

United States Senate
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510-6175

September 15, 2016

Chairman Elliot F. Kaye
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Dear Chairman Kaye:

As you move forward in developing the Consumer Product Safety Commission's (CPSC) final regulation regarding phthalates and phthalate alternatives, (79 Fed. Reg. 78324), I would like to emphasize with you a number of outstanding concerns.

First, the proposed regulation put forth by the CPSC, which closely aligns with the report from the Chronic Hazard Advisory Panel (CHAP), indicated that the sole basis for proposing to make permanent the ban on one interim-banned phthalate (diisononyl phthalate, also known as DINP) was its contribution to the cumulative risk calculated by the CHAP. I have previously shared my serious concerns regarding taking regulatory action based on the use of a cumulative risk assessment methodology that has not been a part of the established regulatory decision-making process for chemicals used in consumer products, in either the United States or the European Union. The CHAP should not have relied solely on this method as its basis for recommendation, nor should the CPSC use it as the basis for regulatory action. Please note that while we charged the CHAP with considering the cumulative effect of total exposure to phthalates, that was not a dictate to either the CHAP or CPSC to base its decision on a novel cumulative risk assessment.

Second, the contribution of DINP to the cumulative risk calculated by the CHAP was minimal. That minimal contribution was from exposure to all sources of DINP, of which exposure from toys and children's products is a mere fraction. Additionally the contribution of DINP was assumed based on observation of slight effects in rats, even though those effects were not actually adverse. Our direction was for CPSC to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety, not to unreasonably chase risk into theoretical, de minimis corners.

Third, I was pleased that the Commission took the initiative, at the behest of Congress, to re-evaluate the chemical risks using more current data. I understand that the CPSC is still evaluating public comments from this reanalysis and encourage that as you move forward with your rulemaking, the CPSC should evaluate, as prescribed in CPSIA Section 108 (b)(2)(B)(iii), exposure levels "based on a reasonable estimation of normal and foreseeable use of such products." As you are aware from your reanalysis, the report produced by the CHAP was out-of-date far before it was released in final form for use by the agency. The original exposure data collected and analyzed by the panel were from 1999 through 2006, while the law itself was signed in 2008. More recent data were available to the CHAP prior to its sending final

recommendations to the Commission in 2014. The reanalysis completed by the agency utilizing current data revealed that the levels of risk have been reduced well below levels of concern.

Fourth, the CPSC in promulgating a final rule should rely on widely accepted statistical standards for evaluation of risk. For example, the CHAP's report relied on the median or 95th percentile of exposure in its own evaluation of individual phthalate risk. I would advise that use of higher percentiles for any aspect of the final rulemaking would be outside the realm of appropriate regulation of chemicals in consumer products. Given the chronic nature of the risk and the use of spot samples for exposure, the CHAP's evaluation of individual risk at the median and 95th percentile of exposure is also an appropriate level for quantifying cumulative risk and provides the adequate margin of safety necessary for promulgation of the rule.

Fifth, in its analyses, CPSC should ensure that it is considering current and foreseeable exposures. The CDC's National Health and Nutrition Examination Survey (NHANES) exposure trends, showing decreased exposure to those phthalates that were permanently banned by the CPSIA, are also seen in the published data for The Infant Development and Environment Study (TIDES), which updates the Study for Future Families (SFF) data. Should there be any remaining concern regarding the sufficiency of the NHANES and TIDES data to address risk to any specific population, CPSC could request and analyze the TIDES data for that population to ensure your rulemaking reflects the existing use of these chemicals in consumer products.

Finally, it has come to my attention that one of the primary studies considered by the CHAP as part of its rationale for determining the human relevance of animal studies was recently called into question. The Boberg et al. (2011) study examined the reproductive and behavioral effects of DINP in rats. Many of the results of the study were unable to be reproduced using the report's raw data. This was brought to the attention of the study authors who acknowledged the shortcomings of the report. I urge your agency to carefully consider this information and its effect on the validity of the CHAP report's findings given the prominence of this study in the CHAP's evaluation of DINP.

I ask that the Commission carefully consider my concerns as you move forward and finalize the proposed rulemaking. It is crucial that sound science and appropriate policy decision-making practices are followed as part of any major regulatory decision the Commission considers.

Sincerely,



James M. Inhofe
U.S. Senator