November 14, 2014

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

Dear Chairman Kaye:

On behalf of the High Phthalates Panel of the American Chemistry Council, I want to thank you again for meeting with us to discuss the report from the CHAP on phthalates and the science issues related to diisononyl phthalate (DINP). We agree that there are scientific issues regarding phthalates that are unsettled. For example, it is a matter of scientific debate whether low doses of substances cause health effects and if so, whether this applies to only some hormone-receptor interactions. Additionally, some have argued that observed cases of undescended testes in young boys leading to testicular cancer illustrate the impact of some phthalates on hormones, but the assumption that this effect is related to phthalate exposure appears tenuous, especially since these substances have been used and tested since the 1950s. And, although the CHAP accepted findings from rat studies, ACC continues to question the scientific relevance of such studies to predicting human risk.

However, the 2009-10 NHANES biomonitoring data from the U.S. Centers for Disease Control and Prevention (CDC) clearly show a marked decrease in overall phthalate exposure since the 2005-06 data cycle used by the CHAP, including a significant reduction in exposure to DEHP since the enactment of the CPSIA. This trend persists, as seen in the 2011-12 CDC data released this year. Exposures to DINP remain extremely low with margins of exposure (MOEs) that are many times above the concentrations that induce adverse effects in rats. In fact, when the CHAP cumulative risk methodology is used with the 2009-10 data, the Hazard Index (HI) is well below 1, indicating current exposure levels do not pose a risk to human health. Furthermore, using either the 2005-06 data or the 2009-10 data, the contribution of DINP to cumulative risk is negligible, even at the 95th percentile.

As I noted in my letter dated September 11, 2014, and at our meeting, although the CHAP based its recommendations on CDC biomonitoring data from 2005-06, there was more recent data available at the time of its examination, including data after the enactment of the interim and permanent bans on the use of certain phthalates in toys and child care articles pursuant to the CPSIA. The CHAP report states that “[t]he stopping point for CHAP analysis and interpretation was information available by the end of 2012” (emphasis added) and that the 2005-06 reporting cycle was the most recent version in which phthalate data were available when it was performing its analysis. However, the CDC released updated tables for the Fourth National Report on Human Exposure to Environmental Chemicals, which included biomonitoring data for phthalate metabolites through the

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1 The 2009-10 data was available during the CHAP review, but not used in the CHAP’s analysis (as discussed below).
2 CHAP Report at 12.
3 CHAP Report at 35.
2009-10 reporting cycle, on September 26, 2012.\textsuperscript{4} Thus, the 2009-10 CDC data was “information available by the end of 2012” but was not used by the CHAP.

Had the CHAP examined this 2009-10 data, it would have seen that overall exposures to phthalates are decreasing among children ages 6-11 and women. Additionally, the CHAP would have seen that although exposures to DINP have increased since the 2005-06 reporting cycle, such increases have been small, and exposures have remained extremely low, well below the Acceptable Daily Intake (ADI) \textsuperscript{5} of 120 micrograms/kg/day derived by the CHAP on DINP in 2001. For example, using the 2009-10 data, normalizing the urinary concentrations to the amount of creatinine excreted and using the most sensitive metabolite for DINP measured (MCOP), the mean exposure for children ages 6-11 is approximately 3 micrograms/kg/day while the mean exposure for women is approximately 3.9 micrograms/kg/day.\textsuperscript{6} Even for the 95\textsuperscript{th} percentile exposure level, the 2009-10 data show that exposures continue to be well below the ADI. The 95\textsuperscript{th} percentile exposure for children ages 6-11 is approximately 21.93 micrograms/kg/day and the 95\textsuperscript{th} percentile exposure for women is approximately 35.29 micrograms/kg/day.

Additionally, even using outdated 2005-06 data, the CHAP found that DINP poses no meaningful risk because the MOE for male developmental effects for total exposure ranged from 640 to 42,000 using the 95\textsuperscript{th} percentile while the MOE for pregnant women ranged from 1,000 to 68,000 using the 95\textsuperscript{th} percentile. The CHAP acknowledged that “typically MOEs exceeding 100-1000 are considered adequate for public health.”\textsuperscript{7}

Despite that finding, seemingly because DINP can induce weak antiandrogenic effects in rodents at high doses, the CHAP recommends that the interim ban on DINP be made permanent “because DINP does induce antiandrogenic effects in animals, although with lesser potency than other active phthalates, and therefore can contribute to the cumulative risk from other antiandrogenic phthalates.” However, this broad statement that DINP “can contribute” to cumulative risk is not correlated to any particular finding in the actual cumulative risk assessment, chiefly because its contribution is negligible and other phthalates drive over 99\% of the risk. (See Attachment 1) In its analysis of cumulative risk, using the 2005-06 CDC data, the CHAP states, “[i]n all cases, DEHP and DBP contributed strongly to the HI [Hazard Index] while DIBP and DINP contributed considerably less.” The CHAP’s cumulative risk assessment demonstrates that DINP contributes less than 1\% of the cumulative risk. For example, in PEAA Case #1, the HI for pregnant women at the 95\textsuperscript{th} percentile is 6.1. Of that, the HI for DINP is 0.01.

Had it used the 2009-10 CDC data when assessing cumulative risk, the CHAP would have concluded that there was no risk because the Hazard Index is well below 1. (See Attachment 1) As noted above, DEHP exposure levels, and overall exposure, have decreased dramatically. For example, using the 2009-10 data and the CHAP methodology, the HI for pregnant women at the 95th percentile under PEAA Case #1 would be 0.34 for all phthalates (and all exposures) and for children 6-11 at the 95th percentile it would be 0.468. Thus, even with

\textsuperscript{4} See the press bulletin at: http://content.govdelivery.com/accounts/USCDC/bulletins/55005b. The September 2012 tables were updated again in February 2013, see: http://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Sep2012.pdf

\textsuperscript{5} The acceptable daily intake (ADI) is an estimate of the amount of chemical a person can be exposed to on a daily basis over an extended period of time (up to lifetime) with a negligible risk of suffering deleterious effects.

\textsuperscript{6} The urinary concentrations of phthalate monoesters reported by CDC were converted to daily intake of the parent phthalate using the methodology described in David, R. (2000).

\textsuperscript{7} CHAP Report at 99.
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increases in DINP exposure, overall exposures are far below the Hazard Index value of 1. As the CHAP indicated, only an HI greater than 1 indicates unacceptable exposure, therefore an HI below one is considered protective of human health.

Since the CHAP failed to consider the most recently available data – data directly relevant as it was collected post-CPSIA – its report should not be used as the basis for significant regulatory decision-making. We hope that the CPSC science staff carefully considers the most recently available CDC data and recalculates cumulative risk using the CHAP methodology and the CDC data from 2009-10 and 2011-12, and that you will carefully weigh the CHAP’s recommendations concerning DINP since they are based on outdated data and a negligible contribution to possible cumulative risk. DINP poses no risk in isolation, and the Hazard Index for cumulative risk demonstrates that current exposures to all phthalates are protective of human health.

Sincerely,

Eileen Conneely

Eileen Conneely, M.P.H., J.D.  
Manager, High Phthalates Panel  
Director, Chemical Products and Technology Division  
American Chemistry Council

cc: Commissioner Robert Adler  
Commissioner Ann Marie Buerkle  
Commissioner Joseph Mohorovic  
Commissioner Marietta Robinson
Attachment 1

Figure 5\textsuperscript{15} Hazard Index calculated based on the 95\textsuperscript{th} percentile urinary metabolite data taken from the NHANES 2005-2006 through NHANES 2011-2012 reports for (a) pregnant women and (b) women of reproductive age (15-45). NHANES values include sampling weights and methodology for calculating Daily Intake and Hazard Quotients (HQ), as laid out in the CHAP report, were followed.

(a)