UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Ballot Vote Sheet

CPSC/OFFICE OF THE SECRETARY

'99 JUL 19 P 12

Date: July 19, 1999

TO : The Commission
Sadye E. Dunn, Secretary

FROM : Jeffrey S. Bromme, General Counsel
Stephen Lemberg, Asst. General Counsel
Harleigh Ewell, Attorney, GCRA (ext. 2217) HE

SUBJECT : Federal Register Notice Inviting Comments on Mouthing Behavior Study

BALLOT VOTE DUE: JUL 22, 1999.

The staff plans to study the mouthing behaviors of children. These behaviors are relevant to the degree to which children are exposed to DINP, or other potentially harmful substances, in objects that children place in their mouths. This study involves a "collection of information" under the Paperwork Reduction Act (PRA) and, at least initially, is subject to approval by the Office of Management and Budget (OMB). 44 U.S.C. §§ 3501-3520. The staff has prepared a request to OMB for approval of this collection of information.

As required by the PRA, the Commission previously provided a 60-day opportunity for comment on the proposed study. 64 Fed. Reg. 13,854 (March 22, 1999). The Commission received one comment in response to that notice, from the Toy Manufacturers of America, Inc. The staff's discussion of the issues raised by that comment are discussed in section A.8.a of the request to OMB for approval, which is attached at Tab A.

The PRA further requires the Commission to announce in the Federal Register a 30-day opportunity to comment on the proposed study when the Commission submits its request for approval to OMB. The draft notice at Tab B describes the study and would announce the 30-day opportunity for comment.

Please indicate your vote on the following options.

NOTE: This document has not been reviewed or accepted by the Commission.
Initial _____ **Date** 7/19/99

CPSA 6 (b)(1) Cleared
No Mfrs/PrvtLblrs 7/19/99
Products Identified
Excepted by
Firms Notified,
Comments Processed.

I. PUBLISH THE DRAFT FEDERAL REGISTER NOTICE AT TAB B WITHOUT CHANGE.

_____ _____
(Signature) (Date)

II. PUBLISH THE DRAFT FEDERAL REGISTER NOTICE AT TAB B WITH CHANGES (please specify).

_____ _____
(Signature) (Date)

III. DO NOT PUBLISH THE FEDERAL REGISTER NOTICE.

_____ _____
(Signature) (Date)

Attachment

Comments/Instructions:

TAB A

A.7. Inconsistencies with the 5 CFR 1320.6 guidelines.

The procedures proposed for this data collection activity are in accordance with the guidelines established in 5 CFR 1320.6. No circumstances require deviation from these guidelines.

A.8. Federal Register Notice, summary of public comments received, and, response to comments, and expert consultation.

A.8.a Federal Register Notice

A copy of the Federal Register Notice is provided in Appendix C. The notice appeared in the Federal Register 64:11, March 11, 1999 Pages 12153-12154. The comment period was originally posted with a closing date of June 9, 1999; however, this was incorrect. The corrected closing date of May 9, 1999, was posted in the FR on 3/22/99. CPSC received comments from one trade association; they are attached in their entirety in Appendix D. The comments are summarized below, followed by a summary of the CPSC staff response. The CPSC staff response in its entirety is attached in Appendix E.

The Toy Manufacturers of America, Inc (TMA) commented on several areas of the study. First, they stated their belief that the Dutch Consensus data and the Fisher-Price data "provide substantial and adequate data on the mouthing behavior of children with respect to the products involved". Second, they expressed concerns about the accuracy of the data collection. Third, they expressed concern with the method of collecting data from parents of children over 3 years of age. They stated that the telephone survey for older children will be unreliable because the results will be based on memory and generalizations.

CPSC Staff Response: The CPSC staff used the Dutch Consensus Group data to conduct the initial hazard assessment of phthalates. However, as stated above, the data were limited, involving parental observations of only 42 children from 3 to 36 months of age. While the Fisher-Price study was much larger (217 subjects), the data were not consistently nor objectively reported and therefore could not be reliably analyzed. Therefore, the proposed CPSC study is not a duplication of these studies, but is needed to accurately and objectively quantify the amount of time young children mouth toys and other objects.

This information will be collected by conducting in-home and in-childcare observations by trained professional observers and will be based on actual real-life mouthing behaviors. Finally, with regard to the telephone surveys, the parents will not be responding based on memory. They will be mailed a questionnaire with instructions on how to observe their child and how to record the data. This data will be used to determine the need for more extensive data collection for older children.

TAB B

Draft

6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

Proposed Collection of Information Under OMB Review; Mouthing Behavior Study

AGENCY: Consumer Product Safety Commission (CPSC).

ACTION: Notice.

SUMMARY: As the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires, the U.S. Consumer Product Safety Commission (CPSC or Commission) announces that the Information Collection Request (ICR) described below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The proposed collection of information consists of a study to observe 200 children ages 3 months through 35 months to record what items they put in their mouths and for how long. The study also includes a telephone survey of the parents of about 400 children between 36 and 72 months old to estimate the mouthing behavior of these children. The information will help the Commission assess the risks associated with children mouthing products containing potentially harmful substances. Comments on the study should be submitted to OMB and CPSC.

DATES: Written comments must be received on or before [insert date that is 30 days after publication in the Federal Register].

ADDRESSES: Written comments should be captioned "Mouthing Behavior Study" and mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for CPSC, 725 17th Street, NW, Washington, DC 20503. Copies of comments also may be: mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207; delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland, telephone (301) 504-0800; or filed by telefacsimile to (301)504-0127 or by email to cpsc-os@cpsc.gov.

FOR FURTHER INFORMATION OR A COPY CONTACT: Celestine T. Kiss, Engineering Psychologist, Consumer Product Safety Commission, Washington, D.C. 20207; 301-504-0468 ext. 1284 or by email to ckiss@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

The U.S. Consumer Product Safety Commission staff is investigating the potential exposure and health risks to children from teethers, rattles, and toys that are made of polyvinyl chloride (PVC) that contains various dialkyl phthalate (DAP) plasticizers, especially diisononyl phthalate (DINP). Manufacturers use plasticizers to soften

the PVC. Tests using animals exposed to high levels of certain DAP plasticizers have caused concerns that PVC children's products might present a risk of liver or other organ toxicity to children. Whether DINP would cause toxic effects in humans depends on the amount of DINP that is ingested. Thus, determining the amount of time children have DINP-containing products in their mouths is one important component of the risk assessment.

The CPSC staff recently released a report, The Risk of Chronic Toxicity Associated with Exposure to Diisononyl Phthalate (DINP) in Children's Products (Dec. 1998), which concluded that, based on the best available information, few, if any, children are at risk of liver or other organ toxicity from PVC toys that contain DINP. This was based on estimates of the amount of DINP ingested, which indicated that DINP exposure did not reach a potentially harmful level. However, the staff believes that there are a number of uncertainties in this assessment, particularly regarding the types of toys that children are mouthing and how long they typically mouth these toys. In addition, the staff at that time did not address the potential carcinogenic risk from DINP, which is being investigated by a Chronic Hazard Advisory Panel (CHAP) appointed by the Commission. After the CHAP provides advice on the carcinogenic risk of DINP, accurate exposure data will be needed in order to perform a risk assessment. Therefore, CPSC will perform this study to

gather better data on which to base the health-risk assessment.

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to the agency or a third party. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. The Federal Register notice with a 60-day comment period soliciting comments on this collection of information was published on March 11, 1999 (64 FR 12153)(corrected comment submission date published March 22, 1999(64 FR 13854)). One comment was received, from the Toy Manufacturers of America, Inc. (TMA). The points raised in that comment are addressed in the request for approval of this collection of information that was submitted to OMB.

B. Description of the Collection of Information

This extensive exposure study is intended to obtain a better estimate of the amount of time children mouth products that could contain phthalates. The CPSC is also interested in how mouthing time varies with age, gender, and socioeconomic strata. The Commission also can use information from this study to assess potential hazards associated with other children's products, such as exposure to lead. The title of this collection of information is "Mouthing Behavior Study."

The observation portion of the study involves 200 children between 3 and 35 months old. The observations will be conducted over 2 days for 3 hours per day. For 20 continuous minutes out of each half-hour, the child's mouthing activities will be recorded. This will include (1) the specific object being mouthed, (2) the length of the mouthing episode and (3) whether the object was placed to the lips, or put into the mouth. Mouthing is defined, for purposes of this study, as placing any item to the child's lips, tongue, and/or into the mouth.

In addition to the observations, a contractor will conduct a telephone survey to determine mouthing behaviors of 400 children from 36 to 72 months old, as reported by the parent. This age group will not be observed.

The Commission will use all this information to estimate the frequency and duration of children's mouthing activities, by age. Interested persons may obtain a copy of

the request to OMB for approval, containing a more detailed description of the intended study, from the Commission's Office of the Secretary.

C. Burden on Respondents

Two hundred subjects will be used for the observation portion of the study. Each subject's total participation time will be approximately 13 hours. For most of this time, however, the child and the caregiver will be engaged in their regular activities. (Time spent in the normal course of a respondent's activities does not count as part of the burden of a collection of information. 5 CFR 1320.3(b)(2).)

The Commission's staff estimates that each child in the observation study, and the persons associated with that child (including parents and other caregivers), will spend an average total of about 4.5 hours among them in reacting specifically to the observer. This is calculated by estimating 15 minutes for one person to participate in the telephone interview, 1 hour for one person to observe the subject and fill out the questionnaire, 15 minutes for that person to report the results to the contractor, 1 hour each for two persons during the in-home interview/habituation period (2 hours total), and an average of 30 person-minutes of interaction relating to the study for each of the 2 observation sessions (1 hour total). Therefore, the total burden hours for these respondents will be about 900 hours (200 x 4.5 hours).

The number of subjects required for the older children telephone survey portion of the study is 400. Each subject's total time will be approximately 1.5 hours. This is calculated by estimating 15 minutes for the initial phone interview, 1 hour observing the subject and filling out the questionnaire, and 15 minutes for reporting the results to the contractor by telephone. Therefore, the total burden hours for the telephone survey will be about 600 hours. Thus, the estimated one-time reporting burden for this collection is 1500 hours.

C. Requests for Comments

Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to the addresses given at the beginning of this notice.

Dated: _____, 1999.

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Sadye E. Dunn, Secretary

U.S. Consumer Product Safety Commission