

ExxonMobil Chemical Company  
22777 Springwoods Village Parkway  
Spring, Texas 77389  
832-625-4062 Telephone

Elissa Sterry  
Vice President  
Intermediates



August 28, 2015

Chairman Elliot Kaye (via email: [EKaye@cpsc.gov](mailto:EKaye@cpsc.gov))  
U.S. Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, Maryland 20814

Dear Chairman Kaye,

It was a pleasure to have you visit our research facility and visit with ExxonMobil Biomedical Sciences Management in Clinton, New Jersey. We appreciated the opportunity to share views on chemicals management and product safety, and we hope you found the meeting useful, as we certainly did. During our meeting on June 19, we identified several areas for follow-up and I wanted to advise you of our progress over the past couple of months.

First, you asked us to meet with your legal staff to discuss our view of the CPSC's obligations to accept the CHAP recommendations outright and legal considerations around rulemaking. We had constructive discussions with the CPSC General Counsel on July 24 and with the other Commissioners and/or their staff on July 31.

In summary, we highlighted that in our view the CPSIA does not bind the CPSC to adopt the CHAP's recommendations, if, under scrutiny, they are not warranted. Contrary to some media representations, we of course did not state that the Commission cannot follow the CHAP recommendations as a general principle. However, under APA 553, the CPSC must disregard the CHAP report if it is based on incorrect or outdated data. When read in the full statutory context, CPSIA Section 108(b)(3)(A) provides legal latitude for the Commission to use its best judgment during the rulemaking process with the CHAP acting solely in an advisory capacity.

We also noted that the CPSIA does not mandate a quantitative cumulative risk assessment, but, if CPSC exercises its discretion to consider such an analysis, the question is whether the Commission can have a reasonable certainty of no harm if the interim ban is lifted. As expected, the scientific evidence gives a strong "yes" response consistent with a long history of review and analysis by multiple authoritative organizations. A last point is that by using NHANES data, the CPSC has adequately addressed potential misuse of products containing phthalates – an issue we also touched on with you while in New Jersey.

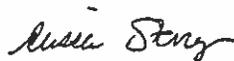
Shortly after your visit, the CPSC's re-analysis of the CHAP cumulative risk analysis using the most up-to-date data was made public. Overall we appreciate the Commission directing the science staff to update the CHAP's assessment with more current data and commend the staff for their work on the re-analysis. Their analysis confirms that the cumulative risk hazard indices for selected phthalates (including DINP) are less than one. The analysis also shows that the cumulative risk from identified phthalates has significantly declined since the 2006 data due to a reduction in the use of DEHP. We noted that the CHAP's "Case 2" which was carried forward in the staff analysis, is scientifically invalid as it assumes a theoretical basis for DINP potency whereas Cases 1 and 3 utilize actual data. There is no reason to make assumptions where real data exist.

Importantly, Table 7 of the report can give the impression that individuals with results above the 95<sup>th</sup> percentile are at risk and that this translates to a meaningful portion of the population also being placed at risk. This is simply not a correct conclusion. The NHANES dataset utilizes spot samples which can "spike" in a single instance but cannot be assumed to be representative of chronic exposures.

The handouts we used with the other Commissioners and staff to discuss these points are attached for your reference. We appreciate your willingness to consider these important issues, and we are happy to provide any additional information that would assist the CPSC as you progress the rulemaking process.

If you have any questions, please do not hesitate to contact me at 832-625-4062.

Sincerely,



EPS:nat  
Attachments

c – w/attachments:  
Jana Fong-Swamidoss  
Julia Richardson  
Jonathan Midgett  
Stephen McGoogan

## CPSC CHAP Reanalysis Review

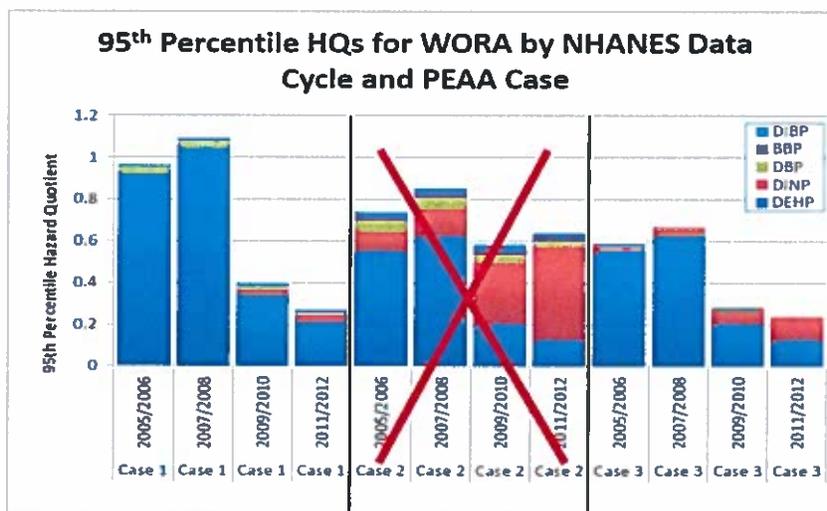
July 2015

- **The CPSC Scientific Staff analysis of the most recent NHANES data confirms that the cumulative risk hazard indices for selected phthalates (including DINP) are <1.** Last month, the CPSC published a Notice in the *Federal Register* of their analysis of the latest CDC NHANES data sets that had not been analyzed in the CHAP report released last year. This new analysis completed by the CPSC scientific staff is critical to ensuring that the appropriate and most current data sets are reviewed and made available to the public for comment and consideration prior to the final promulgation of the phthalate and phthalate alternatives rulemaking.

The CHAP found no unacceptable risk posed by DINP itself, but recommended that DINP be prohibited in children's products, because it could contribute to a cumulative risk Hazard Index calculated by the CHAP, using older data, to exceed a value of 1. The CPSC Scientific staff reanalysis shows that in all three cases originally examined by the CHAP and reexamined by the Agency using the most recent data, cumulative exposure to the phthalates identified is within safe limits. **All scenarios fall below the level of concern for recommending a ban (Hazard Index <1), based on assessment of exposure at the 95<sup>th</sup> percentile of cumulative risk exposure.**

- **"Case 2" is scientifically invalid.** The reanalysis includes results using the CHAP's "Case 2" model. Those results should be completely disregarded, because Case 2 used a model to derive the hazard value for DINP. But no modeling was necessary because actual data are available and were used for Cases 1 and 3. It would be scientifically incorrect to use modeled data where actual data are available.
- **Cumulative risk from identified phthalates has significantly declined since the initial NHANES data set due to reduced use of DEHP.** The new analysis shows that total cumulative risk of exposure to phthalates has reduced significantly over the span of the NHANES surveys, largely due to decreased use of DEHP, which contributed the most risk to the overall hazard index. In each of the three exposure cases evaluated by the CHAP, and more recently by the agency, DINP was noted to be less potent than DEHP. This demonstrates that while DINP has largely taken the place of DEHP in the marketplace, its proportion of the contribution to the Hazard Index is far lower than what DEHP contributed.

Figure 7: 95<sup>th</sup> Percentile HQs for Women of Reproductive Age by NHANES Data Cycle and PEA Case



\*95th percentile HQ estimates for DIBP in 2005/2006, DBP in 2009/2010, and DEHP in 2009/2010 have large variances. Estimates are not considered stable.

- **The CPSC should not use anything above the 95<sup>th</sup> percentile data to inform their rulemaking.** Use of the 95<sup>th</sup> percentile in assessing cumulative exposure is generally acknowledged as protective of any highly exposed individuals in the population where, as with the phthalates, the hazard is chronic (that is, repeated exposure over a long period is required to cause adverse effects). For example, when using NHANES data to assess exposures for its additive risk evaluations, FDA uses the 90th percentile to protect "high exposure" consumers over their life time. CPSC itself appropriately did not go above the 95<sup>th</sup> percentile in justifying its proposed rule for phthalates
- **Individuals with results above the 95<sup>th</sup> percentile in the reanalysis are NOT at risk.** This is because the hazard that is the basis for the cumulative risk assessment is a chronic hazard, but the samples used for the exposure data were spot samples taken at a single time point.
  1. One cannot use a single exposure to assess an individual's risk of a chronic hazard because an individual's exposure levels fluctuate day-to-day and hour-to-hour. A single high exposure for a given person does not consistently translate to that person's exposure over time. Thus, one cannot conclude that a woman in the top 5%, based on spot sampling, is at risk of the chronic effect.
  2. To our knowledge, no federal regulatory agency relies on utilizing individual exposure levels to assess a chronic risk, but instead uses the 95% or 90% percentile (versus the median) to capture highly exposed individuals.
- **The recent NHANES data for women of reproductive age are the appropriate data on which to base a determination.** The CPSC staff reanalysis correctly demonstrates that women of reproductive age are a reliable surrogate for pregnant women and that NHANES data for that population are appropriately used because of greater numbers giving greater statistical reliability. The staff reanalysis using the most recent NHANES data is the correct basis for evaluating potential risks from phthalate exposures, using the CHAP cumulative risk methodology.

The CHAP also calculated hazard indices using pregnant women and infant data from the "SFF" study, but these data and results are not appropriate for the Commission to use because:

- The SFF exposure data were collected before the large declines in DEHP use, and a current update for pregnant women (the TIDES study) shows DEHP exposures are now 50% lower. A similar decrease would have occurred in infants; and

Note that, even using the outdated SFF data, all hazard indices at the 95th percentile are less than 1. Any individuals with an HI greater than 1 would not be at risk for the same reasons as discussed above with respect to the NHANES data (spot exposure data, but a chronic hazard).

- In summary, the CPSC decision to rerun the cumulative risk analysis using the most recent phthalate exposure data revealed that cumulative risks have been substantially reduced as compared to risks calculated from the older data set used by the CHAP. The recommendation to continue a ban on those phthalates subject to the interim ban was inappropriately based on their negligible contribution to a cumulative risk. With the newer data, it is even more evident that the interim ban on DINP can be lifted with reasonable certainty of no harm. **Therefore, the new cumulative risk analysis using the most recent exposure data further demonstrates that the proposed regulatory ban should not be adopted in the final rule.**

# Legal Issues Pertaining to CPSC Implementation of CPSIA Section 108(b)(3)

Ann Claassen  
Latham & Watkins LLP  
July 31, 2015

## Section 108(b)(3)

- (3) PERMANENT PROHIBITION BY RULE.—Not later than 180 days after receiving the report of the panel under paragraph (2)(C), the Commission shall, pursuant to section 553 of title 5, United States Code, promulgate a final rule to—
- (A) determine, based on such report, whether to continue in effect the prohibition under paragraph (1), in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety; and
  - (B) evaluate the findings and recommendations of the Chronic Hazard Advisory Panel and declare any children’s product containing any phthalates to be a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057), as the Commission determines necessary to protect the health of children.

## CPSIA Does Not Bind CPSC to Follow the CHAP Recommendations

- Section 108(b)(3)(A) must be read in the full statutory context
- Constitutional, statutory and administrative law principles require CPSC to critically review the CHAP's report and its conclusions and then promulgate its rulemaking
- CPSC has a duty to independently make its determination in light of public comment and current data, even if contrary to the CHAP's recommendations

## “Based on” Does Not Mean “Rigidly Adhere To”

- “Based on” in plain English encompasses many approaches, e.g.
  - foundation
  - starting point
  - consideration of
    - See US English entry for “base” at [OxfordDictionaries.com](https://www.oxforddictionaries.com), Oxford University Press (2015)
- For example, the Reanalysis is based on the CHAP report
  - staff recreated the CHAP’s cumulative risk model
  - plugged current data into that model

## Requiring Rigid Adherence to the CHAP Report Raises Serious Constitutional Issues

- CHAP is an advisory committee of private individuals (not officers or employees of the Federal Government)
- Vesting the “coercive power of government” in a private entity would violate Constitution provisions, including the nondelegation doctrine
  - *Carter v. Carter Coal Co.*, 298 U.S. 238, 311 (1936)
  - *Ass’n of Am. R.R. v. United States DOT*, 721 F.3d 666, 670 (D.C. Cir. 2013), reversed on other grounds by *Department of Transportation v. Association of American Railroads*, \_\_ U.S. \_\_ (2015)
- Such Constitutional concern must be and is avoided because the statute clearly establishes that the CHAP’s role is limited and advisory
  - *Nat’l Fed’s of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2593 (2012) (Roberts, C.J.).

## CPSIA Plain Language Establishes the Limited and Purely Advisory Role of the Phthalate CHAP

- “A” CHAP appointed under CPSA 28
- CHAP operates through the Commission
- CHAP is advisory – makes recommendations but does not implement or enforce them
- The CHAP makes a recommendation; the Commission makes a determination
- CPSIA does not state CPSC must base its determination “solely” or “exclusively” on the CHAP report

*Sierra Club v. EPA* 325 F.3d 374, 377 (D.C. Cir. 2003)

## Under APA 553, CPSC Must Disregard CHAP Report if It Is Based on Incorrect or Outdated Data

- CPSC Must Provide Sufficient Opportunity for Public Comment
  - *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983)
  - If CHAP recommendation must be followed, there is no actual opportunity for public comment
- CPSC Determination Must Not Be Arbitrary and Capricious
  - CPSC cannot fail to examine relevant data
    - *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)
  - CPSC cannot fail to respond meaningfully to the evidence
    - *Mistick PBT v. Chao*, 440 F.3d 503, 512 (D.C. Cir. 2006)

## CPSIA Did Not Mandate that the CHAP Conduct a Cumulative Risk Assessment

- As part of its 108(b)(2)(B) examination, CHAP was to “consider the cumulative effect of total exposure to phthalates.”
- “Consider” does not equate to “conduct a quantitative cumulative risk assessment”
- CHAP was charged to make recommendations on phthalates which should be considered “banned hazardous substances” – FHSA defined term
- FHSA allows ban of mixtures of substances, but not of a single substance based on cumulative effect of the mixture
  - CHAP did not recommend ban of the mixture but of an individual phthalate

## CPSIA Does Not Mandate that CPSC Base Its Determination on a Cumulative Risk Assessment

- Reference to “cumulative effect” is in the charge to CHAP, not the charge to the CPSC
- If CPSC relies on a cumulative risk assessment, the issue for CPSC is whether the results indicate a ban is necessary to ensure a reasonable certainty of no harm

## Reasonable Certainty of No Harm Does Not Mean Zero Risk or 100% Certainty

- If negligible contribution to a cumulative risk were sufficient to maintain ban, the CHAP examination and CPSC determination would be superfluous
  - *TRW, Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (Ginsburg, J.) (quoting *Duncan v. Walker*, 533 U.S. 167, 173 (2001) (O'Connor, J.)).
- The scientific evidence so strongly indicates DINP does not significantly contribute to CRA that continuing the ban would be arbitrary and capricious

## Foreseeable Misuse/Abuse is Accounted for by Use of the NHANES Biomonitoring Data

- NHANES samples carefully designed to be representative of the US population
- Thus they encompass both those who normally use and those who misuse/abuse the products
- By using NHANES data, Commission has considered foreseeable misuse/abuse

Questions?

Thank you

Figure 1: Lifting the interim ban on DINP has no appreciable impact on risk (HI <1)

### Women of reproductive age (15-45)

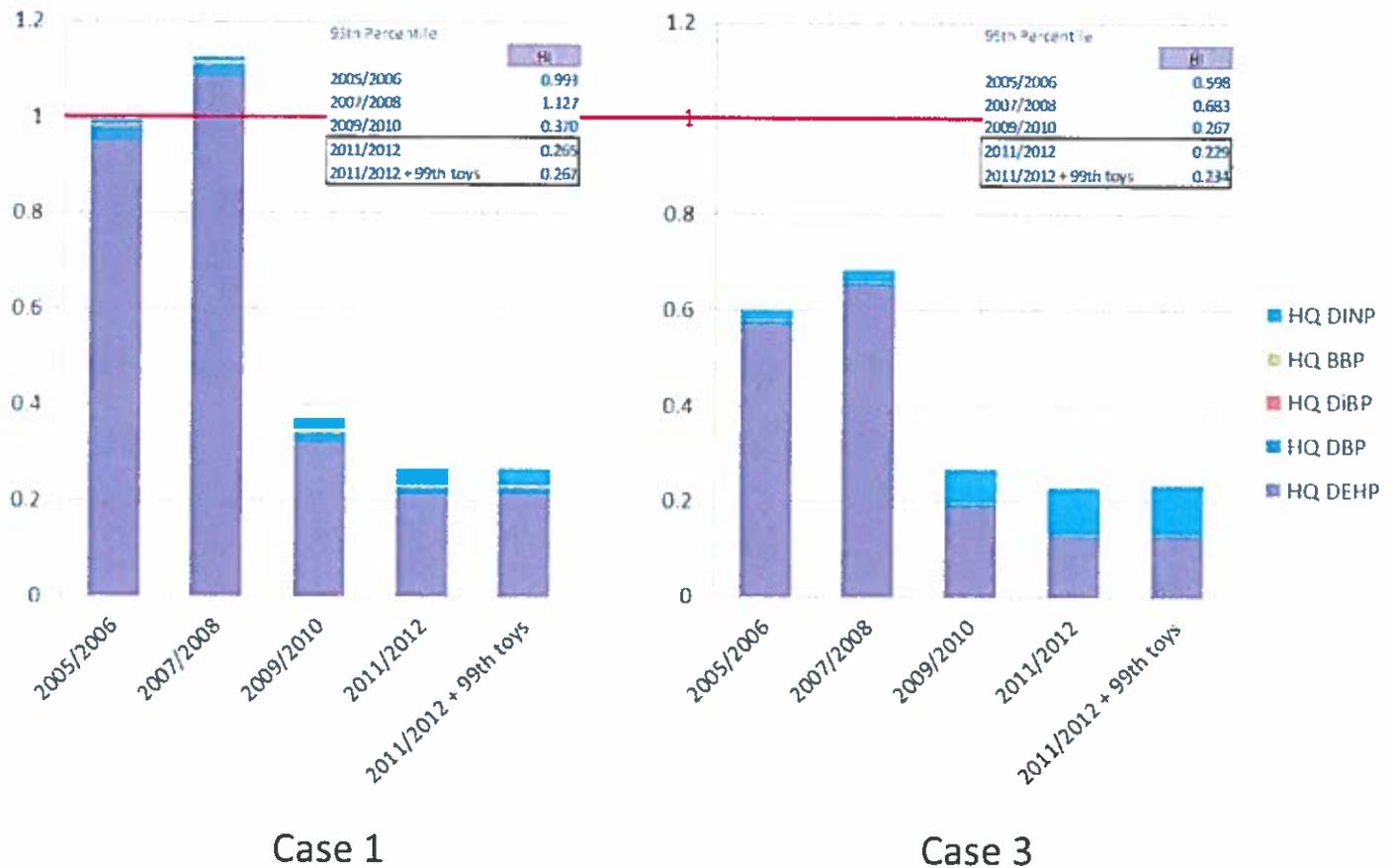


Figure 1: Given the potential reintroduction of DINP into children’s products if the ban is lifted, an analysis was conducted on how this would affect the HI. Previous to the interim ban on DINP, the CPSC staff scientists conducted a “Risk assessment of oral exposure to diisononyl phthalate from children’s products”.<sup>1</sup> As part of the risk assessment the CPSC staff determined that the estimated exposure to DINP for children in the most highly exposed age range was 0.08 ug/kg-d (median) and 2.4 ug/kg-d (99<sup>th</sup> percentile). Using the 99<sup>th</sup> percentile exposure estimate developed by the CPSC staff the impact of the lifting the ban on the HI’s for women of reproductive age was assessed. As can be seen in the graph, and inset, lifting the ban on DINP will have a negligible impact on HI’s for the sensitive subpopulation. Of note, pregnant women are likely to have a lower exposure estimate from toys than children that are actively mouthing soft plastic, which is the population for which the estimate was derived.

<sup>1</sup> Babich, M. A., Chen, S. B., Greene, M. A., Kiss, C. T., Porter, W. K., Smith, T. P., ... & Zamula, W. W. (2004). Risk assessment of oral exposure to diisononyl phthalate from children’s products. *Regulatory Toxicology and Pharmacology*, 40(2), 151-167.

Figure 2: DINP exposure levels may continue to rise, however risk will continue to decrease as DINP replaces more potent phthalates

Women of reproductive age (15-45)

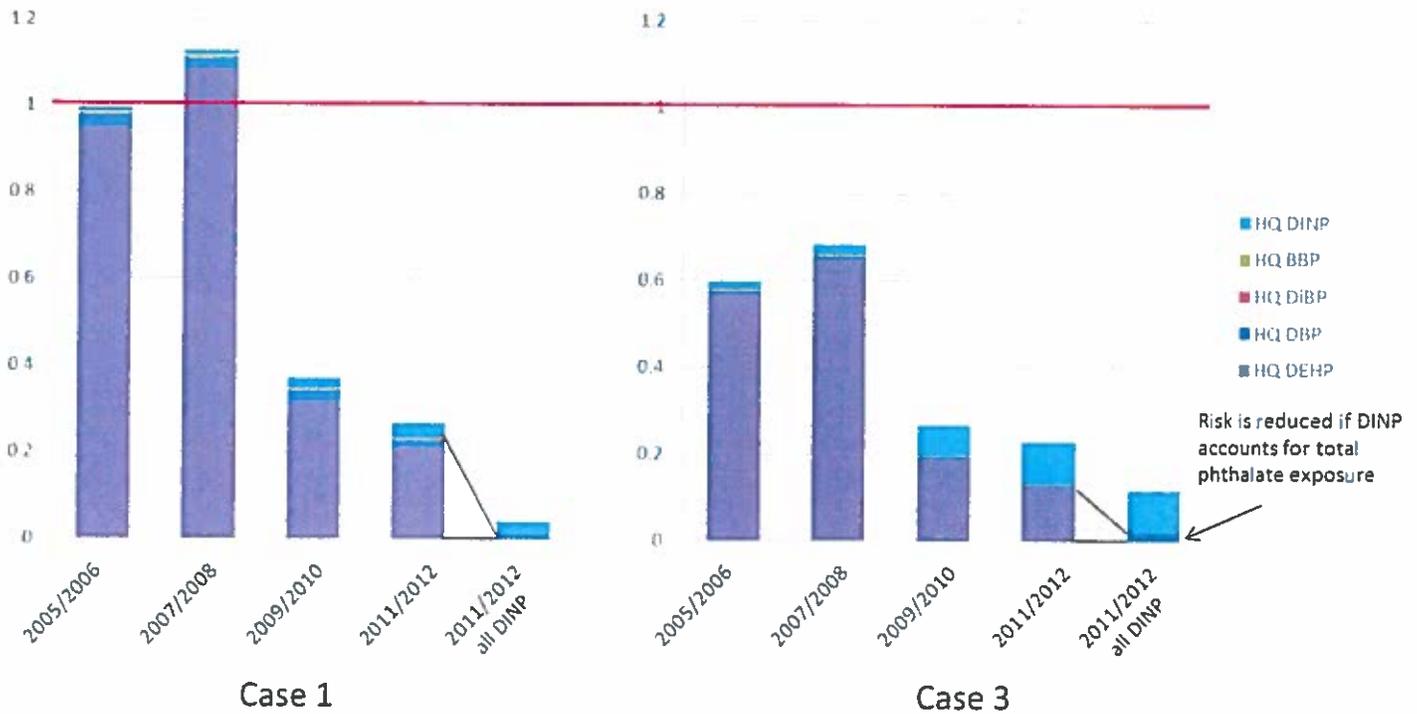
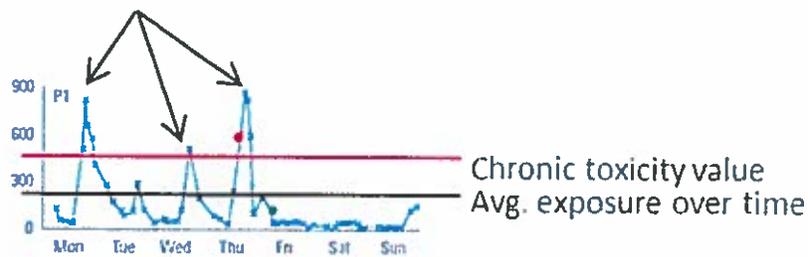


Figure 2: Adaptation of Figure 8 page 2-39 of EMCC's April comments. Hazard Index values, calculated based on the 95<sup>th</sup> percentile urinary metabolite data taken from the NHANES 2005-2006 through NHANES 2011-2012 reports for women of reproductive age (15-45), are shown as bars. The bars labeled with just the date period (e.g., 2005/2006) show the cumulative risk value (HI) for each cycle, with the risk contributions from each phthalate indicated by the different colors. The bars labeled "2011/2012 all DINP" is the effect on the HI of attributing all the exposure from 2011/12 solely to DINP. The lighter turquoise color is the amount of risk attributed from actual DINP exposure, the darker turquoise color (a thin line at the bottom of the bar) is risk of the other phthalates converted to DINP. Thus, increased replacement of phthalates by DINP will lower the cumulative risk yet further than at present.

Figure A-1: Acute exposure should not be compared to a chronic hazard for risk estimation

peak events do not drive designated toxicity



when exposure < toxicity,  $HI < 1$

- spot urine sample from Thursday would give  $HI > 1$
  - spot urine sample from Friday would give  $HI < 1$
- actual  $HI < 1$ , but could not determine from single spot urine sample

Figure A-1: Phthalates are metabolized quickly and exposure levels over the course of a day or a week vary greatly depending upon when a measurement is taken versus when the last exposure occurred. The figure shows an example of an individual's exposure levels to a phthalate over a one week period, based on multiple spot urine samples. As can be seen in the figure, the average exposure over that period can be lower, or higher, than any single measurement. When toxicity is based on chronic exposures, as is the case for the reproductive effects for phthalates in rodents, it is appropriate to compare the toxicity value to the average exposure value over time. When the exposure value is less than the toxicity value a person is deemed not at risk ( $HI < 1$ ).

Figure A-4: NHANES data are a compilation of acute individual exposure measures which, at the 95<sup>th</sup> percentile, will be an overestimate of an individual's exposure over time

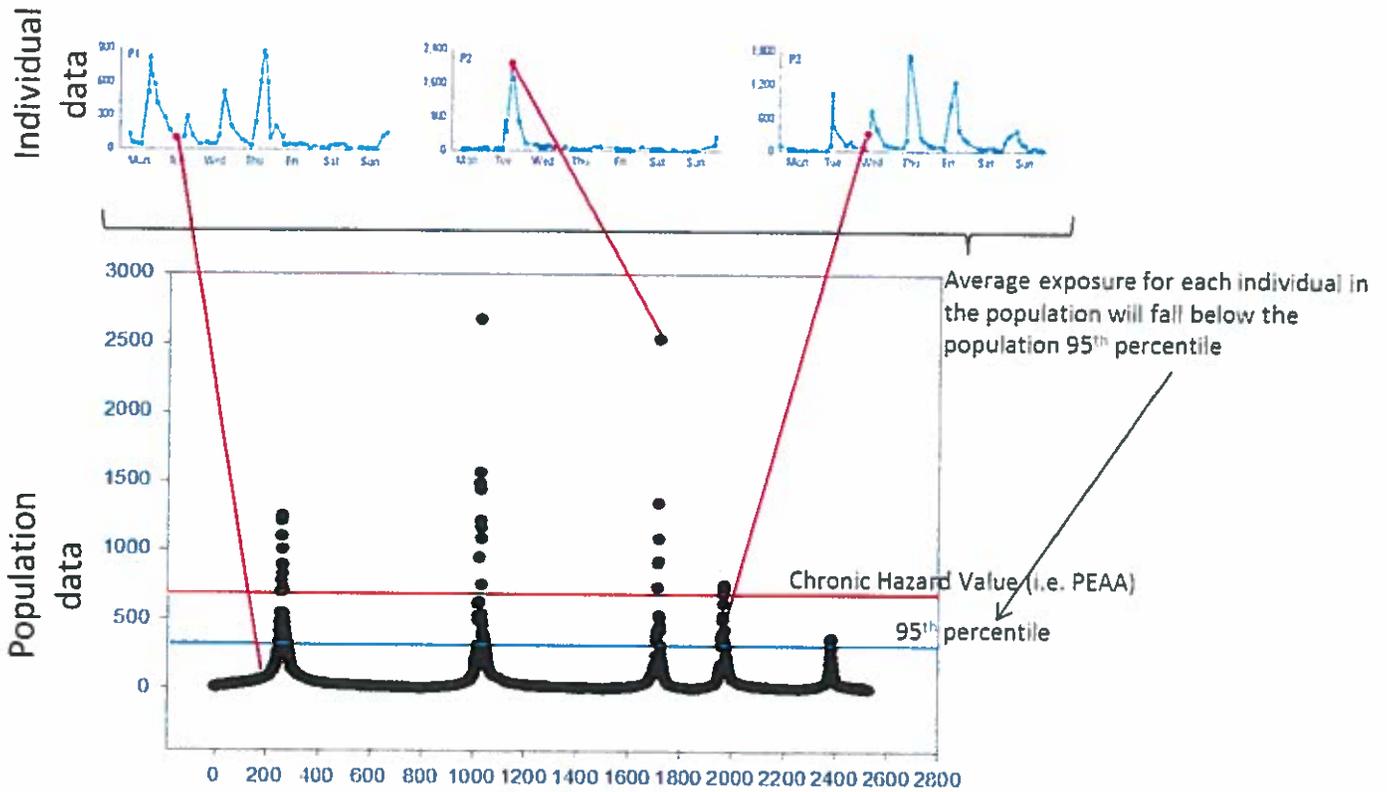


Figure A-4: One can be reasonably certain that a population of individuals that, based on spot urine samples, generates a 95th percentile HI<1 does not contain any individuals within that population with high-enough exposures over time to generate an individual chronic HI>1. A population with individuals that have higher exposures over time would have an increased probability of being sampled when urine levels are high and thus would generate a larger population 95th percentile.