



Flexible Vinyl Alliance

Comments of the Flexible Vinyl Alliance on:

**Estimated Phthalate Exposure and Risk to
Pregnant Women and Women of
Reproductive Age as Assessed Using
2013/2014 NHANES Biomonitoring Data
Docket Number CPSC-2014-0033
82 Fed. Reg. 11348**

March 24, 2017

The Honorable Ann Marie Buerkle
Acting Chairperson
U.S. Consumer Products Safety Commission
4330 East West Highway
Bethesda, MD 20814

Dear Acting Chairperson Buerkle:

These comments are submitted on behalf of the Flexible Vinyl Alliance (FVA) and the more than 200,000 workers in the flexible vinyl products industry. We are writing with concern to the potential ramifications of the recent CPSC assessment of 2013/2014 NHANES biomonitoring data, relevant to the estimated phthalate exposure risks to pregnant women and women of reproduction age.

As background, the FVA was formed in 2009 as an independent coalition of more than 900 business concerns including trade organizations, raw materials suppliers, compounders, formulators, molders and fabricators representing the full value chain of the flexible polyvinyl chloride (PVC) industry, a \$20B US market.

While FVA members are necessarily concerned with business and regulatory matters around the full deployment and availability of flexible vinyl products in an open marketplace, we are also committed to the safety and efficacy of any PVC products that employ phthalate plasticizers. These plasticizers are the subject of this CPSC/NHANES analysis, as well as the Chronic Hazard Advisory Panel (CHAP), as enabled by the Consumer Product Safety Improvement Act (CPSIA) of 2008.

Phthalates, as vinyl additives, have been closely studied by independent scientists, the federal government and industry, and used safely for more than 50 years. Valid risk assessments, inclusive of dose and exposure, peer-reviews, reproducibility, weight of evidence and the size and scope of studies, all matter when assessing chemical safety, and all still point to the safety of phthalates.

In regard to the subject of this docket, in a 2014 letter to then-Chairman Kaye, the FVA encouraged the CPSC, as a follow-up to the CHAP Report, published in 2014, to, in fact, expand its analysis of phthalates, to:

“.....take into account the science, risk assessments, exposure data and the so-called NHANES report, which if properly applied in a rigorous way, would reveal the safety and efficacy of these chemicals, and calm the politically-driven, chemo phobic hysteria, perhaps to a degree. To that end, had the CHAP used more current NHANES data... it would have derived a different outcome - - that there is no significant cumulative risk associated with (any) phthalates.....”

The FVA welcomes the February 2017 publication of the 2013/2014 NHANES dataset for exposures and risks to women of reproductive age. And, with the previous CPSC staff report looking at the additional intermediate datasets from June 2015, the CPSC did, in fact, address this data assessment/re-assessment request. We thank you.

Next, in assessing the latest NHANES data, it is apparent that all of these additional assessments show cumulative risk from phthalates has steadily fallen, making the original conclusions from the CHAP report outdated and incomplete. The calculated Hazard Index for exposures to phthalates has fallen below the level of one with the latest analysis, a critical safety benchmark.

The FVA submits that the proposed Cumulative Risk Assessment conclusions from the CHAP report are now not supported by the actual measured data from the NHANES studies and are thus not valid.

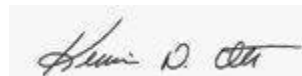
In this new light, we encourage the Commission to review the proposed actions from the CHAP report in the context of the newer data and to make revisions to the action plan and proposed rule that correctly align with the safety of phthalates, as evidenced by NHANES data enhancements.

In closing, we strongly advocate for good science to lead the way in fulfilling our mutual industry/government goal to provide safe products to our consuming public. To that end, risk- based chemical regulation is essential where “exposure matters” and dose and duration are central to the research and outcome. This, coupled with peer review, reproducibility, the weight of evidence, and study size and quality all matter.

The FVA encourages the CPSC to provide an opportunity for further substantive public comment on the CHAP report prior to initiating an informed federal rule-making process.

Thank you for your attention to our concerns, and we look forward to working with you in the months ahead.

Regards,



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