



October 30, 2015

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Dear Dr. Norman,

Re: Proposed Approach to Cumulative Risk Assessment (CRA) of Phthalates

Thank you for the extra time provided to review the multiple documents released for consultation in August of this year pertaining to the proposed approach to cumulative risk assessment (CRA) of phthalates.

We had hoped to retain specialized expertise to review these documents on our behalf but time and resources did not permit.

In the alternative, we have been able to review the human health risk assessment portion of the proposed approach to CRA for phthalates. Within the limits of our collective expertise, we wish to express our general support for this document and offer the following brief comments.

Overall, while the writing in this report can at times be hard to follow, and a list of acronyms would help the reader quite a lot, the proposed approach is laudable and should be acted upon quickly.

Specifically, we support the application of what appears to be best practices from the international arena where some of this work has already occurred or is ongoing. We also agree with what appears to be an intention to address a larger list of phthalates than has occurred/is occurring in other jurisdictions.

We reviewed the document with an eye to ensuring and verifying that you have relied upon leading, published reports and researchers in the fields of phthalate toxicity, mixture toxicity, and cumulative exposure assessment.

We support the proposed comprehensive exposure assessment that includes sources beyond typical CEPA categories of chemicals, that is, to be sure that you are including exposures from cosmetics and personal care products. Likewise, we agree that it is essential to consider exposure and effects during prenatal periods of fetal vulnerability.

One caveat with respect to the discussion of exposure assessment is that we consider the conservativeness of the cumulative exposure assessment (noted on page 40 of the document) to be a good thing. Overestimating exposure can only add safety margins to an inherently uncertain set of calculations. Similarly, conservativeness in cumulative exposure assessment will also be in line with the National Academy of Sciences (NAS) report on the CRA of phthalates. In this regard, as noted on page 23 of the document, you are proposing an approach to human health CRA that, as the NAS recommended, focuses on adverse health outcomes as opposed to the pathways that lead to those adverse outcomes. We strongly support this approach. However, the NAS report also recommends that such a focus on endpoints should consider all similar and even dissimilar chemicals (i.e., in this context, not just a mixture of phthalates) that can contribute to adverse health outcomes. Hence, an approach that is inherently conservative in estimating exposure has the potential to provide some degree of precaution in the face of real-world exposure circumstances where there may be multiple other substances implicated in the health concerns raised by phthalates.

We hope that the federal government will proceed expeditiously to implement a CRA for phthalates.

All of which is respectfully submitted.

Yours truly,

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