March 13, 2015

Office of the Secretary
Consumer Products Safety Commission
Room 820
4330 East West Highway
Bethesda, MD 20814

RE: 16 CFR Part 1307
Docket No. CPSC-2014-0033

Comments on: Notice of Proposed Rulemaking: Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates

Dear Mr. Secretary:

Thank you for the opportunity to comment on CFR Part 1307, as cited above. These comments are submitted on behalf of the Flexible Vinyl Alliance (FVA) and are intended as a broad commentary and critique of the Notice of Proposed Rulemaking (NPR) and the very lengthy and complex procedural process that led to the Chronic Hazard Advisory Panel (CHAP) Report (July, 2014) on which the near-entirety of this proposed rulemaking is based. We do, however, have serious concerns with the *methods* employed, post-CHAP, to fast-track this significant rulemaking without adequate public comment and concerned-industry business input on the repercussions of such a rule.

As background, the Flexible Vinyl Alliance (FVA) was formed in 2009 as an independent, informal 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) product market, which in the United States represents a $20B endeavor. Thus, we are also writing on behalf of the more than 200,000 workers in the flexible vinyl products industry supply-chain concerning the potential federal policy ramifications of this proposal on U.S. businesses.

By including the term 'flexible vinyl" in our title, it is obvious that the energetic industry we represent utilizes a range of plasticizers in their products, and has done so safely and effectively for more than five decades. Products ranging from camping tents, PVC-jacketed charging cords, food packaging, auto interiors, child car-seats, playroom floors, yoga mats, bathtub "no-slip" appliqués, wound bandages, beach balls, school lunch pouches, moon-bounce tents, back yard water-slides and wading pools are all fashioned, in whole or in part, from flexible PVC.

This Notice of Proposed Rulemaking (NPR) will unfortunately lead manufacturers of "children's products" to face further uncertainty in attempting to revise product formulations (upping their manufacturing costs), be subject now to increased product liability concerns, and have one more regulatory compliance burden placed on their shoulders as manufacturers, small and large, of such consumer goods suitable for children. This compliance uncertainty is illustrated, if not exacerbated, by 16 CFR 1200 *Definition of Children's Product Under the Consumer Product Safety Act* (published in the Federal Register on October 14, 2010) which attempts to define what, and what is not, a children's product. This notice introduces, in its attempt to "clarify" product categories, a complex set of subjective judgments (in determining what might be a children's product) based on such things as packaging (perhaps featuring bright colors or decorated with "childish features"); where a product might be displayed in a store (toy section or elsewhere); a product's size (sports balls); and, a product's intended use (such as collectible or non-collectible "plush bears" which are cited in the guidance.)

Interpreting this guidance on the part of the product makers who make such articles strikes us a totally subjective, arbitrary and ill-defined (at best) and just adds to overall industry uncertainty as to how to comply with complex federal regulations.

While the subject NPR may be seen as a necessary move to insure "safer" products, FVA would respectfully point out that valid risk assessments (inclusive of dose and exposure), peer-reviews, reproducibility, weight of evidence and the size and scope of studies, <u>all</u> matter when assessing chemical safety. In particular, exposure is a critical component in addition to potential hazard, in determining the risk of a chemical and the regulatory response, if any, that is needed.

Further, the Proposed Rule implements <u>nearly every</u> proposed restriction recommended by CPSC's Chronic Hazard Advisory Panel (CHAP) in its long-delayed July 2014 report. Thus, the CPSC has essentially codified the CHAP report, granting this seven-person panel de-facto rulemaking authority. In our opinion, federal rulemaking should encompass reason, need, transparency, full stakeholder input, current and relevant science, and opportunity for comment. We believe that the CPSC, with this rulemaking, has failed on all six counts, with the opportunity to comment (75 days, as compared to a 5-year CHAP process) appearing to be a

formality vs. a true "deep dive" into the ramifications of this rule, based on this huge discrepancy of time allowances.

In addition, we question whether the CHAP report was subject to an adequate public comment period in accordance with the Office of Management and Budget's (OMB) *Final Information Quality Bulletin for Peer Review.* This OMB Bulletin establishes strict minimum requirements for peer review of highly influential scientific assessments, inclusive of public meeting(s) where oral presentations on scientific issues can be made to peer reviewers by interested members of the public, such as impacted industry parties. So, while the CHAP Report released peer reviewers' comments upon its publication, the report was *not* made available for public scrutiny *and review* before its finalization.

Thus, there is much to be concerned about in this rulemaking, beyond the impact on product-makers, the lack of public comment opportunity, the guidance language, the timing (six years elapsed between the original *Consumer Product Safety Improvement Act of 2008* (CPSIA) enactment, and the 2014 CHAP deliverable) and now a proposed rulemaking, allowing a mere 75 days for comment. But above and beyond these concerns, among other FVA concerns are:

Cumulative Risk: If finalized, the rule would become one of the first federal actions regulating a chemical on the basis of cumulative risk. On this basis, this may mark the beginning of an era in which federal regulators, acting on the opinions of anointed scientific panels, begin to impose restrictions on chemicals in commerce, that have been deemed safe by several scientific studies, many within the timeframe of the past five years, going well beyond the scope of the CHAP Report;

"Fresh" Scientific Rigor: The casual observer of scientific progress, and perhaps even its practitioners, would probably grant you the notion that six-years is a long time, in this age of rapid discoveries and scientific investigations. We question whether the CPSC, by endorsing the CHAP Report with this NPR, is taking into account all the information relevant to phthalates since 2008. Science and invention march on, inexorably, and we respectfully ask that you look at all the new data, and determine if all the facts about phthalates have been fully vetted by the CPSC in the intervening years between the 2008 CPSIA and 2014 CHAP Report, and base NPR deliberations on those data as well.

Methodology Flaws: As previously mentioned, opportunity for stakeholder input, and transparency of process should be the hallmark of federal regulatory actions. As you are well aware, the CPSIA called on your commission to take action on phthalates and phthalate alternatives to ensure a reasonable certainty of safety for consumers potentially exposed to these chemicals, especially children. Our FVA members are committed to safe products and

assert that the most effective products follow a safety regime that is based on the highest quality information available.

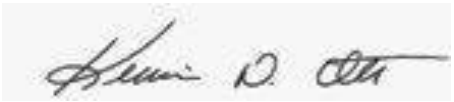
In summary, we respectfully take issue with the general methodology of the CHAP, the lack of a comment period *prior* to the CHAP Report findings being released in July of 2014 as well as the limited 75- day comment period post-CHAP. To now take this un-vetted report as the basis for developing regulatory policies on phthalates seems to us to be taking the approach that builds policy on assumptions, and then moving too rapidly to codify them.

The impact of these decisions will weigh heavily on an industry that relies on access to safe and affordable ingredients and chemicals as the bases for critical product applications. Since this will affect the approach of other federal agencies, this NPR should be subject to the highest level of public scrutiny including broad scientific review before they are used as a basis for CPSC, or any other agency's rulemaking efforts.

Separately, and finally, the FVA filed an appeal on March 2, 2015 to the CPSC Office of the Secretary to ask for an extension of this comment period for 60-days. At a minimum, this seems to be a prudent action to take, and we hope for a positive decision on this request.

Thank you for your consideration of FVA's viewpoint on this Notice of Proposed Rulemaking, and your attention to our overall concerns with this NPR.

Sincerely,



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