual Respondent Burden and Costs Estimates**

COLLECTION ACTIVITY	Annual Total	
	Hours	Cost
<b>REPORTING BURDENS</b>		
Letters of commitment	77	\$5,565
Robust Summaries for Hazard Assessments	1,160	\$70,972
Exposure Assessments	16,300	\$1,123,502
Risk Assessments	8,533	\$588,173
Comments on Data Needs Decision	967	\$69,561
<b>REPORTING TOTALS</b>	<b>27,037</b>	<b>\$1,857,773</b>
<b>NON-REPORTING BURDENS</b>		
Initial burden	315	\$23,554
Lab testing for Hazard Assessments	94,023	\$7,977,998
File Searches	1,866	\$134,763
Non-Reporting Administrative	28,542	\$2,337,737
Data Needs Assessment	1,582	\$113,841
Public meetings	967	\$69,561
<b>NON-REPORTING TOTALS</b>	<b>127,295</b>	<b>\$10,657,454</b>
<b>TOTAL BURDEN AND COSTS</b>	<b>154,332</b>	<b>\$12,515,227</b>

6(c)(ii) Agency Tally

The burden hours and costs for the government have been calculated above in Section 6(b). These estimates are translated to annual estimates by dividing each by three years. The VCCEP will require 2,100 agency-hours annually and \$615,992. Of the total cost, \$500,000 is for peer review consultations for which no hours have been estimated. These estimates are summarized below in Table 10.

**Table 10. Summary of Agency Burden and Costs Estimates**

COLLECTION ACTIVITY	TOTAL ANNUAL AGENCY BURDEN AND COSTS	
	BURDEN (Hours)	COSTS
Receive PCDs	2,100	\$115,992
Review Letters of Commitment		
Track commitments		
Respond to sponsors		
Communicate results on website		
Manage program		
Review Peer Consultation reports		
Make data needs decision		
Arrange Peer Consultations		
<b>GRAND TOTAL</b>	<b>2,100</b>	<b>\$615,992</b>

**6(d) Burden Statement**

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-[tbd], is estimated to average 519.6 hours per response. 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 currently valid OMB control number. The OMB control number for this information collection appears above. In addition, the OMB control numbers for EPA's regulations, after initial display in the Federal Register, are listed in 40 CFR part 9, as well as in any applicable collection instrument.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division (2822), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave, NW, Washington, D.C. 20460. Include the OMB control number in any correspondence, but do not

submit the requested information to this address. The requested information should be submitted in accordance with the instructions accompanying the form, or as specified in the corresponding regulation.

## **ATTACHMENTS**

[NOTE: Unless otherwise noted, an electronic version of the listed attachment appears in the electronic file for the ICR, following the main text of the Supporting Statement.]

Attachment 1 - Wage Rates Estimation

Attachment 2 - Voluntary Children's Chemical Evaluation Program; Notice. 65 FR 81699, December 26, 2000. For an electronic copy of this notice go to <http://www.epa.gov/oppt/chemrtk/chldhfr.htm>.

Attachment 3 - Toxic Substances Control Act Section 4 (15 USC 2603) (For an electronic copy of this law go to <http://www.epa.gov/opptsfrs/home/rules.htm>.)

Attachment 4 - 40 CFR 790 - Procedures Governing Testing Consent Agreements and Test Rules (For an electronic copy of this regulation go to <http://www.epa.gov/opptsfrs/home/rules.htm>.)

Attachment 5 - Public Notice Required Prior to ICR Submission to OMB, [to be added when ICR goes to OMB].

Attachment 6 - Response to Comments [if applicable]