

UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION 4330 EAST WEST HIGHWAY BETHESDA, MD 20814 This documents

This document has been electronically approved and signed.

DATE: February 10, 2017

BALLOT VOTE SHEET

- TO: The Commission Todd A. Stevenson, Secretary
- **THROUGH:** Patricia H. Adkins, Executive Director Mary T. Boyle, General Counsel
- **FROM:** Patricia M. Pollitzer, Assistant General Counsel David M. DiMatteo, Attorney, OGC
- **SUBJECT:** Draft Notice of Availability: Staff document, "Estimated Phthalate Exposure and Risk to Women of Reproductive Age as Assessed Using 2013/2014 NHANES Biomonitoring Data"

BALLOT VOTE DUE: Thursday, February 16, 2017

Commission staff is forwarding to the Commission a draft notice of availability (NOA) for the CPSC staff document, "Estimated Phthalate Exposure and Risk to Women of Reproductive Age as Assessed Using 2013/2014 NHANES Biomonitoring Data," for the Commission's approval. The draft *Federal Register* notice will announce the availability of the staff memorandum and will ask for public comment on the memorandum.

Please indicate your vote on the following options:

I. Approve publication of the attached NOA in the *Federal Register*, as drafted.

(Signature)

(Date)

CPSC Hotline: 1-800-638-CPSC(2772) ★ CPSC's Web Site: <u>http://www.cpsc.gov</u>

Biomonitoring Data"

(Signature)	(Date)
Do not approve publication of the attache	ed NOA in the Federal Register.
(Signature)	(Date)
Take other action. (Please specify.)	

Approve publication of the attached NOA in the *Federal Register*, with changes. II. (Please

[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

Notice of Availability: Estimated Phthalate Exposure and Risk to Women of Reproductive Age as Assessed Using 2013/2014 NHANES Biomonitoring Data [Docket No. CPSC- 2014-0033]

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of availability.

SUMMARY: The Consumer Product Safety Commission (Commission, or CPSC) is announcing the availability of a document titled, "Estimated Phthalate Exposure and Risk to Women of Reproductive Age as Assessed Using 2013/2014 NHANES Biomonitoring Data."

DATES: Submit comments by [Insert date 30 days after publication in the *Federal Register*].

ADDRESSES: You may submit comments, identified by Docket No. CPSC- 2014-0033, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <u>http://www.regulations.gov</u>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (e-mail), except through <u>www.regulations.gov</u>. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923. *Instructions*: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: http://www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: <u>http://www.regulations.gov</u>, and insert the docket number CPSC- 2014-0033, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Kent R. Carlson, Ph.D., Toxicologist, Division of Toxicology & Risk Assessment, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850–3213; email: <u>kcarlson@cpsc.gov</u>.

SUPPLEMENTARY INFORMATION: Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) required the Commission to appoint a Chronic Hazard Advisory Panel (CHAP) to study the effects on children's health of phthalates and phthalate alternatives in children's toys and child care articles. Pub. L. 110-314, Section 108(b)(2)(A). The CHAP report is available at:

http://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf.

The CPSIA also required that the CHAP issue a report to the Commission and that the Commission conduct rulemaking based on the CHAP report. *Id.* Section 108(b)(2)(C);

108(b)(3). On December 30, 2014, the Commission issued a notice of proposed rulemaking (NPR) that would prohibit children's toys and child care articles containing specified phthalates. 79 FR 78324 (December 30, 2014).

The CHAP assessed human exposure to phthalates, in part, through human biomonitoring analysis. Among the data sources the CHAP considered were data from the National Human Health and Nutrition Survey (NHANES). *See* 79 FR at 78327. Specifically, the CHAP used biomonitoring data from the 2005/2006 NHANES data set.

In June 2015, CPSC staff released a document, "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)."¹ The June 2015 analysis reviewed the 2005/2006 NHANES data set to replicate the CHAP's methodology and reviewed the subsequent NHANES data sets from 2007/2008, 2009/2010, 2011/2012). On June 23, 2015, the Commission published a notice of availability (NOA) in the *Federal Register* requesting public comment on the June 2015 staff analysis document. 80 FR 35938 (June 23, 2015).

Since the June 2015 staff analysis, the Centers for Disease Control released the NHANES 2013/14 data set. In response to the release of the NHANES 2013/14 data set, CPSC staff has prepared a document reflecting the staff's analysis of the NHANES 2013/2014 data set: "Estimated Phthalate Exposure and Risk to Women of Reproductive Age as Assessed Using 2013/2014 NHANES Biomonitoring Data." The document is available on the Commission's website at: [INSERT LINK FOR MEMORANDUM

¹ The 2015 staff report is available at <u>http://www.cpsc.gov/Global/Regulations-Laws-and-</u> Standards/CPSIA/CHAP/NHANES-Biomonitoring-analysis-for-Commission.pdf.

HERE] and from the Commission's Office of the Secretary at the location listed in the **ADDRESSES** section of this notice.

The Commission invites comment on the document, "Estimated Phthalate Exposure and Risk to Women of Reproductive Age as Assessed Using 2013/2014 NHANES Biomonitoring Data." Comments should be submitted by [Insert date 30 days after publication in the *Federal Register*]. Information on how to submit comments can be found in the **ADDRESSES** section of this notice.

Dated:

Todd A. Stevenson, Secretary Consumer Product Safety Commission