

Interim VCCEP Evaluation Summary of Comments On the VCCEP Pilot Program

U.S. Environmental Protection Agency

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1.0 INTRODUCTION

On November 20, 2006, EPA issued a notice in the Federal Register requesting comment on the implementation of the pilot phase of the Voluntary Children's Chemical Evaluation Program (VCCEP) (71 FR 67121). VCCEP was designed to collect health effects, exposure, and risk information on chemicals to which children are likely to be exposed, and to make that information available to the public so the public may better understand the potential health risks to children associated with certain chemical exposures. EPA announced the Program in December 2000 and requested chemical manufacturers and importers to participate in a pilot of the Program by voluntarily sponsoring their chemical if it were among those selected by EPA. The pilot began in 2001 when companies volunteered to sponsor their chemicals in response to EPA's request.

At approximately the midpoint in the implementation of the pilot phase of VCCEP, EPA requested input via the November 20, 2006, Federal Register Notice to better enable the Agency to evaluate how well it is meeting its objectives for VCCEP. To this end, EPA sought comments evaluating the operations and experience under the VCCEP pilot to this point and additionally developed a list of questions in order to focus comments on certain features of the VCCEP pilot on which the Agency particularly wants input. The comments received in response to the notice are summarized in this document, which will assist EPA in determining what modifications might be made to make the program run more efficiently and/or better meet the objectives of VCCEP.

2.0 SUMMARY

EPA received comments from 11 interested parties in response to the Federal Register (FR) Notice request (71 FR 67121). The responses provided feedback on the progress of the VCCEP Pilot Program.

The comment documents submitted by interested parties were reviewed by EPA for content pertaining to the questions posed in the FR Notice, as well as any additional information relevant to the VCCEP Pilot Program in general. Review of the submissions yielded 138 individual comments relevant to the VCCEP Pilot Program from the 11 submitters.

This document organizes the comments into five primary categories:

- 1) Comments on Sponsor-Submitted Assessments (10 comments);
- 2) Comments on the VCCEP Peer Consultation Process (37 comments);
- 3) Comments on Other Aspects of the VCCEP Pilot Program Process (34 comments);
- 4) Comments on Progress Toward Meeting Objectives and Communicating Information (20 comments); and,
- 5) General and Other VCCEP-Related Comments (37 comments).

Brief summaries of the comments within each category are presented below, and more detailed discussion is presented in Sections 3.1 through 3.5. The full comment submissions are available in the public docket for this FR notice (EPA-HQ-OPPT-2006-0341).

Sponsor-Submitted Assessments

In the FR Notice, EPA solicited responses to the following questions related to sponsor-submitted assessments:

- Have the hazard, exposure, and risk assessments submitted by the sponsors provided sufficient information to enable the Peer Consultation panel to

adequately evaluate these aspects as they relate to children from the chemicals in question?

- Have the Data Needs Assessments prepared by the sponsor been fair and unbiased?

Comments on the sponsor-submitted assessments were generally in agreement that the assessments themselves were adequate, fair and unbiased. However, concern was expressed over the structure of the program failing to mandate sponsor response to public comments. Section 3.1 provides further comment analyses and excerpts from submissions that addressed the sponsor-submitted assessments.

Peer Consultation Process

In the FR Notice, EPA solicited responses to the following questions related to the peer consultation process:

- Has the Peer Consultation process been open, transparent, timely, and useful as a forum for scientists and experts from various stakeholder groups to exchange views on sponsors' assessments and recommended data needs?
- How might the Peer Consultation process be improved?
- Has the Peer Consultation process been efficient?
- If the Peer Consultation process has not been efficient, what improvements could be made?
- Has the Peer Consultation panel adequately considered both toxicology and exposure information in developing its results?
- Does the Peer Consultation process provide a scientifically rigorous and effective means for eliciting comments and opinions from the assembled experts on the Peer Consultation panel and those attending the public meeting, and for assisting EPA in developing decisions?
- Have the communications related to the Peer Consultation process, activities and outcomes been effective and have they facilitated public understanding and use of the information generated from this process?

Conflicting views were expressed over whether the peer consultation process is truly open and transparent. Accounts were given as to how successfully the panel meetings have involved varied panel members who were able to efficiently deal with conflicting viewpoints, compile useful judgments, and highlight data gaps. Comment submitters generally agreed that the peer consultation panel adequately considered information, though the time period required to do so was considerable.

Submitters also noted concerns relating to the peer consultation process. Concern was expressed over the autonomy of the panel, due to perceived potential influence from other components of the VCCEP program (e.g., industry sponsorship) and potential conflicts of interest. Although it was generally agreed that the peer consultation panel provided a scientifically rigorous assessment of information submitted by industry sponsors, concern was expressed that panel members were not encouraged to contribute potentially useful information other than the identification of data gaps. Section 3.2 provides further comment analyses and excerpts from submissions that addressed the peer consultation process.

Other Aspects of the VCCEP Pilot Program Process

In the FR Notice, EPA solicited responses to the following questions related to other aspects of the VCCEP Pilot Program:

- How can the timeliness of activities under the VCCEP pilot be improved?
- Should specific due dates be established for each step in the process? If so, how should a missed due date be addressed?
- Is it better to run the VCCEP pilot with commitments at each tier, i.e., three commitments, or to run the VCCEP pilot with two commitments, i.e., to Tier 1 and to Tiers 2/3?
- Are there ways in which EPA's contributions to the VCCEP pilot's evaluation and data needs decision process could be improved or made more efficient?
- Should the time allowed for sponsor commitment remain the same, i.e., 6 months to commit to Tier 1, and 4 months to commit to subsequent Tiers? (The

commitment period is the time for the sponsor to decide whether to participate in VCCEP, form a consortium, and notify the Agency)

- Should the sponsor be requested to commit to more than one tier at a time?

The timeliness and efficiency of the overall program was addressed by many comment submitters. Suggestions were made for EPA to restructure the program to: establish time frame goals; prioritize chemicals for evaluation; and make data needs decisions publicly available in a more efficient and timely manner. Section 3.3 provides further comment analyses and excerpts from submissions that addressed topics such as time frames for the process and levels of involvement from sponsors and EPA.

Progress Toward Meeting Objectives and Communicating Information

In the FR Notice, EPA solicited responses to the following questions related to progress toward meeting objectives and communicating information:

- Has the VCCEP pilot made significant progress with respect to its objectives?
- The VCCEP pilot was designed to ensure that health effects, exposure, and risk information are made available to the public to enable a better understanding of the potential health risks to children associated with certain chemical exposures. Does the VCCEP website provide easy access to, and adequate explanation of, the information generated by the VCCEP pilot?

The outcome of the pilot program thus far, in regards to the number of chemicals evaluated and communication of results, elicited many comments. Many comment submitters expressed an opinion that public communications and understanding have not been effectively facilitated. Multiple aspects of the program were cited as not having been properly communicated to the public, including the sponsor submissions, outcome of the peer consultations, and general information on the program available through the VCCEP website. Comment submissions that specifically addressed the website were generally of the opinion that the information currently provided on the website is currently not useful to the layperson or non-

scientist. Section 3.4 provides further comment analyses and excerpts from submissions that addressed the progress toward meeting objectives and communicating information.

General Comments

Most of the submitters provided additional feedback on topics not specifically solicited in the FR Notice. For example, multiple commenters questioned whether the tier structure of the VCCEP Pilot provides the most appropriate and effective framework for the VCCEP program. Also, EPA was called upon to reevaluate the selection process for VCCEP chemicals and develop a list of priority chemicals. Section 3.5 provides further comment analyses and excerpts from submissions that addressed each of these general topics. Additionally, Section 3.5 includes submission excerpts that summarized overall views and suggestions for the VCCEP program.

All comment submitters generally approved of the goals, and motivation behind the establishment of the VCCEP (i.e., obtaining information on chemicals potentially hazardous to children and making such information publicly available). From the comments received, the following were consistent themes in favor of the program:

- The pilot process hold much promise;
- All parties have learned much from the pilot process;
- The overall structure of the program is useful; and
- The program has been effective in identifying tools that will be needed to conduct analyses at higher tiers.

Conversely, the following criticisms on the overall structure and even existence of the program in its current structure were repeatedly noted:

- The current tiered structure should be replaced;
- Chemical selection criteria should be reevaluated;
- The peer consultation panels are potentially biased;

- Public understanding of the program has not been achieved;
- The program's timeliness must be improved;
- Several aspects of the program's transparency must be improved (e.g., EPA's involvement, use of resources); and
- EPA should consider terminating the VCCEP program unless there are major changes to its structure.

3.0 COMMENT ANALYSIS

Sections 3.1 through 3.5 detail the comments received in response to the Federal Register (FR) Notice on performance of the VCCEP Pilot Program. These sections are presented as the following:

- Section 3.1 Comments on Sponsor-Submitted Assessments;
- Section 3.2 Comments on Peer Consultation Process;
- Section 3.3 Comments on Other Aspects of the VCCEP Pilot Program Process;
- Section 3.4 Comments on Progress Toward Meeting Objectives and Communicating Information; and,
- Section 3.5 General and Other VCCEP-Related Comments.

Sections 3.1 through 3.4 are further divided into subsections addressing the specific questions posed in the FR Notice. Most of the questions are structured so as to request “yes” or “no” responses. Each subsection presents statistics reflecting the yes versus no responses to specific questions. Because a single submission may have offered multiple comments addressing the same topic, same-submitter comments providing an opinion are grouped by identical numeric comment identifiers, with each individual comment assigned a lower-case letter for differentiation. All submissions were weighted equally for statistical purposes, regardless of the number of comments associated with a submission. For example, if one submitter provided three distinct positive comments to the same question, each comment is presented with a lower-case letter identifier (e.g., a, b, c). However, the combined comments are counted as one positive response.

Section 3.5 contains comments and suggestions that did not pertain to a specific question, but rather commented on the VCCEP Pilot Program in general.

3.1 Comments on Sponsor-Submitted Assessments

The 10 comments discussed in this section relate to the role of the Sponsors of the VCCEP Pilot Program. Questions from the FR Notice are listed in the sections below:

3.1.1 Have the hazard, exposure, and risk assessments submitted by the sponsors provided sufficient information to enable the Peer Consultation panel to adequately evaluate these aspects as they relate to children from the chemicals in question?

EPA received 6 individual comments from 4 different submitters addressing this question. Of the submissions, 50 percent (2 of 4) answered yes, 25 percent (1 of 4) answered no, and 25 percent (1 of 4) provided suggestions for improvement. The tables below present the relevant excerpts from these submissions:

Table 3-1. Comments Agreeing that Assessments Have Provided Sufficient Information

Comment Identifier / Submitter	Comment
3.1.1.1 (a & b) American Chemistry Council (ACC)	(a) Less extensive exposure assessments are scientifically justified in many cases and would streamline the VCCEP process. Although there is no single method or “cookbook” for developing exposure assessments applicable to all substances and all circumstances, adequate exposure assessments can be derived by an approach that utilizes a tiered, iterative process.
	(b) Yes, the hazard, exposure, and risk assessments submitted by the sponsors provided sufficient information to enable the Peer Consultation panel to adequately evaluate these aspects as they relate to children from the chemicals in question. The sponsors were committed to developing quality assessments. Submissions were extensive and complete. In every instance, the submissions were sufficient for the Peer Consultation panel to make recommendations regarding the possibility of risks to children. Sponsors provided all of the information they could amass.
3.1.1.2 People for the Ethical Treatment of Animals (PETA)	For the most part, the dossiers (hazard, exposure and risk assessments) have been adequate, and the exposure assessments in particular have been satisfactory and have placed the hazard data into its proper perspective. In that these are data rich chemicals, particularly with regard to toxicity data, the hazard assessments have been both thorough and complete, with extensive and thorough exposure assessments.

Table 3-2. Comments Stating that Assessments Have Not Provided Sufficient Information

Comment Identifier / Submitter	Comment
3.1.1.3 B. Sachau (Public)	Testing on dogs and cats tells us absolutely nothing about what a toxic chemical will do to a human being. The testing required by EPA is in fact a big joke – except it’s not funny at all. It is producing children with huge problems that they have to meet throughout their life – all because of negligence at EPA. The easy approval by EPA of endless numbers of toxic chemicals is a huge problem for this earth.

Table 3-3. Additional Suggestions Pertaining to Sponsor Assessments Providing Sufficient Information

Comment Identifier / Submitter	Comment
3.1.1.4 Children’s Environmental Health Network (CEHN)	We believe that, ultimately, all chemicals found to be present in biological samples of humans from the general population (above de minimis levels or frequencies of occurrence) should have full toxicity data available, unless (i) those chemicals are no longer being manufactured or are already being phased out; (ii) are already so well-studied that additional data will not enhance risk management (e.g., lead); or (iii) are already being tested under other initiatives (e.g., certain pesticides). In addition, full toxicity data should be available for chemicals for which there is similarly compelling evidence of exposure, but for which biomonitoring is not conducted or is not an effective option due to the physical/chemical nature of the chemical.
3.1.1.5 Children’s Environmental Health Network (CEHN)	The endpoints for the subject chemicals should be those required under the FQPA 10x protocols, but a combined-study protocol should be developed on an expedited basis.

3.1.2 Have the Data Needs Assessments prepared by the sponsor been fair and unbiased?

EPA received 4 individual comments from 4 different submitters addressing this question. Of the submissions, 75 percent (3 of 4) answered yes, while 25 percent (1 of 4) answered no. The tables below present the relevant excerpts from these submissions:

Table 3-4. Comments Agreeing that the Assessments Have Been Fair and Unbiased

Comment Identifier / Submitter	Comment
3.1.2.1 American Chemistry Council (ACC)	Yes, the Data Need Assessments prepared by the sponsors have been fair and unbiased. Overall, the comprehensive Sponsor submissions on each substance were made publicly available and subjected to thorough review and analysis by a panel of independent expert scientists through the peer consultation process. The Peer Consultation panel reports provide independent verification that a submission is scientifically sound, comprehensive, transparent and unbiased.
3.1.2.2 People for the Ethical Treatment of Animals (PETA)	The Data Needs Assessments prepared by the sponsors have generally been fair and unbiased.
3.1.2.3 Consumer Specialty Products Association (CSPA)	... the hazard, exposure and risk assessments in the Chemical Assessment documents developed by sponsors have been exemplary in their comprehensiveness and quality, and have shown no hint of bias. The exposure characterizations have been particularly exemplary.

Table 3-5. Comments Stating that the Assessments Have Not Been Fair and Unbiased

Comment Identifier / Submitter	Comment
3.1.2.4 Environmental Defense (ED)	We believe the structure of the program, which fails to provide true peer review or requirements of industry sponsors to respond to comments from the public and "peer consultants", has provided opportunities for biased presentations of data and conclusions in some instances.

3.2 VCCEP Peer Consultation Process

The 37 comments discussed in this section relate to the effectiveness of the Peer Consultation Process. Questions posed are listed in the sections below:

3.2.1 Has the Peer Consultation process been open, transparent, timely, and useful as a forum for scientists and experts from various stakeholder groups to exchange views on sponsors' assessments and recommended data needs?

EPA received 12 individual comments from 9 different submitters addressing this question. Of the submissions, 56 percent (5 of 9) answered yes, while 44 percent (4 of 9) answered no. The tables below present the relevant excerpts from these submissions:

Table 3-6. Comments Agreeing that the Peer Consultation Process Has Been Open, Transparent, Timely and Useful

Comment Identifier / Submitter	Comment
3.2.1.1 American Chemistry Council (ACC)	Yes, the Peer Consultation process has been open, transparent, timely, and useful as a forum for scientists and experts from various stakeholder groups to exchange views on sponsors' assessments and recommended data needs. The Peer Consultation meetings were an excellent forum for a critically needed exchange of ideas on how to best assess a chemical's risk to children. The meetings were professionally run and moved through the reviews at an appropriate pace. The Peer Consultation process was balanced, provided ample opportunity for stakeholder involvement, and was transparent. The Peer Consultation provided a very good review and assessment of the VCCEP assessments. One of the strengths of the Peer Consultation is that the panel did not attempt to reach consensus, but rather focused on free and open discussion of the assessments and data needs. ACC strongly believes the Peer Consultations should continue and EPA should continue to conduct and fund the Peer Consultations.
3.2.1.2 People for the Ethical Treatment of Animals (PETA)	This process has been open, transparent, and useful. The process has been wanting in terms of timeliness, but the tradeoff—reasoned, scientific review of the dossiers—is worth the wait. The best way to protect children is to clearly identify actual exposure and risk, so that the hazard data can be placed in the appropriate context.
3.2.1.3 Toxicology Excellence for Risk Assessment (TERA)	The peer consultation discussions highlighted the general lack of exposure data for significant exposure scenarios that are important to children, such as household consumer products and exposures in schools.
3.2.1.4 Halogenated Solvents Industry Alliance, Inc. (HSIA)	The peer consultations have involved large panels, balanced in terms of participation. The members of the panels addressed topics in depth and have applied impressive scientific judgment in their analyses. The opinions that have resulted are reliable and must be considered credible.
3.2.1.5 Consumer Specialty Products Association (CSPA)	The Peer Consultation process has been well handled and very successful. The open discussions these Peer Consultations facilitated provided greater value than a process aimed at achieving expeditious consensus. It is important, however, that a common understanding is attained of the difference between data gaps (i.e., data that is not available) and “data needs” (i.e., data this is not available but essential to the safety assessment).

Table 3-7. Comments Stating that the Peer Consultation Process Has Not Been Open, Transparent, Timely and Useful

Comment Identifier / Submitter	Comment
<p>3.2.1.6 (a – d) Natural Resource Defense Council (NRDC)</p>	<p>(a) EPA’s use of cooperative agreements or grants to acquire the services of third parties to manage the review process raises the foremost concerns. As EPA explains, under these cooperative agreements EPA is precluded from “providing instructions to [the outside party] with regard to how to conduct or manage the Peer Consultation, or otherwise directing [the outside party] as if it were an EPA contractor.” By sidestepping the confines of contractual agreements and the requirements of the Federal Advisory Committee Act (FACA), EPA and these outside parties avoid the organizational conflict of interest disclosures that apply to federal contractors. This leads to public concerns of bias and “stacked” committees. Whether or not these concerns are borne out, the perception of conflicts compromises the credibility of the committee, and by extension, the work product of the committee.</p> <p>(b) the outside party managing VCCEP, TERA (Toxicological Excellence in Risk Assessment), has a conflict of interest policy that only bars the membership of individuals who are explicitly and directly connected to the chemical being reviewed, the company sponsoring the review, or the assessment documents submitted to the panel. There is no requirement to address, neutralize or mitigate any secondary or potential conflicts that are disclosed.</p> <p>This permissive policy has given rise to the appointment of corporate consultants who have an ongoing relationship with the chemical industry and who are likely to serve the interests of their industry clients/employers, even when they are between contracts.</p> <p>(c) The policy, combined with the lack of public or EPA oversight, has even given rise to a direct financial conflict being allowed on a panel.</p> <p>(d) Direct conflicts of interest are not the only concern. The lack of EPA oversight allows potentially biased and unbalanced panels to be relied upon for these reports.</p>
<p>3.2.1.7 Children’s Health Protection Advisory Committee (CHPAC)</p>	<p>The peer consultation process is not a true peer review process in that it does not require industry sponsors to respond to reviewer's comments on their document and the interpretation of the assembled data. In addition, EPA provides no official evaluation of this voluntary submission, but instead produces its own Data Needs Decision document, which summarizes the voluntary submission and then renders EPA's opinion on whether there are additional data needs.</p>
<p>3.2.1.8 Children’s Environmental Health Network (CEHN)</p>	<p>The sponsors of the chemicals being studied have extensive access and influence in the development of the reports generated by the panels.</p>
<p>3.2.1.9 Environmental Defense (ED)</p>	<p>Although the evaluation of the peer consultation panel and EPA’s letter outlining its response to the sponsor are available on EPA’s website, the deliberative process at EPA has not been transparent.</p>

3.2.2 How might the Peer Consultation process be improved?

EPA received 5 individual comments from 4 different submitters addressing this question. The table below presents the relevant excerpts from these submissions.

Table 3-8. Suggestions for Improvement of the Peer Consultation Process

Comment Identifier / Submitter	Comment
3.2.2.1 Children’s Health Protection Advisory Committee (CHPAC)	The mechanism of engaging the third party organization to run the peer consultation process prohibits EPA control over that process, thus compromising governmental accountability. While this has provided some measure of flexibility appropriate for the development of the pilot, program, a contractual arrangement, as stated in the original Federal Register notice describing the VCCEP, may be preferable.
3.2.2.2 Children’s Environmental Health Network (CEHN)	In lieu of an initial peer consultation, we believe industry should review the existing literature, develop robust summaries of key existing studies, and prepare a test plan for the endpoints that currently lack adequate existing studies. That robust study summary and test plan should be made publicly available via the Internet for a 120-day comment period. This process is identical to the one used for the High Production Volume testing initiative. Rather than inviting endless debates about which endpoints should be evaluated for a particular chemical, it focuses attention on whether existing studies for the relevant endpoints have been identified, and if so whether they are scientifically adequate so that further testing for that endpoint is not needed.
3.2.2.3 Children’s Environmental Health Network (CEHN)	Finally, the peer consultation would consider only one question: whether a particular chemical should undergo a cancer bioassay where it has not yet done so. (This assumes that it is determined that there is, in fact, an adequate scientific basis for making carcinogenicity a triggered test which we do not regard as a settled question.)
3.2.2.4 American Chemistry Council (ACC)	Some improvements could be made to the Peer Consultation process. For example, it would have been helpful for the panel to better distinguish data needs from data gaps within the overall context and framework of the VCCEP Pilot Tiers. In some cases, discussion seemed to range somewhat far afield. In that regard, it may be beneficial, for EPA, in consultation with TERA and industry Sponsors, to discuss the possibility of developing appropriate guidance to help keep the peer consultation discussions focused on the VCCEP programmatic objectives. In addition, the time from the issuance of the Peer Consultation written report until issuance of the EPA data needs assessment report appears to continue to be rather extensive.
3.2.2.5 Environmental Defense (ED)	Since EPA is the regulatory agency responsible for the management of chemicals, its involvement is of considerable importance. For example, the deliberation of EPA staff on the sponsors’ submissions of chemical assessments is not documented in the public files. Neither is the degree of reliance of EPA staff on the peer consultation findings and recommendations. EPA should make the minutes of any meetings, conference calls, or other formal discussions regarding the VCCEP available to the public so that the decision-making process can be evaluated by stakeholders.

3.2.3 Has the Peer Consultation process been efficient?

EPA received 4 individual comments from 4 different submitters addressing this question. Of the submissions, 75 percent (3 of 4) answered yes, while 25 percent (1 of 4) answered no. The tables below present the relevant excerpts from these submissions:

Table 3-9. Comments Agreeing That the Peer Consultation Process Has Been Efficient

Comment Identifier / Submitter	Comment
3.2.3.1 American Chemistry Council (ACC)	Yes, the Peer Consultation process generally has been efficient. Importantly, the process has worked well. TERA should be complimented for its excellent job in managing the program. TERA has done a good job in choosing the panelists, based on their scientific expertise, to cover the range of disciplines needed to provide comprehensive reviews and critical analyses of the VCCEP pilot submissions. TERA has also performed exceptionally well in managing the meetings, circulating documents and capturing comments. The panelists were well informed and appeared well prepared to discuss the substances and sponsor submissions.
3.2.3.2 People for the Ethical Treatment of Animals (PETA)	... the Peer Consultation process has perhaps not been as timely as was originally hoped. However, the transparent, reasoned review of chemical dossiers is appropriate for this program.
3.2.3.3 Consumer Specialty Products Association (CSPA)	The Peer Consultation process has been very efficient, and well handled by TERA. We have no specific recommendations for improvements.

Table 3-10. Comments Stating that the Peer Consultation Process Has Not Been Efficient

Comment Identifier / Submitter	Comment
3.2.3.4 American Academy of Pediatrics (AAP)	The AAP is concerned, however, that in the six years of VCCEP's existence, only 12 chemicals have been peer-reviewed, and EPA has completed its review of only half of those 12.

3.2.4 If the Peer Consultation process has not been efficient, what improvements could be made?

EPA received 1 comment addressing this question. The table below presents the relevant excerpt from this submission.

Table 3-11. Suggestions Pertaining to Improving the Efficiency of the Peer Consultation Process

Comment Identifier / Submitter	Comment
3.2.4.1 Toxicology Excellence for Risk Assessment (TERA)	During the VCCEP peer consultation meetings, panelists often suggested additional text or analyses, revisions, and clarifications to the sponsors' submission document. The VCCEP process however, does not provide for revision of the assessments prior to EPA's review and data needs decisions. In the future, it might be more efficient to have sponsors revise their assessments to address panel comments (and public comments) prior to EPA review.

3.2.5 Has the Peer Consultation panel adequately considered both toxicology and exposure information in developing its results?

EPA received 3 individual comments from 3 different submitters addressing this question. Of the submissions, all (3 of 3) answered yes. The table below presents relevant excerpts from these submissions.

Table 3-12. Comments Agreeing that the Peer Consultation Process Considered Both Toxicology and Exposure Information in Developing Its Results

Comment Identifier / Submitter	Comment
3.2.5.1 American Chemistry Council (ACC)	Yes, the Peer Consultation panel adequately considered both toxicology and exposure information in developing its results. Since TERA ensured both disciplines were included in the panels, both toxicology and exposure were adequately considered.
3.2.5.2 People for the Ethical Treatment of Animals (PETA)	We believe the panel has met its charge in this regard. In particular, the panel has used the extensive exposure information available to put the hazard information into perspective. In most cases, the majority of panel members have recommended very little new hazard testing, even when the hazard is judged to be significant. The low anticipated exposures have often been used as a basis to judge that even when hazard data indicate a potential problem, the actual risks are low enough to allay safety and health concerns. This is a scientifically appropriate approach to conserve resources and avoid animal testing for low risk chemicals.
3.2.5.3 Consumer Specialty Products Association (CSPA)	We believe that both toxicology and exposure information were adequately considered by the Peer Consultation panels.

3.2.6 Does the Peer Consultation process provide a scientifically rigorous and effective means for eliciting comments and opinions from the assembled experts on the Peer Consultation panel and those attending the public meeting, and for assisting EPA in developing decisions?

EPA received 7 individual comments from 6 different submitters addressing this question. Of the submissions, 43 percent (3 of 7) answered yes, 43 percent (3 of 7) answered no, and 14 percent (1 of 7) provided a suggestion. The tables below present the relevant excerpts from these submissions.

Table 3-13. Comments Agreeing that the Peer Consultation Process Provides a Rigorous and Effective Means for Eliciting Comments and Opinions

Comment Identifier / Submitter	Comment
3.2.6.1 American Chemistry Council (ACC)	Yes, the Peer Consultation process provides a scientifically rigorous and effective means for eliciting comments and opinions from the assembled experts on the Peer Consultation panel and those attending the public meeting, and for assisting EPA in developing decisions. The Peer Consultation process provided an excellent vehicle for a chemical sponsor to hear the perspective of independent experts and stakeholder concerns.
3.2.6.2 People for the Ethical Treatment of Animals (PETA)	The process is scientifically rigorous; during the meetings, areas of the hazard, exposure and risk assessments that might have been underdeveloped or deemed otherwise lacking are vetted and discussed between panel members with questions clarified by the sponsors. All of this becomes part of the Peer Consultation meeting report which is submitted to EPA. Thus, this process and the subsequent report provide EPA with independent expert scientific opinion in addition to the sponsors' assessments alone. This is an excellent way for these assessments to receive an independent expert review as well as a subsequent analysis by EPA, and the process has proven to be both transparent and rigorous.
3.2.6.3 Consumer Specialty Products Association (CSPA)	The Peer Consultation process provided an excellent forum for discussion between the sponsors and independent scientific experts.

Table 3-14. Comments Stating that the Peer Consultation Process Does Not Provide a Rigorous and Effective Means for Eliciting Comments and Opinion

Comment Identifier / Submitter	Comment
3.2.6.4 Natural Resources Defense Council (NRDC)	Finally, the panel has been hamstrung by an inability to comment on the quality or conclusions of the industry-submitted summaries. By design of the voluntary process, the panel is invited to do no more than identify data gaps, after time-consuming reviews of potentially massive volumes of industry data reports and summaries. Furthermore, the panel report does not make clear recommendations, and does not obligate EPA to formally request the data identified as needed by the review panel.
3.2.6.5 Children's Environmental Health Network (CEHN)	The Network was gratified to see the resources that EPA provided to support scientists' ability to participate in the peer consultation panels. However, the program to date illustrates not just the heavy reliance it places on volunteer public interest science support but also that in many cases, even with the backing of EPA resources, such support does not exist. The VCCEP requires a huge investment of time and resources for very little result.
3.2.6.6 Environmental Defense (ED)	Although access to chemical assessment, peer consultation documents, and EPA letters is a simple process, this does not add up to an adequate explanation of the information generated by the VCCEP pilot. As explained above, EPA's TEACH program may be a more useful model for translating scientific data and analyses into meaningful information, and we strongly recommend that OPPTS review what is being accomplished by TEACH, and consider using these reports as examples for the VCCEP program.

Table 3-15. Additional Comments Pertaining to the Peer Consultation Process Providing Rigorous and Effective Means for Eliciting Comments and Opinion

Comment Identifier / Submitter	Comment
3.2.6.7 Environmental Defense (ED)	The outcome of the peer consultation is highly dependent on the members of the panel. The past VCCEP peer consultation panels have efficiently produced high quality documents that consider both toxicology and exposure information. We are concerned, however, that the nature of the third party agreement does not provide sufficient safeguards to ensure that future panels are similarly balanced. In restructuring the program, we believe it would be preferable for the EPA to maintain greater oversight and accountability for the selection of peer consultation panel members and the conduct of the review by using a funding mechanism other than a cooperative agreement, which gives the agency the least control of the process.

3.2.7 Have the communications related to the Peer Consultation process, activities and outcomes been effective and have they facilitated public understanding and use of the information generated from this process?

EPA received 5 individual comments from 4 different submitters addressing this question. Of the submissions, 75 percent (3 of 4) answered yes, while 25 percent (1 of 4) offered suggestions. The tables below present the relevant excerpts from these submissions.

Table 3-16. Comments Stating the Communications Related to the Peer Consultation Process, Activities, and Outcomes Have Not Been Effective

Comment Identifier / Submitter	Comment
3.2.7.1 People for the Ethical Treatment of Animals (PETA)	We have not evaluated this aspect of the program, but know of no actions that have resulted thus far on these first six VCCEP chemicals. We are interested to know if EPA has received any information or commitments from the sponsors which might change the manner in which these chemicals are produced, transported, or used. We would be especially interested to know if new testing has been proposed. Indeed, if new testing is proposed, we would appreciate the opportunity to review the commitments, the rationale and any other related information before any new animal testing is initiated on such data rich chemicals.
3.2.7.2 (a – b) American Chemistry Council (ACC)	(a) Information from the Peer Consultation and the submissions themselves has been made publicly available on the internet by TERA and EPA’s web site provides links to TERA... However, as discussed in our general comments, the existence of the submissions and Peer Consultations are not well known among US regulators and public health officials who have been looking at issues concerning some of the VCCEP compounds. Indeed, the information does not appear to be well disseminated within EPA. Further, little effort has been made to make the information available and understandable to the public. (b) It is unclear whether there has been adequate communication following the Peer Consultation process and whether outcomes of the Peer Consultation have facilitated public understanding and use of information.
3.2.7.3 Environmental Defense (ED)	For scientific information to be useful to the general public, it must be presented in a context that is accessible and understandable. Simply placing large amounts of data and technical documents on EPA websites is not user friendly and does not promote effective use by the general public. The EPA has a responsibility to provide document and data summaries directed at the different stakeholders, such as physicians, and the general public.

Table 3-17. Additional Suggestions Pertaining to the Effectiveness of Communications Related to the Peer Consultation Process, Activities, and Outcomes

Comment Identifier / Submitter	Comment
3.2.7.4 Consumer Specialty Products Association (CSPA)	While the results of the VCCEP pilot chemical reviews are available on the TERA web site and linked to the EPA web site, we have seen no evidence that there has been any public notice or use of the assessments. As the program progresses, more focus needs to be made on assuring that regulators and others are aware of the excellent resource that these VCCEP assessments represent.

3.3 Comments on Other Aspects of the VCCEP Pilot Program Process

The 34 comments discussed in this section relate to other aspects of the VCCEP Pilot Program including: timeliness of activities, establishing due dates, test tier commitments, and improving EPA’s contributions. Questions posed are listed in the sections below:

3.3.1 How can the timeliness of activities under the VCCEP pilot be improved?

EPA received 4 individual comments from 3 different submitters addressing this question. Of the submissions, all (3 of 3) offer suggestions for improvement. The table below presents the relevant excerpts from these submissions:

Table 3-18. Suggestions Pertaining to Improving the Timeliness of Activities under the VCCEP Pilot Program

Comment Identifier / Submitter	Comment
3.3.1.1 Children’s Health Protection Advisory Committee (CHPAC)	The timeliness of the EPA reviews of the voluntary submissions should also be improved. To ensure accountability in the VCCEP, EPA should clearly identify the party who will be accountable for the timely progress of the program.
3.3.1.2 Children’s Health Protection Advisory Committee (CHPAC)	A reasonable timeline for completion of a set number of evaluations should be specified and progress measured against that timeline. To achieve results in a timely manner, the VCCEP should minimize unnecessary steps and generate the most important data on the most important chemicals first. Instead, the current tiered structure of the program has led to ambiguity and inefficiency.
3.3.1.3 American Chemistry Council (ACC)	In addition to working to improve the timeliness of this program overall, ACC thinks EPA should enhance its communications about VCCEP – to the public, to other EPA program offices and to other Federal and State agencies. In addition, EPA should make the information generated under this program more accessible. EPA should also discuss with other EPA program offices how the information it is receiving under VCCEP will be reflected in chemical risk assessments such as those in the Air and Water offices and in IRIS assessment updates.
3.3.1.4 Environmental Defense (ED)	Although this is a pilot program, these achievements are clearly disappointing. One way to reduce the time and effort needed to produce initial data needs assessments would be to eliminate the risk assessments from the sponsor's documents and leave that step and the final data needs determination to the agency. In order for this to lead to greater efficiencies, substantial resources would have to be devoted to conducting such assessments. Without this commitment, it is unlikely that the process or the product will be significantly improved.

3.3.2 Should specific due dates be established for each step in the process? If so, how should a missed due date be addressed?

EPA received 2 individual comments from 2 different submitters addressing this question. Of the submissions, 50 percent (1 of 2) answered yes, while 50 percent (1 of 2) answered no. The tables below present the relevant excerpts from these submissions.

Table 3-19. Comments Agreeing that Specific Due Dates Should Be Established for Each Step in the VCCEP Process

Comment Identifier / Submitter	Comment
3.3.2.1 People for the Ethical Treatment of Animals (PETA)	It might be useful to establish due dates for the submission of the dossiers, the conduct of the Peer Consultation and, especially, for EPA's own Data Needs Assessment.

Table 3-20. Comments Stating that Specific Due Dates Should Not Be Established for Each Step in the VCCEP Process

Comment Identifier / Submitter	Comment
3.3.2.2 Consumer Specialty Products Association (CSPA)	Specific due dates for various steps would not be helpful; quality is more important than quantity in this type of program, especially in the pilot phase.

3.3.3 Is it better to run the VCCEP pilot with commitments at each tier, i.e., three commitments, or to run the VCCEP pilot with two commitments, i.e., to Tier 1 and to Tiers 2/3?

EPA received 6 individual comments from 4 different submitters addressing this question. Of the submissions, all (4 of 4) answered yes. The table below presents the relevant excerpts from these submissions.

Table 3-21. Comments Agreeing that It Is Better to Run the VCCEP Pilot with Commitments at Each Tier

Comment Identifier / Submitter	Comment
3.3.3.1 (a – c) American Chemistry Council (ACC)	<p>(a) ACC objects to EPA’s proposal to expedite the VCCEP pilot by collapsing Tier 2 and Tier 3 into a single Tier.</p> <p>(b) ACC strongly believes that EPA should maintain the current tiered approach in VCCEP because tiered testing provides the most efficient and therefore health protective, mechanism to obtain needed information.</p> <p>(c) A tiered risk-based approach is an approach that fosters scientifically appropriate and valid reductions in the number of laboratory animals, without diminishing the degree of scientific certainty necessary for hazard evaluations and risk characterizations. Devoting resources to such toxicity “data gaps” irrespective of whether the specific information is actually needed (that is, data or information which is viewed as necessary to characterize children’s risks with an adequate degree of scientific certainty), would be scientifically unjustifiable, require unnecessary animal testing and unwarranted costs.</p>
3.3.3.2 People for the Ethical Treatment of Animals (PETA)	We assume that sponsors will continue to include all hazard data in their dossiers as available for all tiers. At present, however, we see no need to change the way the program is structured. The separate nature of each tier allows for the evaluation of available data and a reasoned assessment of actual data needs; premature commitments to higher tiers might result in the sponsors’ anticipatory conduct of additional data generation when such data generation is not warranted.
3.3.3.3 Consumer Specialty Products Association (CSPA)	CSPA believes that the program should be maintained with separate commitment decisions between each tier. The current three-tier approach remains preferable.
3.3.3.4 Halogenated Solvents Industry Alliance, Inc. (HSIA)	A sponsor should not be pressured into combining tiers and, in the nature of a voluntary program, should be allowed freedom of choice.

3.3.4 Are there ways in which EPA’s contributions to the VCCEP pilot’s evaluation and data needs decision process could be improved or made more efficient?

EPA received 17 individual comments from 8 different submitters addressing this question. Of the submissions, all (8 of 8) answered yes. The table below presents the relevant excerpts from these submissions.

Table 3-22. Comments Agreeing that EPA’s Contributions to the VCCEP Pilot’s Evaluation and Data Needs Decision Process Could Be Improved Or Made More Efficient

Comment Identifier / Submitter	Comment
3.3.4.1 (a – f) American Chemistry Council (ACC)	(a)... a multi-stakeholder meeting to discuss the pilot would probably be more beneficial to EPA at the conclusion of the pilot, rather than now at this mid-point.
	(b) EPA should strive to provide data need decisions in a timelier manner. As we noted, delays were to be expected due to the amount of information submitted and the newness of the program. ACC anticipates that the process will move more quickly as the program progresses and less data rich chemicals are addressed.
	(c) EPA should also openly discuss how the information it receives will be reflected in health assessments, not only within OPPT and OPPTS, but across all relevant EPA programs and offices.
	(d) In many cases, it has taken considerable amount of time for EPA to issue the formal Agency Data Needs Decisions. See Table 2. We believe it would be beneficial for the Agency to consider ways in which this time frame could be reduced. However, as noted above, rather than focusing solely on concerns that the program is moving too slowly, or suggesting that the sponsors caused the delay, the Agency should acknowledge that both the pilot nature of this program and the data rich nature of most of the chemicals selected has resulted in a longer timeline for Tier 1. It should also acknowledge that, in many cases, EPA has frequently received sufficient information in Tier 1 to complete a full assessment and characterization of a chemical with respect to the potential risk posed to children.
	(e) It would be helpful to have EPA be present in person at all of the Peer Consultations to clarify issues as needed (such as the distinction between data needs and data gaps) and to hear the discussions first hand. EPA has participated in person at some of the peer consultation meetings, but by web casts at others. Further, not only should OPPT staff be present to listen to the details of the data submissions and the peer consultation discussions, but it would be beneficial if representatives of other EPA program offices (offices which have an interest in a particular substance and who engage in the discussions about EPA’s data needs decisions), were also present or participating via the web casts.
	(f) EPA should better communicate to the public, other agencies, health care professionals, and other offices within EPA, the merits of the VCCEP pilot program and its conclusions. EPA should make the information generated in the VCCEP pilot program more accessible and should provide lay summaries for chemicals examined in the program. EPA should also openly discuss how the information it receives will be reflected in health assessments and utilize that information in its risk assessments throughout the Agency.
3.3.4.2 People for the Ethical Treatment of Animals (PETA)	EPA should conduct its reviews and post their data needs decisions in a timelier manner. This would help inform both the sponsors and the expert panel on EPA’s own approach to the assessment of these chemical and perhaps lead to a more efficient review process by all parties involved in the VCCEP program.

Comment Identifier / Submitter	Comment
3.3.4.3 Natural Resources Defense Council (NRDC)	A priority list should consist of the chemicals with the greatest exposure and potential toxicity to children and should be reviewed within one year. Other candidate chemicals should be similarly prioritized by EPA and timely reviewed as well.
3.3.4.4 (a – b) Children’s Health Protection Advisory Committee (CHPAC)	(a) To improve the VCCEP's credibility, EPA and industry sponsors should share responsibility for interpreting the assembled data and conducting the risk assessment, with EPA formally reviewing and commenting on all critical data and assumptions underlying the results of the risk assessment. A public workshop or other stakeholder process would be helpful to address how best to promote stakeholder confidence in the VCCEP results.
	(b) EPA should develop VCCEP-specific guidance and criteria for conducting an exposure assessment, interpreting the toxicological database with respect to hazard for children (i.e. a child-specific weight-of evidence), and determining an appropriate algorithm for filling data gaps. Ongoing progress in methods development should be formally monitored. This could be accomplished in conjunction with the annual reporting process recommended later in this letter.
3.3.4.5 (a – b) Children’s Environmental Health Network (CEHN)	(a) We suggest that the National Toxicology Program be asked to conduct, on a high-priority expedited basis, a workshop to define a combined protocol.
	(b) Indeed, given that SAP supported EPA’s initial single-tier approach, it appears that EPA’s basis for proposing a tiered system is the fact that the Chemical Manufacturers Association (CMA)* and other industry representatives want such an approach. In support of its position, CMA has proffered a retrospective evaluation of nine chemicals. In effect, CMA’s study appears to be the foundation for the agency’s proposal to proceed with a tiered testing approach. To date, that study, the chemicals included, the methodology used, and its conclusions, have not been made public nor have they undergone peer review. The agency should at least make public its scientists’ review of this study and should sponsor an expedited independent external peer review of the CMA evaluation if EPA is going to continue to consider a tiered approach.
3.3.4.6 Toxicology Excellence for Risk Assessment (TERA)	The pilot process and scope of the submission documents has provided EPA with information and the means to understand the available data; however, these types of risk assessments are complex, and, by necessity, the submission documents are written in technical language more appropriate for scientific readers than for the general public. Some submissions contained lay public executive summaries and all the peer consultation meeting reports included executive summaries, but the direct communication of information from the VCCEP process to the public has not occurred to an adequate extent. In the future, once a chemical has completed the process and the EPA Data Needs Decision has been issued, EPA should consider providing a layperson summary.
3.3.4.7 (a – b) Environmental Defense (ED)	(a) The EPA should work more proactively with sponsors and other stakeholders to determine the best approach to developing exposure assessments given the chemical’s characteristics and available data.
	(b) There is no public record of EPA’s deliberative process regarding the sponsors’ submissions of chemical or the peer consultation findings and recommendations. This lack of transparency is unacceptable. EPA must make such records available to the public so that the decision-making process can be evaluated by stakeholders.

Comment Identifier / Submitter	Comment
3.3.4.8 (a – b) Consumer Specialty Products Association (CSPA)	<p>(a) It will become more important in the future that EPA make its data-needs decisions expeditiously after the conclusion of the Peer Consultation, and fully communicate the results of all finalized assessments to interested parties.</p> <p>(b) The program has been less successful to date, however, in testing and establishing the mechanisms for the Tiered approach to safety evaluation. This is primarily due to the selection of chemicals for the program which has targeted chemicals for which extensive hazard data is already available. While this has facilitated some aspects of the program, it has deterred evaluation of the tiered approach wherein the hazard and exposure information in each tier is used to determine specific further data needs. We believe that it is important that EPA continue this voluntary program and in the future identify some less “data-rich” chemicals to better evaluate and establish the appropriate process and criteria for identifying actual data needs in a tiered approach that does not simply default into a “check all the boxes” battery of tests.</p>

3.3.5 Should the time allowed for sponsor commitment remain the same, i.e., 6 months to commit to Tier 1, and 4 months to commit to subsequent Tiers? (The commitment period is the time for the sponsor to decide whether to participate in VCCEP, form a consortium, and notify the Agency)

EPA received 4 individual comments from 4 different submitters addressing this question. Of the submissions, 75 percent (4 of 4) answered yes, while 25 percent (1 of 4) answered no. The tables below present the relevant excerpts from these submissions.

Table 3-23. Comments Agreeing that the Time Allowed for Sponsor Commitment Remain the Same

Comment Identifier / Submitter	Comment
3.3.5.1 American Chemistry Council (ACC)	The time periods for Sponsor commitment are appropriate and should not be changed. For Data Needs decisions in higher Tiers, the complexity of the studies requires adequate time for development and agreement by all parties including EPA in many cases, on study design issues. The VCCEP time periods are needed to review the Agency’s Data Needs decision document, to consider alternative approaches to collecting the desired information and data, to develop time lines and cost estimates for such studies to evaluate the alternatives, decide upon the best course of action and to develop appropriate partnerships and consortia to participate collectively.
3.3.5.2 Consumer Specialty Products Association (CSPA)	CSPA sees no reason to change the time allowed for sponsor commitments. Shortening this time could deter many sponsorships, especially for chemicals with multiple potential sponsors that must seek to form a consortium, and deter decisions to continue in the program toward higher tiers.
3.3.5.3 People for the Ethical Treatment of Animals (PETA)	These times allowed seem reasonable and we have no suggestions for changes.

Table 3-24. Comments Stating that the Time Allowed for Sponsor Commitment Should Not Remain the Same

Comment Identifier / Submitter	Comment
3.3.5.4 Environmental Defense (ED)	We believe that time frames should be re-evaluated in the context of a substantially revised program structure.

3.3.6 Should the sponsor be requested to commit to more than one tier at a time?

EPA received 1 comment addressing this question. The table below presents a suggestion related to this topic.

Table 3-25. Suggestion Pertaining to Requesting Sponsors Commitment to More Than One Tier at a Time

Comment Identifier / Submitter	Comment
3.3.6.1 Children’s Environmental Health Network (CEHN)	A sponsor’s commitment to participate in this program should mean taking responsibility for filling all of the necessary data gaps. A step-wise commitment does not make sense in light of industry’s professed desire (as stated in their Responsible Care Guidelines) to provide information on health or environmental risks and pursue protective measures for employees, the public, and other stakeholders and to support education and research on the health, safety and environmental effects of our products and processes. Moreover, it is very unlikely that the public will understand the nuances of a multi-step commitment process. If industry wishes public recognition for making commitments to assure the availability of the data needed to evaluate the safety of a particular chemical to which children are exposed, then they should commit to making all of those data available.

3.4 Comments on Progress Toward Meeting Objectives and Communicating Information

The 20 comments discussed in this section relate to the progress made in the VCCEP Pilot Program. Questions posed are listed in the sections below:

3.4.1 Has the VCCEP pilot made significant progress with respect to its objectives?

EPA received 15 different comments from 10 different submitters addressing this question. Of the submissions, 30 percent (3 of 10) answered yes, while 70 (7 of 10) answered no. The tables below present the relevant excerpts from these submissions:

Table 3-26. Comments Agreeing that the VCCEP Pilot Made Significant Progress With Respect to Its Objectives

Comment Identifier / Submitter	Comment
3.4.1.1 American Chemistry Council (ACC)	Experience thus far has demonstrated that the VCCEP framework – of integrating hazard and exposure information -- has worked well to provide extensive, reliable information related to children’s health that will enable EPA to determine whether additional testing and/or exposure data are needed to adequately characterize potential risks to children, with a reasonable degree of scientific certainty.
3.4.1.2 Consumer Specialty Products Association (CSPA)	CSPA believes that the VCCEP has made very significant progress toward the objective of developing reliable safety assessments focused on children’s exposures and risks for the chemicals chosen for the pilot program. Excellent progress has also been made in developing the Peer Consultation process. Limited progress has been made in evaluating the tiered testing process, and work remains to be accomplished, especially as it relates to toxicity-testing triggers in determining what data gaps are actual data needs.
3.4.1.3 Halogenated Solvents Industry Alliance, Inc, (HSIA)	Performance to date has been impressive. The sponsors have submitted analyses that incorporated large volumes of information with detailed hazard evaluations. These were matched by sophisticated and credible exposure assessments. Brought together, these elements provided sound risk assessments focused on children.
3.4.1.4 People for the Ethical Treatment of Animals (PETA)	The chemicals that have been all the way through the process have met the goals of the program. Our comments on timeliness notwithstanding, a faster pace of completion of the last eight chemicals would demonstrate that the learning curve on the first six has resulted in a more efficient process for the longer term, while continuing the program’s history of reasoned scientific evaluation.

Table 3-27. Comments Stating that the VCCEP Pilot Has Not Made Significant Progress With Respect to Its Objectives

Comment Identifier / Submitter	Comment
3.4.1.5 B. Sachau (Public)	At this point, it makes no sense to gather this information for two reasons. The public is not being told exactly what has been submitted to the profiteers and secondly, the profiteers are not telling you about the all bad things that their products do to children.
3.4.1.6 (a – c) Children’s Health Protection Advisory Committee (CHPAC)	<p>(a) Despite it being a stated goal of the pilot, the VCCEP has not developed a systematic evaluation of the best methods for either conducting an exposure assessment or determining the adequacy of toxicological studies in the context of assessing children’s risks from toxic chemicals. Instead, each analysis has relied on the judgment of those who develop the industry’s documents submitted for peer consultation.</p> <p>(b) The pilot program as implemented, however, is not on track to fulfilling its stated goal. Even within the scope of this pilot, there has been limited information on specific chemicals relevant to children’s health provided to the public. Moreover, an opportunity has been lost to develop and disseminate more advanced methods for assessing children’s exposures and consequent risks.</p>

Comment Identifier / Submitter	Comment
	(c) Lastly, the pilot program has not achieved adequate involvement of its multiple stakeholders. While there have been opportunities for involvement during the peer consultation on the industry documents, there has been minimal participation by most groups, including the public. Efforts to educate stakeholders, such as pediatricians and other health care professionals, academic researchers, parents, community groups, state risk assessors, and public health organizations have been minimal. To achieve broad stakeholder engagement, EPA should make a stronger effort to inform all stakeholders of the program's results on an annual basis, through means such as reports, press releases, website updates, and periodic workshops. In addition to helping fulfill the goal of informing the public, greater outreach efforts could also provide motivation for improved program efficiency and performance.
3.4.1.7 Children's Environmental Health Network (CEHN)	The Voluntary Children's Chemical Evaluation Program (VCCEP) is deeply flawed in both science and process and, after six years, has produced virtually no useful information.
3.4.1.8 American Academy of Pediatrics (AAP)	The AAP is concerned that, as currently operating, the VCCEP is failing to provide useful information to the public or health care providers.
3.4.1.9 American Chemistry Council (ACC)	Unfortunately, EPA has done very little with respect to communicating the merits of this pilot program. EPA's communications efforts to date appear to be mostly passive, consisting of posting information and materials in the OPPT Right-To-Know web site. ACC believes the Agency can do much more in terms of outreach across Agency programs and to the States and public at large to communicate about the VCCEP.
3.4.1.10 (a – b) Natural Resources Defense Council (NRDC)	(a) An additional concern with the unregulated nature of these panels is the limited access granted to the public. Meeting minutes, docketing rules, and locations of hearings are all decided by the outside party, without the requirement to consider the public's right to know. For example, while the meetings are ostensibly open to the public, locating them in Cincinnati does not provide a convenient location for those most likely to participate to do so. These concerns would be reduced if the outside parties were bound to the same public participation requirements by which EPA must abide. (b) First, the small number of completed reviews trickling out of VCCEP is a major concern.
3.4.1.11 (a – b) Environmental Defense (ED)	(a) Based on a review of the available chemical assessments and peer consultation documents, the VCCEP pilot has not made significant progress, and Environmental Defense has concluded that this program should be discontinued unless there are major changes to its structure. (b) While one of the initial goals of the VCCEP program was to develop better methods for exposure assessment, this has yet to be accomplished.

3.4.2 The VCCEP pilot was designed to ensure that health effects, exposure, and risk information are made available to the public to enable a better understanding of the potential health risks to children associated with certain chemical exposures. Does the VCCEP website provide easy access to, and adequate explanation of, the information generated by the VCCEP pilot?

EPA received 5 individual comments from 5 different submitters addressing this question. Of the submissions, all (5 of 5) answered no. The table below presents the relevant excerpts from these submissions.

Table 3-28. Comments Stating that the Website Is Not Easily Accessible and Does Not Adequately Explain the Information Provided

Comment Identifier / Submitter	Comment
3.4.2.1 B. Sachau (Public)	I went to the website to verify information that had been submitted to date. The website does not work. You can send me any information you have on what the chemical profiteers have been telling you so I can comment further.
3.4.2.2 American Academy of Pediatrics (AAP)	The VCCEP website is not organized in a manner that is useful to pediatricians or families. Information is not presented in a format or language that is easily understood by the layperson or non-scientist, but makes heavy use of jargon, acronyms, and scientific terminology. The website lacks information as basic as common sources for the chemicals listed, which would enable parents to determine their child's potential routes of exposure. Similarly, the website contains no area specific to health care providers, which could focus upon the information most likely to be of use in medical practice. Moreover, the site fails to give any resources or recommendations for parents or health care providers in minimizing exposure to potentially hazardous chemicals.
3.4.2.3 People for the Ethical Treatment of Animals (PETA)	The information generated by the VCCEP pilot program has the potential to be helpful to better understand actual risks posed by certain chemical exposures, since it includes both hazard and potential exposure analyses. While the information is made available on the EPA Web site, it is unclear as to how this information is used, or would be used, by the general public to protect children. Ultimately, it is the responsibility of the EPA to regulate the production and use of chemicals to minimize exposure and risks to children, and how VCCEP will affect this process is still unclear
3.4.2.4 American Chemistry Council (ACC)	Although EPA posts, cites and links to information on its Right-To-Know web site that information can be difficult to find and retrieve. EPA should make the information generated in the VCCEP program more accessible to the public, other EPA offices and other agencies. In addition to making information easier to find, EPA should provide lay summaries for chemicals that are examined in VCCEP pilot. The summaries should provide an Agency determination concerning the sufficiency of submitted data and of potential risks posed to children's health.
3.4.2.5 Consumer Specialty Products Association (CSPA)	The results of the work from the program are available in a form usable by most scientists, but not in a form understandable by policy makers and the public. EPA should consider developing a way to make executive summaries of the findings available.

3.5 General and Other VCCEP-Related Comments

EPA received 37 comments that did not pertain to a specific question from the FR notice, but did reflect information relevant to the VCCEP program. Of the submissions, 6 comments addressed the chemical scope of the program, 8 comments addressed the overall tier structure of the program, and 23 comments provided assessments of the program in general. The tables below present the relevant excerpts from these submissions:

Table 3-29. Comments Pertaining to the Chemical Scope of the VCCEP Program

Comment Identifier / Submitter	Comment
3.5.1 National Resources Defense Council (NRDC)	Adding insult to injury, the chemicals that are reviewed are not prioritized by toxicity. As a result, oftentimes, less toxic chemicals end up being reviewed before the more pernicious ones. The public is left waiting for information on chemicals with the potential for serious health risks while reports are produced regarding chemicals with lower risk to human health, albeit more rich, existing datasets.
3.5.2 Children’s Health Protection Advisory Committee (CHPAC)	The chemicals selected for the program must be carefully prioritized based on their potential threat to the health of children. This can be based on considerations of actual or potential exposure (including increasing production), and any readily available existing information about toxicity.
3.5.3 Children’s Environmental Health Network (CEHN)	The proposed group of approximately 50 candidate chemicals is generally appropriate for an initial effort, but additional contaminants should be added to the initial list.
3.5.4 Children’s Environmental Health Network (CEHN)	EPA should include the chemicals recently identified in Swedish breast milk monitoring programs – namely polychlorinated naphthalenes and polybrominated diphenyl ethers – unless adequate information is brought forward to indicate that the sources of Swedish populations’ exposure to those chemicals do not occur in the US.
3.5.5 Environmental Defense (ED)	A more rigorous, child-specific toxicity testing approach should be taken to evaluate the toxicity data, and EPA should develop specific guidance and criteria regarding the interpretation of toxicological studies. Chemicals should be selected for the VCCEP priority list on the basis of clear exposure or toxicological data to suggest grounds for concern. Child-specific toxicity tests for VCCEP chemicals should not be delayed; rather the collection of child-specific data should be central to this program and routinely developed from the outset.
3.5.6 Halogenated Solvents Industry Alliance, Inc. (HSIA)	A key to the future relevance of the VCCEP beyond the pilot phase will be the manner in which subject chemicals are identified. It is recommended that a transparent, equitable process be established with input from representatives of potential sponsors that will identify priority candidates (i.e., those where children’s exposure is expected and the toxicological database is limited).

Table 3-30. Comments Pertaining to the Tier Structure of the VCCEP Program

Comment Identifier / Submitter	Comment
3.5.7 Children’s Environmental Health Network (CEHN)	The proposed tiered test-selection process is inappropriate and not supported by science. For chemicals found to be actually present in human tissues (above de minimis levels or frequencies of occurrence), tiering is not appropriate. Since a tiered approach by definition proceeds from simpler, less costly, and less accurate tests to more complex, expensive, and definitive tests, we believe that a tiered approach is not acceptable for such compounds. The one possible exception may--and we stress MAY--be carcinogenicity.
3.5.8 Children’s Environmental Health Network (CEHN)	The EPA has not justified the implementation of a tiered approach. Indeed, as EPA itself acknowledges, In this case, EPA’s analysis, which was supported by the SAP [Scientific Advisory Panel] in its review, indicates that the understanding needed to support triggers based on biology does not presently exist.

Comment Identifier / Submitter	Comment
3.5.9 Children's Environmental Health Network (CEHN)	A key failing is the "tiered" structure used, where chemicals would not necessarily be tested for the potential to cause cancer or damage developing nervous systems. While the concept of tiering" tests is often an appropriate approach, in this instance "tiering" does not make sense because: (1) the lowest tier is too low; (2) there are no clear criteria for moving from one tier to the next highest tier; and (3) the process is too cumbersome and unproductive.
3.5.10 Children's Health Protection Advisory Committee (CHPAC)	The current tiered structure should be replaced by a more flexible and sophisticated structure that separates the approaches to the review of existing studies, generation of new toxicological studies, and conduct of exposure assessments. Risk assessments should not be conducted within this specialized program with inadequate, lower tier exposure and toxicological data. As stated previously, clear guidance on what specific findings or data would trigger the need for additional toxicological and/or exposure data must be developed for any future voluntary children's chemical evaluation program.
3.5.11 American Chemistry Council (ACC)	ACC believes that EPA should continue to adhere to essential features of the VCCEP, which include: <ul style="list-style-type: none"> • A true tiered process with endpoint-specific decisions (or triggering) about the need for developing additional hazard and/or exposure information. • A risk based process in which at various decision points hazard information is evaluated in conjunction with exposure information to reduce uncertainties in characterizing potential risk. • Three independent tiers. Each should have a separate point of commitment. • A peer consultation process.
3.5.12 Environmental Defense (ED)	We have concluded that this program should be discontinued unless there are major changes to its structure. These changes include: <ul style="list-style-type: none"> • Doing away with the tiered program structure and replacing it with one that bases decisions about children's risks on data specific to children's risks. • Creation of more specific guidance and criteria regarding the interpretation of toxicological studies and estimation of exposure. • Greater EPA oversight and accountability for the VCCEP; this involves limiting the unilateral assessment and analysis performed by the industry sponsors and greater involvement by agency scientists in those activities.
3.5.13 Environmental Defense (ED)	Rather than a tiered testing system, VCCEP should concentrate on incorporating testing that is focused on child-specific health risks into its basic information requirements. Child-specific toxicity testing, based on exposures during critical windows (i.e., pre-conception, fetal, neonatal – adolescence) should be required of all chemicals in the program, unless there are already sufficient data to indicate that these tests are not necessary. The VCCEP framework should assume that for most chemicals, the current Tier 1 data set will be available through another program such as EPA HPV, or OECD SIDS, and that the focus of VCCEP should be to build upon this database through further testing to directly and more fully address specific children's risks. If these initial data are not available, then the sponsor should have the additional responsibility to collect these data; however, this should be considered a prerequisite step, rather than the first (and possibly only) step to be taken in VCCEP.
3.5.14 Environmental Defense (ED)	The three tiered chemical testing process is not likely to help VCCEP meet its goals in a timely fashion. VCCEP would be much more efficient if it were to be reorganized to focus on chemical testing that is specific for child-risk endpoints, as described in detail above.

Table 3-31. General Comments Pertaining to the VCCEP Program

Comment Identifier / Submitter	Comment
3.5.15 Natural Resources Defense Council (NRDC)	As it is currently implemented, VCCEP does not work. First, farming out the management to unregulated third parties has created panels stacked in favor of the chemical. Second, VCCEP works too slowly and inefficiently to evaluate chemicals that could have adverse effects on children's health.
3.5.16 Children's Environmental Health Network (CEHN)	Thus, the Network agrees with the need for more and improved testing of the many substances that have been introduced into our environments for their impact on children and other vulnerable populations.
3.5.17 Children's Environmental Health Network (CEHN)	The Network would like to associate itself with the general concerns about this program raised in the comments already submitted by the Children's Health Protection Advisory Committee (CHPAC), the American Academy of Pediatrics, and the Natural Resources Defense Council (NRDC).
3.5.18 Children's Environmental Health Network (CEHN)	This project is not transparent. It is essentially directed and shaped by industry.
3.5.19 Children's Environmental Health Network (CEHN)	These myriad problems lead the Network, with the benefit of its in-depth knowledge and history of this program, to call for its termination or, at least, a massive overhaul.
3.5.20 Children's Environmental Health Network (CEHN)	A comprehensive, prevention-focused, testing program is called for if we are to adequately understand and thus protect children from substances introduced into their environments.
3.5.21 Children's Environmental Health Network (CEHN)	The Network urges the Agency to either discontinue VCCEP or fundamentally overhaul the program to involve a broader array of stakeholders. The CHPAC may be the appropriate mechanism for such a revisioning.
3.5.22 American Chemistry Council (ACC)	ACC believes the process has worked well to provide extensive, reliable information related to children's health that will enable EPA to determine whether additional testing and/or exposure data are needed to adequately characterize potential risks to children, with a reasonable degree of scientific certainty.
3.5.23 American Chemistry Council (ACC)	The risk-based evaluative process imbedded in the VCCEP Pilot holds much promise to demonstrate how risk-based decision making can maximize risk information, and at the same time minimize laboratory animal testing, without compromising the scientific certainty needed for decision-making.
3.5.24 American Chemistry Council (ACC)	Industry, EPA and other stakeholders have learned much about working together cooperatively and voluntarily to assess the risk to children from chemical exposures. All parties have learned much concerning the chemical assessment process and about risks posed by specific chemicals.
3.5.25 American Chemistry Council (ACC)	ACC thinks a public meeting would be more beneficial at the end of the pilot, or when all of the components of the VCCEP are available for 75% or so of the pilot chemicals, rather than now. We think that can be accomplished by mid 2008.
3.5.26 American Chemistry Council (ACC)	EPA should conclude in this evaluation, that the basic structure of the pilot is sound and that only minimal improvements are needed to address program efficiencies through the remainder of the pilot. Industry has lived up to its commitments under this voluntary program and the ACC believes EPA and industry should follow through on their commitments related to the pilot.

Comment Identifier / Submitter	Comment
3.5.27 American Chemistry Council (ACC)	It must also be acknowledged that EPA has taken longer than expected to reach data needs decisions under the program.
3.5.28 Toxicology Excellence for Risk Assessment (TERA)	The scope of VCCEP is unique in two respects. The first is that the sponsors are asked to provide a summary of the available hazard data, an assessment of all potential routes of exposures to children in the general US population, and to consider both the hazard and the exposure to characterize what is known about the potential risks to children who may be exposed to the chemical. They are then asked to evaluate whether the available data are sufficient or if additional data are needed to characterize risk. Few assessments have taken this focus.
3.5.29 Toxicology Excellence for Risk Assessment (TERA)	The submissions and subsequent peer consultation discussions have identified general areas where data and analytical tools are lacking. For example, risk characterization tools such as margin of exposure and hazard quotients were used, but better tools in risk characterization should be developed for the higher tiers.
3.5.30 Toxicology Excellence for Risk Assessment (TERA)	The submissions and peer consultations have expanded risk assessors thinking and discussion on how children may be exposed.
3.5.31 Toxicology Excellence for Risk Assessment (TERA)	The VCCEP pilot Federal Register notice (65 FR 81700) provided general guidance for the format and content of the submissions, but did not dictate specific approaches to use. Because specific guidance was lacking, the industry submissions used a variety of approaches. This provides an opportunity to evaluate these different approaches to determine how these types of assessments might best be approached.
3.5.32 Consumer Specialty Products Association (CSPA)	CSPA believes that these initial twelve chemical reviews have been very successful in terms of the development of comprehensive Chemical Assessment documents and the Peer Consultations that have reviewed those documents. We especially believe that the program has served to validate the usefulness of considering hazard and exposure data together in evaluating chemical health and safety risks.
3.5.33 Children's Health Protection Advisory Committee (CHPAC)	As part of a formal evaluation of the program, an estimate of the resources needed to meet the program goals in accordance with the principles emphasized above should be made. If this estimate is excessive under budgetary constraints, consideration should be given to other models of data generation. Thus far, no estimate of the costs of this program, either to EPA or to the industry sponsors, has been offered.
3.5.34 Children's Health Protection Advisory Committee (CHPAC)	The transparency of the overall program must be improved. All decisions and processes should be carefully documented in publicly available documents. Our review has shown that while the peer consultation reports are relatively clear and transparent records of the expert deliberations on and opinions of the industry sponsors' evaluations, there are many parts of the VCCEP process that are not transparent. The initial selection of the third party organization conducting the peer consultation was not made in a transparent manner, and the nature and degree of input to industry sponsors by the third party organization during development of the sponsor documents is unclear. Additionally, it is extremely important that the Data Needs Determination by EPA is transparent, subject to review by other EPA programs with expertise relevant to children's health risks, and open to the public comment process.
3.5.35 American Academy of Pediatrics (AAP)	... urges the Environmental Protection Agency to terminate or substantially reshape the Voluntary Children's Chemical Evaluation Program.
3.5.36 American Academy of Pediatrics (AAP)	Overall, the AAP believes that the VCCEP has failed in its goal of providing the public and pediatricians with timely, useful information on chemical exposures and their implications. The EPA should consider terminating this pilot and replacing it with a mandatory program with stricter deadlines and a more transparent, accountable review system.

Comment Identifier / Submitter	Comment
3.5.37 Halogenated Solvents Industry Alliance, Inc, (HSIA)	<p>The VCCEP pilot program represents a successful partnership between EPA and sponsors with an important contribution to that success being due to TERA's management of the peer consultations. As yet, no mechanism has been employed to make the results of the peer consultations and EPA's subsequent decisions widely available within the Agency or to the public. Since the outcome of the peer consultation is significant for risk managers, placing the information on the Integrated Risk Information System (IRIS) is one step that should be implemented to reach that audience.</p>

Appendix A
FEDERAL REGISTER NOTICE

restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: November 13, 2006.

Peter W. Preuss,

Director, National Center for Environmental Assessment.

[FR Doc. E6-19558 Filed 11-17-06; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2006-0341; FRL-8057-1]

Implementation of the Pilot Voluntary Children's Chemical Evaluation Program; Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is requesting comment on the implementation of the pilot phase of the Voluntary Children's Chemical Evaluation Program (VCCEP). VCCEP was designed to collect health effects, exposure, and risk information on chemicals to which children are likely to be exposed, and to make that information available to the public so the public may better understand the potential health risks to children associated with certain chemical exposures. EPA announced the program in December 2000 and the pilot began in 2001 when companies volunteered to sponsor their chemicals under VCCEP. At what is approximately the midpoint in the implementation of the pilot phase of VCCEP, EPA is preparing to evaluate how well it is meeting its objectives for VCCEP. To this end, EPA is seeking comments from participants and observers about the operations and experience under the VCCEP pilot to this point. If requested, EPA will hold a public meeting to take comment on the implementation of the pilot phase of VCCEP.

DATES: Comments must be received on or before January 19, 2007.

Requests for a public meeting must be received on or before December 11, 2006.

ADDRESSES: *To submit comments:* Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2006-0341, by one of the following methods.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2006-0341. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2006-0341. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as

copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket, EPA Docket Center (EPA/DC). The EPA/DC suffered structural damage due to flooding in June 2006. Although the EPA/DC is continuing operations, there will be temporary changes to the EPA/DC during the clean-up. The EPA/DC Public Reading Room, which was temporarily closed due to flooding, has been relocated in the EPA Headquarters Library, Infoterra Room (Room Number 3334) in EPA West, located at 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 of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. EPA visitors are required to show photographic identification and sign the EPA visitor log. Visitors to the EPA/DC Public Reading Room will be provided with an EPA/DC badge that must be visible at all times while in the EPA Building and returned to the guard upon departure. In addition, security personnel will escort visitors to and from the new EPA/DC Public Reading Room location. Up-to-date information about the EPA/DC is on the EPA website at <http://www.epa.gov/epahome/dockets.htm>.

To request a public meeting: Submit your request, identified by docket ID number EPA-HQ-OPPT-2006-0341, to Catherine Roman by one of the following methods:

- *E-mail address:*

roman.catherine@epa.gov.

- *Mail:* Chemical Control Division (7405M), Office Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: Catherine Roman.

- *Hand Delivery:* 1201 Constitution Ave., NW., Washington, DC, EPA East, ATTN: Catherine Roman. Ask the reception desk to call (202) 564-4780. Such deliveries should be made during normal working hours, 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone

number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Catherine Roman, Chemical Control Division (7405M), Office Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4780; e-mail address: roman.catherine@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of particular interest to those chemical manufacturers (including importers) who produce or import chemical substances that are subject to the Toxic Substances Control Act (TSCA), individuals or groups concerned with chemical testing and children's health, and animal welfare groups. Because other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at the estimate.

vi. Provide specific examples to illustrate your concerns, and suggested alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is requesting comment from stakeholders, interested parties, and the general public on the implementation of the VCCEP pilot and is also evaluating the progress of the VCCEP pilot toward meeting its objectives. VCCEP was designed to collect health effects, exposure, and risk information on chemicals to which children are likely to be exposed, and to make that information available to the public so the public may better understand the potential health risks to children associated with certain chemical exposures, and to allow EPA and others to evaluate the risks of these chemicals so that mitigation measures may be taken as appropriate.

EPA announced VCCEP in a December 26, 2000 **Federal Register** notice (Ref. 1) and requested chemical manufacturers and importers to participate in a VCCEP pilot by voluntarily committing to sponsor an information collection on 23 chemicals. The VCCEP pilot is intended to allow EPA to gain insight as to how best to design and implement VCCEP in order to effectively provide the Agency and the public with the means to understand the potential health risks to children associated with exposure to chemicals to which children may be exposed. EPA intends the VCCEP pilot to be the means of identifying efficiencies which can be applied to the subsequent implementation of VCCEP.

Several factors were considered in selecting the 23 chemicals for the VCCEP pilot; they included substantial production/importation (one million lbs. or more per year), presence in the environment, and biomonitoring evidence of presence in humans. A detailed description of the selection process used by EPA is in the document entitled *Methodology for Selecting*

Chemicals for the Voluntary Children's Chemical Evaluation Program (VCCEP) Pilot (Ref. 2).

The requested commitment for the VCCEP pilot was for Tier 1 information, with the potential for EPA to request participants to make additional commitments to Tier 2 and Tier 3 information based on an evaluation of the Tier 1 submission. As part of their Tier 1 commitments, sponsors were asked to include an expected submission date that, as described in the December 2000 notice, is based on the amount of time EPA considered necessary to gather the information (or perform testing, if necessary) and prepare the assessments. Other guidance on timeliness provided in the December 2000 notice included the following:

- Within 6 months from the publication of the December 2000 notice was the recommended deadline to commit to Tier 1.
- Within 4 months after announcing EPA's Data Needs Decision was the recommended deadline to commit to upper tiers.
- Within 1 month after receiving a chemical assessment was EPA's goal to make it publicly available on the VCCEP website.

During 2001, 35 companies and 10 consortia voluntarily committed to sponsor 20 of the 23 chemicals in the VCCEP pilot. Three of the twenty-three chemicals were not sponsored and remain unsponsored. Also in 2001, EPA arranged for a third party, Toxicology for Excellence in Risk Assessment (TERA), to organize and facilitate public Peer Consultation meetings to evaluate the chemical assessments to be submitted by the chemical sponsors. At a Peer Consultation meeting, a panel of scientific experts with extensive and broad experience in toxicity testing, exposure evaluation, or the specific chemical discuss the chemical assessment and offer their opinions on its adequacy and possible additional data needs. This discussion is held at a public meeting where interested parties may also present comments. TERA prepares a report summarizing the opinions expressed at the public meeting and submits this report to EPA. EPA considers this report when it reviews the chemical assessment prior to forming its decision regarding additional data needs of the chemical.

In terms of progress, by the end of August 2006, the VCCEP pilot sponsors had submitted Tier 1 chemical assessments for 12 of the 20 chemicals; all 12 chemical assessments had been evaluated in public Peer Consultation meetings; summary reports of the Peer Consultation meetings for the 12

chemical assessments were made available; and EPA had reviewed the Peer Consultation reports and issued Data Needs Decisions for 6 of the 12 chemicals. EPA is in the process of developing Data Needs Decisions for the remaining 6 chemicals.

In its six Data Needs Decisions, EPA decided that additional data were needed for three chemicals. A consortium of three companies organized by the American Chemistry Council (ACC) has agreed to proceed to Tier 2 of the VCCEP pilot and sponsor the additional information collection for one of the chemicals. The Tier 1 sponsor of the other two chemicals with additional data needs informed the Agency that it will not commit to participate in Tier 2 for those chemicals. For the other three chemicals for which Data Needs Decisions have been issued, EPA concluded that the Tier 1 assessments provide sufficient information to adequately characterize the risk to children of exposure to those chemicals, and EPA considers the evaluation of these three chemicals to be completed for purposes of the VCCEP pilot. To summarize the activity and progress of the VCCEP pilot through August 2006, the table in this unit indicates how many chemicals have completed successive stages in the VCCEP pilot:

Stages in the VCCEP Process	Number of chemicals which have completed each stage
Agency informed it will not receive sponsor commitment to provide Tier 2 information	2

* As noted on the VCCEP website, the submission of chemical assessments for four chemicals (ethylbenzene, ethylene dichloride, perchloroethylene, and trichloroethylene) has been delayed due to other commitments to develop the data as part of another effort or program.

The most recent information on the progress of specific chemicals in the VCCEP pilot is presented on the VCCEP website (<http://www.epa.gov/chemrtk/vccep>). Since the Fall of 2001, EPA has kept the public informed of activities in the VCCEP pilot through the VCCEP website. The website describes VCCEP and how it was developed. It also lists the chemicals and their sponsors, the date of sponsor commitments to each tier, the submission dates of chemical assessments, the dates of upcoming public Peer Consultation meetings, and the completion dates of Peer Consultation reports and EPA's Data Needs Decisions. Most importantly, the website makes the cited information available to the public by providing links to the chemical assessments, the Peer Consultation reports, and EPA's Data Needs Decisions.

In terms of timeliness for EPA, TERA, and the sponsors meeting the scheduled goals for the VCCEP pilot, the following observations are made:

- All sponsors committed to Tier 1 by the 6-month deadline.
- As part of their Tier 1 commitments, the sponsors for 5 of the 12 chemicals for which EPA has received a chemical assessment as of August 2006, provided a projected submission date for their Tier 1 chemical assessment. The chemical assessment for only one of the five chemicals (decabromodiphenyl ether) was received by EPA by the projected submission date.
- Some of the projected submission dates originally provided by the sponsors were subsequently revised at the request of the sponsor, or due to TERA scheduling of Peer Consultation meetings.
- EPA made all the chemical assessments available on the VCCEP website within 1 month of receipt.
- Although a recommended deadline for scheduling the Peer Consultation meetings was not specified in the December 2000 notice, the meetings for the 12 chemicals for which EPA has

received a chemical assessment as of August 2006 were held within an average of 2.4 months of receiving the chemical assessment.

- Although a recommended deadline for TERA to issue its report summarizing a Peer Consultation meeting was not specified in the December 2000 notice, TERA issued its reports for the 12 chemicals for which EPA has received a chemical assessment as of August 2006, within an average of 4.1 months after each meeting.

The notice announcing VCCEP (Ref. 1, p. 81714) stated that EPA expected to evaluate the VCCEP pilot at 3 and 6 years after its initiation. EPA chose not to conduct an evaluation at 3 years because a sufficient number of chemicals had not gone through the public Peer Consultation process and, as a consequence of this, there was insufficient information to prepare a useful evaluation. Consequently, EPA decided to conduct a single evaluation at a point 5 years, approximately midway, into the program (i.e., 2006).

B. What is the Agency's Authority for Taking this Action?

Congress gave EPA the authority to implement TSCA for the purpose of protecting human health and the environment, in part, by requiring testing and, if necessary, by restricting the manufacture, processing, distribution in commerce, use, or disposal of certain chemical substances. VCCEP is a voluntary program which focuses on collecting information and developing data necessary to protect children from risks associated with chemical substances to which they are likely to be exposed. This notice seeks public involvement in a midpoint evaluation of how the VCCEP pilot is meeting its objectives and the overall objectives of VCCEP.

III. Request for Comment

EPA is requesting comment from stakeholders, interested parties, and the general public on the implementation of the VCCEP pilot, what modifications might be made to make the VCCEP pilot run more efficiently, and how well the VCCEP pilot is meeting the objectives of VCCEP. The main objectives of VCCEP are:

- To collect exposure, hazard, and risk information on chemicals to which children are likely to be exposed.
- To make the information available to the public so the public may better understand the potential health risks to children associated with certain chemical exposures.

The Agency is particularly interested in receiving your feedback with regard

Stages in the VCCEP Process	Number of chemicals which have completed each stage
Sponsor commitment to provide Tier 1 information	20
Tier 1 chemical assessment submitted	12 *
Tier 1 chemical assessment has gone through Peer Consultation	12
Peer Consultation report available	12
EPA issued a Data Needs Decision (3 chemicals had Tier 2 data needs, 3 chemicals did not have Tier 2 data needs.)	6
Received a sponsor commitment to provide Tier 2 information	1

OR

to the list of questions in this Unit III. Commenters should not feel that they must confine their comments to the following specific questions, nor should they feel they must respond to any or all of the questions. Commenters, however, should attempt to provide comments on the aspects of the VCCEP pilot with which they have had experience and/or have formed a definite opinion. To be most helpful in the Agency's evaluation, please provide enough detail to explain or illustrate conclusions that you have reached based on your experiences.

- Have the hazard, exposure, and risk assessments submitted by the sponsors provided sufficient information to enable the Peer Consultation panel to adequately evaluate these aspects as they relate to children from the chemicals in question? Have the Data Needs Assessments prepared by the sponsors been fair and unbiased?

- Has the Peer Consultation process been open, transparent, timely, and useful as a forum for scientists and experts from various stakeholder groups to exchange views on sponsors' assessments and recommended data needs? How might it be improved?

- Has the Peer Consultation process been efficient? If not, what improvements could be made?

- Has the Peer Consultation panel adequately considered both toxicology and exposure information in developing its results?

- Does the Peer Consultation process provide a scientifically rigorous and effective means for eliciting comments and opinions from the assembled experts on the Peer Consultation panel and those attending the public meeting, and for assisting EPA in developing decisions?

- Have the communications related to the Peer Consultation process, activities and outcomes been effective and have they facilitated public understanding and use of the information generated from this process?

- Should the time allowed for sponsor commitment remain the same, i.e., 6 months to commit to Tier 1, and 4 months to commit to subsequent Tiers? (The commitment period is the time for the sponsor to decide whether to participate in VCCEP, form a consortium, and notify the Agency.)

- How can the timeliness of activities under the VCCEP pilot be improved? Should specific due dates be established for each step in the process? If so, how should a missed due date be addressed?

- Should the sponsor be requested to commit to more than one tier at a time? Is it better to run the VCCEP pilot with commitments at each tier, i.e., three

commitments, or to run the VCCEP pilot with two commitments, i.e., to Tier 1 and to Tiers 2/3?

- Are there any ways in which EPA's contributions to the VCCEP pilot's evaluation and data needs decision process could be improved or made more effective?

- Has the VCCEP pilot made significant progress with respect to its objectives?

- The VCCEP pilot was designed to ensure that health effects, exposure, and risk information are made available to the public to enable a better understanding of the potential health risks to children associated with certain chemical exposures. Does the VCCEP website provide easy access to and adequate explanation of the information generated by the VCCEP pilot?

Commenters should follow the guidance provided in Unit I.B. and under **ADDRESSES** when preparing and submitting their comments.

IV. Comments Document

EPA will prepare a Comments Document summarizing the comments received in response to this notice and at a public meeting, if held. The Comments Document will identify any common themes and will assist EPA in determining what modifications might be made to make the program run more efficiently and/or better meet the objectives of VCCEP. Significant program modifications which the Agency is considering as a result of this evaluation will be discussed with stakeholders before implementing.

At this time, once the Comments Document is complete, EPA expects to make the Comments Document available to the public on the VCCEP website. The Comments Document will not be published in the **Federal Register**, nor will a notice of availability be published in the **Federal Register** announcing its appearance on the VCCEP website. However, if you provide your e-mail address, EPA will notify you by e-mail when the Comments Document is available on the VCCEP website at <http://www.epa.gov/chemrtk/vccep>.

V. Public Meeting

If there are requests to do so, EPA will hold a public meeting to discuss and take comment on the implementation of the VCCEP pilot. To request a public meeting, follow the directions under **ADDRESSES**.

VI. Materials in the Docket

An official docket was established for this VCCEP pilot evaluation under docket ID number EPA-HQ-OPPT-

2006-0341. The docket includes information considered by EPA in developing this notice such as the documents specifically referenced in this action, any public comments received, and other information related to this action. In addition, interested parties should consult documents that are referenced in the documents that EPA has placed in the public docket, regardless of whether these referenced documents are physically located in the public docket. For assistance in locating documents that are referenced in documents that EPA has placed in the public docket, but that are not physically located in the docket, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**. The public docket is available for review as specified under **ADDRESSES**.

1. EPA. Voluntary Children's Chemical Evaluation Program. **Federal Register** (65 FR 81700, December 26, 2000) (FRL-6758-5). Available on-line at: <http://www.epa.gov/chemrtk/vccep/pubs/ts00274d.pdf>.

2. EPA. Methodology for Selecting Chemicals for the Voluntary Children's Chemical Evaluation Program (VCCEP) Pilot. December 5, 2000. Available on-line at: http://www.epa.gov/chemrtk/vccep/vccep_mth.htm.

List of Subjects

Environmental protection, Chemicals, Child health.

Dated: November 9, 2006.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. E6-19574 Filed 11-17-06; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[FRL-8243-7]

2007 Blue Ribbon Water Quality Trading Awards—Call for Nominations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initiation of an EPA recognition and leadership program for excellence in water quality trading, "Blue Ribbon Water Quality Trading Awards," and solicits nominations for possible award to water quality trading programs and policies which have achieved or are expected to achieve environmental and economic benefits. Blue Ribbon Water Quality Trading Awards will encourage

Appendix B

LIST OF ORGANIZATIONS SUBMITTING COMMENTS

American Academy of Pediatrics (AAP)
Jay E. Berkelhamer, MD, FAAP (President)
141 Northwest Point Blvd.
Elk Grove Village, IL 60007-1098
Phone: (847) 434-4000
Fax: (847) 434-8000
E-mail: kidsdocs@aap.org

American Chemistry Council (ACC)
Sarah Brozena
Phone: (703) 741-5159
Email:
Sarah_Brozena@americanchemistry.com
Rick Becker
Phone: (703) 741-5210
Email: Rick_Becker@americanchemistry.com

B. Sachau
15 Elm St.
Florham Park, NJ 07932

Children's Environmental Health Network
Nsedu O. Witherspoon, MPH
(Executive Director)
110 Maryland Avenue NE, Suite 505
Washington, DC 20002
Phone: (202) 543-4033
Fax: (202) 543-8797
E-mail: cehn@cehn.org

Children's Health Protection Advisory Committee (CHPAC)
Melanie A. Marty, Ph.D (Chair)
CA/EPA Office of Environmental Health
Hazard Assessment
1515 Clay St. 16th Floor
Oakland, CA 94612
Phone: (510) 622-3154

Consumer Specialty Products Association (CSPA)
D. Douglas Fratz (VP, Scientific and Technical Affairs)
900 17th Street, NW Suite 300
Washington, DC 20006
Phone: (202) 872-8110
Fax: (202) 872-8114

Environmental Defense
257 Park Avenue South
New York, NY 10010
Phone: (212) 505-2100
Fax: (212) 505-2375

Halogenated Solvents Industry Alliance, Inc. (HSIA)
Paul H. Dugard, Ph.D (Director of Scientific Programs)
1300 Wilson Boulevard
Arlington, VA 22209
Phone: (703) 741-5780
Fax: (703) 741-6077
E-mail: pdugard@hsia.org

Natural Resources Defense Council (NRDC)
Jennifer Sass, Ph.D (Senior Scientist)
Mae C. Wu (Program Attorney)
1200 New York Avenue, NW, Suite 400
Washington, DC 20005

People for the Ethical Treatment of Animals (PETA)
Jessica Sander (Director, Regulatory Testing Division)
501 Front St.
Norfolk, VA 23510
Phone: (757) 622-PETA
Fax: (757) 628-0781

Toxicology Excellence for Risk Assessment (TERA)
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