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: Voluntary Children's Chemical Evaluation Program (VCCEP)

EPA ICR No.: 2055.03 OMB Control No.: 2070-0165

1(b) Short Characterization

The Voluntary Children's Chemical Evaluation Program (VCCEP) is a voluntary program 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 risks of chemicals to which children have a high likelihood of exposure. This is the second renewal of the Information Collection Request (ICR) that covers the activities related to the pilot of VCCEP, which with this renewal will also cover new, non-pilot chemicals to be added to and evaluated in VCCEP. EPA decided to run a pilot of the VCCEP so it could evaluate the program and, if necessary, make changes to increase the efficiency of the program's implementation and influence how chemicals should be handled in VCCEP in the future. Of particular interest was the Peer Consultation Process that was being used for the first time in such a program.

EPA conducted an interim evaluation of the pilot in 2006 – 2007. After consulting stakeholders at a 2008 public meeting, EPA is considering modifying VCCEP in the following 4 ways: 1) EPA may include tests from both Tier 2 and 3 in a single Data Needs Decision and request sponsorship of both tiers in a single commitment, 2) the sponsor may be responsible for paying the organization that manages the Peer Consultation process, 3) the sponsor may revise its Peer Consultation Document because of comments at the Peer Consultation before that document is used by EPA to prepare its Data Needs Decision, and 4)VCCEP may accept additional chemicals for review if requested by Agency officials or other government agencies.

This ICR covers the paperwork activities related to the testing and evaluation of the remaining VCCEP pilot chemicals and additional chemicals that may be added to VCCEP. Specifically, this ICR covers the commitment letters, activities, VCCEP-related comments/information, data, chemical assessments, and revised chemical assessments to be requested by EPA so

that the objectives of VCCEP as that program is described in the December 26, 2000, Federal Register Notice (65 FR 81700) (see Attachment 1) can be met.

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 parties through an extensive stakeholder involvement process that included individuals from the chemical industry, various government agencies, child health groups, environmental groups, animal welfare groups, and the general public. Through the VCCEP and commitments by chemical sponsors, EPA will obtain data on chemicals to which children are likely to be exposed. Participation in the VCCEP and submission of data are voluntary. Industry has the opportunity to make a separate commitment for each of three tiers and each commitment is initiated by a letter to EPA identifying the chemical and tier of information that a company is volunteering to sponsor. However, because of program changes under consideration, sponsors may be asked to commit to sponsor both upper tiers together instead of separately in the future. Sponsors then collect or develop data that provide information on health effects, exposure, risk, and additional data needs of the sponsored chemicals. EPA will use a publicly conducted Peer Consultation Process to help assess whether the submitted data are adequate to fully characterize the risk to children and, if not, what additional data are needed.

The VCCEP is also designed to ensure that health effects, exposure, and risk information collected on chemicals are made publicly available to allow EPA and others to pursue any necessary risk management or regulatory action with respect to a chemical, 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. EPA makes the collected data publicly available on the VCCEP website at http://www.epa.gov/oppt/vccep/index.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 manufacture or import the specified chemical, or a consortium formed by these entities, will develop the specified data and report the results to EPA.

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 certain findings for hazard and/or exposure are made by EPA. 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 the general population had 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 in or imported into the United States. Other chemicals were deferred because of ongoing assessments that are similar in scope to the VCCEP.

If EPA acts on changes being considered, EPA may include additional chemicals in the VCCEP if requested by Agency officials or other government agencies.

2(b) Use/Users of the Data

The information collected through the VCCEP will provide critical information on health effects, exposure, risk, and additional data needed to evaluate the risks of chemicals to which children have a high likelihood of exposure. This will enable EPA and others to properly assess and manage health risks to children that may be posed by exposure to certain TSCA chemicals evaluated by VCCEP. This information will also be made publicly 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 health risk to children from exposure to any of the VCCEP chemicals has been adequately characterized. In determining whether exposure to a VCCEP chemical poses a risk to children's health and whether data from the next VCCEP Tier are needed, the EPA scientists will rely on the opinions of the scientific experts at the Peer Consultation and public comment processes. If EPA's Data Needs Decision differs substantially from the approach indicated by the report of the Peer Consultation meeting, EPA will provide a supporting rationale indicating the basis for its approach. Concurrence on the Data Needs Decision will be obtained from other EPA Offices before the decision is final. EPA has provided guidance to the

chemical sponsors that explain how to develop an acceptable assessment document, and how to assess risk to children. The Peer Consultation Group will use accepted scientific standards when reviewing the assessment documents provided by the sponsor. EPA also intends to apply the accepted scientific standards and principles, as is currently done in making risk determinations under other TSCA programs.

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. 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. For example, six of the first thirteen Peer Consultations conducted under the VCCEP resulted in recommendations that no further data were needed to characterize risks to children.

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.

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 and animal welfare groups) to discuss the appropriate test battery to evaluate chemicals of concern for children's 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 EPA Science Advisory Panel (SAP) identified such a test battery. The stakeholder involvement process also identified a tiering process that would stagger the submission of 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, or, due to the program changes under consideration, to Tier 1 and Tier 2/3. Before conducting any new testing, it is the VCCEP sponsor's responsibility to review available data and existing studies so 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 occur 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 the VCCEP will be posted on the EPA website, where they will be available to the public (see http://www.epa.gov/oppt/vccep/).

3(a)(2) Exemptions

Exemptions are not required or necessary for this program because participation in the program is voluntary.

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

In proposing to renew this ICR, EPA provided a 60-day public notice and comment period that ended on February 23, 2009 (73 FR 79086, December 24, 2008). EPA received one comment during the comment

period from the Halogenated Solvents Industry Alliance (HSIA). This comment, and EPA's response to the comment, is in Attachment 4.

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 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. Five years after the initiation of the pilot, EPA evaluated the pilot program to consider what modifications might be made that would make the VCCEP run more efficiently. Stakeholders, the organization that manages the Peer Consultation process and the general public were consulted in this evaluation.

Additionally, under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an ICR to OMB for review and approval. In accordance with this regulation, EPA submitted questions to nine parties via email. The individuals contacted were:

Dr. John Balbus,
Environmental Defense
jbalbus@edf.com

Ms. Lynn Jones Batshon,
Synthetic Organic Chemical
Manufacturers Assoc.
jones@socma.com

Ms. Leslie Berry,
American Chemistry Council (ACC),
Leslie_Berry@americanchemistry.com

Dr. Paul H. Dugard,
Halogenated Solvents Industry Alliance
pdugard@hsia.org

Ms. Sally Kokie Hall, Dow Chemical Co.
skokke-hall@dow.com

Mr. Michael Hulse, Shell Chemical Co.
michael.hulse@shell.com

Ms. Sarah McLallen, ACC
Sarah_McLallen@americanchemistry.com

Mr. Richard Opatick, ACC
Richard_Opatick@americanchemistry.com

Mr. Derek Swick, American Petroleum Institute
swickd@api.org

EPA received one response to its solicitation for consultations, in the form of a supportive comment. A copy of EPA's consultation e-mail to the above nine potential respondents and the one response received is in Attachment 5.

3(d) Effects of Less Frequent Collection

As designed, this program minimizes overall burden by utilizing a tiering process for submissions and by allowing companies to jointly sponsor a chemical, limiting submissions per chemical to the minimum, i.e., only one response per chemical per tier (or per two tiers if a commitment is made to Tier 2/3). 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 the tier(s) of the program committed to. A sponsor may commit to three separate tiers or two separate tiers (Tier 1 and Tier 2/3, per program changes under consideration), and the sponsor for each tier may vary. The sponsor is 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 Practice Standards (GLPS) to be retained for ten years from the effective date of the applicable test rule or publication date of the consent order (40 CFR 792). 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 three tiers, an additional 12 months would be added to the time requirement for the program (8 months if a Data Needs Decision addresses Tier 2/3 data needs in the same decision). Also, the VCCEP is a tiered testing program and, for some pilot chemicals, Tier 3 testing might not begin until eight 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 (approximately two months), the report of the organization that manages the Peer Consultation process (approx. 2 months), EPA's announcement of its Data Needs Decision (approx. 6 months), and 4 months for the sponsor to commit to the next tier of testing. This additional time of 14 months would be required for both Tier 1 and Tier 2, while Tier 3 would require only 4 additional months since it does not have a Data Needs Decision. Therefore, the VCCEP may require an additional 32 months 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 needed.

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 GLP. Thus, the Paperwork Reduction Act (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 in Unit 3(f).

4 THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

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

Type of Entity	NAICS	Examples of Potentially Affected Entities
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

(mmmmmmmmmmlxxx) 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 represent costs and burdens not captured in existing information collections.

In general, Sponsors will be asked to submit a letter of commitment to sponsor a chemical in a specific tier or tiers; submit a Peer Consultation Document for each commitment which will contain four assessments; and retain the required records related to the assessments for ten years after the date they are submitted to EPA.

The table below summarizes the information that a Sponsor will need to submit to EPA:

Information Collections	Description
Initial participation burden	Program familiarization and response determination.
Letters of commitment	A company wishing to volunteer to sponsor its chemical must send a letter to EPA committing to do so by the deadline specified by EPA. Letters of commitment are due 4 months after the announcement of EPA's Data Needs Decision.
File searches	Performing data searches and reviews.
Non-reporting administrative burden	Part of the administrative costs and burdens including efforts of respondents to organize a testing program, obtaining and reviewing bids from labs, and preparing and submitting samples to the lab for testing.

Robust summaries for hazard assessments	Robust summaries include an objective discussion of methods, results and conclusions, and should provide sufficient information to allow a technically qualified person to make an independent assessment of a given study report.
Hazard assessment	A separate Hazard Assessment is prepared for each tier for each chemical to which a sponsor commits. It will include a summary of the studies conducted for a particular tier and any existing relevant studies.
Exposure assessments	The Exposure Assessment is a summary of existing exposure information and any exposure studies conducted by the sponsor.
Risk assessments	The Risk Assessment integrates the information in the Hazard Assessment and the Exposure Assessment for the purposes of characterizing the risk to children's health from exposure to the chemical in question.
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.
Peer consultation document preparation	Preparation and presentation of assessments at Peer Consultation meetings.
EPA VCCEP surveys	EPA may poll or ask VCCEP participants and stakeholders to comment on certain aspects of VCCEP.

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 scope of testing/data development for each chemical is limited to the tier(s) for which a commitment to sponsor has been received, and to the tests/data specified for that tier(s). However, if there are existing studies, even though they address an endpoint in an upper tier not yet committed to, the sponsor is expected to include that study in the relevant assessment prepared for the lower tier. The assessments are to be submitted in a single document, the Peer Consultation Document, and prepared for each tier(s) to which a company or consortium commits.

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

Table 1.--Three Tiers of VCCEP Tests

Tier	Test	Test Guideline
1[1]	Acute oral toxicity (up/down) OR Acute inhalation toxicity	OECD 425 or ASTM E1163-98 OECD 403 or 40 CFR 799.9130
	In vitro 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
	In vitro chromosomal aberrations OR *In vivo* chromosomal aberrations OR *In vivo* 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
2	90-day subchronic toxicity in rodents	870.3100 (oral), or 870.3250 (dermal), or 870.3465 (inhalation) or 40 CFR 799.9346 (inhalation)
	Reproduction and fertility effects	870.3800 or 40 CFR 799.9380
	Prenatal developmental toxicity (two species)	870.3700 or 40 CFR 799.9370
	In vivo mammalian bone marrow chromosomal aberrations, OR *In vivo* mammalian erythrocyte micronucleus Triggered off results from *in vitro* 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
3	Carcinogenicity OR chronic toxicity/carcinogenicity	870.4200 or 40 CFR 799.9420 870.4300
	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 Organization for Economic Cooperation and Development (OECD) guidelines, the American Society for Testing and Materials (ASTM) International guideline, or the OPPTS harmonized guidelines in the 870 series (Health Effects Test

Guidelines). The OPPTS harmonized test guidelines have been developed for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations. Initiated several years ago, the purpose of harmonizing the guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the Agency's data requirements for submissions under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. 136-136y). In establishing the harmonized guidelines, the Agency considers available guidelines, including those that might have been developed by EPA for pesticides or toxic substances, as well as those developed by OECD. Today, the harmonized guidelines may also be newly developed through a cooperative process reflecting all three organizations, as well as others in the scientific community. In general, the process for developing the OPPTS harmonized test guidelines is scientifically rigorous and includes both peer review and public comment opportunities. To access copies of the OPPTS harmonized guidelines, go to http://www.epa.gov/opptsfrs/home/guidelin.htm.

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 or both parents), during prenatal development, and post-natally 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. The specific content of a particular exposure assessment is dependent upon the specific chemical involved and the information available at the time that the assessment is performed. For example, if during Tier 1 it is determined that the chemical in question is only used in industrial settings and using a closed process, it is unlikely that the exposure assessment would need to consider all of the factors that could be included in a complete exposure assessment as listed below. When a question arises about the content of a particular exposure assessment, the sponsor will be able to consult with EPA and other participants before proceeding. To assist the sponsors in preparing a complete Exposure Assessment, the Agency has also made several detailed guidance documents available to sponsors that are also used by EPA staff and others to prepare the exposure assessments that are submitted to or otherwise used by the Agency in decision-making. These documents can be found under Guidance Documents at http://www.epa.gov/oppt/vccep/pubs/submit.htm#F.

Although the guidance documents cited above provide more specific detail about what to include in an Exposure Assessment, the following is a list of the specific types of information that the Agency has told sponsors that they should submit in an Exposure Assessment (see also the discussion that begins on 65 FR 81710):

- 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) has prepared a document entitled Child-Specific Exposure Factors Handbook that consolidates all child exposure factors and related data in one document. After considering public comment, the final Handbook was issued on September 1, 2002 (Child-specific Exposure Factors Handbook (Interim Report), USEPA EPA-600-P-00-002B, 01 Sep 2002) and is easily accessible under Guidance Documents at http://www.epa.gov/oppt/vccep/pubs/submit.htm#F.

The exposure information that is provided for the VCCEP should be transparent and should 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. It is important to note that given the tier structure of the VCCEP, the Exposure Assessment may need to be amended when the chemical proceeds to the next tier. As is always the case, the specific content of a particular exposure assessment is dependent upon the specific chemical involved and the information available to the Sponsor at the time that the assessment is being performed. For example, if during Tier 1 it is determined that the chemical in question is only used in industrial settings and using a closed process, it is unlikely that the exposure assessment would need to consider all of the factors listed. When a question arises, the Sponsor will be able to consult with EPA and other participants before proceeding.

In determining the adequacy of existing data under Tier 1, EPA and the Sponsors agreed to use the same approach contained in the guidance provided for the HPV Challenge Program, a copy of which is available at http://www.epa.gov/chemrtk/pubs/general/datadfin.htm. This document

provides basic guidance for accepting or rejecting data used to describe the basic hazard of a chemical, but the approach presented is also generally used for determining whether available data are adequate to describe the potential health effects of a chemical. Basically, the approach used has two steps. In Step 1, established criteria should be used to assess overall scientific integrity of the information. Any data or information that do not meet the Step 1 criteria are to be rejected from further consideration. In Step 2, a more rigorous evaluation of existing data that have passed Step 1 occurs (existing data generated via OECD or equivalent guidelines can enter directly into Step 2 evaluation). The specific criteria are test specific and described in detail in the guidance document referenced above.

In determining whether a chemical will proceed to Tier 2 or to Tier 2/3, the Agency will review all of the assessments submitted by the Sponsor, along with the Peer Consultation report, and prepare a Data Needs Decision at the completion of Tier 2. If Tier 2 data are submitted, a Data Needs Decision must also be submitted at the completion of Tier 2. For the most part, the Agency's Data Needs Decision is expected to mirror the general opinion of the Peer Consultation report. As described in the December 2000 Federal Register Notice describing the VCCEP, the Agency considers the following factors when making a Data Needs Decision under the VCCEP (see also the discussion that begins on 65 FR 81712):

(1) EPA will utilize a risk-based, scientifically sound process to make decisions on the need for further information gathering or risk reduction action (65 FR 81715).

(2) When the risk characterization is adequate to characterize the relative level of risk to children and, where relevant, prospective parents, additional studies or data from the next tier will not be pursued (65 FR 81712).

(3) In making a data needs decision, EPA will use a weight-of-evidence approach to evaluate both the hazard and exposure data prepared by the sponsor (65 FR 81712).

(4) An appropriately conservative screening level assessment can help rule out certain exposures (65 FR 81711).

(5) If specific toxicity studies are indicated, they should be chosen from the next tier(s) of studies within the overall framework and should allow flexibility, if possible, to pursue either additional toxicity testing and/or exposure evaluation, allowing sponsors to select the option that will most quickly, directly, and cost-effectively reduce uncertainty (65 FR 81713). And,

(6) Other factors may also be considered, as appropriate. See also the discussion that begins on 65 FR 81712.

4(c) Respondent (Sponsor) Activities

Sponsors of VCCEP chemicals and pilot VCCEP chemicals 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 for the subject chemical(s), and EPA's decision on the need for additional data on the chemical(s). The maximum number and type of activities that a Sponsor of a VCCEP chemical or pilot VCCEP chemical can be anticipated to undertake per tier commitment are listed below for all three tiers, even though many of the VCCEP chemicals may not complete all three tiers of evaluation during the effective period of this ICR, but the majority of the pilot VCCEP chemicals have completed most of their evaluation under VCCEP.

Tier 1:

(10764) Review notice announcing the VCCEP.
(10765) Submit Letter of Commitment to EPA volunteering to sponsor a chemical in Tier
1.
(10766) Conduct file search for relevant existing data on toxicity and exposure. If existing
data are found:
- Prepare summaries of existing data.
- Add summaries to Hazard and Exposure Assessments.
(10767) 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 the Peer Consultation Document for Tier 1 to the organization that
manages the Peer Consultation process.
(9) Present the assessments to the Peer Consultation Group at the public meeting.
(10) Revise Peer Consultation Document if so advised by the Peer Consultation
Group and in accordance with its comments. Resubmit the Peer Consultation

Document to the organization that manages the Peer Consultation process and three copies and one electronic copy to EPA.
(11) Maintain test data records and Peer Consultation Documents for ten years.

Tier 2:

(11432) Submit Letter of Commitment to EPA volunteering to sponsor a chemical in Tier
2.
(11433) Conduct file search for any new existing data on toxicity and exposure. If existing data are found:
- Prepare summaries of existing data.
- Add summaries to Hazard and Exposure Assessments.
(11434) Plan necessary activities, e.g., consortia, arrange for conduct of studies, etc.
(11435) Prepare Hazard Assessment, Exposure Assessment, Risk Assessment and Data
Needs Assessment for Tier 2 for each chemical committed to.
(11436) Prepare Peer Consultation Document for Tier 2 for each chemical committed to.
(11437) Review Peer Consultation Document for CBI.
(11438) Submit the Peer Consultation Document for Tier 2 to the organization that
manages the Peer Consultation process.
(11439) Present the assessments to the Peer Consultation Group at the public meeting.
(11440) Revise Peer Consultation Document if so advised by the Peer Consultation
Group and in accordance with its comments. Resubmit the Peer Consultation
Document to the organization that manages the Peer Consultation process and
three copies and one electronic copy to EPA.
(11441) Maintain test data records and Peer Consultation Documents for ten years.

Tier 2/3 or Tier 3:

() Submit Letter of Commitment to EPA volunteering to sponsor a chemical in Tier 2/3 or Tier 3.
() Conduct file search for any new existing data on toxicity and exposure. If existing data are found:
- Prepare summaries of existing data.
- Add summaries to Hazard and Exposure Assessments.

() Plan necessary activities, e.g., consortia, arrange for conduct of studies, etc.
() Prepare Hazard Assessment, Exposure Assessment and Risk Assessment for Tier 2/3 or Tier 3 for each chemical committed to.
() Prepare Peer Consultation Document for Tier 2/3 or Tier 3 for each chemical committed to.
() Review Peer Consultation Document for CBI.
() Submit the Peer Consultation Document to the organization that manages the Peer Consultation process.
() Present the assessments to the Peer Consultation Group at the public meeting.
() Revise Peer Consultation Document if so advised by the Peer Consultation Group and in accordance with its comments. Resubmit the Peer Consultation Document to the organization that manages the Peer Consultation process and three copies and one electronic copy to EPA.
() Maintain test data records and Peer Consultation Documents for ten years.

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

() Letter of Commitment: A company wishing to volunteer to sponsor its chemical in the VCCEP must send a letter to EPA committing to do so by the deadline specified by EPA. 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, and the anticipated submission date to EPA. Letters of commitment for Tier 1 have been received for 20 chemicals; letters of commitment for Tier 2 have been received for two chemicals (decabromodiphenyl ether and benzene). Letters of commitment are due 4 months after the announcement of EPA’s Data Needs Decision.

() Hazard Assessment: A separate Hazard Assessment is to be prepared for each tier for each chemical to which a sponsor commits. The Hazard Assessment should be a 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 of each study is to 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 2/3 or Tier 3 commitment, the sponsor should develop a Hazard Assessment that includes summaries of those Tier 2/3 or Tier 3 studies that EPA has announced in its Data Needs Decision. In addition to the new hazard data developed for Tier 2/3 or Tier 3, the Tier 2/3 or Tier 3 Hazard Assessment should also contain all the information from the previous Hazard Assessment(s), which should be revised as appropriate to reflect new insights provided by the new hazard data developed for Tier 2/3 or Tier 3.

() Exposure Assessment: The Exposure Assessment should be a 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 90th 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.

() 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.

() 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.

() 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 the organization that manages the Peer Consultation. Revisions addressing comments of the Peer Consultation Group will be submitted to the organization that manages the Peer Consultation process and to EPA (two copies and one electronic copy). EPA will put one copy in the TSCA Nonconfidential Information Center (NCIC) docket.

() Data Needs Decision: The Data Needs Decision is prepared by EPA and is a decision concerning which tests in the next tier(s) of the VCCEP are needed. EPA makes this decision after reviewing the report of the Peer Consultation (prepared by the organization that manages the Peer Consultation process), and expects to rely on the opinions in the report. If EPA's Data Needs Decision differs substantially from the approach indicated by the Peer Consultation report, EPA will provide a supporting rationale

indicating the basis for its approach. Concurrence on the Data Needs Decision will be obtained from other EPA Offices before issued as a final decision.

As a voluntary program, it is not necessary for anyone to request an exemption under the VCCEP. However, companies may submit relevant information that indicates that specific chemicals included in the VCCEP because of 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 that is no longer HPV from the 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

4(d) Respondent (Sponsor) Activities from 2002 - 2009.

During the seven years from October 2002 through July 2009, the sponsors have completed or EPA expects they will complete the following activities:

- By July 2008, the sponsors of 15 VCCEP chemicals submitted Tier 1 Peer Consultation Documents to EPA. EPA expects that sponsors of 3 more chemicals will submit Tier 1 Peer Consultation Documents by the end of July 2009. Therefore, for the period from October 2002 through July 2009, EPA expects that sponsors will have submitted a total of 18Tier 1 Peer Consultation Documents to EPA under the VCCEP.

- By July 2008, the sponsors presented the results of their chemical assessments at 11 public Peer Consultation meetings that addressed 15 VCCEP chemicals. (Two meetings addressed two chemicals each and another meeting addressed three chemicals, the remaining eight meetings addressed one chemical each). EPA expects that sponsors will present Tier 1 chemical assessments at 3 more Peer Consultation meetings that will cover 3 chemicals. Therefore, for the period from October 2002 through July 2009, EPA expects that sponsors will have presented Tier 1 chemical assessments for 18 VCCEP chemicals at 14 public Peer Consultation meetings.

- The sponsors responded to EPA's request for upper tier data as follows:

  -On August 25, 2005, EPA requested sponsors of three chemicals that had completed the Tier 1 process to conduct some Tier 2 tests. The basis for the request was contained in EPA's Data Needs Decision documents for decabrominateddiphenyl ether (DBDE), octabrominated- diphenyl ether (OBDE), and

pentabrominateddiphenyl ether (PBDE). EPA requested that fate and transport tests be conducted for DBDE and that 2-generation reproductive toxicity tests be conducted for OBDE and PBDE, and requested sponsors to volunteer within four months. The company sponsor of OBDE and PBDE declined to sponsor its chemicals in the upper tiers of VCCEP. On December 20, 2005, the trade association representing the company sponsors of DBDE committed to sponsor DBDE in Tier 2. By May 2008, adequate Tier 2 studies had not been submitted and EPA terminated DBDE's participation in VCCEP. VCCEP did not obtain the requested Tier 2 data on the three brominated diphenyl ethers.

- On March 9, 2007, EPA requested the sponsors of m-xylene and o-xylene to conduct Tier 2 tests including a neurotoxicity screening battery and the developmental neurotoxicity test. In March 2009, the sponsor declined to do further testing.

- On July 2, 2007, EPA requested the sponsors of benzene to provide additional Tier 1 exposure and environmental fate information and to conduct Tier 3 tests including a neurotoxicity screening battery and the developmental neurotoxicity test. In a letter dated February 21, 2008, the American Chemistry Council, acting on behalf of the sponsors, provided additional exposure and environmental fate information, but declined to sponsor the Tier 3 neurotoxicity tests.

- On May 1, 2008, EPA requested the sponsors of toluene to provide Tier 2 information on occupational and general population exposure. In May 2009, the sponsor declined to do further testing.

The following Table 2 lists the dates when the sponsors submitted their Tier 1 chemical assessments, made their presentations at the Peer Consultation meetings, and, where applicable, committed to or declined to conduct Tier 2 or Tier 3 testing requested by EPA during the period from October 2002 through July 2009. For dates listed in 2009 and late 2008, EPA has estimated the date when it expects an activity to occur.

Table 2.BSponsor Activities from October 2002 through July 2009.

Chemical Name/ CAS No.	Submission Date of Tier 1 Peer Consultation Document	Date of Peer Consultation Meeting	Date of Tier 2 or Tier 3 Commitment	Submission Date of Adequate Tier 2 or Tier 3 Data
Vinylidene chloride	12/30/02	01/29-30/03	NA	

75-35-4				
Decabrominated diphenylether 1163-19-5	12/20/02	04/02B03/03	12/20/05	Not provided.
Octabrominated diphenylether 32536-52-0	04/21/03	06/04-05/03	No commitment	
Pentabrominated diphenylether 32534-81-9	04/21/03	06/03-04/03	No commitment	
Acetone 67-64-1	09/10/03	11/18-19/03	NA	
Methyl ethyl ketone 78-93-3	12/04/03	02/19/04	NA	
n-Dodecane 112-40-3	06/17/04	09/14/04	NA	
Undecane 1120-21-4	06/17/04	09/14/04	NA	
Decane 124-18-5	06/17/04	09/14/04	NA	
m-Xylene 108-38-3	10/07/05	12/13-14/05	No commitment 3/30/09	
o-Xylene 95-47-6	10/07/05	12/13-14/05	No commitment 3/30/09	
Toluene 108-88-3	9/29/06	11/7-8/06	No commitment 3/30/09	
Benzene 71-43-2	3/30/06	8/8/06	No commitment	
p-Dioxane 123-91-1	3/13/07	5/1-2/07	Maybe NA.	
Ethylbenzene 100-41-4	12/12/06	2/22-23/07	Maybe NA.	
Dichlorobenzene 106-46-7	Oct 2008*	Dec 2008*	Maybe NA.	
Ethylene Dichloride	After Aug 2009	After Aug 2009	Maybe NA.	

107-06-2				
Alpha-Pinene 80-56-8	Oct 2008*	Dec 2008*	Maybe NA.	
Tetrachloroethylene 127-18-4	After Aug 2009	After Aug 2009	Maybe NA.	
Trichloroethylene 79-01-6	Jan 2009*	Mar 2009*	Maybe NA.	

*Estimated date.
NA =Not applicable because Tier 2 testing was not requested by EPA.
Maybe NA = Maybe not applicable because the need for Tier 2 data has not yet been determined.
NS = Not scheduled.

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

5(a) Agency Activities

In order to sustain three tiers of VCCEP, EPA performs the following applicable activities:

reviews letters of commitment for Tiers 1, 2, and 3, or Tiers 1 and 2/3 (separate letter for each tier or combined tiers) for completeness;

provides information on the commitments and progress of program on the VCCEP website and updates as needed;

maintains a cooperative agreement with the organization that manages the Peer Consultation process 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 the report to EPA and the sponsor;

reviews the sponsor-prepared Peer Consultation Documents and the report of the Peer Consultation meeting; drafts Data Needs Decisions; and coordinates review and approval of the Data Needs Decisions with EPA offices before approval by OPPT Director;

announces the Data Needs Decisions after reviewing submissions for Tiers 1 and 2 on the VCCEP website and in letters to relevant sponsors;

provides explanation of Data Needs Decisions if they differ substantially from the report of the Peer Consultation meeting;

makes the Peer Consultation Documents, the Peer Consultation meeting reports, and the Data Needs Decisions available to the public in the TSCA NCIC and on the VCCEP website; and

h) monitors progress and efficiency of VCCEP by requesting and evaluating information from participants and other stakeholders.

In addition to the activities cited above, the Agency may also participate in other activities related to this program, e.g., relevant workshops, other voluntary efforts to identify data needs 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.

In carrying out the activities related to the VCCEP pilot, EPA will use existing EPA guidance and policies, and follow acceptable scientific standards to conduct its reviews and make decisions. Guidance related to the assessments conducted under the VCCEP has been provided to the sponsors and is available publicly on the VCCEP website, along with Agency Guidance on risk characterizations and assessing risks to children.

During the seven years from October 2002 through July 2009, EPA and the organization that manages the Peer Consultation process completed or plan to complete the following activities:

- The organization that manages the Peer Consultation process held 11 Peer Consultation meetings that evaluated chemical assessments submitted for 15 VCCEP chemicals. EPA expects the organization that manages the Peer Consultation process to hold 6 more Peer Consultation meetings by the end of July 2009, which will cover 3 additional pilot VCCEP chemicals and 3 chemicals newly referred to the VCCEP for evaluation. Therefore, for the period from October 2002 through July 2009, EPA expects that the organization that manages the Peer Consultation process will have held 18 Peer Consultation meetings covering 21 VCCEP chemicals (18 pilot VCCEP and 3 chemicals newly referred to the VCCEP for evaluation).

- The organization that manages the Peer Consultation process prepared summary reports of 11 Peer Consultation meetings covering

15 VCCEP chemicals. EPA expects the organization that manages the Peer Consultation process will prepare 6 more reports of Peer Consultation meetings covering 6 chemicals by the end of July 2009, for a total of 17 summary reports covering 21 VCCEP chemicals (18 pilot VCCEP and 3 chemicals newly referred to the VCCEP for evaluation) for the period from October 2002 through July 2009.

- EPA issued Data Needs Decisions for 6 chemicals on September 20, 2005, 2 chemicals on March 9, 2007, 3 chemicals on April 16, 2007, 1 chemical on July 9, 2007, and 1 chemical on May 1, 2008, for a total 11 Data Needs Decisions covering 13 chemicals
    - EPA asked for additional data from Tier 2 for 7 of the 13 chemicals.
    - EPA decided that additional data were not needed for 6 of the 13 chemicals to characterize their risk to children.

EPA expects to release Data Needs Decisions for 2 more chemicals before the end of July 2009. Therefore, for the period from October 2002 through July 2009, EPA expects to have released Data Needs Decisions for 15 chemicals.

- EPA met with sponsors and/or their representatives to discuss and clarify the additional Tier 1 or upper tier data which EPA had requested.

- EPA cancelled the participation in VCCEP of decabromo-diphenyl ether because adequate Tier 2 data had not been provided to the Agency.

The following Table 3 lists the dates of the Peer Consultation meetings, the release dates of the summary reports of the Peer Consultation meetings, the announcement date of EPA's Data Needs Decisions for the 15 chemicals addressed during the period from October 2002 through July 2009, the Tier 2 testing requested by EPA, and EPA's response to the upper tier submissions. For dates listed in late 2008 to 2009, the last year of the second ICR, EPA has estimated the dates when activities will occur.

Table 3. VCCEP Activities of the Agency and the organization managing the Peer Consultation process from October 2002 through July 2009.

Chemical Name/CAS No.	Date of Peer Consul-tation Meeting	Release Date of Peer Consul-tation Meeting Report	Announce-ment Date of EPA's Data Needs Decisions	Tier 2 or Tier 3 Testing Requested by EPA	EPA's Response to Upper Tier Submis-sions
Vinylidene chloride 75-35-4	01/29-30/03	06/03/03	09/20/05	None	
Decabrominated diphenylether 1163-19-5	04/02-03/03	09/30/03	09/20/05	Tier 2: Fate and transport	Cancelled participation in VCCEP.
Octabrominated diphenylether 32536-52-0	06/04-05/03	01/22/04	09/20/05	Tier 2: 2-gen repro tox with body burden satellite	
Pentabrominated diphenylether 32534-81-9	06/03-04/03	01/22/04	09/20/05	Tier 2: 2-gen repro tox with body burden satellite	
Acetone 67-64-1	11/18-19/03	03/05/04	09/20/05	None	
Methyl ethyl ketone 78-93-3	02/19/04	04/29/04	09/20/05	None	
n-Dodecane 112-40-3	09/14/04	01/07/05	04/16/07	None	
Undecane 1120-21-4	09/14/04	01/07/05	04/16/07	None	
Decane 124-18-5	09/14/04	01/07/05	04/16/07	None	
m-Xylene	12/13-	02/23/06	03/09/07	Tier 3:	

108-38-3	14/05			neurotox screening battery & Dev neuro	
o-Xylene 95-47-6	12/13-14/05	02/23/06	03/09/07	Tier 3: neurotox screening battery & Dev neuro	
Toluene 108-88-3	11/7-8/06	01/16/07	05/01/08	Tier 2: occup & general population exp	
Benzene 71-43-2	6/15-16/06	08/08/06	07/09/07	Tier 3: neurotox screening battery & Dev neuro	
p-Dioxane 123-91-1	5/1-2/07	7/27/07	July 08*		
Ethylben-zene 100-41-4	2/22-23/07	5/31/07	July 08*		
Dichloro-benzene 106-46-7	Dec 2008*	Feb 2009*	After Aug 2009		
Ethylene Dichloride 107-06-2	After Aug 2009	After Aug 2009	After Aug 2009		
Alpha-Pinene 80-56-8	Dec 2008*	Feb 2009*	After Aug 2009		
Tetrachloro-ethylene 127-18-4	After Aug 2009	After Aug 2009	After Aug 2009		
Trichloro-ethylene 79-01-6	Jan 2009*	Mar 2009*	After Aug 2009		

*Estimated date.

5(b) Collection Methodology and Management

Data collected under the VCCEP are received by the TSCA Nonconfidential Information Center (NCIC) which thentransfers the data to the program manager in the Office of Pollution Prevention and Toxics,

Chemical Control Division (CCD), Chemical Testing and Information Branch (CITB), where the data are reviewed for completeness and then, depending on the data received, routed as follows:

- Letters of Commitment are routed to the person in CITB assigned to track the progress of the VCCEP and posted on the VCCEP website.
-Peer Consultation Documents are routed to the organization that manages the Peer Consultation (one copy), to the person in CITB maintaining the VCCEP files (one copy and the electronic copy), to the OPPT workgroup that drafts the Data Needs Decision (one copy), and posted on the VCCEP Website.
- Peer Consultation meeting reports prepared by the organization that manages the Peer Consultation are routed to the person in CITB maintaining the VCCEP files (one copy), to the OPPT workgroup that drafts the Data Needs Decision (one copy), and posted on the VCCEP Website.
- EPA's Data Needs Decision document is routed to the person in CITB maintaining the VCCEP files (one copy), to the OPPT workgroup that drafted the Data Needs Decision (one copy), and posted on the VCCEP Website.

The Peer Consultation Document prepared by the sponsor for Tier 1 contains hazard, exposure, risk, and data needs assessments. The sponsor presents its assessments to the Peer Consultation that will then discuss the assessments with emphasis on the data needs assessment. TERA, the third party scientific organization that has arranged and facilitated the meeting, summarizes the results of the Peer Consultation meeting and sends a report to EPA and the sponsor. EPA reviews the third party's report and the Peer Consultation Document and decides whether any information from the next tier is needed to assess the risks to children of the chemical in question. EPA announces any data needs on the VCCEP website and in a letter to the sponsor. If EPA's decision differs substantially from the meeting report of the organization that manages the Peer Consultation, EPA provides an explanation for its decision. There is a 4-month period for the sponsor or others to volunteer to provide the data requested in Tier 2 or Tier 2/3. The steps in Tier 1 are repeated for Tier 2; the steps in Tier 1 are repeated in Tier 2/3 and in Tier 3 up to but not including a Data Needs Decision. At the end of Tier 2/3 or 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, 3, or 2/3 (which will not be known with certainty until EPA issues its

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) which is posted on the VCCEP Website.

Participants in the VCCEP will submit some information electronically to allow EPA to respond to public requests for information more efficiently. EPA requests one electronic copy and 2 hard copies of the Peer Consultation Document for each chemical at each tier(s) committed to. The organization that manages the Peer Consultation must also be sent one electronic copy of the Peer Consultation Document. If a Peer Consultation Document were developed for each of the 20 pilot VCCEP chemicals and 12 chemicals newly referred to the VCCEP for evaluation for each of the three tiers there could be as many as 96 electronic submissions ((3 x 20) + (3 x 12)). EPA already knows, however, that 6 pilot VCCEP chemicals will have only Tier 1 information submitted, reducing the maximum number of electronic submissions of Peer Consultations Documents to 84 (96 – (6 x 2)).

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 sole 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. Needed testing is conducted only once, and each related submission is a one-time on-occasion submission. The time 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 4, are the times that EPA believes are reasonable to complete each test, if needed, in the VCCEP. It is assumed that tests in the same tier or combined tier (i.e., Tier 2/3) will be conducted simultaneously.

Table 4.--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[1]
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.

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 covering August 2009 through July 2012, 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 are based on the assumptions listed below. These assumptions are based on historical experience with the TSCA testing and information

gathering programs, conservative projections for the VCCEP and its pilot over the period August 2009 through July 2012, and the progress made in information collection from October 2002 through July 2009 (described in Units 4(d) and 5(a)). These assumptions are used only to estimate burden and costs that are presented in this ICR and should not be considered to be a presumption of testing needs. The need for testing will be science driven and testing will be required only to the extent that it is reasonably necessary to characterize potential health risks to children.

The first ICR assumed that the entire VCCEP pilot would be completed in the three-year ICR period. As stated in section 4(d) and 5(a), 3 of the 20 pilot chemicals were not completed in the six years of the first and second ICRs. Although EPA believes that the remaining three pilot chemicals will be completed during the third ICR, along with other chemicals that may be newly included in the VCCEP, the estimates of cost and burden in this ICR should be seen as extremely conservative. See also Assumption 4.

1) EPA assumes that data will be collected on 20 chemicals during the course of the VCCEP pilot. Although 23 chemicals had been selected for the VCCEP pilot, thus far only 20 chemicals have been sponsored. Thirty-five companies acting through ten consortia are the sponsors.

2) Of the 20 pilot VCCEP chemicals listed in Tables 2 and 3, the Tier 1 information collection was addressed or is expected to be addressed for 18 chemicals by the end of the second ICR. Data Needs Decisions will have been issued for 15 chemicals before the expiration date of the second ICR. To date, i.e., June 2008, Data Needs Decisions for 13 chemicals have been issued and 6 of the 13 chemicals have been determined to have sufficient data to characterize their risk to children based on the Tier 1 information collection. Additional information has been requested for 7 of the 13 chemicals, but to date such information has not been provided or no commitment has been received.

3) Although EPA also assumes that the Tier 1 Peer Consultation Document will be completed for the other 3 of the 18 chemicals (listed in Tables 2 and 3 and below) and 3 other chemicals that may be newly included in the VCCEP by the end of the second ICR, EPA assumes that Data Needs Decisions for these 6 chemicals will not be issued during the effective period of the second ICR.

alpha-Pinene (CAS No. 80-56-8)
p-Dichlorobenzene (CAS No. 106-46-7)
Trichloroethylene (CAS No. 79-01-6)

4) EPA assumes that sponsors of the remaining two pilot VCCEP chemicals, listed below, will begin and complete the entire three-tier process

or be judged to have sufficient data short of the three tiers during the effective period of the third ICR, i.e., from August 2009 through July 2012:

Ethylene dichloride (CAS 107-06-2)
Tetrachloroethylene (CAS No. 127-18-4)

EPA understands that the initiation of VCCEP testing of ethylene dichloride and tetrachloroethylene has been delayed pending the release of ongoing evaluations by ATSDR and NAS, respectively.

5) EPA assumes that five to ten additional chemicals will be included in the VCCEP per year for consideration to be evaluated in VCCEP between July 2008 until the end of the third ICR(July 2012), but that only three chemicals per year will be accepted for evaluation in VCCEP. It should be noted, that "three chemicals per year" is only an estimate.

6) EPA assumes that the work to be addressed during the period of the third ICR will include:

- The preparation and submission of **11 Tier 1 Peer Consultation Documents (and likely subsequent revisions)** for Ethylene Dichloride, Tetrachloroethylene, and 9 additional VCCEP chemicals by the sponsors.

- The preparation and submission of **11 Tier 1 Peer Consultation meeting reports** covering 11 chemicals (Ethylene Dichloride, Tetrachloroethylene, and 9 additional VCCEP chemicals) by the organization that manages the Peer Consultation.

- The preparation of **17 Tier 2 Data Needs Decisions** for alpha-Pinene, p-Dichlorobenzene, Trichloroethylene, Ethylene Dichloride, Tetrachloroethylene, and 12 additional VCCEP chemicals by EPA, as the last step in Tier 1.

- The **conduct of Tier 2 tests and information collection for 17 chemicals**. The "17 chemicals" come from the 26 chemicals that will at some point reach Tier 2 during the period of the third ICR; those 26 chemicals are alpha-Pinene, p-Dichlorobenzene, Trichloroethylene, Ethylene Dichloride, Tetrachloroethylene, 12 additional VCCEP chemicals), 7 VCCEP chemicals with previously identified, but not provided Tier 2 data needs, and 2 pilot VCCEP chemicals with yet to be announced (as of June 2008) Tier 2 tier data needs. Of the 26 chemicals, 7 are known to have Tier 2 data needs and it is assumed that of the remaining 19 (26 – 7), 50% or 10 will have Tier 2 data needs, making a total of 17 chemicals (7 + 10).

- The preparation and submission of **17 Tier 2 Peer Consultation Documents (and likely subsequent revisions)** by the sponsors.

- The preparation and submission of **17 Tier 2 Peer Consultation meeting reports** covering 17 chemicals by the organization that manages the Peer Consultation.

- The preparation of **17 Tier 3 Data Needs Decisions** by EPA, as the last step in Tier 2.

- The **conduct of Tier 3 tests and information collection for nine chemicals**. The "nine chemicals" come from the 17 chemicals that were in Tier 2 during the period of the third ICR. Of the 17 chemicals, it is assumed that 50% or 9 will have Tier 3 data needs, making a total of 9 chemicals that may be in Tier 3 during the period of the third ICR.

- The preparation and submission of **nine Tier 3 Peer Consultation Documents (and likely subsequent revisions)** by the sponsors.

- The preparation and submission of **nine Tier 3 Peer Consultation meeting reports** covering nine chemicals by the organization that manages the Peer Consultation.

7) The assumptions provided in this ICR renewal are a conservative estimate of the cost and burden associated with the VCCEP and its pilot. In the event that fewer than 32 chemicals (20 pilot chemicals and 12 additional VCCEP chemicals) complete 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 assumed, the process for any of the 32 chemicals lasts beyond the expiration date of the third ICR, then the total burden and cost will be extended over a longer time frame, thus reducing the annual burden and cost of the program.

8) One or several chemicals may be sponsored by one company or a consortium representing several companies.[1] 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 manufacture the chemical. Thus, the total number of respondents for the pilot VCCEP will be no more than 20 and no more than 12 additional chemicals to be included in VCCEP, for a total of 32 respondents.

1 ? In most instances, test sponsors have formed consortia 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.

9) The three 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 5.

10) 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 67% of the subchronic tests will be conducted by inhalation (guideline 799.9346), and 33% 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.)

11) Each respondent must submit one letter of commitment, and one Peer Consultation Document for each chemical they have committed to for each Tier or combined Tiers. 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. An initial review by the Peer Consultation may recommend that the document be revised before being evaluated by EPA. At this point, the sponsor will revise and resubmit his Peer Consultation Document.

12) In conducting any test that will be submitted to EPA under TSCA, the respondent must comply with Good Laboratory Practice Standards (GLPS). Because 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 5.

13) EPA assumes that all of the chemicals have Tier 1 test data available through the EPA High Production Volume (HPV) Challenge program, the OECD SIDS program, or other chemical evaluation programs.

14) EPA assumes some of the Tier 2 and Tier 3 tests identified in Table 1 of this ICR have been conducted for some of the VCCEP pilot chemicals

and the chemicals to be added to VCCEP. 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.

15) Judging from the VCCEP experience discussed in Unit 5(a), EPA estimates that 50% of the chemicals in the pilot will move on to the Tier 2 or 2/3 chemical assessment, and 50% which have had a Tier 2 assessment will require Tier 3. Again, EPA stresses that these assumptions are used only to estimate burden and costs that are presented in this ICR and should not be considered to be a presumption of testing needs. The need for testing will be determined through the VCCEP process.

16) 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. Some respondents, however, may use their own facilities to conduct the testing.

17) The programs established for the VCCEP and HPV Challenge chemicals are voluntary initiatives under which manufacturers (including importers) of chemicals targeted for information gathering and possible testing will voluntarily submit data on hazard endpoints; the VCCEP also includes exposure, risk, and data needs information.

18) 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 TSCA 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.[2] The costs and burden associated with these data searches are included as reporting costs and are described below under Reporting Costs and Burdens.

19) Due to the program changes under consideration, the cost of the organization that manages the Peer Consultation process is expected to be paid by the sponsors for half of the Peer Consultations.

20) Based on previous requests for comment, EPA estimates that any future poll of VCCEP participants and stakeholders for their opinions on

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

VCCEP-related matters will result in 6 to 12 responses (average of 9) when there are 20 chemicals in the program. A response may vary from one to ten pages (average of four).

6(a) Respondent Cost and Burden

For purposes of calculating the PRA paperwork-related burden and costs for this ICR, the Agency estimated costs for both non-paperwork burdens (e.g., laboratory testing costs) and paperwork burdens (e.g., administrative costs and burden) participants will incur in the program. For costs such as the laboratory testing costs, only a portion of the total cost may be attributed to the paperwork-related requirements (i.e., reporting burden) that EPA imposes on the participants. EPA is presenting all costs, not just paperwork or reporting burden, in the ICR.

The unit burden for each activity is based upon previous TSCA section 4 ICRs and EPA's best estimates of the burdens that will be incurred under the VCCEP over the next three-year period. Loaded hourly labor rates, including fringe costs and overhead are $60.29 for management time, $51.95 for technical time, and $25.82 for clerical time. These labor rates adhere to the latest Bureau of Labor Statistics (BLS) data[3] and are summarized as follows:

INDUSTRY LABOR CATEGORY	LOADED HOURLY RATE ($2008)
Managerial	$60.29
Technical	$51.95
Secretarial	$25.82

Based upon the assumptions and labor rates 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 (including import) the chemical. Thus, there will be 20 total respondents for the VCCEP and 12 for the other chemicals. 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

3 [?] Labor rates are unpublished March 2008 data from BLS for private industry workers. The estimates include fringe benefits and 17% overhead.

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 some burden and costs related to their participation in the consortium, described below. At this time, a total of 45 entities (35 pilot chemical companies and 10 pilot chemical consortia) are 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 responding to VCCEP surveys. EPA's estimated costs and burdens for each of these respondent activities are discussed below.

Laboratory Costs and Burdens (Hazard Assessments)

Each chemical that is sponsored in the VCCEP pilot is expected to 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 the 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 7 above. Table 5 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. Costs and burden for the protocols are best estimates taken from a database EPA generates and maintains. As mentioned previously, laboratory testing costs are not paperwork costs under the PRA, but are presented for completeness.

EPA expects that at least some of these chemicals will already have been subjected 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 could require each specific test. Table 5 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 5). 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 the number of chemicals participating in that Tier and then subtracting the result from the total number of chemicals for each tier.[4] 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 $23.1 million and 210,253 hours of labor over the three-year ICR period. EPA estimates that a total of 59 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 $392,181 per study ($23.1 million / 59 studies).

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 three 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 17 chemicals (6 tests * 17 chemicals = 102) plus the number of tests in Tier 3 multiplied by 9 chemicals (3 tests * 9 chemicals = 27), for a total of 129 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 2,580 hours and $117,177 over the same period.[5]

Administrative Costs and Burdens

Part of the administrative costs and burdens associated with this ICR include preparing letters of commitment and performing data searches and reviews. EPA has summarized its estimates for these categories in Table 6, and discusses each below.

For letters of commitment, EPA assumed that each sponsor would submit one letter for each tier. Thus, a total of 26 letters would be received over the three-year ICR period (17 in Tier 2, plus 9 in Tier 3; Tier 1 is completed). Consistent with other TSCA ICRs, EPA assumed that submitting these letters would impose a burden of four hours of technical labor for each

4 ? 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 (33 percent) and those that would receive inhalation route testing (67 percent). This adjustment is explained in more detail in assumption number 10 above and in the notes to Table 5.

5 ? The costs for this requirement are estimated as: (129 studies)*[(15 hours technical time)*($51.95)+ (5 hours clerical time)*($25.82)].

submission. This implies a total burden of 104 hours and $5,403 over the three-year ICR period. These costs and burden hours are considered reporting burdens by EPA.

Table 5. 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,c,d]	Total Testing Cost	Total Testing Burden (Hours)
Tier 1: 11 Chemicals participating								
1	Acute inhalation toxicity	OECD 403	$ 18,740	184	100%	0	$ -	-
2	*In vitro* gene mutation: Bacterial reverse mutation assay	799.9510	$ 9,404	61	100%	0	$ -	-
3	Repeated dose oral toxicity	OECD 407	$ 51,708	328	100%	0	$ -	-
4	*In vivo* mammalian erythrocyte micronucleus	799.9539	$ 19,291	132	100%	0	$ -	-
	TOTAL FOR TIER 1		*$ 99,143*	*705*		*0*	*$ -*	-
Tier 2: 17 Chemicals participating								
1	90-day subchronic toxicity in rodents	870.3100	$ 133,726	757	81.8%	1[c]	$ 133,726	757
		799.9346	$ 388,807	2,458	81.8%	2[d]	$ 777,614	4,916
2	Preproduction and fertility effects	799.9380	$ 1,052,082	9,449	29.5%	12	$ 12,624,984	113,388
3	Prenatal developmental toxicity (two species)	799.9370	$ 112,565	1,079	38.6%	10	$ 1,125,650	10,790
4	*In vivo* mammalian erythrocyte micronucleus	799.9539	$ 19,291	132	81.8%	3	$ 57,873	396
5	Immunotox	870.7800	$ 80,703	415	31.8%	12	$ 968,436	4,980
6	Metabolism and pharmacokinetics	870.7485	$ 40,227	330	90.9%	2	$ 80,454	660
	TOTAL FOR TIER 2		*$ 1,827,401*	*14,620*		*42*	*$ 15,768,737*	*135,887*
Tier 3: 9 Chemicals participating								
1	Carcinogenicity	799.9420	$ 1,603,145	17,953	68.2%	3	$ 4,809,435	53,859
2	Neurotoxicity screening battery	799.9620	$ 127,268	883	45.5%	5	$ 636,340	4,415
3	Developmental neurotoxicity	870.6300	$ 213,798	1,788	4.5%	9	$ 1,924,182	16,092
	TOTAL FOR TIER 3		*$ 1,944,211*	*20,624*		*17*	*$ 7,369,957*	*74,366*
GRAND TOTALS						59	$ 23,138,694	210,253

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

[b] To calculate the number of tests for any tier, EPA multiplied the baseline testing rate by the number of chemicals in that tier, and then subtracted the result from the number of chemicals in that tier.

[c] To calculate the number of tests performed in Tier 2 by the oral route, EPA multiplied the number of chemicals needing testing (3) by 33 percent, per assumption 10.

[d] To calculate the number of tests performed in Tier 2 by inhalation, EPA multiplied the number of chemicals needing testing (3) by 67 percent, per assumption 10.

Table 6. Administrative Costs and Burden

Category	Letters of Commitment	Data Searches	TOTAL
Tier 2			
Number	17	51	**68**
Burden	68	1,641	**1,709**
Cost	$ 3,533	$ 84,038	**$ 87,571**
Tier 3			
Number	9	27	**36**
Burden	36	869	**905**
Cost	$ 1,870	$ 44,491	**$ 46,361**
TOTALS			
Number	**26**	**78**	**104**
Burden	**104**	**2,509**	**2,613**
Cost	**$ 5,403**	**$ 128,529**	**$ 133,931**

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 35 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 51 searches will occur for Tier 2 and 27 searches will occur under Tier 3. This results in a total of 78 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, 1 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 2,509 hours and $128,529 over the three-year ICR period. This is a non-reporting burden.

Other non-reporting administrative activities include the effort of respondents to organize a testing program, obtain and review bids from laboratories that would conduct the testing, and prepare and submit samples to the laboratory for testing. EPA's experience in test rule development has shown that these administrative costs and burdens associated with testing programs to be approximately 25 percent of the laboratory costs. EPA applied this assumption to the Tier 2 and 3 estimates (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. 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 481 hours ($25,000 / $51.95 per hour). For the sake of this ICR analysis, EPA estimates that this paperwork burden will be about 494 hours.

From Table 5, Tiers 2 and 3 testing involve a total cost of $23.1 million and 210,253 hours. To calculate total administrative costs (reporting plus non-reporting administrative) for Tiers 2 and 3, EPA multiplies each estimate by 25 percent to get $5.8 million and 52,563 hours over the three-year ICR period. Because 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 reporting 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 initial 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 ($241.16), 16 hours for technical ($831.20) and 1 hour for clerical ($25.82). With 45 entities currently participating in the program, the total burden for this activity would be 945 hours (21 hours * 45 participants), with a cost of $49,418 ($1,098.18 * 45). This is also considered a non-paperwork burden.

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 exposure assessment need defined in the Federal Register notice for the VCCEP pilot. 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. Thus, over the three-year ICR period, 37 exposure assessments will take place (11 remaining in Tier 1, 17 in Tier 2, plus 9 in Tier 3). Table 7 summarizes EPA's estimates for exposure assessments for the VCCEP pilot. Based on EPA's information, the exposure assessment for the VCCEP pilot will result in a three-year burden of 33,300 hours and $1.7 million.

A sponsor typically hires a contractor to conduct an exposure assessment, but EPA still considers the total cost of the assessment as paperwork burden and costs. EPA also assumes that the exposure assessment will impose some non-reporting administrative costs and burdens. As with testing costs, EPA estimates that these costs and burdens will amount to 25 percent of the estimated cost for performing the Exposure Assessment, or 8,325 hours and $414,202 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 (testing) and risk assessment.

Table 7. 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		
Exposure Assessment						
Tier 1	425	50	25	500	5,500	$ 273,647
Tier 2	850	100	50	1,000	17,000	$ 845,818
Tier 3	1,020	120	60	1,200	10,800	$ 537,343
Total					***33,300***	***$ 1,656,808***
Risk Assessment						
					3,300	$ 164,188

Tier 1	255	30	15	300		
Tier 2	425	50	25	500	8,500	$ 422,909
Tier 3	510	60	30	600	5,400	$ 268,672
Total					***17,200***	***$855,769***

[a] Total burden is calculated by multiplying the total burden per chemical by 11 chemicals for Tier 1, 17 chemicals for Tier 2, and 9 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 ($51.95 for technical labor, $25.82 for clerical labor, and $60.29 for managerial labor), adding, and then multiplying by 11 chemicals for Tier 1, 17 chemicals for Tier 2, and 9 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. Thus, over the three-year ICR period, 37 risk assessments will take place (11 remaining in Tier 1, 17 in Tier 2, and 9 in Tier 3). Table 7 also summarizes EPA's estimates for risk assessments for the VCCEP pilot. Based on EPA's information, the risk assessment for the VCCEP will result in a three-year burden of 17,200 hours and $855,769.

A sponsor typically hires a contractor to conduct a risk assessment but EPA still considers the total cost of the assessment as paperwork burden and costs. EPA also assumes 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 4,300 hours and $213,942 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 (testing) and exposure assessment.

Data Needs Assessment

The data needs assessment for the VCCEP program involves identifying 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 expected to be submitted with Tiers 1 and 2, but not with Tier 3. Thus, a total of 28 data needs assessments will be prepared and submitted under the ICR (11 chemicals in Tier 1 plus 17 chemicals in Tier 2).

To estimate the costs associated with this activity, EPA assumed that the burden would be proportional to the time that sponsors spend on the hazard, exposure, and risk assessments because the data needs assessment is derived from these three other assessments. EPA further expects that the time for this activity 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 5 and 6, hazard assessments, exposure assessments, and risk assessments are estimated to impose 170,187 hours for Tiers 1 and 2.[6] Based on the two-percent assumption, the data needs assessment will impose a burden of 3,404 hours over the three-year ICR period. Assuming all of this labor is technical labor results in a three-year cost of $176,824 (3,404 * $51.95).

Peer Consultation Document

EPA assumes that the Peer Consultation Document (PCD) will not involve any significant additional time. The PCD is a compilation of the hazard assessment, exposure assessment, risk assessment, and data needs assessment. The costs associated with these activities have already been accounted for above. EPA expects that respondents will develop each of these components in a manner that can be readily combined into the Peer Consultation Document.

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 51 hours. Based on this assumption, this task will involve a three-year burden of 1,850 hours (51hours per chemical * 37 chemicals [11 chemicals remaining in Tier 1, 17 chemicals for Tier 2, 9 chemicals in Tier 3]). Assuming all labor is technical labor results in a three-year cost of $96,108. In response to public comments on a previous ICR, EPA has included travel costs to attend the public meetings at $1,000 per person. Travel costs would add $74,000 to the three-year costs ($1,000 per person * 2 persons per meeting * 37 meetings (11 remaining meetings for Tier 1, 17 for Tier 2, and 9 meetings for Tier 3). Therefore, the cost of

6 [7] From Table 5, the hazard assessment imposes 0 hours for Tier 1 and 135,887 hours for Tier 2. From Table 7, the exposure assessment imposes 5,500 hours for Tier 1 and 17,000 hours for Tier 2. Also from Table 7, the risk assessment imposes 3,300 hours for Tier 1 and 8,500 hours for Tier 2. The total of these six estimates is 170,187 hours.

presenting assessments at the public meetings would be $170,108 over three years. These figures represent a very conservative cost estimate (i.e., a likely overestimate), as experience with the VCCEP has shown that some meetings will cover two or three chemicals.

EPA VCCEP Surveys

As needed, EPA may poll or ask VCCEP participants and stakeholders to comment on certain aspects of VCCEP. EPA will most likely use the VCCEP website and e-mail to request and receive comments. As noted above, EPA expects to receive an average of 9 responses averaging 4 pages in length. The burden associated with this task is limited to writing out comments only. No time is assumed for data collection or analysis. Based on best professional judgment, VCCEP participants are expected to spend up to one hour composing each page of their comments. Therefore, the total three year burden is estimated to be 36 hours (9 responses * 4 pages per response * 1 hour per page). Assuming all of this labor is technical labor results in a three-year cost of $1,870 (36 * $51.95).

Total Cost and Burden

Table 8 summarizes the total and annual number of responses, costs, and reporting burdens associated with the VCCEP pilot. To derive the annual estimates, EPA divided the relevant numbers by three years. EPA estimates that the VCCEP pilot will result in paperwork burdens of 53,220 hours and $2,637,027 over the three-year ICR period. The estimated annual industry reporting burdens for the VCCEP are 17,740 hours and $879,008.

EPA has also estimated 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 that respondents will incur. EPA estimates that these non-reporting burdens will total 284,149 hours and $30.0 million over the three-year ICR period, or 94,716 hours and $10.0 million annually.

Therefore, the total annual industry burden and costs associated with this information collection are estimated to be 112,456 hours and $10.9 million.

Number of Responses

EPA estimates that the total number of responses (reporting burdens only) for the VCCEP pilot will be 238 over the three-year ICR period, or 79 responses annually. The average number of responses per respondent is therefore 7.4 responses (238/32) over the three-year period (2.5 responses annually). Additionally, the average response

will take 224 hours (53,220 hours/238) at a cost of $11,080 ($2,637,027/238).[7]

7 Note that the average response burden and cost will differ slightly in tables 8 and 10 due to rounding in tables.

Table 8. Summary of Respondent Cost and Burden Estimates

ACTIVITY	THREE-YEAR TOTALS			ANNUAL TOTALS		
	Number	Burden Hours	Costs	Number	Burden Hours	Costs
REPORTING BURDENS						
Letters of commitment	26	104	$ 5,403	9	35	$ 1,801
Robust Summaries for Hazard Assessments	129	2,580	$ 117,177	43	860	$ 39,059
Exposure Assessments	37	33,300	$ 1,656,808	12	11,100	$ 552,269
Risk Assessments	37	17,200	$ 855,769	12	5,733	$ 285,256
EPA VCCEP Surveys	***9***	***36***	$ 1,870	***3***	***12***	$ 623
REPORTING TOTALS	***238***	***53,220***	***$ 2,637,027***	***79***	***17,740***	***$ 879,008***
NON-REPORTING BURDENS						
Initial Burden	45	945	$ 49,418	15	315	$ 16,473
Hazard Assessments	59	210,253	$ 23,138,694	20	70,084	$ 7,712,898
File Searches	78	2,509	$ 128,529	26	836	$ 42,843
Non-Reporting Administrative [a]	133	65,188	$ 6,412,818	44	21,729	$ 2,137,606
Data Needs Assessment	28	3,404	$ 176,824	9	1,135	$ 58,941
Public meetings	37	1,850	$ 170,108	12	617	$ 56,703
NON-REPORTING TOTALS	***380***	***284,149***	***$ 30,076,390***	***126***	***94,716***	***$ 10,025,464***
TOTAL BURDEN AND COSTS	**618**	**337,369**	**$ 32,713,417**	**205**	**112,456**	**$ 10,904,472**

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 9.

EPA is assuming that the Agency collection activities will continue to be performed by GS-14 Step 1 employees and GS-11 Step 1 employees. The U.S. Office of Personnel Management reports hourly rates for all GS levels for 2007 in the Washington, DC area. EPA added 60 percent to these hourly rates to account for benefits and overhead

burden. Thus, the 2007 loaded hourly rate for a GS-14, Step 1 employee is $71.94 and for a GS-11 Step 1 employee is $42.70. In addition, the final review and final decision-making activities will be performed by GS-15 Step 1 employees. The Office of Personnel Management 2007 hourly labor rate for the Washington, DC area, plus 60 percent, results in a loaded hourly rate of $84.61 for the GS-15 Step 1 employee.

AGENCY LABOR CATEGORY	LOADED HOURLY RATE ($2007)
GS-15, Step 1	$84.61
GS-14, Step 1	$71.94
GS-11, Step 1	$42.70

EPA employees will perform a number of activities under the VCCEP pilot 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 20% of the GS-14 employees' time and 10% of the GS-11 employees' time over the period of the ICR, or annually 400 and 200 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 $250,000 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 9 summarizes EPA's estimate. Based on EPA's assumptions, the Agency activities will result in 3,300 labor hours over the three-year ICR period and $1.0 million. Of the total dollar amount, $750,000 represents costs associated with the Peer Consultation process, for which no labor hours are estimated.

Table 9. 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								
Manage program								
Poll VCCEP Participants								
Review Peer Consultation reports								
Make data needs decision	1,500	$126,912	1,200	$86,323	600	$25,622	3,300	$238,858
Arranges and Reports on Peer Consultations			NA	NA	NA	NA	NA	$750,000
GRAND TOTAL			**1,200**	**$86,323**	**600**	**$25,622**	**3,300**	**$988,858**

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

6(c)(i) Respondent Tally

Table 10 summarizes the average annual burden and cost per response. EPA estimates that this ICR will impose an average annual paperwork burden of 549 hours per response on 205 annual responses over the three-year ICR period, at an average annual cost of about $53,000 per response. Therefore, EPA estimates the annual burden for all responses to be 112,456 hours at a cost of $10,904,472

Table 10. Average Annual Burden Hours per Response

COLLECTION ACTIVITY	ANNUAL RESPONDENT BURDEN PER RESPONSE				
	TOTAL RESPONSES	TOTAL HOURS	HOURS PER RESPONSE [a]	TOTAL COST	COST PER RESPONSE [b]
REPORTING BURDENS					
Letters of Commitment	9	35	3.9	$ 1,801	$ 200
Robust Summaries for Hazard Assessments	43	860	20.0	$ 39,059	$ 908
Exposure Assessments	12	11,100	925.0	$ 552,269	$ 46,022
Risk Assessments	12	5,733	477.8	$ 285,256	$ 23,771
EPA VCCEP Surveys	3	12	4.0	$ 623	$ 208
REPORTING TOTALS	***79***	***17,740***	***224.6***	***$ 879,008***	***$ 11,127***
NON-REPORTING BURDENS					
Initial Participation Burden	15	315	21.0	$ 16,473	$ 1,098
Hazard Assessments	20	70,084	3,504.2	$ 7,712,898	$ 385,645
File Searches	26	836	32.2	$ 42,843	$ 1,648
Non-Reporting Administrative	44	21,729	493.8	$ 2,137,606	$ 48,582
Data Needs Assessment	9	1,135	126.1	$ 58,941	$ 6,549
Public meetings	12	617	51.4	$ 56,703	$ 4,725
NON-REPORTING TOTALS	***126***	***94,716***	***751.7***	***$10,025,464***	***$ 79,567***
TOTAL BURDEN AND COST	**205**	**112,456**	***548.6***	**$10,904,472**	**$ 53,193**

Note: Totals may contain some rounding error from previous tables
[a] = Total hours/Total responses
[b] = Total cost/Total responses

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 1,100 agency-hours annually and $329,619. Of the total cost, $250,000 is for peer review consultations for which no hours have been estimated. These estimates are summarized below in Table 11.

Table 11. Summary of Agency Burden and Costs Estimates

COLLECTION ACTIVITY	TOTAL ANNUAL AGENCY BURDEN AND COSTS	
	BURDEN (Hours)	COSTS
Receive PCDs		
Review Letters of Commitment		
Track commitments		
Respond to sponsors		
Communicate results on website		
Manage program		
Review Peer Consultation reports		
Make data needs decision	1,100	$79,619
Arranges and Reports on Peer Consultations	NA	$250,000
GRAND TOTAL	**1,100**	**$329,619**

6(d) Reasons for Change in Burden

There is an increase of 6,200 hours (from 106,256 to 112,456 hours) in the total estimated paperwork respondent burden in this information collection compared with that identified in the information collection last approved by OMB. This increase represents the net effect of changes in estimates and assumptions made since the previous VCCEP ICR due to the inclusion of the additional chemicals in the program as well as the recent inclusion of VCCEP participant surveys.

Estimates for respondent costs have also increased for the following reasons. Costs for the test protocols were increased based on the most-recent EPA estimates. Also, labor wage rates were updated (increased) to current year dollars.

6(e) Burden Statement

The annual paperwork burden for this collection of information is estimated to average about 549 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, “burden” 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. 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.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2008-0816, which is available for online viewing at www.regulations.gov, or in person viewing at the Pollution Prevention and Toxics Docket in the EPA Docket Center (EPA/DC). The EPA/DC Public Reading Room is located in the EPA West Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280. You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques.

Comments may be submitted to EPA electronically through http://www.regulations.gov or by mail addressed to Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. You can also send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Include docket ID No. EPA-HQ-OPPT-2008-0816 and OMB control number 2070-0165 in any correspondence.

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 B 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/chemrtk/vccep/pubs/ts00274d.pdf.

Attachment 2 B Toxic Substances Control Act Section 4 (15 USC 2603)

Attachment 3 B Procedures Governing Testing Consent Agreements and Test Rules (40 CFR 790)

Attachment 4 – Copy of Public Comment on ICR Renewal and EPA's Response

Attachment 5 – Copy of EPA's Consultation Request to Potential Respondents and Response