U.S. CONSUMER PRODUCT SAFETY COMMISSION
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MINUTES OF COMMISSION MEETING

October 18, 2017

Acting Chairman Ann Marie Buerkle convened the October 18, 2017, 10:00 a.m., meeting of the U.S. Consumer Product Safety Commission in open session. Commissioner Robert S. Adler, Commissioner Marietta S. Robinson, Commissioner Elliot F. Kaye and Commissioner Joseph P. Mohorovic were in attendance. Acting Chairman Buerkle made welcoming remarks and summarized the agenda for the meeting.

- Decisional Matter: Draft Final Rule: Prohibition of Children's Toys & Child Care Articles Containing Specified Phthalates, and
- Revision of the Notice of Requirements (NOR) for Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates –Notice of Proposed Rulemaking

(Briefing package dated September 13, 2017, OS No. 3477)

After introducing the matter, Acting Chairman Buerkle called for any comments or questions on the matter. Present to respond to any questions were Dr. Michael Babich, Director, Division of Toxicology and Risk Assessment and David DiMatteo, Office of the General Counsel. The Commissioners did not have any questions for staff, and staff was excused.

Acting Chairman Buerkle called for motions or amendments. Commissioner Kaye moved that the Commission direct staff to change language at certain parts of the preamble of the final rule, Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates. Commissioner Robinson seconded the motion. Commissioner Kaye explained his amendment, and the Commission discussed the amendment. After the discussion, Acting Chairman Buerkle called for a vote on the amendment. The Commission voted (4-1) to adopt Commissioner Kaye's amendment. Commissioner Kaye, Commissioner Adler, Commissioner Robinson and Commissioner Mohorovic voted to adopt the amendment. Acting Chairman Buerkle voted not to adopt the amendment. The adopted amendment is attached.

Acting Chairman Buerkle called for other motions and amendments. Hearing none, Acting Chairman Buerkle moved to consideration of the final rule as amended. Acting Chairman Buerkle called for any questions and hearing none, called for a vote on the matter. The Commission voted (3-2) to approve the staff's final rule, as amended, for publication in the *Federal Register*. Commissioner Adler, Commissioner Robinson and Commissioner Kaye voted

to adopt the final rule as amended. Acting Chairman Buerkle and Commissioner Mohorovic voted to not adopt the final rule.

Acting Chairman Buerkle turned to the second matter on the agenda, which was the Revision to the Notice of Requirements (NOR) for Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates – Notice of Proposed Rulemaking.

Acting Chairman Buerkle called for any motions, amendments or questions and hearing none, called for a vote on the matter. The Commission voted unanimously (5-0) to approve the publication of the Notice of Proposed Rulemaking in the *Federal Register*.

Acting Chairman Buerkle called for closing statements. Each Commissioner gave closing statements.

There being no other business, Acting Chairman Buerkle adjourned the meeting at 10:59 a.m.

For the Commission:

Alberta E. Mills
Acting Secretariat

Attachments – Amendment from Commissioner Elliot F. Kaye

Statement of Acting Chairman Ann Marie Buerkle Regarding the Commission's Final Rule on Phthalates

Statement of Commissioner Robert S. Adler on the Approval of a Final Rule Prohibiting Children's Toys and Child Care Articles

Statement of Commissioner Elliot F. Kaye on the Approval of a Final Rule Prohibiting Children's Toys and Child Care Articles Containing Specified Phthalates

Statement of Commissioner Joseph P. Mohorovic on the Commission's Final Rule Prohibiting children's Toys and Child Care Articles Containing Specified Phthalates

Commissioner Kaye Amendment to Draft Final Rule:
Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates

Direct staff to make the following changes to the preamble of the final rule:

On page 78, line 11, at the end of the first paragraph, add the following language:

> To repeat, the CHAP neither used nor suggested a specific percentile as threshold for recommendations or regulatory proposals.

On page 88, line 11, after "Response:," add the following language:

> The CRA using current exposure data indicates that least some of the actual WORA in the NHANES data had HIs greater than one, showing that there is not a reasonable certainty of no harm with an adequate margin of safety. Moreover,

On page 88, line 16, delete the word "individuals" and replace with the following language: "actual women from the NHANES sample"

On page 89, line 3, after "Response:," add the following language:

> Neither the CHAP nor staff used the 95th percentile (or any other percentile) as a threshold for recommendations or regulatory proposals in evaluating individual or cumulative risks.

On page 89, line 6, delete the words "people in the NHANES sample" and replace with the following language: "actual women from the NHANES sample"

On page 89, line 6, after "greater than one.," add a new paragraph with the following language:

> For its cumulative risk assessment, the CHAP addressed the range of HI in representative populations – including but not limited to the 50th percentile, 95th percentile, and 99th percentile. In all analyses of the updated NHANES data for WORA and in the rule, staff does not rely on any particular percentile as a threshold for recommendations or regulatory proposals, but on the fact that at least some of the actual WORA from the NHANES samples had HIs greater than one. Because at least some of the actual WORA from the NHANES samples had HIs greater than one in every NHANES data cycle analyzed, there is not a reasonable certainty of no harm with an adequate margin of safety. For example, for the 2013-14 NHANES data, between two and nine real women from the sample of 538 WORAs had an HI greater than one, depending on the case model used. The CHAP emphasized, and the Commission continues to agree, that an HI greater than one is the metric that defines excess exposure.

On page 89, line 7, start a new paragraph at "CPSC disagrees..."

On page 89, lines 14-15, after "However," delete the word "individuals" and add the following language: "as noted above, actual women"

On page 109, line 10, delete the word "WORA" and replace with the following language: "actual WORA sampled"

On page 111, lines 10-11, delete the words "WORA individuals" and replace with the following language: "actual WORA."

Statement of Acting Chairman Ann Marie Buerkle
Regarding the Commission's Final Rule on Phthalates

The Commission's final rule on phthalates represents the culmination of a huge effort spanning almost a decade. I want to thank the CPSC staff for their enormous contribution to this matter. They not only assisted the Chronic Hazard Advisory Panel (CHAP) in developing the report that is the primary basis for the rule, but also analyzed a great deal of scientific data—particularly exposure data—that was not addressed in the CHAP report. They also reviewed and responded to dozens of public comments, many of which involve highly technical points. The Staff Briefing Package (Sept. 13, 2017)[hereinafter cited as BP] is voluminous, but it is well-organized and addresses a wide range of issues. The legal memo from the Office of General Counsel is also very helpful in making an incisive and candid assessment of many challenging legal questions under section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), 15 U.S.C. § 2057c, and other statutes.

I agree with the decision to lift the interim prohibitions on diisodecyl phthalate (DIDP) and di-n-octyl phthalate (DnOP).[1] Where I part company with the majority is on the decisions (1) to make permanent the interim prohibition of diisononyl phthalate (DINP) in child care articles and toys that can be mouthed; and (2) to extend the scope of the permanent prohibition to a much larger class of toys. In my view, the data do not justify either decision.

I. MAKING PERMANENT THE INTERIM PROHIBITION FOR DINP

The Commission's decision to prohibit DINP permanently hinges on its contribution to a cumulative risk assessment of several different phthalates, and the Commission's interpretation of the legal standard for making the interim prohibition permanent. I discuss each of these in turn.

A. The Cumulative Risk Assessment (CRA)

The primary basis for the decision to perpetuate the ban on DINP is a cumulative risk assessment, which attempts to evaluate the risk of exposure to five phthalates simultaneously.[2] The Commission's 2014 proposed rule hinged on an earlier version of the cumulative risk assessment that was produced by the CHAP. Notice of Proposed Rulemaking, 79 Fed. Reg. 78324, 78327 (Dec. 30, 2014); CHAP Report at Table 2.16. That earlier assessment was seriously flawed. While one of the major problems with it has been corrected, others remain.

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[1] See BP at 44-45; Comments of Washington Legal Foundation (April 15, 2015), Docket No. CPSC-2011-0033-0096, at 5-6.

[2] The five are di(2-ethlhexyl) phthalate (DEHP); dibutyl phthalate (DBP); benzyl butyl phthalate (BBP); diisobutyl phthalate (DIBP) and diisononyl phthalate (DINP). CPSIA section 108(a)(1) prohibited any children's toy or child care article that contains more than 0.1 percent of the first three of these. 15 U.S.C. § 2057c(a)(1). The same statute adopted an interim prohibition on "any children's toy that can be placed in a child's mouth or child care article that contains concentrations of more than 0.1 percent of [DINP, DIDP or DnOP]." Id. § 2057c(b)(1).

Obsolete exposure data. The CHAP's original CRA relied on human biomonitoring data from the 2005-2006 National Health and Nutrition Examination Survey (NHANES).[3] More recent biomonitoring data were available long before our Notice of Proposed Rulemaking was issued, but the Commission majority refused to wait for an analysis of these data sets before deciding what to propose. Instead, it formulated its proposal based on biomonitoring data known to be obsolete and directed the staff to analyze the later data sets after the NPR was issued.[4]

The NHANES surveys reflect decreasing exposures to DEHP, which is one of the "active" phthalates most associated with adverse health effects in rats. The later surveys also reflect increasing exposure to DINP. Compared to DEHP and the other three phthalates included in the CRA, DINP is much less potent. For that reason, these offsetting changes in exposures are a net plus for safety.

The CHAP's original assessment looked particularly at exposures to pregnant women. This is because the health hazard of primary concern—broadly defined as male reproductive developmental effects or MRDE—results from the exposure of male fetuses *in utero*, as a function of their mothers' exposure to phthalates. The 2005-2006 NHANES survey had more data on pregnant women than did later surveys, due to CDC's intentional "oversampling" of pregnant women in those years—a practice it has since discontinued.

To update the exposure data, the CPSC staff first compared the exposures of pregnant women in the original 2005-2006 NHANES data with those of "women of reproductive age" (WORA) in the same data set.[5] The staff found the exposures of both groups to be similar. They concluded that in analyzing the later NHANES data sets, it would be acceptable to use the WORA exposure as a surrogate for the exposure of pregnant women.

Having decided that the exposures of pregnant women and women of reproductive age were sufficiently similar, the staff should have combined the biomonitoring data from both groups in all of its subsequent analyses.[6] Instead, it continued to examine the women of reproductive age

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[3] The staff's Briefing Package explains that "Human biomonitoring (HBM) is the measurement of a chemical or its metabolite in human biological samples, such as blood or urine. The concentration of urinary phthalate metabolites in HBM samples can be used to estimate exposure to the parent phthalate." BP at 15.

[4] As I pointed out in my statement on the Proposed Rule, the Commission also refused to allow public comment on the CHAP report—a "highly influential scientific assessment" if there ever was one—before deciding what to propose. This was wrongheaded if not illegal. The Commission majority professed concern about the deadline set by Congress, but its precipitous action hardly expedited the rulemaking, which has taken nearly three years. Instead, it appeared to foreordain the result on DINP. The final rule does nothing to dispel that impression. To the contrary, the majority seems to be adhering to its proposal to prohibit DINP no matter the facts.

[5] K. Carlson, S. Garland, "Estimated Phthalate Exposure and Risk to Pregnant Women and Women of Reproductive Age as Assessed Using Four NHANES Biomonitoring Data Sets (2005/2006, 2007/2008, 2009/2010, 2011/2012)" (2015) [hereinafter cited as "Staff 2015 Exposure Update"]. The Commission made this analysis available for public comment. See 80 Fed. Reg. 35938 (June 23, 2015), Docket No. CPSC-2014-0033-0102.

[6] In December 2016, the results of another two-year NHANES survey became available. The staff again updated its analysis. K. Carlson, W. Szeszel-Fedorowicz, "Estimated Phthalate Exposure and Risk to Women of Reproductive

as a separate group. As discussed below, this decision has very significant implications for the final rule.

Before turning to the results of the staff's updated CRA, I pause to consider a few additional problems with the CHAP's cumulative risk assessment that were never cured by the staff's later work.

Inconsistent potency estimates. For its cumulative risk assessment, the CHAP used three alternative sets of potency estimates for anti-androgenicity (PEAA). These are referred to simply as Case 1, Case 2 and Case 3. All three use points of departure based exclusively on rat studies.[7] All three then divide by an uncertainty factor of at least 100—a factor of 10 for interspecies differences (assuming, contrary to the evidence, that humans are ten times more sensitive to phthalates than are rats), and a factor of 10 for intraspecies differences (assuming that some individuals are much more sensitive than others).

Case 1 uses potency estimates from a study previously conducted by one of the CHAP's members. Case 3 reflects the CHAP's own work, deriving potency estimates from its independent review of the published, peer-reviewed literature.

Case 2 is the most problematic. It develops a theoretical potency estimate for DINP based on two mismatched ingredients. The first is a study called Hannas *et al.* (2011), which compared the effects of different phthalates, including DEHP and DINP, on the production of testosterone from male rat fetuses *in vitro*. Hannas *et al.* found that DEHP was 2.3 times more potent than DINP in this regard. The CHAP then made the assumption that the same relative potency would apply to different health endpoints. Specifically, it took a "conservative" no-observed-adverse-effect level of 5 milligrams/kilogram/day for DEHP, CHAP Report at 90, and multiplied it by 2.3 to derive a hypothetical no-observed-adverse-effect level for DINP of 11.5 mg/kg/day. That is the value used by the CHAP as the "point of departure" for Case 2. *See* CHAP Report at 64; *id.* Appendix D, p. 20 (Table D-8); *cf.* Comments of ExxonMobil Chemical Company (March 24, 2017), Docket No. CPSC-2014-0033-0140, Appendix B.

The key problem with Case 2 is that this theoretical no-observed-adverse-effect level for DINP is refuted by the scientific evidence. Experiments have shown no MRDE effects even at substantially higher doses. Case 3, which reflects the CHAP's own review of the scientific literature, uses 50 mg/kg/day as an admittedly "conservative" point of departure for DINP.[8] Case 1 uses an even higher point of departure for DINP than Case 3, reflecting a judgment that

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Age as Assessed Using 2013-2014 NHANES Biomonitoring Data" (2017) [hereinafter cited as "Staff 2017 Exposure Update"]. The Commission also made this analysis available for public comment. See Notice of Availability, 82 Fed. Reg. 11348 (Feb. 22, 2017), Docket No. CPSC-2014-0033-0134.

[7] CHAP Report at 72. The CHAP acknowledged this as a weakness of its own analysis. Id.

[8] CHAP Report at 98; id. at Appendix D, p. 20 (Table D-8). Case 3 also uses much higher points of departure than Case 2 for all the other phthalates in the cumulative risk assessment. Id.

DINP is less toxic.[9] In short, all of the scientific data support a higher no-observed-adverse-effect level for DINP, and no experimental data support the hypothetical Case 2 level.

As the staff points out, the CHAP said it was interested in exploring different approaches to potency estimates as a way of understanding the sensitivity of the results to different methodologies. BP at 17. In fact, the three cases did not yield markedly different results when the CHAP produced its report. *See* CHAP Report at Appendix D, p. 41. This was because the outdated 2005-2006 biomonitoring data on which the CHAP then relied included very little exposure from DINP. But as the exposures to different phthalates have shifted over time, the distortion caused by Case 2's modeled no-observed-adverse-effect level for DINP is becoming more and more significant.

The CPSC staff attempts to defend the continued use of Case 2 on the grounds that the Hannas *et al.* study was particularly reliable. The staff emphasizes that it involved the exposure of pregnant female rats to many different phthalates (and mixtures) in the same laboratory using the same methodology. BP at 17. Others have pointed out problems with Hannas *et al.* that undermine any notion of special reliability. For example, the rats used by Hannas *et al.* for DINP exposures were from a different laboratory than the rats used for DEHP exposures.[10] Hannas *et al.* also used fewer rats per exposure group than is desirable. Summit Toxicology at 6. This magnifies the effect of chance, making the results <u>less</u> robust than in other studies.

But the staff never comes to grips with the key problem of Case 2, which is not the reliability of Hannas *et al.*, but the further unsupported assumption that the relative potency identified in that study will apply to other, more serious health effects when the weight of the evidence is to the contrary. Other studies have shown that DEHP is 10 to 20 times more potent than DINP. To use 11.5 mg/kg/day as the point of departure for DINP, as Case 2 does, is not supported by <u>any</u> experimental results. It is based solely on an assumption, pure and simple. In my view, such an assumption cannot legitimately serve as the basis for permanently prohibiting the use of a substance in a wide range of consumer products.

No matter the CHAP's thinking, the Commission cannot simultaneously rely on three analyses that contradict one another. The Commission has a responsibility to state, as clearly as possible, the basis for its decision. If it does not agree with the CHAP's own analysis of the science, as reflected in Case 3, or if it actually credits Case 2 for some reason, it should say so. But holding

[9] CHAP Report, Appendix D, p. 20 (Table D-8). Ironically, the Hannas *et al.* (2011) study, on which the relative potency of 2.3 is based, itself would support a much higher no-observed-adverse-effect level. See CHAP Report at 97.

[10] See Summit Toxicology, Comments on Consumer Product Safety Commission Report on "Estimated Phthalate Exposure and Risk to Pregnant Women and Women of Reproductive Age" - June 2015 (Aug. 6, 2015)[hereinafter cited as "Summit Toxicology"], attached to Comments of the American Chemistry Council (March 24, 2017), Docket No. CPSC-2014-0033-0139. The rats from these two different labs had different rates of testosterone production even when they weren't exposed to any phthalates. Id. at 6.

up three inconsistent analyses and saying the answer is in there somewhere is not reasoned decision-making—it amounts to a regulatory shell game.

Spot urine samples. A second major issue with the CHAP's cumulative risk assessment relates to the use of "spot" urine samples. A key point about phthalates is that they do not build up in the body; they are rapidly excreted. The NHANES biomonitoring data used by the CHAP to estimate exposures are what are called "spot" urine samples. Instead of collecting multiple urine samples from a survey participant throughout a 24 hour period (or longer), the survey uses a single sample for each participant. Each of the five phthalates evaluated in the cumulative risk assessment has one or more characteristic metabolites that will show up in the urine sample. By measuring the amount of each related metabolite, it is possible to back-calculate the intake of each "parent" phthalate for each individual in the survey.

There is nothing wrong with using spot urine samples to develop exposure estimates. In the case of phthalates, however, it is inappropriate to treat the exposure estimates calculated from spot samples as if they represent an individual's exposure over a full day or even longer.[11]

To see why this is inappropriate, it is helpful to understand that much, if not most, human exposure to phthalates comes not from toys or child care articles, but from food. The amount of different phthalates excreted therefore depends to a large extent on timing—for example, how long it has been since the last meal. A person whose urine reflects high exposure to phthalates in one spot sample would rarely if ever show the same high exposure in the next spot sample. Conversely, a person whose urine sample reflects low exposure might show a higher exposure in the next sample.

These accidents of timing tend to be balanced out in a large population. For that reason, the median exposure will accurately reflect the general population's exposure as a whole. At the extremes of the distribution, however, the exposure picture becomes severely distorted. The spot samples show that a few individuals have recently had a much larger dose than most people; what they do not show is that these individuals (or any other individuals) have *consistently* high exposure.

The Centers for Disease Control (CDC) has studied this issue carefully as it plays a very important role in the design of the NHANES surveys. CDC sponsored research in which scientists collected <u>every</u> urine sample from eight different individuals over an entire week. The researchers then measured the metabolite concentrations of certain phthalates for every spot

[11] The staff analyses refer to the estimates from spot samples as "daily estimates," but that is a misnomer, at least in this context.

sample.[12] The results show that for all eight participants, the metabolite concentrations varied enormously from one spot sample to the next. *See* Summit Toxicology at 11.

For our purposes, this means that while there are a few individuals in the NHANES surveys whose exposure, as measured by a spot sample, is temporarily much higher than most people's, it is erroneous to conclude that any of those individuals (or anyone else in the population) is exposed at those elevated exposures for even 24 hours much less any longer term. Instead, the 95th percentile exposure is a very conservative estimate of the maximum 24-hour exposures in the population.[13]

The CPSC staff does not dispute these exposure studies nor has it identified any other studies that show a different picture. Instead, the Briefing Package says only that "staff considers spot urine samples adequate for assessing exposures from MRDE-inducing phthalates because short-term exposures (which are reflected in a spot urine sample) have been demonstrated to induce MRDE effects in laboratory animals." BP at 17. In reality, however, the studies from which the CRA potency estimates were derived all involve *repeated* exposures to pregnant rats *throughout* the critical period during which the reproductive system of a male fetus was developing. In the rat, this "male programming window" is only a few days, whereas in humans it lasts about six weeks.[14] Therefore, the few highest spot samples at the extreme end of the distribution cannot be used as a basis for concluding that those individuals are at risk, much less any larger portion of the population.[15]

Other overestimates of exposure. In developing the exposure estimates from the NHANES biomonitoring data, the CHAP estimated exposure to DEHP based on four different metabolites. In developing the exposure estimate for DINP, however, the CHAP did not make use of all the relevant metabolites available in the data. One commenter calculated that if both metabolites of

[12] Preau, J.L., Wong, L.Y., Silva, M.J., Needham, L.L., and Calafat, A.M. (2010). Variability over 1 week in the urinary concentrations of metabolites of diethyl phthalate and di (2-ethylhexyl) phthalate among eight adults: an observational study. Environmental Health Perspectives, 118(2), 1748-1754.

[13] Summit Toxicology demonstrated that for one DEHP metabolite, the 95th percentile of spot samples would overestimate the 95th percentile of individual 24-hour concentrations by a factor of 1.3 and the 7-day average by a factor of 2.8. Summit Toxicology at 5.

[14] The male programming window in the rat is gestation days 16-18, which corresponds to approximately gestation weeks 8-14 in the human. National Academy of Sciences, Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals (2017) at 43. The CHAP actually discounted various studies that found little or no MRDE effects because the exposures to male rats *in utero* were outside the male programming window. *See* CHAP Report at 71 ("pregnant animals need to be exposed during the appropriate period of gestation").

[15] The staff states that longer-term exposures "are not necessarily required to cause MRDE" because "numerous studies in animals have demonstrated that MRDE and related effects can occur after one or a few doses." BP, App. B at 55. In these studies, however, the effects were seen at exposures far above the highest NHANES exposures. Even then, these shorter-term elevated exposures could be related to adverse health effects in the fetus, only "if the exposure occurs during the window of susceptibility." Id. In the staff's analysis of later NHANES data, however, there is no exposure to a male fetus because none of the women is pregnant.

DINP are used to analyze later NHANES data, the staff's estimates of DINP exposure would be reduced by 17 percent.[16]

The staff gave this argument short shrift, stating only that it used one metabolite (MCOP) so as to be consistent with the CHAP and that the metabolite ignored by the CHAP (MINP) was detected less frequently than the one it used. BP at App. B, pp. 58-59. That response is unsatisfying to say the least. The staff doesn't claim that the unused metabolite data are unreliable nor explain why a low detection rate would weigh against using whatever data are available. Although I am unable to evaluate the merits of this claim, if it is true that using the additional data would substantially lower the estimated DINP exposure, then this factor alone could potentially change the outcome of this proceeding. Therefore, I believe that this point warranted more investigation or at least more explanation.

Another commenter pointed out that in the 2009-2010 NHANES data set, CDC began requiring the collection of additional data that allows more precise estimates of individual exposures.[17] Using the additional data now available, the commenter calculated that the exposures for DINP and DEHP in the 2009-2010 data set would be more than 25% lower than the CPSC staff's estimated exposures both at the median and at the 95th percentile. Summit Toxicology at 3.

The staff acknowledges that the CHAP did not have access to the information that is now available to calculate excretion rates directly, and therefore "the extrapolation method was the only option available to the CHAP." BP at App. B, p. 57. The staff then "chose" to use the same methods as the CHAP to calculate estimates from the later NHANES data. *Id.*

Again, this response falls flat. The staff was not required to do everything the same way as the CHAP. In this instance, better data became available, and the staff should have taken full advantage of it. There was no need to maintain consistency with the CHAP's original analysis, which is obsolete anyway.

The Staff's Cumulative Risk Assessment. The staff's updated CRA does not attempt to correct any of the problems discussed above and highlighted in public comments. Instead, it merely replicates the CHAP's analysis using more recent biomonitoring data instead of the obsolete 2005-2006 NHANES data. *See* Tab A to the Staff's Briefing Package, Table 7.

The staff's discussion of the revised assessment downplays the impact of the new exposure data. *See, e.g.*, BP at 5. The revised assessment actually shows that the cumulative risk of exposure to the five phthalates has decreased dramatically. The median risk for Cases 1 and 3, as measured by the Hazard Index (HI), has declined by 50% from 2005-2006 to 2013-2014. Tab A to the

[16] See Comments of ExxonMobil Chemical Company (March 24, 2017), CPSC Docket No. 2014-0033-0140, at 10.

[17] Specifically, NHANES began collecting information on the time since last urine void and the total urine volume excreted. Summit Toxicology at 2. This new information makes it possible to calculate urinary mass excretion rates directly rather than extrapolate from population average rates based on height, weight and other factors. Id. at 4.

Staff's Briefing Package, Table 7. The risk at the 95th percentile exposure has declined to an even greater extent. Even at the extreme 99th percentile exposure level, the Hazard Index is below 1 for both Cases 1 and 3. *Id.*

The staff concedes that the HI values at the 99th percentile level are so unstable that it is impossible to draw conclusions from them about the general population. *See* BP at 6, 16. The staff points out, however, that in the 2013-2014 NHANES data, there are still a few women (from 2 to 9 depending on which potency estimates are used) with a Hazard Index above 1. In the staff's view, this means that "a portion of the potentially sensitive population is at risk" and therefore the legal standard for lifting the interim prohibition on DINP has not been satisfied. BP at 48.

I cannot agree. First, because these HI values are based on spot samples, it is a virtual certainty that none of these women would have the same degree of exposure for as long as 24 hours. It is even more unlikely that they would have such high exposure for a week or longer. The 95th percentile values provide strong evidence that no harm exists in the entire U.S. population. *See* pp. 4-6, above.

Second, even if these individual women actually had the same extremely unusual high phthalate exposures for weeks—a hypothesis for which there is no support whatsoever in the rulemaking record—they still would not themselves be at risk. Rather, only if they were pregnant during that period of high exposure would there be a risk, and then only to a male fetus at a particular stage of reproductive development. This would apply to a small fraction of women of reproductive age at most. In the staff's analysis of the 2011-2012 and 2013-2014 NHANES data, none of the women with HI above 1 was pregnant when her sample was taken.[18]

This point is of crucial significance. The CHAP's cumulative risk assessment, based on the outdated 2005-2006 NHANES data, found that almost ten percent of pregnant women had a Hazard Index of 1 or higher (in some cases, much, much higher). For those women, a male fetus might have been at risk if they were at a certain point in their pregnancy. The staff's analysis, by contrast, excluded pregnant women. Although it found a few women with a Hazard Index above 1, that finding no longer has the significance it did in the CHAP report. These individuals are

[18] The staff's analyses of later NHANES data all exclude pregnant women from the class of "women of reproductive age." See Staff 2017 Exposure Update at 2. Thus, none of the 538 women in the staff's analysis of the 2013-2014 NHANES data was pregnant when her spot sample was taken. One commenter calculated the Hazard Index for each of the pregnant women in the 2009-2010 and 2011-2012 NHANES data sets, using the same potency estimates as the CHAP. None of the pregnant women had a Hazard Index above 1 either, even when the scientifically indefensible Case 2 potency estimates were used. Comments of ExxonMobil Chemical Company (Aug. 6, 2015), Docket No. CPSC-2014-0033-0105, at 14.

not pregnant at all, much less pregnant with a male fetus during the critical developmental window. [19]

Third, it is also important to recall that the CHAP's potency estimates all incorporate at least a 100-fold margin of safety. That is, a Hazard Index of 1 actually means that if a developing male fetus were exposed to its mother's cumulative phthalate intake during the critical developmental window, it would be exposed to only 1/100 of the amount necessary to produce arguably adverse effects in rats. Moreover, there is evidence in the rulemaking record demonstrating that humans and other primates are less sensitive to these adverse effects than rats.[20]

When all of these factors are taken into account, it is apparent that the updated cumulative risk assessment fundamentally changes the risk picture. The risks to women are not only below the threshold of concern but also decreasing over time. Of the few individual women whose Hazard Index is above 1, none is pregnant and therefore no male fetus is at risk.

Inadequate Notice. Another objection to the decision reached by the majority is that the Notice of Proposed Rulemaking utterly failed to explain how the Commission would decide whether to make the prohibition of DINP permanent. It not only kept commenters guessing as to which of the three inconsistent sets of potency estimates the Commission might choose, but also it never identified any benchmark that the Commission would regard as sufficiently protective of the vulnerable populations. Certainly there was no hint that a permanent prohibition would be based on a few women with unusually high spot samples who were not even pregnant. This situation might have been avoided had the Commission waited until the later NHANES data were analyzed before formulating its proposal. *See* note 4, *supra*. Alternatively, the Commission might have disclosed some of its thinking when it solicited comments on the staff's two analyses of later NHANES data sets. That didn't happen either. The upshot is that commenters had no opportunity to address the combination of factors that became dispositive of the permanent prohibition issue. Even though the Final Rule reaches the same result as the NPR, its rationale for that result was unpredictable.

Exposures to Infants and Toddlers. In addition to its cumulative risk assessment based on the exposures of pregnant women, the CHAP also made an assessment based on estimated exposures of young children (under 30 months of age). Unfortunately, none of the NHANES data sets

[19] The staff makes reference to the Commission's chronic hazard guidelines, which define the acceptable risk for a reproductive or developmental toxicant as an exposure equal to or less than the acceptable daily intake "for the population affected by the toxicant." BP at 30. The staff analogizes the Hazard Index here to the acceptable daily intake, but the analogy falls apart because the individual women with a Hazard Index above 1 in the latest NHANES data sets are not the true "population affected by the toxicant."

[20] The staff begrudgingly admits that "a few studies suggest that humans may be less sensitive than rodents to phthalate effects." BP at 14. The CHAP discounted these studies for various reasons, but since that time, other studies have addressed the concerns raised by the CHAP and have shown that they proved to be invalid. Comments of ExxonMobil Chemical Company (March 24, 2017), Docket No. CPSC-2014-0033-0140, at 20-24.

contains biomonitoring data on children under 6 years old. The CHAP therefore turned to some very limited biomonitoring data from the Studies for Future Families (SFF).

Unlike the NHANES biomonitoring data, the SFF data are not the result of any national sampling protocol. Thus, they are not even arguably representative of national exposures. The SFF data were collected in 1999-2005 and therefore are even older than the obsolete NHANES data originally used by the CHAP to estimate exposures of pregnant women. Given what we now know about the trends in phthalate exposures from the later NHANES data, I do not see how the outdated SFF data could be used to make any valid regulatory decision in 2017.

The staff states that children's exposures to phthalates are "generally" twice as high as their mothers'. BP at 33. This was true of the average exposures in the outdated SFF data, but those data were not even representative of 1999-2005 exposures, much less the likely levels today. Even back then, the most extreme (99^{th} percentile) exposures from the SFF were lower than those of pregnant women from NHANES. *See* CHAP Report, Appendix D at p. D-9.

As the staff concedes, there is every reason to believe that the exposures of young children in more recent years will have followed the same trends as the exposures of adults. BP at 32. Indeed, if young children get proportionately more of their exposure to phthalates from mouthing toys and child care articles than adults, it stands to reason that the permanent prohibition of DEHP in toys and child care articles by Congress in 2008 would have decreased infants' exposures to that potent phthalate more than it did the exposures of adult women. It is the decrease in DEHP exposure that has so greatly improved the risk picture in the staff's analyses of more recent NHANES data.

The CHAP's cumulative risk assessment using the outdated SFF data is also subject to most of the problems concerning potency and exposure estimates discussed above in connection with its CRA for pregnant women. There is another major problem, however, that is unique to the CRA for infants. As discussed earlier, the anti-androgenic effects of some phthalates in rats are associated with exposures to male fetuses in the window of susceptibility. The same effects do not occur if the exposure comes outside the male programming window. Some phthalates can cause other types of effects in neonatal and juvenile male rats, but only at exposures that are much higher. *See* Comments of ExxonMobil Chemical Company (April 14, 2015), Docket No. CPSC-2014-0033-0086, at pp. 1-32 to 1-33. For that reason, it is arbitrary and capricious to use the same potency estimates in the cumulative risk assessment for infants and toddlers as were used in the CRA for pregnant women (as a surrogate for a male fetus).[21] In short, even apart from the outdated exposure data, the CHAP's cumulative risk assessment for infants and toddlers does not support making the interim prohibition for DINP permanent.

[21] The SFF data used by the CHAP included measurements for both male and female infants. See CHAP Report, App. D at p. D-16. If female infants were included in the CHAP's cumulative risk assessment, as appears to be the case, then using the same potency estimates as apply to male fetuses is even less justified.

The staff expresses concern that if the interim prohibition on DINP is not made permanent, exposure to infants from toys and child care articles could increase to the point where it accounts for up to 29% of their total exposure. BP at 35. That this worst-case assumption would actually materialize, however, is pure speculation. After nine years of using substitutes, it is unlikely that many manufacturers will switch back to DINP at this point. It is also quite possible that infants' (and others') exposure to DEHP will continue to decrease sharply in the future if FDA disallows its use in food contact materials, as it was petitioned last year to do. *See* Docket FDA-2016-F-1253. This would further lower the cumulative risk of phthalates because food, not toys, is the dominant source of exposure.

In my view, it is not appropriate to ban a substance based on the mere possibility that exposures could change for the worse in the future. If exposures actually increase to a significant extent in the future or if new studies suggest a greater risk from DINP than is currently known, then the Commission can take action at that time.

B. Reasonable Certainty of No Harm

The legal standard for making the interim prohibition permanent is not an absolute certainty of no harm, but a reasonable certainty. BP at App. B, p. 131 (staff agrees that "a reasonable certainty of no harm" is not "100% certainty of no harm"). Nevertheless, the Commission majority concludes that the existence of a few women with a Hazard Index above 1 in the 2013-2014 NHANES data would make it legally impossible to lift the interim prohibition of DINP.

I disagree. Here, as in most other regulatory statutes, Congress plainly did not intend to require that all risk be eliminated. Moreover, as discussed above, even the few women with exposures at the 99th percentile level are not themselves at risk. Studies demonstrate that a single high exposure, as measured by a spot sample, is not representative of even 24-hour exposure levels, much less weekly or longer. For harm to occur, these women would not only have to experience prolonged high exposures, but experience them at the same time as they are pregnant with male fetuses during the critical window for development of the reproductive system. Even then, the exposure of any male fetus would be at most 1/100 of the level associated with adverse effects in rats. For infants, both the exposure data and the potency estimates used by the CHAP are unjustifiable.

Under these circumstances, I am quite comfortable in concluding that making the interim prohibition on DINP permanent is not necessary to ensure a reasonable certainty of no harm to vulnerable populations with an adequate margin of safety.

II. EXPANDING THE SCOPE OF THE DINP PROHIBITION

Besides making the interim prohibition of DINP permanent, the Commission majority also voted to expand the scope of that prohibition to a broader class of toys. While the interim prohibition

applied only to "any children's toys that can be placed in the mouth," 15 U.S.C. § 2057c(b)(1), the Commission's action extends the permanent prohibition to all children's toys.

CPSIA section 108 does not clearly authorize this expansion. The legal standard for making the interim prohibition permanent does not apply. Instead, the staff applied the legal standard for regulating other phthalates, namely that such action is "necessary to protect children's health." 15 U.S.C. § 2057c(b)(3)(B).

The staff's rationale for expanding the scope of the prohibition amounts to nothing more than an observation that a child's exposure can also result from handling or licking toys without placing them in the mouth. BP at 19. This is a weak reed indeed. The staff makes no attempt to quantify what additional exposure might reasonably be expected to occur through these pathways. The expansion is not even limited to toys that are intended for children under 30 months (the focus of the CHAP's risk assessment) or under 4 years of age (the age applicable to "child care articles" under CPSIA section 108).

I note that analysis of the recent NHANES biomonitoring data for children between the ages of 6 and 11 (the youngest who are included in the survey) shows the same trends as are apparent for women of reproductive age. *See* Comments of ExxonMobil Chemical Company (Aug. 6, 2015), CPSC Docket No. 2014-0033-0105, at 15 and Appendix B. In fact, the 95th percentile exposures for children 6-11 are similar to or below the exposures for women of reproductive age during the same time frame. *Compare id.* at App. B, p. B-2 *with id.* at App. B, p, B-4. It seems clear that these children are not getting a disproportionate amount of DINP exposure from toys. It is therefore difficult to understand why infants would get substantially greater exposure from the toys marketed for older children.

As discussed above, the record contains no evidence that infants are at risk from current exposures (or even the outdated exposures) any more than women are. The NHANES biomonitoring data for older children show similar changes in exposure that result in lower risk. Therefore, I see no basis for the conclusion that expanding the scope of the DINP prohibition is "necessary to protect children's health."

CONCLUSION

The Commission's decision to make permanent the interim prohibition on DINP rests on cumulative risk analyses that employ outdated exposure data, invalid assumptions about current exposures, unjustifiably conservative potency estimates and a precautionary interpretation of the law that goes well beyond what Congress intended. The Commission should have lifted the interim prohibition on the use of DINP as it did for DIDP and DnOP. The extension of the DINP prohibition to a larger class of toys is even less warranted.

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STATEMENT OF COMMISSIONER ELLIOT F. KAYE ON THE APPROVAL OF A FINAL RULE PROHIBITING CHILDREN'S TOYS AND CHILD CARE ARTICLES CONTAINING SPECIFIED PHTHALATES

October 18, 2017

I am pleased that today the Commission voted 3—2 to issue a final rule prohibiting children's toys and child care articles containing certain harmful chemicals. One would think that no society would ever tolerate a system where its citizens – especially its youngest children – are used as guinea pigs to determine if they are being poisoned every day by chemicals in their food, their homes and their household products. But that is exactly how it works in our country when it comes to chemical management.

Our public policy in this area consists of all of us, especially our children, blindly being exposed each day to scores of chemicals, both individually but more often in combinations, and without any certainty that these chemicals are not causing cancer in adults, are not preventing women from having children, and are not causing children to suffer intellectual and developmental delays.

And the effects are not just felt on an individual basis. Credible concerns have been raised that some violent behavior and its effects on and costs to society might in part be caused from exposure to certain chemicals that impair the brain. The prevalence of chemical exposures is believed to be at least partially responsible for the explosion of certain chronic diseases and adverse health effects across society. The impacts on our bodies and our health care system are far from insignificant.

In an exceedingly rare and overwhelming bipartisan way, Congress stepped into this sad state of affairs in 2008. Congress directed our agency, the Consumer Product Safety Commission, to convene a panel of the world's top scientists, to study phthalates as a group of chemicals of very high concern and directed us to act

based on the panel's findings as necessary to protect us all, especially the most vulnerable among us. Phthalates are ubiquitous in our society because they are mostly used to soften plastic.

The science around these chemicals had matured to the point where Congress felt compelled to outright ban three of them immediately, place an interim ban on three more and charge us with studying and acting on those phthalates and phthalate alternatives that harm the public.

There were at least three strong health protective provisions in the related section of the law Congress passed. First, the scientific panel was charged to look not only at the impact of chemicals in isolation, but also as mixtures through a cumulative risk assessment. This direction made sense, since we are all exposed in real time not just to a single chemical but actually to cocktails of them. Second, Congress said we should draw the safety line in a place where we felt there was "a reasonable certainly of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety." In other words, Congress clearly instructed us to err on the side of being extremely health protective, especially when it comes to the most vulnerable among us. Third, Congress sought to avoid what is called "regrettable substitution" by having the panel of scientists consider phthalates and phthalate alternatives, with the hope that any resulting regulatory action would not just take away one harmful chemical to have it replaced by another.

Nine years later, we are finally fulfilling the Congressional vision toward a saner, more rational and, certainly, more health-protective system, at least with respect to this one type of chemical. After all the strong and compelling scientific work put into it, our decision today should have come with unanimous support. Sadly it did not.

I find that all the more curious because no one among us is immune to the effects of these chemicals. We all have families and friends that we would do anything to protect. Except, it seems, when it comes to chemicals. Even when Congress spoke so clearly about the need to protect infants, children, pregnant women and the rest of us. There was inexplicable opposition here at the Commission and there will very likely be judicial review down the line.

I would like to speak to that issue. More specifically, I would like to speak to the judges and law clerks who may look over this record and make a final determination. First, please see how specific Congress was in the statute with its charge, how highly protective of the health and safety of vulnerable populations in a

preventative way the standard it established is, and how that differs from our other statutes in a meaningful way.

Second, please note the fidelity with which the panel of independent scientific experts, the CHAP, followed Congressional and Commission direction, how thorough the CHAP was and how its methods and conclusions were validated by a substantial peer review.

Next, please observe how carefully the Commission and its staff reviewed the scientific report, as well as the public comments at each stage of the rulemaking and how this effort and the analysis included the latest and most credible and relevant scientific data available.

And finally, please look to the actual science and the way the CHAP and the Commission relied on that science and valid scientific methodologies to address points raised at each step of the process. Some of those points were valid; some appear less so. Regardless, each was addressed with great care and broad support throughout the rulemaking record.

I want to express my gratitude to our expert staff for their tremendous work on this rulemaking, as well as all of the independent scientific experts who served on the CHAP, and all those stakeholders who took the time to provide comments throughout this rulemaking process.

This safety effort was years in the making and the result serves the public health very well. The result is also 100 percent consistent with the direction from Congress. The only policy limitation is that the process unfortunately addresses just a part of one group of chemicals. That is due to the lack of investment in the science necessary to find answers sooner. Meanwhile, we still allow ourselves, our families and our friends to be poisoned each day by numerous other chemicals before we slowly act.

None of us is well-served by such a system, and we all are paying for it one way or another. Even though the Commission has just approved this rule, today was sadly not the day for us to all join together for a safer and better world for our children. Hopefully, tomorrow will be.

Statement of Commissioner Joseph P. Mohorovic on the Commission's Final Rule Prohibiting Children's Toys and Child Care Articles Containing Specified Phthalates

October 18, 2017

Today the U.S. Consumer Product Safety Commission voted to issue a Final Rule prohibiting children's toys and child care articles containing certain phthalates. I was unable to join in this decision because the Final Rule is contrary to the most recent and best available scientific data.

The Final Rule Does Not Follow the Data

One of my colleagues commented that the Commission's regulation of phthalates should "follow the data." I agree. However, it is clear from today's decision that the Commission willfully ignored the data to justify its predetermined decision to approve the Final Rule. I regret that today's vote was a missed opportunity to pass a reasoned, evidence-based rule prohibiting the phthalates that pose actual risk to consumers.

The Consumer Product Safety Improvement Act ("CPSIA") banned certain phthalates known to be potentially harmful to consumers (namely, DEHP, DBP, and BBP). The Commission was charged with deciding whether to permanently ban additional phthalates based upon studies conducted by the Chronic Hazard Advisory Panel ("CHAP"). The CHAP was required to "review all relevant data, including the most recent, best-available, peer-reviewed, scientific studies" of the specified phthalates.[1] The Commission's final determination was to be based upon the standard of "a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety."[2]

However, the "reasonable certainty of no harm" test has been inconsistently applied by the Commission throughout this rulemaking process—from the proposed rule, to the evaluation of phthalates in isolation and in combination with other phthalates, and in the Final Rule. The Notice of Proposed Rulemaking ("NPR") was based upon the cumulative risk assessment conducted by the CHAP, which found that up to 10% of pregnant women in the U.S. population and up to 5% of infants had a Hazard Index ("HI") greater than one and, therefore, may be at risk for the adverse effects of phthalate exposure. Based upon the CHAP's findings, the Commission proposed rulemaking prohibiting certain phthalates because this portion of the population at risk of adverse effects did not meet the standard of a reasonable certainty of no harm with an adequate margin of safety.[3]

The CHAP's findings, however, were based upon data from 2005, which predated the CPSIA's permanent and temporary bans on certain phthalates. Since that time, exposure to DEHP, the most potent phthalate, has markedly decreased while exposure to the much less potent DINP has increased. Because of this, the most recent biomonitoring data shows that the cumulative risk of

[1] 15 U.S.C. 2057c(b)(2)(B)(v).
[2] *Id.* (b)(3)(A).
[3] 79 FR 78322.

adverse effects from phthalate exposure has decreased to such a statistically insignificant amount that it cannot even be calculated with certainty.[4] Specifically, an HI greater than one only was detected in the 99th percentile of the most recent data set, which staff characterized as "statistically unstable," and warned that "one should use caution when drawing conclusions" about these estimates. The Commission even acknowledges in the Final Rule that the agency is unable to make any reliable estimate of the precise number of women of a reproductive age with HIs greater than one in the general population. [5]

Simply put, this Commission cannot say with confidence that *any* of the general population is exposed to an unacceptable level of risk. This is shaky footing for rulemaking.

Additionally, there is also scant evidence showing that the products covered by the Final Rule—toys and child care articles—contribute in any measurable way to overall phthalate exposure for the vulnerable population. It is undisputed that dietary sources contribute the most to overall phthalate exposure. The agency has been unable to rebut the point made by many commenters that toys and child care articles contribute very little to exposure. Although the Final Rule hypothesizes that 29% of infant exposure to DINP could come from toys and child care articles, it also notes that it is impossible to quantify the number of these products that would contain DINP if the ban was lifted or the effect on overall risk.[6] Moreover, the basis for banning DINP in the Final Rule is, in part, the risk to women of a reproductive age, and there simply is no evidence that children's toys and child care articles present a significant exposure risk to this population.

In sum, the evidence shows that DINP is known to be less potent, exposure to the vulnerable population is uncertain, and the cumulative risk assessment has dwindled to levels that cannot be stated with any degree of confidence or scientific certainty. For these reasons, I find that the Final Rule does not meet the "reasonable certainty"—or even the straight face—test.

The Commission Failed to Provide Proper Notice and Comment

I furthermore oppose the Final Rule because it is in no way a logical outgrowth of the proposed rule. It differs so significantly from the proposed rule in the fundamental basis, scientific rationale, and technical justification that I could not have seen this coming, nor could anyone else really, in looking at the NPR and the Final Rule.

After all, in the NPR, the Commission gave every impression that the agency would determine "reasonable certainty of no harm" and "necessary to protect the health of children" based upon the finding that 10% and 5% of the vulnerable populations (pregnant women and infants,

[4] *See* CPSC Report, "Estimated Phthalate Exposure and Risk to Women of Reproductive Age as Assessed Using 2013/2014 NHANES Biomonitoring Data" (Feb. 2017).
[5] Final Rule at 89.
[6] *Id.* at 73.

respectively) demonstrated unacceptable risk. There was no notice, comment, or reason to expect that staff would make recommendations based upon regulating at the 99th percentile.

Now that the bottom has fallen out of the findings on which the NPR was based, the agency has merely moved the goal posts. The end result is a Final Rule that lacks any rational connection to the underlying factual findings. This is very definition of arbitrary and capricious rulemaking and, accordingly, I could not vote in favor of the Final Rule.