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To Docket #CPSC-2014-0033:

On July 30, 2015, representatives of ExxonMobil Chemical Company (EMCC) met with Commissioner Buerkle to discuss scientific and legal topics important to the Commission's decision-making for the final phthalate rule. A representative of the Natural Resources Defense Council (NRDC) attended that meeting and subsequently submitted comments to the phthalate rule docket (Docket Number CPSC-2014-0033-0109). Although perhaps unintentional, the comments read in a way that could misrepresent what EMCC's representatives presented. We therefore would like to correct any misunderstanding the NRDC comments may have engendered, and to address some potentially misleading information in the NRDC submission.

Potentially misleading statements about EMCC presentations

Right of CPSC to follow CHAP recommendations

NRDC states (p. 2) that "Exxon Mobil and corporate law firm Latham & Watkins have challenged the ability, and even the right, of CPSC to follow CHAP report recommendations, and in particular to extend the ban to include DINP." This phrasing seems to assert that we stated as a general principle that CPSC cannot follow the CHAP recommendations. (See also Section 1 of the NRDC comments.) We did not make that assertion. There would be no point in Congress directing the CPSC establish a CHAP if CPSC in general had no right to follow its recommendations.

EMCC's comments were addressing a view we understood some at CPSC held that, under the CPSIA, the Commission is required to follow the CHAP's recommendations, regardless of what subsequent data or other scientific evidence might show. We explained that this cannot be the case, as it would render the CPSIA unconstitutional. We appreciate that NRDC does agree with us (p. 2) "that the CHAP's recommendations are advisory only and that CPSC need not adhere fully to the recommendations."

Right of CHAP to conduct a cumulative risk assessment

NRDC asserts (p. 2) that EMCC argued, "the CHAP went beyond its charge when it produced a risk assessment," and NRDC's Section 3 could be read as a rebuttal to such a position and as a rebuttal to a position that the CPSC could not rely on a cumulative risk assessment. To the contrary, while we pointed out that the CPSIA did not mandate a quantitative cumulative risk

assessment, we explicitly stated that either the CHAP or the CPSC could choose to undertake one.

The issue is not whether CPSIA allows a cumulative risk assessment; it is whether it mandates one. A further issue is, if a cumulative risk assessment is undertaken, how can the CHAP or CPSC use its results. With respect to the CHAP, see the next subsection (Scope of FHSA). With respect to the CPSC, for the interim-banned phthalates, the cumulative risk results must be evaluated under the standard given by CPSIA 108(b)(3)(A), rather than by simply accepting the CHAP's recommendation wholesale.

Scope of FHSA

NRDC indicates (p. 4) that we suggested that the Federal Hazardous Substances Act (FHSA) limits the scope of hazardous substances to mixtures.¹ We did not assert this.

In our presentation to you, we noted that the CPSIA charged the CHAP with providing recommendations on whether any phthalates should be declared "banned hazardous substances" – a term defined by the FHSA. Under the FHSA, the CPSC can ban a product containing an individual substance, if it is hazardous, or a mixture of substances, if the mixture is hazardous. There is no authority to ban an individual substance that is not itself hazardous, on the basis that the mixture is hazardous.

The CHAP found that DINP by itself does not pose an unacceptable risk. Its recommendation to extend the ban of DINP was based solely on the fact that DINP was part of the risk from a mixture of phthalates that the CHAP deemed of concern. This is not a recommendation in accordance with the FHSA.

Opportunity for public comment

Section 2 of the NRDC comments discusses the many opportunities for public comment through the CHAP process and the input of industry to the process. One could infer from this section that EMCC stated it had not been given adequate opportunity for public comment.² EMCC did not state this. What we said was that, if CPSC were to follow the CHAP recommendations regardless of what science or other evidence anyone brought forth, that would in effect foreclose public comment and would be in violation of the Administrative Procedures Act.

We would like to point out that, although CPSC has accepted public comment, including comments from EMCC, over the period of the CHAP deliberations and now the proposed rule, that does not necessarily indicate that the opportunity to comment has had full consideration by the CPSC. The CPSC science staff's reanalysis using recent NHANES data, conducted several months after release of the proposed rule, is the first indication that the CPSC considered any portion of the comments.

¹ "Moreover, contrary to industry's suggestion, the Federal Hazardous Substances Act (FHSA) does not limit the ambit of hazardous substances to mixtures." (NRDC, p. 4)

² E.g., "Industry cannot reasonably make an argument that it has not had opportunity to voice its position to either the CHAP or CPSC."

Potentially misleading statements about the science

Cumulative risk assessment methodology

NRDC asserts (p. 4) that the cumulative risk methodology of the CHAP “is a well understood and science-based approach also used by other regulatory agencies.” For this assertion, NRDC cites to the 2012 Committee on Risk Assessment (RAC) opinion on an Annex XV dossier proposing restrictions on four phthalates (this was under the European Union REACH regulations). That opinion (p. 8) concludes that the hazard index methodology (which was the CHAP’s methodology) is “appropriate for first tier risk assessment, with due consideration of the uncertainties and conservativeness involved when interpreting the [results].” This is consistent with our point that the CHAP’s methodology is a screening methodology only (i.e., a first tier assessment). A screen can be used to eliminate risk; it cannot be used to confirm risk but only to point to need for further inquiry. In this context, the analysis completed by the CHAP suggests that the contribution to risk from DINP is marginal and does not merit further investigation.

Of note, the RAC opinion concluded (p. 2), “RAC considers that the proposed restriction is not justified because the available data do not indicate that currently (2012) there is a risk from combined exposure to the four phthalates.” Those four phthalates were DEHP, DBP, BBP and DIBP. Based on trends for decreased exposure, the RAC determined cumulative risk values derived from available but older data were likely out of date, and that there actually was no risk. The CHAP used those same four phthalates plus DINP, which was only a minor contributor to the calculated cumulative risk. As with the RAC analysis, the exposure values used by the CHAP were outdated, but rather than accounting for changes in exposure and drawing sound scientific conclusions based on those changes (i.e., giving “due consideration of the uncertainties and conservativeness involved when interpreting the [results],” the CHAP based its conclusions on information known to be outdated.

NRDC also asserts (p. 4) that the CHAP’s, “recommendations regarding cumulative risk to CPSC are reasonable, scientifically-defensible, and consistent with existing methods.” To the contrary, the authoritative body to which the NRDC alludes as using cumulative risk assessment, the RAC, had different recommendations than the CHAP although using a similar methodology. EMCC has submitted extensive comments detailing the scientific flaws in the CHAP’s cumulative risk methodology and its recommendation for DINP.

Percentage of population with HI >1

EMCC’s April 14 and August 6 comments, as well as other industry comments, explain that extrapolating the quoted percentages to the full U.S. population is a misuse of statistics. Stated briefly, the cumulative risk assessment uses spot samples of exposure, but the effect is chronic. Spot samples cannot be used to indicate what an individual’s chronic exposure is. In the CPSC reanalysis, at the 95th percentile, there was no HI above 1. The 95th percentile of spot samples provides a very conservative estimate of chronic exposures in the population. Thus, it is unlikely that there are *any* women with a chronic HI greater than 1. The data, as well, indicate there likely are no infants with HI >1.

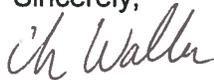
Potentially misleading statements about the trend in risk

Section 5 of the NRDC comments potentially could be read to mean that, because DINP use is increasing, so is the risk from phthalates.³ Such an understanding would confuse increasing exposure with increasing risk. Risk is a function of both exposure and hazard. Because the hazard of DINP is so much lower, and arguably not present, in relation to DEHP, the overall risk decreases as DINP replaces DEHP. This was explained in our presentation to you on July 30, and is shown in our comments of August 6 (Figure 2, p. 19, Docket Number CPSC-2014-0033-0105).

NRDC states (p. 6): "The reality is that we know very little about the hazards of the replacement phthalates, and so their contribution to the cumulative risk is largely unknown...." This has been our point all along. We do know quite a lot about the potential hazards of DINP, and both the 2000 CHAP and the recent CHAP have determined that DINP itself poses little risk. It therefore makes sense to replace DEHP with DINP. It does not make sense to ban the well-studied, low-toxicity DINP, thereby forcing the market to use replacement plasticizers about which we know much less.

We hope that these clarifications are helpful to you. Please let us know if you have any questions or would like any additional information.

Sincerely,



Cc: Chairman E. Kaye (EKaye@cpsc.gov)
Commissioner R. Adler (RAdler@cpsc.gov)
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³ "As phthalates like DINP replace DEHP their contribution to the HI will increase, so phthalates that seem 'insignificant' now are likely to become significant contributors to risk as their commercial uses increase." (NRDC, p. 6)