



UNITED STATES  
CONSUMER PRODUCT SAFETY COMMISSION  
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## Memorandum

Date: December 16, 2014

TO : The Commission  
Todd Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel  
Patricia H. Adkins, Executive Director

FROM : George A. Borlase, Ph.D., P.E., Assistant Executive Director  
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SUBJECT : Staff Responses to Questions for the Record from Chairman Kaye about the  
Notice of Proposed Rulemaking (NPR): Prohibition of Children's Toys and  
Child Care Articles Containing Specified Phthalates

This memorandum provides the staff response to the question for the record from Chairman Kaye about the NPR for the Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates.

### Question from Chairman Kaye

*Could you clarify which NHANES datasets were reviewed by the CHAP?*

As explained below, the CHAP based their calculations on the 2005-2006 dataset (this data was revised in 2012). The CHAP also reviewed the 2007-2008 NHANES summary data. In addition to the NHANES data, the CHAP also relied upon data from the Study for Future Families (SFF) for data on infants.

As shown in Figure 1, there have been 4 NHANES data sets between 2005 and 2012. As described on the CDC website<sup>1</sup>, the NHANES data sets are revised, on occasion, due to errors in chemical analyses or errors in the statistical weighting of the NHANES population. The timeline found in Figure 1 updates the timeline provided by Commissioner Buerkle in the hearing on December 5 to show when NHANES data sets were revised. Below, we discuss these NHANES datasets.

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<sup>1</sup> <http://www.cdc.gov/exposurereport/>

*NHANES 2005-2006 Dataset.* The CHAP based their calculations of the hazard index for pregnant women on exposure data in the latest NHANES data that were available at the time of the CHAP's analyses, which is the 2005–2006 data, as revised in February 2012. As explained in the CHAP report (CHAP 2014, p. 35):

“This cycle of NHANES was the most recent version in which phthalate data were available at the time of our analyses. Previous cycles were not combined with the 2005–2006 data due to study design changes associated with fasting requirements.”

The 2005–2006 data were revised by NHANES in February 2012 (CDC 2012a, b). The CHAP revised its analyses to include the revised data (i.e., from the 2012 revision) before completing the draft CHAP report (Figure 1). The 2005-2006 NHANES data set included data on larger numbers of pregnant women than the subsequent NHANES data sets.

*NHANES 2007-2008 Dataset.* As reflected in multiple locations in the CHAP report, the CHAP also reviewed the 2007–2008 NHANES summary data. The CHAP considered and discussed 2007–2008 NHANES summary data for the general population when comparing to the 2005–2006 data set and in relation to concentrations of individual phthalates (CHAP 2014, pp. 39, 42, 74, 75, 87, 98, 111). The 2007–2008 NHANES data first became available in October 2010, but were revised in September 2011 and January 2012.

*NHANES 2009-2010 Dataset.* NHANES data for 2009–2010 became available in September 2012. These data became available after the analysis was completed. Thus, the CHAP did not review the 2009-2010 dataset.

*NHANES 2011-2012 Dataset.* The 2011–2012 NHANES data were available in July 2014, then withdrawn August 2014. The revised 2011–2012 NHANES data were available in October 2014.

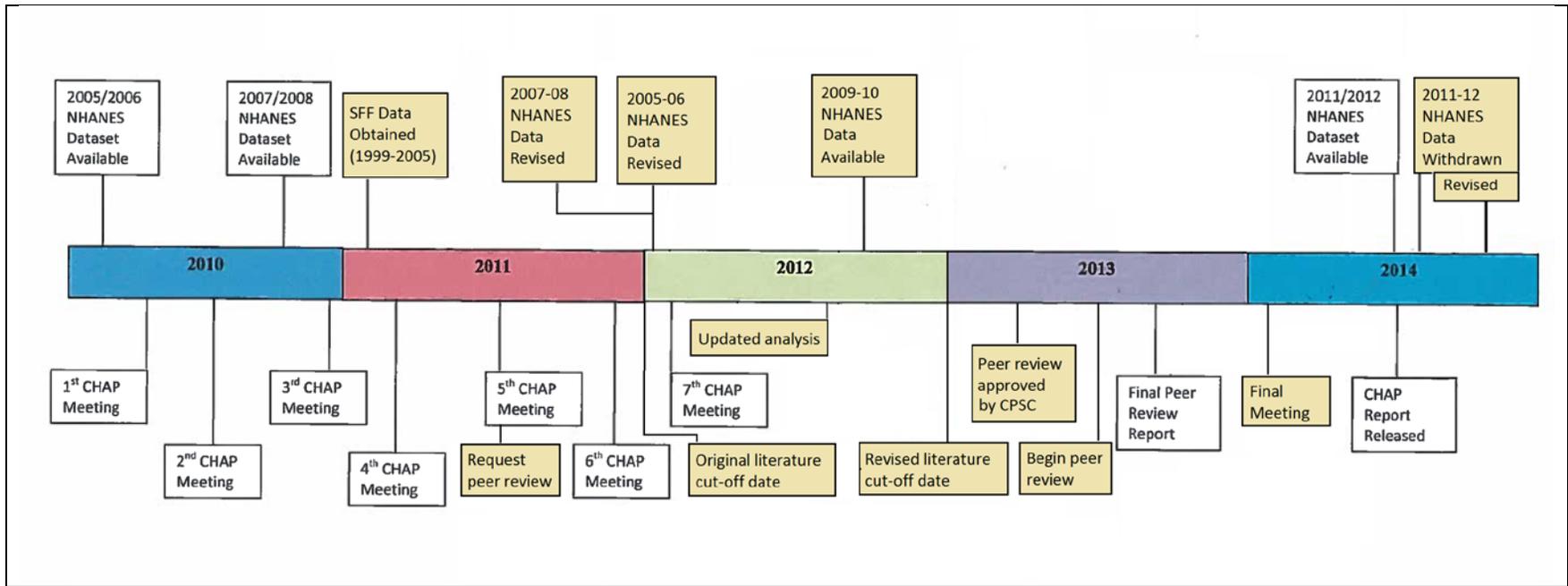
*SFF Data.* NHANES does not include data on children younger than age 6 years old. Therefore, the CHAP used additional data from the Study for Future Families (SFF) to obtain data on infants. This study covers the time period 1999–2005. The SFF is a study of infant-mother pairs. Mothers were tested both during and after pregnancy. To staff's knowledge, there is no plan to update this study. Even if the hazard index for pregnant women was recalculated based on new NHANES exposure data, the risk estimates for infants and their mothers would remain the same because the SFF data is separate from the NHANES data. Using the SFF data, the CHAP estimated that up to five percent of pregnant women and infants had a hazard index greater than one.

## References

CDC, 2012a. Fourth National Report on Human Exposure to Environmental Chemicals. Updated Tables, February 2012. Centers for Disease Control and Prevention. Atlanta, GA.

CDC, 2012b. National Health and Nutrition Examination Survey Data, National Center for Health Statistics. Department of Health and Human Services. Hyattsville, MD.

CHAP, 2014. Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives. U.S. Consumer Product Safety Commission, Bethesda, MD. July 2014. <http://www.cpsc.gov/chap>.



**Figure 1.** Revised timeline showing availability of NHANES and SFF data above the line and CHAP activities below the line. New information is highlighted in gold.