United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

CPSC/OFFICE OF
THE SECRETARY

1998 DEC 10 P 12: 55

BALLOT VOTE SHEET

DATE: December 9, 1998

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: Request for Approval of (1) a Chronic Advisory Hazard Panel for Phthalates and (2) FY 1999 Funds to Perform a Child Observation (Mouthing) Study

BALLOT VOTE DUE: DECEMBER 17, 1998

Attached is a staff memorandum recommending that the Commission convene a chronic hazard advisory panel (CHAP) to evaluate chronic hazards of diisononyl phthalate (DINP) in children's products made of polyvinyl chloride (PVC). The memorandum also recommends reprogramming specified FY 1999 funds to conduct a child observation study to estimate the time children spend mouthing products that may contain phthalates.

Please indicate your vote on the following options.

I. AS TO THE FORMATION OF A CHAP:

A. DIRECT THE STAFF TO BEGIN THE PROCESS OF FORMING A CHAP FOR DINP.

(Signature) (Date)

(Option I continued on page 2.)

NOTE: This document has not been reviewed or accepted by the Commission.
Initial HL **Date** 12/10/98

CPSA 6 (b)(1) Cleared
X No Mfrs/PrvtLblrs or Products Identified
___ Excepted by ___
___ Firms Notified,
Comments Processed.
12/10/98

(Option I continued.)

B. DO NOT SEEK A CHAP FOR DINP AT THIS TIME.

_____ _____
(Signature) (Date)

C. TAKE OTHER ACTION (please specify).

_____ _____
(Signature) (Date)

II. AS TO REPROGRAMMING FY 1999 FUNDS FOR A CHILD OBSERVATION STUDY:

A. REPROGRAM THE IDENTIFIED FY 1999 FUNDS.

_____ _____
(Signature) (Date)

B. DO NOT CONDUCT THE REQUESTED STUDY AT THIS TIME.

_____ _____
(Signature) (Date)

C. TAKE OTHER ACTION (please specify).

_____ _____
(Signature) (Date)

Comments/Instructions:

[redacted]

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MEMORANDUM

DATE: December 8, 1998

TO : The Commission
Sadye E. Dunn, Secretary

Through: Jeffrey Bromme, General Counsel
Through: Pamela Gilbert, Executive Director

FROM : Ronald L. Medford RLM
Assistant Executive Director
for Hazard Identification and Reduction

SUBJECT: Additional Phthalate Work

The staff has just completed its study of the risks posed to children under three years of age by the plasticizer diisononyl phthalate (DINP) which is used to soften some children's teethers, rattles and toys made from polyvinyl chloride (PVC). DINP was found to leach from these products when they are mouthed and, as a result, the phthalate can be ingested by children. DINP has been shown to cause liver and other organ toxicity in laboratory animals.

The report (provided to the Commission on December 2, 1998) includes the staff's recommendations for additional work to resolve some uncertainties that remain that could affect the staff's estimate of the health risks to children. These uncertainties include the potential cancer risk to humans, the effect of background exposure to this or other phthalates, and the length of exposure (mouthing time) of children to phthalate-containing products. To gather the information needed to resolve these uncertainties requires the expenditure of funds not included in the FY 1999 Operating Plan.

The two areas of additional work that require Commission approval and the reallocation of funds are: 1) convening a Chronic Hazard Advisory Panel (CHAP), and 2) conducting an observation study of the mouthing behavior of young children.

NOTE: This document has not been reviewed or accepted by the Commission.
Initial RL **Date** 12/10/98

CPSA 6 (b)(1) Cleared
12/10/98
No Mfrs/Prvtlbrs or
Products Identified
Excepted by
Firms Notified

A CHAP is needed to evaluate the existing scientific information regarding the mechanism by which DINP causes cancer and the implications of this on the potential cancer risk to children. A CHAP is composed of seven scientists chosen by the Commission from a list of 21 scientists recommended by the National Academy of Sciences. The CHAP would provide a written report to the Commission of its evaluation of the existing information regarding chronic toxicity, including cancer, and would recommend the appropriate method(s) to use in estimating the risks to children. The CHAP would also consider the possible effect of background phthalate exposure. The staff estimates that a CHAP will require about $50,000 to cover the costs of the scientists' time and expenses. The Office of Hazard Identification and Reduction has sufficient money in its contract support fund to cover this cost. However, a Commission vote is needed to convene a CHAP on DINP.

The only data currently available to estimate the time children mouth products that may contain DINP are from the Dutch Consensus Study in which 42 children were observed. The staff believes that a larger study in which at least 200 children are observed is needed to more accurately estimate the time children mouth products that may contain phthalates. The staff estimates that $200,000 will be needed to conduct this work.

We have reviewed the contract funds available from EXHR projects and recommend that the following projects be deferred and the money reprogrammed to fund the child observation study: 1) $100,000 from the Age Determination Guidelines project, and 2) $50,000 from the Child Restraint project. We recommend that the remaining $50,000 be taken from agency salary savings that have accrued during this fiscal year.

At mid-year review, the staff will evaluate whether to recommend that the two studies being deferred receive priority funding later in the year, depending on the availability of staff, and Commission priorities.

Thus, the staff recommends that the Commission approve: 1) convening a CHAP on DINP, and 2) reprogramming FY 1999 funds as outlined above to conduct the child observation study.