Children's Health Protection Advisory Committee

June 30, 2006

Stephen L. Johnson, Administrator
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: VCCEP Evaluation

Dear Administrator Johnson:

The Children's Health Protection Advisory Committee (CHPAC) is pleased to have this opportunity to provide EPA with evaluative feedback on the Voluntary Children's Chemical Evaluation Program (VCCEP) pilot. U.S. EPA staff briefed us on VCCEP and we are aware of the pending evaluation of the pilot program. We would like to express strong support for the VCCEP's intended goal of making data on children's risks from exposure to toxic chemicals publicly available. Having reviewed, within our limited resources, the process and results of the VCCEP pilot to date, the CHPAC has strong concerns with its structure and implementation. The following observations and recommendations are intended to assist EPA in evaluating the structure and implementation of the VCCEP pilot.

General observations

The primary goal of the VCCEP is to ensure that there are adequate publicly available data to assess children's health risks from exposure to toxic industrial chemicals. U.S. EPA established the program to gather or develop the toxicology and exposure information on industrial chemicals identified in each tier, in order to adequately assess health risk to children. This goal is of considerable importance and the need for an effective program remains valid.

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.

The results of the pilot, while disappointing, if fully evaluated may lead to critical lessons-learned. We urge EPA to publish the Federal Register notice announcing the planned evaluation, and we hope the findings and recommendations listed below contribute to this process.

Prioritization of chemicals selected for the program

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. Unfortunately, the chemicals studied in the pilot phase were selected based on richness of existing data sets rather than the potential for serious health threats. EPA should identify a manageable list of high priority chemicals based upon exposure and potential toxicity to children, and these chemicals should be reviewed under an expedited process within one year. All other candidate chemicals should be prioritized by EPA based on similar criteria for entry into the VCCEP program in a timely manner.

Improving methods for assessing children's exposures and risks

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. 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.

Improving confidence in the program

Widespread confidence in the VCCEP process among all stakeholders is critical to its success, and requires both the reality and the appearance of careful procedural safeguards. At present, several features of VCCEP may undermine this confidence. The VCCEP's main document providing the public with information on children's risks is written by the industry sponsor. 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. 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.

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.

Improving program accountability

Accountability is also important for the success of the VCCEP. 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. 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.

Improving program efficiency and timeliness

Since this program exists to provide information to safeguard children's health, it is critical that VCCEP generate that information as rapidly as possible without sacrificing quality of the output. Thus far, the pace of the program has been unacceptably slow, with approximately two chemicals reviewed per year at just the first tier level. 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. The selection of chemicals with toxicological data from all three tiers has lead to confusion as to what constitutes a reasonable data need for a "tier 1" review. Moreover, it remains unclear exactly what constitutes the different tiers of exposure assessment. Breaking the review process into three steps, each taking as long as the pilot tier 1 review has taken, is extremely inefficient. Accordingly, 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.

Achieving fiscal clarity and responsibility

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. However, given the degree of effort apparent in the production of the industry sponsor documents and the peer consultation process, the costs appear to be considerable.

Achieving meaningful stakeholder participation

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.

Conclusions

While the CHPAC supports the underlying goals of the Voluntary Children's Chemical Evaluation Program, we believe that this pilot of the full program has revealed severe structural flaws. We urge the administrator to publish the Federal Register notice and thereby solicit feedback on the pilot program from all stakeholders. We also urge the administrator to consider the CHPAC's current recommendations, which are summarized below. Lastly, we strongly urge the administrator to commission an independent assessment of the VCCEP pilot, which will include an accounting of costs to the agency and industry sponsors and a projection of resources required to implement the VCCEP. This review should be directed at determining whether a voluntary program such as a restructured VCCEP program is a more effective means of making information publicly available than other means at the agency's disposal, including a TSCA test rule. We have summarized our recommendations below roughly in the order in which they should be implemented.

Summary of Recommendations

EPA should:

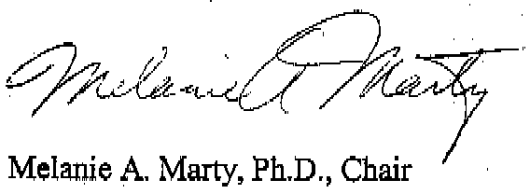
1. Publish the Federal Register notice announcing the public stakeholder evaluation of the VCCEP pilot. Key themes to be addressed in public workshops include improving dissemination of results and stakeholder involvement and confidence in the program.
2. Develop specific guidance and criteria for the VCCEP program regarding exposure assessment, interpretation of toxicological studies with respect to hazard

for children and identification of triggers for seeking additional toxicological and/or exposure data.

3. Retain control of critical elements of the process, including the peer consultation and public information. Consideration should be given to relying on contracts, rather than cooperative agreements, to assure EPA accountability.
4. Replace the current tiered structure with 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.
5. Identify a high priority list of chemicals for an expedited review process. Additional chemicals should also be prioritized for entry into a future program and reviewed with a clear timeline for completion.
6. Initiate a more robust annual reporting process to inform the general public and other key stakeholders of program process. This reporting process could take the form of written reports, website updates, and/or public workshops.
7. Conduct a thorough third party (external to EPA) assessment of the VCCEP pilot program. This assessment should include items such as documentation of initial decisions and costs that were not available to CHPAC and provide a formal estimate of the resources needed to implement the program incorporating the changes that have been recommended. This separate assessment should determine whether a voluntary program such as a restructured VCCEP is the best means of generating new information on children's risks from exposure to toxic chemicals.

We ask that the Agency report to the CHPAC at a future meeting on the progress and results of these recommended actions. We look forward to working with the agency in its efforts to determine how best to address the health threats to children posed by toxic chemicals in their environment, and would be pleased to discuss our concerns regarding the VCCEP pilot program with you and your staff. Thank you in advance for your consideration of these comments and recommendations.

Sincerely,



Melanie A. Marty, Ph.D., Chair
Children's Health Protection Advisory Committee

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