Children's Health Protection Advisory Committee

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

RE: Chemicals Assessment and Management Program;
Voluntary Children's Chemical Evaluation Program

Dear Administrator Johnson:

The Children's Health Protection Advisory Committee (CHPAC) appreciates U.S. EPA's efforts to address some of our concerns about EPA's approach to chemicals policy management. We identified those concerns in letters on chemical policy (July 31, 2007) and on the Voluntary Children's Chemical Evaluation Program (VCCEP) (June 30, 2006). In the July 2007 letter, we made many suggestions for EPA to improve current chemical management practices. One recommendation was to prioritize chemicals in the Toxic Substances Control Act (TSCA) inventory to identify those of special concern to children. EPA is beginning to prioritize chemicals in the TSCA inventory in a new initiative titled Chemicals Assessment and Management Program (ChAMP). This is an important step given that children are exposed on an ongoing basis to multiple chemicals, many of them lacking rigorous regulatory review.

In this letter, CHPAC provides observations, concerns and recommendations for strengthening the overall approach in the ChAMP program, and its linkage to VCCEP. As the Agency embarks on this screening program, it is crucial that the methodology is sound, consistent and transparent. The goal of ChAMP is to prioritize more than 6000 chemicals in a few years. We note that the screening nature of this effort precludes a careful assessment of public health risks from chemical exposures in general, or children's risks in particular.

The CHPAC also reviewed EPA's proposed changes to VCCEP, dated September 25, 2008, intended to improve that program's efficiency. We are especially interested in the proposed linkage between ChAMP and VCCEP if this offers an opportunity to generate and review data needed to adequately assess risks to fetuses, infants, and children from priority chemicals identified by ChAMP. The proposed revisions to VCCEP are a positive step, and offer a higher chance of success than the VCCEP pilot. It is important to remember, however, that VCCEP is a voluntary program that does not guarantee a manufacturer's participation or the generation of new data. Further, VCCEP may be the wrong option for chemicals with high concern scores in ChAMP given that actions to prevent exposure and/or mandatory testing may be more appropriate than entry into a voluntary data generating and assessment process. If VCCEP is adapted in this way, its success hinges on a proper and robust execution of ChAMP.

In order to strengthen ChAMP, EPA must include proactive steps to protect children from the chemicals of highest concern and clearly acknowledge when additional data are needed. The Agency must make it clear that chemicals not identified as "high priority" in ChAMP may still pose health concerns given the screening nature of this prioritization process and limited supporting data. EPA must acknowledge the limitations in the underlying High Production Volume (HPV)/ Screening Information Data Set (SIDS) used for ChAMP screening and think more broadly about how the database for prioritization of TSCA chemicals to identify effects on children can be improved.

CHPAC reviewed 18 of the 35 Risk-Based Prioritizations (RBPs) posted as of October 2nd on the ChAMP website and evaluated whether the RBPs appropriately address children's exposures and risks. The RBPs are the outcome of the ChAMP process in which the hazard and exposure assessments are integrated into an overall priority ranking.

Three of the 18 RBPs reviewed by CHPAC resulted in a high priority ranking. In each case (monoglyme, diglyme, and hexabromocyclododecane), children's concerns were ranked as high priority, which CHPAC reviewers found appropriate. However, the reviewers found some inconsistencies, a lack of transparency, and other concerns in the 18 RBP determinations.

Concerns with ChAMP include:

- The protocol used to assess exposure, hazard, and risk and develop an RBP score is not available on the ChAMP website. Instead, the website refers to general guidance documents which can be applied in many different ways to risk-based screening. Since the Agency does not provide any information on the protocol, one cannot judge whether the RBPs were conducted in a systematic and internally consistent manner. The CHPAC found that RBP scores were sometimes arbitrary and, in certain cases, we disagreed with the outcome (e.g., see Appendix A, N-butylglycidyl ether, methane sulfonic acid examples).

- It appears that EPA placed chemicals into the "high concern" category only if the chemicals ranked high in hazard and high in exposure. However, EPA discounted chemicals if they were of "high concern" in only one of these areas, and "uncertain" in the other. This is disconcerting because having incomplete data can limit the ability to screen for priority chemicals. For example, hazard assessments based upon Organization for Economic Cooperation and Development (OECD)/SIDS do not cover many important children's toxicity endpoints, and the Inventory Update Report (IUR) exposure data are limited as described below.

- The process does not evaluate children's exposures (including those in utero) and vulnerabilities in any substantive way. Exposure assessment should focus on children's exposure pathways including: 1) transplacentally through their pregnant mothers and transfer through breast milk; 2) from building materials used in residential/school environment (e.g., ingredients in flooring, , textiles, adhesives); 3) from chemicals in consumer products. (See Appendix A, 2,4,6-trimethylphenol, methane sulfonic acid examples).

- The chemical use information in the TSCA IUR can be incomplete since manufacturers are not always aware of the ways that customers may use their products. In addition, some of these data are classified as "Confidential Business Information" (CBI), limiting the transparency of the EPA ChAMP review. Further, the IUR does not fully address exposure needs for VCCEP.

- The RBPs are unclear regarding how much CBI data were reviewed by EPA and how EPA used that data to make exposure determinations

- There is no step within ChAMP for a data call-in to gather readily available information from manufacturers that could refine the RBP determination. EPA does not publish a schedule ahead of time to let manufacturers know which chemicals are being reviewed, and thus provide an opportunity for additional data submission.

Concerns with VCCEP include:

- EPA still has not provided VCCEP-specific guidance about how to systematically evaluate children's exposures or to determine the adequacy of available toxicological data to assess risks to children. The CHPAC recommended that EPA develop specific guidance in our July 2006 letter.

- VCCEP is still a voluntary process from start to finish. Sponsors have the option to not participate or to decline to fill data needs (e.g., deca-BDE). The revised VCCEP Step 2 includes language stating that the Agency would consider using TSCA Section 4 to obtain industry participation. However, VCCEP Step 5, where data are required, does not mention use of TSCA authority. It is also

unclear how the Agency will decide whether to use TSCA requirements at any step.

- Referral to VCCEP and a successful outcome from VCCEP requires a robust ChAMP evaluation. However, limitations in ChAMP, especially regarding assessments of data needs, hinder ChAMP's usefulness as input to VCCEP (e.g., see monoglyme and diglyme examples in Appendix).

- EPA proposes to use peer consultation when a sponsor disagrees with a test plan. We acknowledge that there may be disagreements over test plans. We are concerned, however, over perceptions of bias with the peer consultation process if funding comes from sponsors. Additionally, the new VCCEP process appears to call for constituting a new peer consultation group for each test plan review. This could be highly inefficient and ineffective. A standing committee model may allow for developing expertise, and a more efficient and effective review.

Based upon these findings, the CHPAC recommends that the Agency modify its approach to ChAMP and VCCEP in the following ways:

1. Develop and publish a protocol specific to ChAMP that yields transparent, consistent, child health-protective evaluations. This is critical to improve accountability and confidence in the process. The protocol should include the default assumption that children's exposure is possible if the material is used in building materials or consumer products. The protocol should also address uncertainties and data gaps in the HPV/SIDS datasets.
2. The Agency should provide assurance that data on children's exposures was included in the CBI data that EPA reviewed. If the Agency did not review such data, the EPA should disclose that no data on children's exposures were available for review, and note this lack of information as a limitation.
3. Assure that children's exposure scores are not lower than those given to consumers or the general public, which is now the case in some ChAMP assessments (see Appendix).
4. Clearly state the uncertainties and data gaps so that ChAMP can be a better starting point for VCCEP, including gaps on important toxicological endpoints not covered by SIDS. The Agency should explicitly describe these limitations in the hazard characterization and take these limitations into account in evaluating hazards to children.
5. Modify the protocol for ranking concern in the RBP such that chemicals can become high priority by 2 different avenues: a) if they are of high concern in exposure and hazard assessment or b) if they are of high concern in only one of these areas but the other area has considerable uncertainty. The former case should lead to immediate action to mitigate exposure, while the latter should result in steps to gather more data such as a data call-in, VCCEP, or a test rule. Health Canada's prioritization scheme for their Domestic Substances List results in a high priority score if there are high exposure or high hazard concerns.

6. Work with downstream consumers of chemicals to obtain better end-use information; this step will improve the utility of the IUR data for exposure assessment. The Agency should improve IUR questions under Commercial Use and Consumer Use Data to better identify end uses where children may potentially be exposed, including consumer products and building materials. EPA should publish the schedule for their RBP reviews so Industry has the opportunity to submit additional data ahead of time for Agency consideration during the RBP process
7. Simplify VCCEP by moving the exposure data submission from Step 2 into ChAMP. This would create a ChAMP data call-in step involving reasonably tight time lines after the initial RBP determination. This should be mandatory for high priority chemicals to make sure they are evaluated as fully as possible given the limited nature of the data, and to ensure that data needs are properly assessed.
8. Develop VCCEP-specific guidance and criteria for exposure assessment, interpretation of toxicological studies about children's hazards, and identification of triggers for seeking additional toxicological and exposure data.
9. Strengthen VCCEP by being clearer about when and how EPA will use TSCA Section 4 to obtain the needed information should the voluntary process fail. The revised VCCEP protocol should clearly state the potential use of TSCA authority at both Steps 2 and 5. The Agency must promptly use its TSCA authority to obtain critical data or limit chemical uses when there are high priority concerns for children.
10. Create a neutral, standing committee with developed expertise to conduct peer consultation when test rules are in dispute. This will enable EPA to review and arbitrate disagreements over test plans. EPA should fund this process to avoid perceptions of bias on the part of stakeholders.

The CHPAC findings outlined above are described in more detail in the enclosed attachment.

As noted in our July 31, 2007 letter, EPA must take many additional actions beyond relying on ChAMP and VCCEP in order to improve knowledge of children's exposures and risks. For example, EPA should employ models that more thoroughly assess the potential for children's exposure to chemicals in home and school environments, and expand partnerships with Canada and other government agencies that face similar challenges to ensuring children's health.

Prompt action to ensure appropriate screening is conducted under ChAMP is essential because of the need to rapidly screen thousands of TSCA chemicals over the next few years, and because children are potentially exposed to high concern chemicals in their daily lives on an ongoing basis.

We welcome the opportunity to discuss these points, and thank you for your attention to these recommendations.

Sincerely

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

Cc: James Guilford, Assistant Administrator, OPPTS
Charlie Auer, Director, OPPT
Ward Pemberthy, Associate Director, OPPT

Attachment

Attachment A

CHPAC Findings on ChAMP and VCCEP Revisions

The US Environmental Protection Agency's Children's Health Protection Advisory Committee (CHPAC) reviewed 18 of the 35 Risk-based Prioritizations (RBPs) that were available on the Chemical Assessment and Management Program (ChAMP) website as of October 2, 2008. CHPAC members evaluated the hazard and exposure characterizations, and how these findings were incorporated into an RBP. The 18 RBPs were:

2-amino-2,3-dimethylbutanenitrile
Ethylphenols Category
Phenol, 3-chloromethyl-6-1,1-dimethylethyl-2,4-dimethyl-
1,3,5-Trioxane
2,3-Dihydro-2,2-dimethyl-7-benzofuranol
Benzonitrile, 3-methyl-
Cyclopropanecarboxylic Acid
Phenol, 2-[2-methyl-2-propenyloxy] Methyallyloxyphenol
Alkaryl Sulfonate Category
2-Propen-1-ol
2,4,6-Trimethylphenol
Acetamide, N-[5-[bis[2-acetyloxyethyl]amino]-2-[2-bromo-4,6-dinitrophenylazo]-4-methoxyphenyl]-
Butylated Triphenyl Phosphate
Methanesulfonic acid
Oxirane, (butoxymethyl)- (N-butyl blycidyl ether)
1,2,5,6,9,10-Hexabromocyclododecane
Ethane, 1,2-dimethoxy- (monoglyme)
Ethane,1-1'-oxybis[2-methoxy- (diglyme)

Three of the 18 RBPs that CHPAC reviewed were considered high priority. The CHPAC is pleased that high ranking for a concern about children resulted in overall high RBP scoring in these cases.

CHPAC identified the following concerns with the ChAMP hazard, exposure, and risk characterizations:

Issues with ChAMP

ChAMP is an ambitious effort that will involve a broad screen to prioritize thousands of Toxic Substances Control Act (TSCA) chemicals by the year 2012. The CHPAC realizes that ChAMP needs to be quick, efficient, and effective as a first tier screen so that the most worrisome chemicals are identified and prioritized for further action. For this to occur, ChAMP evaluations need to have a well-defined protocol that ensures thoroughness and consistency. The CHPAC strongly recommends making the protocol

for evaluations public, and if one is not available, making the development of such a protocol a priority. Using pieces of existing guidelines is neither transparent nor particularly useful, given the variability in the reviewed RBPs.

An overarching concern is that the evaluation of children's exposures and potential vulnerabilities must play a greater role at each stage of the process (hazard, exposure, and risk characterizations), and in the development of priority scores.

Regarding exposures, EPA should assume that children may be exposed to any chemical used in a consumer product or any chemical used as an ingredient in building materials used in children's homes or schools. For example, solvents may off-gas into indoor air; metals, plasticizers, flame retardants, and dyes in materials may deteriorate and migrate into house dust. These chemicals should receive relatively high priority scores. A chemical should receive an even higher priority score if there is an indication from Inventory Update Report (IUR) data that the chemical is also used in products designed for use by children. The IUR data are not robust or reliable for determining the potential for children's uses and exposures because manufacturers submitting the IUR are often not aware of all potential uses. Ruling out children's exposure based upon the level of analysis currently exhibited in the RBPs is likely to yield an incorrect judgment in numerous cases. If the use pattern is unclear, then, given the high volumes of these compounds, the Agency should assume that environmental and around-the-home exposures to children are possible.

Regarding the hazard rankings, a variety of agents (including neurotoxicants, immunotoxicants, endocrine disruptors and carcinogens) can have greater potency during critical windows of child development. The CHPAC found, however, that the Screening Information Data Set (SIDS) submissions for HPV chemicals typically did not provide this information, except for mutagenesis to some degree. There may be opportunities to use structure-activity relationships (SAR) or data from closely related surrogate chemicals for these toxicity endpoints, but only in select cases. The Agency should spend more effort on identifying the data gaps and needs and uncertainties in their screening analyses. Compounding the uncertainty in hazard analysis is the screening nature of many of the toxicity studies; these often involve low numbers of animals, limited exposure and observation periods, and incomplete assessments of even standard endpoints (e.g., organ weights, clinical chemistry).

In the Risk Characterization, the Agency considers the relationship between exposure and hazard, but the rationale for the final decision is not always coherent or transparent. The CHPAC found that the agency missed opportunities to include information about data gaps and uncertainties in the final RBP.

The following additional concerns arise out of our review of ChAMP evaluations:

1) The exposure assessments are typically very qualitative and vague and lack documentation. Confidential business information (CBI) is often stated as a reason why these assessments cannot be more transparent. In general, the agency

could increase confidence in the assessment by stating the nature and extent of the CBI and other data available (how many manufacturers actually provided IUR data; how many different uses cited; how many pounds accounted for; more information on how the uses were specified).

2) The exposure characterization should go beyond a manufacturer's noting that a chemical is used in consumer products or children's products. For example, the highly volatile chemical 2,4-6-trimethylphenol is used as a solvent in paints and coatings. While no consumer or children's uses were reported under the IUR, adults and children are likely exposed when this solvent is used in homes and volatilizes. While other assessments reviewed by CHPAC were similarly deficient in considering exposure pathways, the exposure assessment for some (e.g., N-butylglycidylether present in sealants, methane sulfonic acid in cleaning products, diglyme in paints and coatings) did acknowledge that their use could lead to children's exposures. In these cases, however, children's exposure potential was only considered moderate even though exposure was ranked as high for the general public. In other cases, it may be possible for a chemical to be an ingredient in a product incorporated into the built environment. For example, 1,3,5-trioxane is listed as a monomer in the production of high molecular weight (MW) polyacetals; 1,3,5-trioxane is also highly volatile. There is no analysis of whether any residual 1,3,5-trioxane may off-gas from polymers used for products in the home or school environment, leading to children's exposures. Thus, the assessment of exposure potential was generally not very robust nor was it consistent chemical-to-chemical or between children and adults.

3) The number of exposed workers in several cases is estimated to be very low (e.g., fewer than 100 workers exposed to Phenol, 3-chloromethyl-6-1,1-dimethylethyl-2,4-dimethyl-). Yet these are all high production chemicals whose volumes are in the hundreds of millions of pounds every year. It is not clear whether these estimates account for workers formulating products that contain these chemicals; it does not seem likely given the production volume.

4) The application of SAR or surrogate chemicals is generally not done, even when there is opportunity to do so (e.g., 1,3,5-trioxane assessment could have referred to the more extensively tested 1,4-dioxane). We found only isolated cases where the hazard evaluation was informed by related chemicals (e.g., monoglyme). In the case of ethylphenols, SAR considerations were qualitative rather than quantitative; it is possible to make a numerical potency comparison across cresols and ethylphenols.

5) The CHPAC is concerned that RBP rankings (low, medium or high) are not consistently applied. The Agency did not describe criteria used to develop RBP rankings from the individual parts of the assessment. The process used to craft the screening prioritizations requires additional transparency. The CHPAC found rankings that did not make sense in a number of cases (see below).

a. RBP Score for N-butylglycidyl ether: this chemical likely off gases from sealants, which merited a medium exposure potential for consumers and children. Further, it is a developmental toxicant with the fetus apparently more sensitive than the mother. It has evidence of positive mutagenicity and clastogenicity. The Agency derived an RBP score of low for this chemical because it is a strong irritant, stating that exposures will be self-limiting. This is not a good reason to downgrade this chemical's risk given the variability in exposure response across the population and the potential that adverse effects may occur below levels required for irritation. Further, inhalation of a strong irritant volatilized from sealants around the home may trigger asthmatic reactions in sensitive children. This score needs to be revisited.
b. Methane Sulfonic Acid: this is an ingredient in cleaning products and other consumer products. Thus there is at least a medium (EPA's rating) if not high children's exposure potential. Methane sulfonic acid was rated high for consumers but only medium for children. It is highly irritating and may be an asthma trigger for children. Yet it was given a low RBP score, in part because of its warning properties (irritation) leading to avoidance and less exposure. This chemical, however, deserves a higher priority score given the likelihood for exposure and health risks to children.
c. The CHPAC found more than one chemical whose exposure scores for children were lower than the scores for the general public. Children are a subset of the general public and consumers who are typically more highly exposed to chemicals through inhalation, in their diet and drinking water, and through indoor environments. Therefore, exposure scores for children should be at least as high as for the general public, unless specific circumstances are described that dictate otherwise. 1,3,5-Trioxane has a high potential risk to the general population, a high potential risk to workers, but low risk score for consumers and children. This resulted in a medium priority decision score. In another example, the exposure ranking for Acetamide, N-[5-[bis[2-acetyloxyethyl]amino]-2-[2-bromo-4,6-dinitrophenylazo]-4-methoxyphenyl]- was moderate for the general population due to the likelihood for exposure to contaminated water, but low for children. The risk concern for this chemical should probably also be high for children if it is high for the general public. In addition, the overall prioritization should reflect the worst scenario rather than be some uncertain and unclear mixing (averaging) of the various areas of concern.
d. A special concern is exposure to children via the workplace, either as "take home" exposures or when a working mother is pregnant or nursing. Where exposure or risks are high for workers, careful thought should be given as to whether that high concern should be transmitted to early life stages. For example, what is the potential for the chemical to migrate across the placenta or into breast milk? What do the reproductive/developmental data show? Unless there are data showing that

children are not disproportionately affected or exposed, a high priority RBP is warranted.

6) The agency's action of referring chemicals to VCCEP should be fully discussed and supported in the RBP. Monoglyme and diglyme are considered high concern to children due to high toxicity and high exposure potential. The assessment did not identify any uncertainties or data needs. Therefore, the CHPAC would expect the Agency to take immediate steps toward use restrictions. However, the Agency is considering referring monoglyme and diglyme to VCCEP, a step that seems pointless given that the main function of VCCEP is to call in additional data and to determine the need for more testing. In general, any referral of a chemical to VCCEP should clearly state the uncertainties and data gaps that that program is expected to address. Hexabromocyclododecane (HBCD) is another high concern chemical for children. The HBCD assessment does a somewhat better job of identifying data gaps but those gaps are described in vague terms and it is unclear how the Agency would use new data.

As stated above, the high, medium, and low rankings are poorly defined and CHPAC recommends establishing and publicizing criteria. Health Canada has established a useful model (see: http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/approach-approche-eng.php). We suggest the following outline to help guide the definition of RBP categories:

High Concern Chemicals: Clearly, the Agency should have a high overall concern if some aspect of the exposure AND hazard characterization merits a high concern. Examples include but are not limited to: presence in consumer products, presence in building materials, clearly positive mutagenicity, strongly irritating, potent acute toxicity, or developmental toxicity. The Agency should also have a high concern if the database supporting the exposure and hazard assessments is so limited that it is difficult to rule out any concerns. The RBP categories of concern should include a high priority category needing immediate action to mitigate exposure if there is both high exposure and high hazard. There should also be a high RBP category when there is either high hazard or high exposure but great uncertainty in the other; additional data-gathering steps should be taken for these chemicals.

Medium Concern: The Agency may have a medium overall concern for chemicals without findings of obvious concern, but for which gaps in the exposure or toxicity information preclude a reliable assessment. This may create a degree of uncertainty that warrants further analysis (e.g., SAR or analogy with similar chemicals) or data request (additional exposure information).

Low Concern: This is appropriate when data are sufficient to conclude that exposure and hazard potential are both low to children and adults, including workers.

Issues with the Proposed Modifications to VCCEP

The latest proposed modifications endeavor to make the process more efficient, largely by having chemicals enter the process from ChAMP. This will provide key starting information (essentially a Tier 1 analysis), and create tighter and better defined time lines. The peer consultation process would only be used if the sponsor disagrees with the Agency's data needs assessment (the ChAMP evaluation) and then hopefully, only on those endpoints to which the sponsor is objecting. The peer consultation process is limited to two months.

These are generally positive steps, and the CHPAC commends the Agency for its willingness to use its Section 4 authority under TSCA to obtain the needed data if these data are not forthcoming from the voluntary process. Certain aspects of the proposed changes, however, particularly regarding the relationship between VCCEP and ChAMP, are of concern:

1) Step 1 of the proposed modifications addresses some concerns raised by CHPAC in 2006, but requires a close examination of ChAMP to ensure that testing priorities focused on early life are identified. As recommended in 2006, CHPAC endorses articulating all desirable testing early and carrying out such testing without undue delay.
2) Step 2 of the proposed modifications has an option for a manufacturer to submit additional exposure information to halt entry into the VCCEP process. Once the Agency has identified a chemical as medium or high priority (modified as our recommendation above) during the ChAMP evaluation, the request for previously unreported data for both exposure and hazard characterization should promptly occur. As EPA notes, the additional data may fill the data gaps identified by ChAMP, and if not, these data are needed whether or not the submitter intends to develop additional data. This iteration of ChAMP may help narrow the array of chemicals which then proceed to VCCEP. The data call-in process should occur within a short time frame (e.g., a few months). The EPA can then notify the submitter if additional data, (whether collected through VCCEP or TSCA) are needed.
3) Step 3 is also a concern. CHPAC recommends that the Agency retain as much control as possible concerning review of the test plan. The Agency should develop guidance and criteria for plan review. Although there may be disagreements over the test plan, the process of setting up a separate peer review for every disagreement will prove unwieldy and time consuming. This process should be open to public review.
4) Steps 4, 5 and 6: CHPAC has found that the EPA has developed excellent web resources for public accessibility to ChAMP data and findings, and endorses increased transparency (Steps 4 and 6) in the proposed modifications. Steps 4 and 5 also describe a series of actions on data development (toxicity testing or collecting exposure data) that CHPAC believes are necessary and laudable. These actions fulfill the fundamental goals of ensuring that information on children's exposures and sensitivities are developed for chemicals to which children are likely exposed.

The utility of the VCCEP hinges upon a well-conducted ChAMP evaluation in which key uncertainties and specific data gaps and needs are identified. Improvements to ChAMP, especially including proactive steps to mitigate exposures to chemicals with high RBP scores based on high exposure and high hazard, will be needed for the proposed ChAMP/VCCEP process to effectively protect children's health.