



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

JUL 24 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Barbara Morrissey, M.S.
Washington State Department of Health
P.O. Box 47846
Olympia, Washington 98504-7846

Dear Ms. Morrissey:

Thank you for your letter of March 30, 2017, to the U.S. Environmental Protection Agency regarding the Children's Health Protection Advisory Committee (CHPAC) recommendations for implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act amendments to the Toxic Substances Control Act (TSCA).

We appreciate the CHPAC taking the time to form a workgroup and consult with us about potentially exposed and susceptible subpopulations under TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. We are especially appreciative that the CHPAC was able to provide input in response to our charge in a short timeframe to meet the needs of our chemical assessment program. The EPA has considered your recommendations and offers the following responses.

Charge 1: Recommend methods and approaches for children's risk evaluation under amended TSCA

Using a Lifestage Approach

The EPA agrees with CHPAC's recommendation to use a lifestage approach, as it is important to consider key age-related characteristics of children in distinct age groups. The EPA has been looking to existing EPA guidance on this topic, including the *Guidance on Selecting Age Groups for Monitoring and Assessing Health Risks of Environmental Exposures to Children* (2005), *A Framework for Assessing Health Risk of Environmental Exposures to Children* (2006), and the *Exposure Factors Handbook* (2011). We appreciate the CHPAC's input regarding other potential frameworks, and we will evaluate how we may use this information going forward.

Screen for Developmental Toxicants in TSCA Risk Evaluations

The EPA agrees with the CHPAC that if exposure to women of child-bearing age and children is likely, developmental toxicity information is critical. The EPA intends to identify such

susceptible subpopulations in conducting risk evaluations under TSCA. If the EPA finds such exposures are likely, but data and information do not exist to conduct a reasoned evaluation, the EPA would likely seek to obtain such information prior to undertaking risk evaluation.

Also, under section 4 of TSCA, the EPA is required to consider approaches that will reduce and replace, to the extent practicable, the use of vertebrate animals in toxicity testing. Prior to making a request for vertebrate testing, the EPA is required to consider the available toxicity information, computational information, bioinformatics, high-throughput methods, and predictive methods. The EPA would consider and use such non-vertebrate information in determining whether vertebrate testing is needed for developmental toxicity endpoints. In fact, the EPA has used structural alerts and "read-across" approaches in our everyday activities under TSCA, particularly for the evaluation of new chemicals. We will certainly consider the recommendations of the National Research Council in 2007 and the National Academies for Sciences, Engineering, and Medicine in 2017 in advancing these efforts.

Use biomonitoring to inform exposure assessment

The EPA agrees with CHPAC's recommendation to use biomonitoring information when it is available, particularly in assessing children's exposure. Regarding submission of biomonitoring data by manufacturers, the EPA notes that manufacturers are required to submit all data in their possession or control on health, safety, and the environment, when submitting a pre-manufacture notice for a new chemical substance. For risk evaluations on existing chemicals, the EPA may use biomonitoring, among many other types of data to inform the hazard assessment.

Charge 2: Priorities for new methods and approaches to improve children's risk evaluations under TSCA

Children's Exposure Information

The EPA agrees with CHPAC's recommendation for improved childhood exposure information. Consistent with your recommendation, in developing the scope for the first ten chemicals to undergo risk evaluation under TSCA, the EPA:

- Held a public meeting and more than forty outreach meetings with industry and other stakeholders, to gather information on uses of chemicals, including consumer and children's products to better understand and assess exposure pathways. The input the EPA received from the public meeting can be found in the EPA's Docket EPA-HQ-OPPT-2017-0002.
- Is aware of the European Scientific Committee on Health and Environmental Risk's 2016 report and finds the recommendations useful. In fact, the EPA has used the CONSEXPO model and approach referenced in the report. Furthermore, the EPA's Consumer Exposure Model (CEM), that is applied in TSCA risk assessments was recently updated to include mouthing and ingestion exposure scenarios described in the report.

- Appreciates your recommendation regarding the need to include aggregate exposures to children and intends to discuss our consideration of aggregate exposure as is required under TSCA section 6(b)(4)(F)(ii).
- Recognizes that while the TSCA program does not directly engage or fund research, it does use NHANES (National Health and Nutrition Examination Survey) data, when appropriate, in evaluating exposures and risks to chemicals.
- Also participates on the EPA Biomonitoring Workgroup for identifying candidate chemicals for NHANES.

Age-Appropriate Safety Factors

The EPA appreciates CHPAC's input on the application of age-appropriate safety factors for children, and agrees that the extra margin may not be needed in all cases. The TSCA program generally adheres to the age-dependent adjustment factors outlined in the Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (2005) and also considers the application of other age-appropriate safety factors when evaluating the available scientific data. The Agency has used safety factors when assessing new chemicals. The EPA will consider the references provided by the CHPAC as we consider this issue further.

Improved Methods to Identify and Characterize Developmental Toxicants

The EPA will consider CHPAC's request to incorporate new approaches to developmental toxicity. In particular, the EPA is considering a wide array of screening and alternative testing approaches (e.g., high-throughput *in vitro* data, computational toxicology, etc.) to incorporate into the prioritization process mandated by TSCA section 6(b)(1)(A). In addition, the EPA is developing a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing, as required by TSCA section 4(h)(2)(A). During the development of these processes, the EPA will be focused on understanding and implementing tiered and alternative testing methods, including those helpful in identifying and characterizing development toxicity. In addition, the EPA is aware of the recent changes to the OECD test guidelines 421 and 422 (July 2016) and is currently recommending them, on a case-by-case basis, when further testing is necessary.

Charge 3: Identification of experts who may be consulted for further help in addressing or developing specific risk evaluation approaches or methodologies for potentially exposed or susceptible subpopulations

The EPA appreciates CHPAC proposing a nomination process and offering to identify individuals with specific expertise in hazard, exposure or risk assessment for help in development of risk assessment approaches. Certainly, the EPA will continue to engage the CHPAC on children's health topics and we thank you for your offer to continue engaging as we continue with TSCA implementation.

The EPA thanks the CHPAC for its continued support of children's health. The recommendations presented by CHPAC will be helpful in the EPA's efforts to protect children's health.

If you have further questions, please contact me or your staff may contact Tala Henry, Director, Risk Assessment Division at henry.tala@epa.gov or (202) 564-2959.

Sincerely,

A handwritten signature in black ink, appearing to read "Wendy C. Hamnett". The signature is written in a cursive style with a long horizontal stroke extending to the right.

Wendy Cleland-Hamnett
Acting Assistant Administrator