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Nick Abraham, Legislative Clerk
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Nick,

Please find attached my responses to the questions for the record, which follows my appearance before the Subcommittee on Environment and the Economy on March 12, 2014 to testify on the discussion draft of the "Chemicals in Commerce Act."

I appreciate the opportunity to further share my views on issues related to meaningful reform of the Toxic Substances Control Act.

Best regards,

[redacted]

Michael Belliveau
Executive Director

Enclosure

Response to Questions for the Record from the Honorable Henry A. Waxman

By Michael Belliveau, Executive Director, Environmental Health Strategy Center, following his testimony at the March 12, 2014 hearing before the Subcommittee on Environment and the Economy, House Committee on Energy and Commerce

The February 2014 draft of the Chemicals in Commerce Act employs the term "potentially exposed subpopulation" instead of referring to "vulnerable populations," and defines the term as follows:

"a group or groups of individuals within the general population who may be differentially exposed to a chemical substance under the intended conditions of use or who may be susceptible to more serious health consequences from chemical substance exposures than the general populations, which where appropriate may include infants, children, pregnant women, workers, and the elderly."

1. **Do you have concerns about this definition?**

YES. The proposed term creates confusion by ignoring the long-established reliance on the concept of "vulnerable populations" in the public health community. The proposed definition is vague and unclear. Everyone is "differentially exposed" – what does that mean? The use of the phrase "intended conditions of use" implies limiting consideration of all exposures, for which there is no scientific basis. The phrase "who may be susceptible to more serious health consequences" is in error. It should read: "who may be more susceptible to serious health consequences;" – vulnerable populations are *more* susceptible than others.

The qualifier "where appropriate" either implies proposed discretionary authority to ignore vulnerable populations, or is in biological error by denying the intrinsic vulnerability of classically recognized subgroups that are at higher risk than the population as a whole – infants, children, pregnant women, workers, and the elderly.

2. **Do you have concerns about creating a new term, rather than using the term "vulnerable populations," which has been widely used?**

YES. Congress should rely instead on scientific expertise in defining the term "vulnerable populations." In 2009, the National Research Council issued six recommendations for modernizing risk assessment, which included "attention should be directed to vulnerable individuals and subpopulations that may be particularly susceptible or more highly exposed." (*Science and Decisions*, National Academy of Science). The U.S. Environmental Protection Agency (EPA) defines: "Vulnerability – Differences in risk resulting from the combination of both intrinsic differences in susceptibility and extrinsic social stress factors such as low socioeconomic status, crime and violence, lack of community resources, crowding,

access to health care, education, poverty, segregation, geography, etc." and "Susceptibility – Differences in risk resulting from variation in both toxicity response (sensitivity) and exposure (as a result of gender, lifestage, and behavior)." See http://www2.epa.gov/children/guidance-tools-and-glossary-key-terms.

Getting this definition right is critical because the draft legislation requires EPA to assess exposures of sub-populations to chemicals during the course of a safety assessment, but it does not explicitly require that safety determinations protect vulnerable populations from those exposures. The legislation should define "vulnerable populations" and explicitly require that they be protected from aggregate exposure to high priority chemicals. In addition, the safety standard itself needs more clarification to ensure it is strictly health-based and protective.

Some have argued that risk assessment under TSCA should focus only a subset of exposures to a chemical, those from intended uses. The Chemicals in Commerce Act goes further by limiting assessment to only a subset of exposures from intended uses, those that are found to be significant on their own as opposed to in aggregate. Some have argued that TSCA should be restricted further, by exempting some sources of exposure such as automotive replacement parts.

3. **In terms of health effects, does the body distinguish between the exposures from intended and unintended uses?**

NO. A person integrates aggregate and cumulative exposure to chemicals from all sources through ingestion, inhalation, hand-to-mouth contact, and dermal contact without regard to whether anybody intended any of the activities that led to any of the exposures. The manufacturers' intention may wildly differ from the reality of real world exposure to multiple sources of a chemical (and to multiple chemicals).

4. **Is there a biological justification for excluding exposures from some sources, such as automotive parts?**

NO. All sources should be assessed in aggregate to assess risk and risk reduction opportunities. Chemical exposure sources associated with the manufacture, use and disposal of articles in a single industrial sector are never inherently more or less risky. Each source needs to be evaluated on its own merit and magnitude.

With regards to the example of automotive parts, there's no historic basis for a special exemption. It's worth noting that the use of elemental mercury in automobiles for switches in trunk lights, ABS brakes and other auto parts were a major source of environmental release of mercury during disposal. (See http://www.epa.gov/mercury/archive/switch/index.html). Auto parts were once, and may still be for some, a significant source of asbestos, a known human

carcinogen. There's no basis for special treatment of auto parts. (See for example http://www2.epa.gov/sites/production/files/documents/brakesfinal-3-07.pdf).

5. **Is there a biological justification for considering only those exposures that are significant on their own, as opposed to in aggregate?**

NO. An individual may be exposed to the same chemical from multiple sources. To reflect real world conditions, the exposures associated with that one chemical need to be aggregated in order to honestly assess the risk to human health. Parsing apart separate sources of exposure, and determining their significance in isolation from one another, invites misleading abuse. If broken into small enough pieces, none of the exposures may be considered "significant," even though in aggregate the risk may be unacceptably high for the vulnerable populations.

6. **In your view, is it important that aggregate exposures to chemicals be considered in assessing their safety?**

YES. If Congress wants to create a risk-based approach to chemical management, then the aggregate risks need to be assessed for all sources of exposure to the same chemical. Otherwise such an isolated risk-based approach fails dishonestly. How could a regulator determine whether the "risk cup" overflows unless all the associated exposures and risks are placed in the cup?

Further, as recommended by the National Research Council in its *Science and Decisions* report, cumulative exposure from multiple chemicals with similar hazards need to also be assessed whenever feasible. The NRC sketched a path forward in its 2008 report, *Phthalates and Cumulative Risk Assessment: The Path Ahead.* Recently, the Chronic Hazard Advisory Panel to the Consumer Product Safety Commission used a cumulative risk assessment to conclude that 5% to 10% of pregnant women and children in the United States are exposed to decidedly unsafe levels of cumulative exposure to five phthalates. (See http://www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/The-Consumer-Product-Safety-Improvement-Act/Phthalates/Chronic-Hazard-Advisory-Panel-CHAP-on-Phthalates/).

The Committee has received testimony that mixtures should not be tested or regulated directly because they have the same health and environmental effects as their components, but research has shown that exposures to chemicals in combination can have additive effects.

7. **In terms of health effects, can all mixtures be understood simply by assessing the health effects of the mixture's components?**

NO. In fact, that's why the National Institute of Environmental Health Sciences (NIEHS) has established as a goal to expressly address combined chemical exposures in its 2012-2017 Strategic Plan. In 2011, NIEHS hosted a comprehensive science workshop entitled, "Advancing Research on Mixtures: New Perspectives and Approaches for Predicting Adverse Human Health Effects." The workshop proceedings can be found at: http://www.niehs.nih.gov/about/visiting/events/pastmtg/2011/mixtures/pdf_workshop_report.pdf.

Under the current Toxic Substances Control Act (TSCA), mixtures are defined as: "Any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of chemical reaction; except that such term does not include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the mixture is a new chemical substance and if the combination could have been manufactured [(including imported)] for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined."

Given the commonplace use of chemical mixtures, and the complexity of human exposure to multiple chemicals, it would be unwise to rollback any of the existing TSCA authority that authorizes regulation of mixtures.