

CAL DOOLEY
PRESIDENT AND CEO



August 26, 2015

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

Dear Chairman Kaye:

The American Chemistry Council (ACC) and members of the High Phthalates Panel have expressed serious concerns throughout the rulemaking process for the proposed “Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates,” especially with regard to the lack of transparency throughout the process, and the U.S. Consumer Product Safety Commission’s (CPSC) decision to base the proposed rule solely and entirely on the Chronic Hazard Advisory Panel (CHAP) report. While we were disappointed that a proposed rule was published prior to CPSC addressing the issues outlined in our previous letters, we commend the Commissioners for directing CPSC staff to reanalyze estimated phthalate exposure and risk to sensitive populations, using the most recent exposure data from the U.S. Centers for Disease Control and Prevention (CDC) National Health and Nutrition Examination Survey (NHANES). The new cumulative risk analysis using the most recent exposure data further demonstrates that the proposed rule and resulting ban on diisononyl phthalate (DINP) is not rooted in sound science and should not be adopted.

Using all the information available to CPSC, including the staff reanalysis and the detailed comments the Commission has received from stakeholders, including those submitted by ACC’s High Phthalates Panel on April 14 and August 7, 2015, CPSC should revise the proposed rule to reflect the most recently-available data, taking into consideration the following fundamental issues:

- The CPSC staff reanalysis of the most recent NHANES data confirms that the cumulative exposure to the phthalates subject to the proposed rule is within safe limits.
- The CPSC staff reanalysis and calculations rely on the CHAP’s three case studies of potency estimates, including “Case 2,” a case study that is not scientifically defensible. It would be scientifically inappropriate to consider each case analyzed by the staff equally; specifically, Case 2 should be disregarded because it is based on a model, with scientific flaws, to derive the hazard value for DINP, when actual data are available. Utilizing flawed models instead of actual data, CPSC incorporated a level of uncertainty into the estimates.



- The interim ban on DINP can be lifted while still meeting the CPSC's statutory obligations. It is clear from the more defensible case studies, Case 1 and Case 3, that the overall cumulative risk from phthalates has significantly declined, even with an increase in the use of DINP. And, the calculated cumulative risks continue to decline with each newer data set.
- The staff reanalysis provides data on percentages of individuals with hazard indices above the 95th percentile, which could suggest that there are more high-risk individuals than in actuality. But, results exceeding the 95th percentile (i.e. 97th, 99th) are not appropriate for evaluating population hazards in this instance. The hazard that is the basis for the cumulative risk assessment is a chronic hazard – meaning repeated exposure over a long period is needed to cause adverse effects. The samples used for the exposure data were single spot samples taken at one point in time. Exposure levels fluctuate hourly and a single high exposure for an individual does not necessarily translate to consistent exposure, over time. The 95th percentile from the spot samples is a conservative estimate of potential chronic hazard. When using NHANES data to assess exposures for its additive risk evaluations, the U.S. Food and Drug Administration uses the 90th percentile to protect “high exposure” consumers over their lifetime.

We encourage CPSC to address the issues outlined above, as well as our previous comments about the proposed rule on phthalates. For the reasons outlined above and as well as those outlined in our previous comments, it is clear that CPSC should not continue the prohibition on DINP.

Sincerely,



Cal Dooley

