Children's Health Protection Advisory Committee

July 31, 2007

Administrator Stephen Johnson
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington D.C.

Subject: Evaluating existing and new chemicals for potential adverse impacts on children

Dear Administrator Johnson:

Over the last year, the Children's Health Protection Advisory Committee (CHPAC) has been discussing the assessment and management of chemicals in commerce. CHPAC believes that improvement is needed in the evaluation of risks to fetuses, infants, children, and adolescents from exposure to chemicals in commerce. Ensuring that children are properly safeguarded from hazardous chemical exposure and associated risks is only possible with appropriate screening, testing, risk assessment, and use restrictions.

We are particularly interested in improving how children's exposures and potential health risks are integrated into EPA's evaluations. Early life exposures can affect health at all ages. Further, the economic burden of disease in childhood attributed to environmental exposure is enormous (billions of dollars), and includes direct costs of health care and indirect costs (e.g. school absenteeism and lower quality of life) (Wong et al, 2004; Landrigan et al., 2002).

To create a healthy and sustainable future for our children, we must ensure there is appropriate systematic prioritization and evaluation of chemicals in commerce to identify problem chemicals that pose children's health risks. Specifically, CHPAC recommends that the EPA:

- Systematically prioritize the Toxic Substances Control Act (TSCA) inventory to identify chemicals of concern with a focus on children's exposures and risks;
- Improve knowledge of children's exposures
  - Systematically gather data on existing and proposed chemical uses, and use models to estimate potential exposures;
  - Make greater use of biomonitoring;

- Move towards a more comprehensive evaluation of children's exposures and risks
  - Strengthen partnerships with other governmental agencies;
  - Develop partnerships with industry;
  - Strengthen partnerships with researchers to develop new screening tools;
  - Integrate EPA's informational resources;
  - Evaluate TSCA chemicals iteratively to incorporate new information;
- Increase support for prevention of hazards through selection of the safest and most environmentally friendly materials
  - Accelerate pollution prevention through green chemistry and design.

Background

In November 2006 and March 2007, the Children's Health Protection Advisory Committee held two workshops to learn about how EPA evaluates both new chemicals and the existing inventory of chemicals in commerce. At the workshops, EPA Staff and experts from the industrial sector briefed CHPAC on how EPA and industry screen for potential public exposures to, and risks from, industrial chemicals. We focused our inquiries on exposures to environmental chemicals from all sources and potential risks to the fetus, infants, children, and adolescents. We also learned from briefings by other agencies and Non Governmental Organizations (NGO's) about other paradigms for chemical management (including the Canadian Environmental Protection Act (CEPA) process, and the new Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) program of the European Union). It is clear from the presentations that there are significant advances underway in these jurisdictions and that much more could be done by EPA.

Within the constraints of existing law, we believe that screening approaches exist to enable the Agency to take a more proactive, scientific stance to protect children from exposure to hazardous chemicals in commerce. The CHPAC's recommendations are summarized in the following paragraphs.

Prioritize Existing TSCA Inventory Chemicals

1. EPA should systematically prioritize the TSCA inventory of chemicals to identify chemicals of concern for the public with a special focus on children's exposure, including prenatal exposures, and risks.

Thorough testing and evaluation of the approximately 75,000 chemical substances in the TSCA Inventory would take many years and a large investment in resources. Since not all chemicals pose equivalent hazards, the EPA needs to apply an efficient screening process to prioritize the Inventory and identify the most worrisome chemicals in terms of impacts on public health, and in particular, on children. The National Pollution Prevention and Toxics Advisory Committee (NPPTAC) recommended application of a screen to the High Production Volume (HPV) Challenge chemicals. Health Canada and Environment Canada implemented a tiered approach under the 1999 Canadian

Environmental Protection Act (CEPA) to prioritize chemicals of concern in their inventory.

The Canadian program evaluated 23,000 chemicals using screening tools that included physicochemical properties to assess potential for bioaccumulation and persistence, information to assess exposure potential (e.g., number of manufacturers, pounds produced), and measures or estimates (using Quantitative Structure Activity Relationship, QSAR) of toxicity such as carcinogenicity, genotoxicity, developmental toxicity and other acute, sub-chronic or chronic toxicity endpoints. Children's age groupings were considered to some extent. The Canadian screen identified 500 chemicals as high priority and 193 that required regulatory action. The Canadian Government is systematically reviewing these high priority chemicals, with data call-ins and public review of the process, to identify actions needed to assess risks and to protect public health.

While no prioritization scheme is perfect, CHPAC believes this type of systematic and transparent prioritization of the existing TSCA Inventory is well overdue. In prioritizing, EPA should draw on new usage information available as part of the Inventory Update Rule (IUR), and on toxicological information coming out of the HPV Challenge program, the Voluntary Children's Chemicals Evaluation Program (VCCEP), and other sources including the scientific literature. Tools such as those used for the Pre-manufacture Notice (PMN) chemicals, those used by Canada in their prioritization, and those used by Food and Drug Administration (FDA) (e.g., the QSAR toxicity screens, Matthews et al., 2006a, b, 2007a, b) should be applied, where appropriate, to the existing TSCA Inventory to prioritize chemicals for both exposure potential and predicted toxicity. EPA should refine its QSAR modeling with a greater emphasis on developmental endpoints (e.g. neurotoxicity), incorporating the recent work by FDA in predictive modeling for developmental endpoints. Bearing in mind that lack of toxicity and exposure data is not evidence of safety, EPA should treat chemicals that lack such information as chemicals of moderate concern until there is sufficient data on exposure potential and toxicity to allow a judgment that the chemical is of low concern.

We recognize that a systematic prioritization, which incorporates the features we are recommending, requires significant time and resources. We also acknowledge that such a prioritization needs to be conducted expeditiously. Therefore, we urge EPA to develop a strategy and time line for implementation in the next 18 months.

Improve Knowledge of Children's Exposure

2. Systematically gather data on existing and proposed chemical uses and employ models to estimate exposure potential.

While EPA is moving forward with voluntary programs such as the HPV challenge to provide more toxicology information on about 2000 HPV chemicals, we also need to improve our understanding of children's exposures to these chemicals, and to non-HPV chemicals with potential to be released into the environment in significant quantities.

More information about exposure potential could be ascertained by asking chemical producers and downstream users to supply EPA with amounts of chemicals that go into particular end uses. Models could then be applied to these data to estimate children's exposure potential. The updated IUR will gather readily obtainable information such as production volume, number of sites producing the chemical, the percentage of the production volume going into commercial and consumer applications, and whether any of the produced chemical will be included in products designed for children. This is a good start, and we look forward to seeing how EPA will apply the information to screen for exposure and risk to children. However, this one tool (IUR) will not provide information about early life exposures, including in utero exposure. Furthermore, information on movement of chemicals from products into the environment is needed to improve our understanding of both exposure potential and risk. Such information needs to be integrated into EPA's exposure modeling and data collection efforts. Exposure screens in use by EPA (e.g., Epi Suite, E-FAST, and ChemSTEER) are not predictive of child-specific pathways. Existing exposure screening tools should be adapted to encompass child-specific exposure routes and pathways (e.g., transfer to human milk, presence in air and dust in schools and homes, frequent hand-to-mouth behavior), and applied to the TSCA inventory to estimate exposure potential.

3. Make greater use of biomonitoring information.

One of the main ways we learn about problem chemicals is through biomonitoring studies, with PBDEs, flouropolymers, and perchlorate being recent examples. This is unfortunate because, by this time, there is typically widespread exposure without adequate safety testing or risk evaluation. We continue to be surprised by biomonitoring results in part because we do not understand the dispersion of chemicals into products, the environment, and ultimately children.

Biomonitoring studies, such as those conducted by the Centers for Disease Control (CDC) for the National Health and Nutrition Examination Survey (NHANES), can tell us about a modest number of chemicals, and these data apply mostly to older children and adults. Improved biomonitoring for an expanded list of chemicals that specifically targets children is needed to better understand children's exposures and risk, and to aide in iterative prioritization of chemicals in the TSCA inventory. EPA has conducted research and developed more methods to understand exposures in young children (e.g. Hu et al, 2004), and there is now an increased opportunity for biomonitoring in infants and children by collecting urine, cord blood, meconium, amniotic fluid, and human milk. CHPAC encourages EPA and its partners to expedite development of this research that will help evaluate children's exposure pathways more fully.

EPA could also contribute to the National Institute of Occupational Safety and Health (NIOSH) research agenda, developed in response to the 1992 Workers Family Protection Act, to investigate the potential for workers producing and handling chemicals to bring home chemical residue on clothing, skin and hair, possibly exposing their infants and children. Further, study of adolescent exposures in the workplace by biomonitoring or other exposure study methods is also warranted.

Move toward a More Comprehensive Evaluation of Children's' Exposures and Risks

4. Strengthen and Expand Partnerships with Governmental Agencies

The current system that compartmentalizes the review of chemicals and products into different federal agencies leads to major gaps in protecting public health, especially children's health. There are, however, many potential opportunities to partner with other agencies' researchers to help prioritize compounds and predict exposure, toxicity, and risk to children.

The prioritization conducted by Health Canada and Environment Canada included chemicals in consumer products, such as cosmetics, that are under FDA purview in the U.S. Personal care products constitute a high exposure category that may not be addressed by standard screens and exposure models. CHPAC is especially concerned about products designed for infants and children (e.g., baby wipes, baby lotions, baby shampoo and diaper creams), and products for use by women of childbearing age (e.g., cosmetics). Thus, EPA should partner with FDA to evaluate exposures of the fetus, infants, and children to chemicals in such products using existing and refined tools.

The Consumer Product Safety Commission (CPSC) is responsible for evaluating the hazards of consumer products such as lead in children's toys and jewelry. EPA should work with CPSC to screen for children's potential exposures to chemicals in consumer products.

5. Develop Partnerships with Industry

During our workshops, CHPAC heard from industry representatives about their efforts to evaluate exposure to chemicals in children's products. Such evaluations included laboratory measures of chemical leaching, and models of exposure to chemicals in a number of different products such as diapers and cleaning solutions. EPA could partner with industries in the forefront of these efforts.

6. Strengthen Partnerships with Other Researchers to Develop Screening Tools.

Partnerships with other researchers to develop tools to evaluate existing or newly acquired data would be well worth EPA's effort. A first step could be to provide funding for pilot projects to use data from the HPV Challenge, and exposure information obtained under the new IUR, to develop better methods for assessing potential exposure and health impacts of HPV chemicals. The EPA's small pilot grants should be followed with more funding to expand existing and develop new tools that screen chemicals in the TSCA Inventory for potential exposure, toxicity, and adverse health impacts on children.

Further, providing information on the TSCA Inventory in a format easily accessible by researchers will further the goals of developing methods to evaluate potential for exposure and risk from existing TSCA chemicals.

7. Integrate EPA's Informational Resources

Integration of a number of databases kept by EPA could be improved to provide information useful for protecting children. For example, looking for linkages between measures of environmental chemicals, the TRI inventory database, and estimates of uses of chemicals in the TSCA IUR, may provide more understanding of exposure potential and routes for infants and children. Further, by linking exposure data with toxicological information obtained through assessments of available information under the HPV challenge, VCCEP program, Canada's CEPA process, U.S.EPA Region V's Toxicity and Exposure Assessment for Children's Health (TEACH) program, the European Union's REACH program, the Children's Centers research programs, and the systematic application of QSAR, the EPA could facilitate the prioritization of TSCA chemicals and identify those of concern to the developing fetus, infants, children, and adolescents. A centralized integration of existing data is essential to accomplish this.

8. Iterative Evaluation of TSCA Chemicals.

After the initial systematic evaluation of the TSCA Inventory is completed, a process needs to be put into place to conduct iterative evaluations in order to account for changes in chemical use patterns and incorporate new information and better tools (for example models and assays) to screen for toxicology, environmental fate, and exposure. As these new methods come on-line and provide more information on hazard, the information should eventually be applied iteratively to an updated chemical inventory.

Further, EPA should evaluate information obtained by other governmental bodies such as those in Canada and Europe to make the most of the exposure and toxicity information obtained under these programs. Leveraging such information should help avoid duplication of effort. In addition, concerns found at the international level for a particular chemical should be acknowledged and acted upon appropriately.

Pollution Prevention: Increase Support for Preventing Hazards through Selection of the Safest and Most Environmentally Friendly Materials

9. Accelerate Pollution Prevention through Green Chemistry and Design

Using less hazardous chemical ingredients in products and safer alternatives are important goals for pollution prevention. The movement towards green chemistry and green design is a very positive development and EPA should be congratulated for supporting this. The Design for the Environment program is an excellent start; however, this and other pollution prevention programs at EPA need more resources, more partners, and a specific focus on children, to tackle the many issues that must be addressed to create a healthy sustainable environment for our children. As a regulatory agency, EPA is

historically focused on regulating and cleaning up hazards. A more prominent focus on pollution prevention and sustainability would help to accelerate risk reduction for all children.

We thank you in advance for considering these recommendations, and would be very interested in discussing the recommendations, and our rationale for them, with you or your designee in the near future.

Sincerely,

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Children's Health Protection Advisory Committee

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