



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Pamela Shubat, Ph.D.
Chair
Children's Health Protection Advisory Committee
Minnesota Department of Health
625 N. Robert Street
St. Paul, MN 55155-2538

Dear Dr. Shubat:

Thank you for your March 31, 2011, letter that highlights the CHPAC's interest in EPA's chemical management program and outlines your recommendations for how EPA can identify chemicals that should be high priority for actions under the Toxic Substances Control Act (TSCA) to protect children's health. Administrator Jackson has asked that I respond to you directly.

As you know, Administrator Jackson has made protecting sensitive subpopulations and life stages, including children and pregnant women, an Agency priority. The Agency is aware of the unique susceptibilities of children to chemicals and pollutants in the environment. EPA continues to support reform and modernization of TSCA to better manage the risks of chemicals, which would likely allow the Agency to more efficiently and effectively address children's health concerns. However, please be assured that my office and the Agency are making every effort to protect children's health given the existing regulatory authority and constraints.

Since September 2009, when Administrator Jackson committed the Agency to enhance EPA's chemical management program, the Agency has released ten chemical action plans that address a range of substances that pose risks to human and environmental health. The chemicals include benzidine dyes, Bisphenol A (BPA), hexabromocyclododecane (HBCD), methylene diphenyl diisocyanate (MDI), nonylphenol and nonylphenol ethoxylates, perfluorinated chemicals (PFCs), phthalates, toluene diisocyanate (TDI), and penta, octa, and decabromodiphenyl ethers (PBDEs).

The Action Plans outline a range of actions EPA intends to initiate to address issues relating to the manufacturing, processing, distribution in commerce, and/or use of the chemicals, including regulatory action under Section 5(b)(4) of TSCA, which authorizes EPA to identify "chemicals of concern" that present or may present an unreasonable risk. A range of other regulatory efforts are also under development, including TSCA Section 4 test rules, TSCA Section 5 Significant New Use Rules, and if appropriate, TSCA Section 6 control actions.

In addition, EPA is utilizing our Design for the Environment (DfE) Alternatives Assessment Partnership Program which helps industries choose safer chemicals for their applications and uses. Alternatives assessments provide a basis for informed decision making by developing an in-depth comparison of potential human health and environmental impacts. The Partnerships bring together environmental organizations, industry leaders, academia, and others to evaluate the environmental and health impacts of potential alternatives to chemicals of concern. The outcome of an Alternatives Assessments Partnership provides industry with the information they need to choose safer chemicals, as well as avoid unintended consequences of switching to a poorly understood substitute. As outlined in the Action Plans, EPA is working with partners to conduct alternatives assessments for decaBDE, NPE, HBCD, and phthalates, as well as for BPA in thermal papers such as cash register receipts and movie tickets.

EPA intends to continue to target our actions on those chemicals that pose the greatest concern. As part of this effort, the Agency plans to use a two-step process identify priority chemical substances for review and possible risk management action under the TSCA. In Step 1 of the process, EPA plans to identify an initial group of chemicals for priority review by using a specific set of data sources to identify chemicals that meet one or more of the Action Plan priority factors, which include chemicals specifically of concern for children's health because of reproductive or developmental toxicity; carcinogens; persistent, bioaccumulative, and toxic chemicals; chemicals in consumer products, especially in children's products; and chemicals found in biomonitoring. In Step 2, EPA intends to refine that group by using a broader range of data sources to further analyze and select specific chemicals from the initial group for further assessment.

EPA's goal is to identify priority chemicals for near-term evaluation, not to screen and prioritize the entire TSCA Inventory of approximately 84,000 chemicals. Identification of a chemical as a priority chemical for review would not itself constitute a finding by the Agency that the chemical presents a risk to human health or the environment. Rather, identification of a chemical as a priority chemical would indicate only that the Agency intends to review it on a priority basis. The Agency believes that identifying these chemicals early in the review process would afford all interested parties the opportunity to bring additional relevant information on those chemicals to the Agency's attention in order to further inform the review. In order to take risk management actions on a chemical substance under various sections of TSCA, the Agency would have to make the appropriate findings required by the specific provisions of the statute.

As you are likely aware, EPA sought input from a wide range of stakeholders this past summer on the criteria and data sources that EPA will use in this two-step process. On September 7, EPA conducted a key stakeholder briefing, with representation from CHPAC, along with a webinar with participation by more than 400 people. Enclosed is the Discussion Guide the Agency used for these discussions or it can be found at <http://www.epa.gov/oppt/existingchemicals/pubs/Chem.Priorization.August2011.DiscussionGuideOnly.pdf>. In addition, EPA made available an on-line discussion forum as an additional vehicle for stakeholders and the public to provide written input. All the comments remain available on the discussion forum website at <http://blog.epa.gov/chemprioritization> and the public dialogue materials can be accessed in the docket. EPA-HQ-OPPT-2011-0516, on [regulations.gov](http://www.regulations.gov) at

<http://www.regulations.gov/#!docketDetail;ct=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=EPA-HQ-OPPT-2011-0516>.

Children's health issues are a primary focus of this effort. Capturing chemicals that may adversely impact children's health through both hazard and exposure characterizations is a significant driver in the criteria for the process. In your letter to the Administrator, the CHPAC recommends that EPA consider factors such as (1) potential for persistence or bioaccumulation; (2) occurrence of chemicals in environments relevant to children; (3) occurrence in humans; (4) ubiquitous chemicals; (5) toxicities of particular concern for children. Based on the input from CHPAC and other stakeholders, we are currently planning to utilize a number of these criteria, including chemicals with reproductive or developmental effects and chemicals used in children's products.

EPA is also currently considering the use of additional criteria for further screening of potential candidate chemicals. Among these criteria are relevant neurological effects and the potential for respiratory sensitization, both factors in children's health issues. Similarly, EPA intends to consider not only chemicals used in children's products, but also commercial and consumer uses of chemicals in such products as cleaning supplies and paints that could contribute to children's exposures through their use in places where children may frequently be present. Examples of sources that could inform the screening process include but are not limited to the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR); publicly available hazard information submitted in chemical dossiers to the European Chemicals Agency (ECHA) under the regulation for Registration, Evaluation, and Authorization of Chemicals (REACH); human biomonitoring conducted by the Centers for Disease Control and Prevention (CDC); studies identifying the presence of chemicals in drinking water or house dust; reports supporting the list of chemicals included in the Washington State Children's Safe Product Act; any report submitted to EPA's Inventory Update Reporting (IUR), now known as Chemical Data Reporting (CDR), database indicating that chemicals were used in products intended for use by children or are used in commercial products that might involve children's exposures; and information from the National Library of Medicine's Household Products Database identifying chemicals being used in household products.

We anticipate identifying the initial group of chemicals for priority review after the beginning of the year and will provide the members of CHPAC this information as soon as it is available. We will also be happy to meet with you to discuss this process in more detail if you are interested.

The identification of some chemicals for priority review does not mean that EPA would not consider other chemicals for risk assessment and potential risk management action. EPA will consider other chemicals if warranted by available information. In addition, EPA may subsequently identify other chemicals for priority review in addition to this initial group. While the chemicals identified as chemicals for review will likely be well-characterized for hazard and have information indicating exposure potential, EPA will continue to use its TSCA information collection, testing, and subpoena authorities, including sections 4, 8, and 11(c) of TSCA, to develop needed information on additional chemicals that currently have less robust hazard or exposure databases.

I also want to make sure that you are aware that EPA has taken a number of significant steps to increase the public's access to critical chemical information. These steps include issuing guidance on EPA's intent to reject confidentiality claims for chemical identity in new health and safety reports submitted by industry, challenging the chemical industry to voluntarily drop CBI claims that are no longer warranted, the declassification of claims for confidentiality of chemical identity in older TSCA health and safety filings, a searchable Chemical Data Access Tool, and for the first time, making the comprehensive TSCA Inventory available on EPA's website and Data.Gov, a website developed by the Obama Administration to provide public access to important government information.

Again, thank you for your recommendations and we look forward to working with you on these important issues. Please contact me or Priscilla Flattery of my staff at 202-564-2718 if you would like to arrange time to discuss these issues in more detail. Thanks again.

Sincerely,

A handwritten signature in black ink, appearing to read "Wendy Cleland-Hamnett". The signature is fluid and cursive, with a large initial "W" and a long, sweeping tail.

Wendy Cleland-Hamnett

Director

Office of Pollution Prevention and Toxics

cc: Peter Grevatt