

**Proposed Modifications to  
Voluntary Children’s Chemical Evaluation Program (VCCEP) Process**

*Background*

VCCEP was designed to collect health effects, exposure, and risk information on chemicals to which children are likely to be exposed, 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 initiated VCCEP in December 2000 (Ref. 1) and requested chemical manufacturers and importers to participate in a pilot of the program by voluntarily sponsoring chemicals selected by EPA. The pilot began in 2001 when companies volunteered to sponsor their chemicals in response to EPA’s request.

In 2006, EPA sought to evaluate how well the pilot was meeting the objectives of VCCEP by requesting that VCCEP stakeholders and the public submit comments on their experience with the pilot phase of VCCEP (Ref. 2). Additionally, EPA developed a list of questions to focus comments on certain features of the VCCEP pilot. The comments EPA received were summarized and made available to the public on the VCCEP website (<http://www.epa.gov/oppt/vccep>). The comments principally concerned the chemicals selected for the pilot program, the timeliness and efficiency of the program, the use of a tiered approach to testing, and the use of a peer consultation process to review chemical assessments. Based on those comments, and on internal Agency discussions, EPA developed a list of modifications to improve the future performance of VCCEP. To share and discuss the contemplated modifications with the VCCEP stakeholders and the public, and to listen to any additional comments, EPA held a public meeting on July 22, 2008 (Ref. 3). The proposed modifications were presented at the public meeting. Most of the stakeholders that presented formal statements and/or submitted written comments to the docket stated that the modifications would not be sufficient to improve VCCEP, which they viewed as too time consuming and not effective in obtaining all of the identified data needs. Some commenters expressed concern that the chemicals included in the VCCEP pilot were a set of particularly well-studied chemicals for which, in most cases, little additional assessment was needed. Comments on tiered testing were both for and against maintaining the current tiered structure, but implicit in most comments was that tiered testing added to the delay in obtaining test results. Although the peer consultation was considered by most to be a fair, transparent, and scientifically rigorous process, some commenters expressed concern that it might be perceived as directed by industry if the sponsors were required to fund it and that EPA should fund and control the process. Another concern was that separate peer consultations organized by different service providers might not produce comparable products, or that chemical assessments would not be evaluated in a consistent, standardized way by different peer consultation panels.

*Proposed Modifications to VCCEP Process*

In recognition of the feedback EPA has received from VCCEP stakeholders, and to establish VCCEP as an ongoing data development and assessment follow-up option for EPA screening level risk evaluations, EPA is proposing a number of important changes to VCCEP's operations in the future. The changes address the major concerns with the program -- chemical selection, timeliness, peer consultation, and tiered testing—and are described in further detail below.

To address the concern that the chemicals covered in the VCCEP pilot were a set of particularly well-studied chemicals for which little additional assessment was needed, future VCCEP chemicals will be primarily selected from chemicals that are identified in the Chemical Assessment and Management Program (ChAMP)<sup>1</sup> Risk-Based Prioritization (RBP) documents as presenting hazard/exposure data needs that are relevant to characterizing risks to children. ChAMP chemicals that also meet the original VCCEP chemical selection criteria, which were evidence of presence in human tissues and in relevant environmental media (e.g., indoor air, drinking water, and food), would remain a particular focus of future VCCEP activity.

To ensure timely completion of chemical evaluations conducted as part of VCCEP, specific timeframes for each step in the proposed, modified process have been identified. These timeframes are relevant to the contributions to the program by the sponsor(s), the public, and EPA. When a sponsor makes a commitment to VCCEP, it is understood to be made with a full understanding and concurrence with the timeframes for each step. Also responding to the timeliness concern, the use of peer consultations in the modified VCCEP will be concerned with resolving scientific and technical issues related to the development of Test Plans, which is a new focus for peer consultations under the program.

The timeliness of, and other concerns about, tiered testing will be addressed by reducing or eliminating tiering. ChAMP prioritization documents will replace the VCCEP Tier 1 hazard and exposure assessment and chemicals will, in most cases, enter the modified VCCEP process at a stage where Tiers 2 and 3 are combined.

A schematic of the new, proposed process is shown in Figure 1 and explained in the following narrative:

*Step 1:* Chemicals selected for VCCEP in the future will primarily be ChAMP chemicals that are determined by EPA to be of high priority and special concern for potential risks to children. RBP documents generated in EPA's ChAMP will identify these chemicals. Because RBP documentation reviews the hazards, exposures, and potential risks of chemicals in order to prioritize them at a screening level and identifies additional data needs and exposures of concern, the RBP documentation generally obviates the need for a VCCEP Tier 1 assessment. Step 1 is initiated when EPA notifies,

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<sup>1</sup> A more detailed description of ChAMP and its risk-based prioritization (RBP) approach is provided at <http://www.epa.gov/ChAMP>.

manufacturers and importers, identified by Inventory Update Rule (IUR) reporting, by letter of a chemical that has become a candidate for VCCEP as a result of a ChAMP evaluation and invites them to sponsor their chemical in VCCEP.

To bring concerns for potential chemical risks to prompt resolution, specific testing priorities from both Tier 2 and 3 of the initial VCCEP pilot will be identified in the ChAMP RBP. If hazard studies from both Tier 2 and Tier 3 are identified as testing priorities in the RBP, an approach that separates Tier 2 from Tier 3 may be acceptable when the sponsor can establish that it is sound scientifically and will not unduly delay the public availability of Tier 3 data. Whether Tiers 2 and 3 are combined or separate, the sponsor will also have the opportunity to establish that data on a particular endpoint should be waived (See Step 3). To the extent that EPA accepts the need for separate tiers, certain aspects of the steps that follow will be repeated to accommodate the 3<sup>rd</sup> tier.

*Step 2:* Manufacturers and importers formalize their decision to participate in VCCEP by submitting a commitment letter to EPA within 1 month of receipt of EPA's invitation. Alternatively, because ChAMP RBPs may be based on a less than robust set of exposure information, manufacturers and importers may decline participation and use the month-long period to make exposure information available to EPA that would improve the understanding of the chemical's potential exposures and risks to children and justify modifications to the RBP decision. EPA commits to promptly review any exposure data submitted by chemical manufacturers and importers. If no manufacturers and importers respond to EPA's VCCEP invitation or decline participation with or without an exposure-based rationale, EPA will consider use of Section 4 of the Toxic Substances Control Act (TSCA) or other appropriate authorities to obtain needed assessment related information.

*Step 3:* After submitting a commitment letter, a sponsor has 2 additional months to submit to EPA a test plan for the hazard and/or exposure endpoints identified in the ChAMP RBP, and a schedule. If the sponsor believes that testing is not needed for some or all of the hazard/exposure endpoints identified in the ChAMP RBP or that tiered testing is a preferred approach for addressing data needs, the sponsor is encouraged to arrange for an independent third party to conduct a public peer consultation at the sponsor's expense to independently review their test plan. If the sponsor opts for a peer consultation, the sponsor will have an additional 2 months to conduct the peer consultation and submit a test plan, schedule, and peer consultation report to EPA; upon request EPA will consider, based on the effort to date, if a one month extension should be granted.

*Step 4:* EPA posts the sponsor's submission on EPA's VCCEP Web site and invites prompt public comment. EPA evaluates the submission within 2 months of receiving it and communicates the next course of action. If EPA concurs with the test plan, the sponsor promptly initiates the agreed testing. If EPA concurs only in part with the test plan, the sponsor conducts the agreed testing and EPA may use its TSCA authorities to obtain the other needed test data. If EPA does not concur with the test plan, or if there is a delay in its submission, EPA will consider use of its TSCA authorities to

obtain needed testing. If the sponsor's submission indicates that testing is not needed and EPA concurs, EPA commits to amending the ChAMP RBP for that chemical.

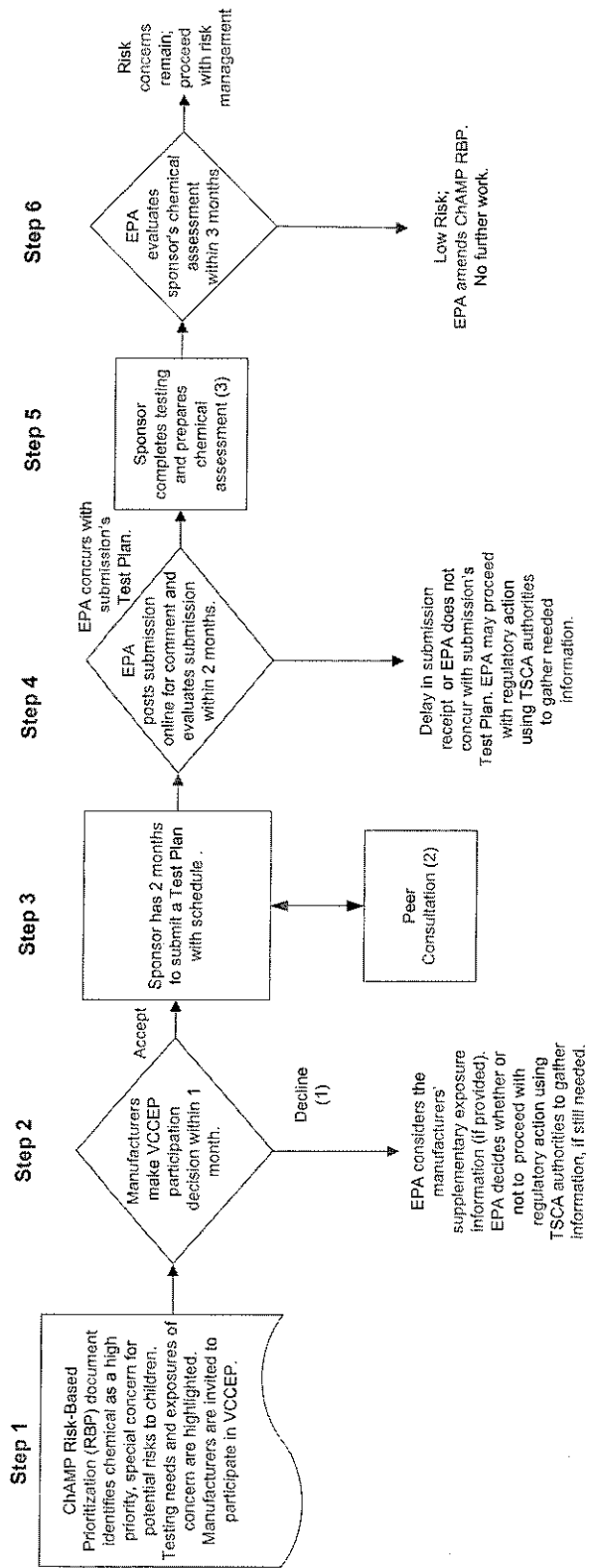
*Step 5:* The sponsor completes the agreed testing. The timeframe to complete the testing depends on the tests being conducted and follows the VCCEP time schedule guidelines noted in Reference 1. For exposure studies, EPA and the sponsor will agree and announce in advance the timeline for completion of the testing. Within 3 months of completing the last study<sup>2</sup>, the sponsor submits the full study reports, robust summaries of those reports and a risk assessment that includes evaluation of the available hazard and exposure information.

*Step 6:* EPA commits to conduct and release an evaluation of the sponsor's submission within 3 months of receiving it. If EPA believes the chemical poses a risk to children, EPA will work to appropriately manage the risk. This could include voluntary efforts involving the sponsors and stakeholders or regulatory actions. If EPA believes the chemical poses a low risk to children, EPA will amend the ChAMP RBP for that chemical.

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<sup>2</sup> Note that immediate submission to the Agency under TSCA Section 8(e) may be required if the information obtained reasonably supports the conclusion that the chemical substance presents a substantial risk. See <http://www.epa.gov/oppt/itc/pubs/sect8e.htm> for more information on TSCA Section 8(e).

**Figure 1**  
**Modified VCCEP Process**  
**Which Supports Follow-up Evaluation of Chemicals of**  
**High Priority, Special Concern Identified in ChAMP**



(1) Because ChAMP RBPs are based on a less than robust set of exposure information, a manufacturer may choose to decline participation and provide EPA with supplementary information to establish that children's exposures need not be a concern within this 1 month period.  
 (2) If the sponsor believes that testing is not needed for some or all of the hazard/exposure endpoints identified in the ChAMP RBP or that tiered testing is a preferred approach, the sponsor should document its case and may have it reviewed by a Peer Consultation; it pays for, prior to EPA consideration. An additional 2 months for Step 3 will be accommodated if a sponsor pursues a Peer Consultation.  
 (3) Timeframe determined by needed testing, as is current VCCEP practice.

**References:**

1. EPA. Voluntary Children’s Chemical Evaluation Program; Notice. **Federal Register** (65 FR 81699, December 26, 2000)( (FRL-6758-5). Available on-line at: <http://www.epa.gov/fedrgstr>.

2. EPA. Implementation of the Pilot Voluntary Children’s Chemical Evaluation Program; Request for Comment; Notice. **Federal Register** (71 FR 67121, November 20, 2006)( (FRL-8057-1). Available on-line at: <http://www.epa.gov/fedrgstr>.

3. EPA. “Overview of Possible Modifications to the Voluntary Children’s Chemical Evaluation Program (VCCEP).” Slide presentation at public meeting, July 22, 2008.