UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

CPSC/OFFICE OF THE SECRETARY

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Date: FEB 13 2003

TO : The Commission

THROUGH: Todd A. Stevenson, Secretary
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SUBJECT : Response to Additional Questions from Commissioner Moore on Petition HP 99-1 to Ban Polyvinyl Chloride in Toys and Other Products

Questions to OGC

1. *If the Commission elects to deny the petition to ban, does it have the authority to issue the "health advisory" proposed by NET, and if so, what findings would it have to make and what procedures would it have to go through to support such an option?*

The Commission could, in its discretion, vote to issue a "health advisory" related to a consumer product within its jurisdiction. There is no statutory provision expressly enabling the Commission to issue health advisories. However, section 2(b)(2) of the Consumer Product Safety Act, which states that one of the purposes of the Act is "to assist consumers in evaluating the comparative safety of consumer products," would provide a basis for such an action. 15 U.S.C. § 2051(b)(2). Such an advisory would be based on a staff assessment of the risk presented to satisfy the minimum standard under the Administrative Procedure Act (APA) for an agency action, *i.e.*, that it not be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C.§ 706 (2)(A).

Here, the National Environmental Trust requested that the Commission issue a "national advisory on the health risks that have been associated with PVC toys and products." The Directorate for Health Sciences states that it is unaware of any data that would support a conclusion that there are any health risks associated with PVC toys and products. Accordingly, it is unclear what sort of health advisory on this issue the Commission could publish that would satisfy the minimum requisite APA standard.

NOTE: This document has not been reviewed or accepted by the Commission.
Initial mh Date 2/13/03

CPSA 6 (b)(1) Cleared
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No Mfrs/PrvtLblrs or Products Identified
Excepted by
Firms Notified,

2. *Could the Commission consider a labeling option along the lines of the EC (European Commission) proposal?*

Labeling of PVC toys that could be placed in a child's mouth is not a viable option under the Federal Hazardous Substances Act (FHSA). This is the case because to require labeling, the Commission would first have to find that the items in question were "hazardous substances." However, since these items are intended for use by children, the result under the FHSA of determining that they were "hazardous substances" would be that they would be banned automatically.[1]

To require labeling under the FHSA, a determination must first be made that polyvinyl chloride-containing toys and other products intended for children five years of age and under are "hazardous substances." FHSA § 2(p)(1); 15 U.S.C. § 1261(p)(1). This determination would be made under section 3(a) of the FHSA. 15 U.S.C. § 1262 (a). The section 3(a) action would address whether such PVC products met the FHSA definition of hazardous substance, which requires in this instance not only that the product be toxic, but that it "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children." 15 U.S.C. § 1261 (f)(1)(A).

If products containing PVC intended for use by children of five years of age and under were ultimately found to be hazardous substances, then those products would be banned automatically under section 2(q)(1)(A) of the FHSA. 15 U.S.C. § 1261 (q)(1)(A). In any event, according to the Health Sciences Directorate, data do not exist to support a determination that PVC-containing toys and products are "hazardous substances" for purposes of the FHSA.

Non-OGC Questions

1. *Given your responses to the Chairman's questions and to certain of mine, do you still agree with this statement on page 267 of the briefing package: "...in view of the amount of time that some children mouth pacifiers, it is possible that a very small number of children might approach the ADI should DINP be used as the plasticizer in pacifiers"?*

The statement made in the briefing package is true but must be understood in context. Staff calculated the hypothetical DINP intake assuming that all pacifier mouthing time was on pacifiers that contained DINP and that the migration rate of DINP from these hypothetical pacifiers was the same as from DINP-containing toys. With these assumptions, the 99th

[1] There are two provisions of the FHSA that provide exemptions from the automatic ban provision, neither of which would be applicable here. The first, for items such as chemistry sets, which by reason of their purpose require inclusion of hazardous substances, is available only where labeling, including directions, is adequate for safe use and the products are "intended for use by children who have attained sufficient maturity, and may reasonably be expected , to read and heed such directions and warnings." FHSA§ 2(q)(1); 15 U.S.C. § 1261(q)(1). The second provides for labeling of certain common fireworks to the extent that such items can be adequately labeled to protect purchasers and users. *Id.*

percentile 3-12 month old child would have an intake of 62.35 μg/kg-d, about half the ADI, with a 95% confidence interval of 23.44-101.47 μg/kg-d.

Staff believes that it is unlikely that DINP in pacifiers would pose a risk even with an increased prevalence, provided that migration rates are in the same general range as DINP-containing toys.

2. Last Friday the CDC issued its Second National Report on Human Exposure to Environmental Chemicals. The study measured chemicals and their metabolites in blood and urine samples from participants in the National Health and Nutrition Examination Survey. The blood and urine levels reflect the amount of the chemical in the environment that actually gets into the body. Certain phthalates, including DINP and DEHP were included in the study. For both of these phthalates, children 6 to 11 years (the youngest age group tested) had higher levels of phthalates in their urine, than the older age groups. (This raises the, as yet, unanswerable question of what would be found if younger children, such as the ones addressed in the petition, were tested.)

Scientists from the U.S. Centers for Disease Control and Prevention (CDC) measured phthalate metabolites in the urine of infants ranging from 11 to 17 months of age, as discussed in the staff briefing package (see TAB L, p. 388). Metabolites of DEHP were lower than for other phthalates. DINP metabolites were below the limit of detection.

a. Is there a way to compare the amount of phthalate excreted in urine (the measure in the CDC study) to our ADI measurement?

This has been done for adults, as discussed in the staff briefing package (TAB L, p. 388). Two independent analyses of the earlier CDC urinary metabolite data have been reported, one by the National Institute for Environmental Health Sciences and another by an industry[2] scientist. In both analyses, the average adult exposure to DINP was below the limit of detection. The 95th percentile DINP exposure was estimated to be in the range of 1 to 2 μg/kg-d, which is roughly 100-fold less than the ADI of 120 μg/kg-d.

b. We know from the study that the amount of DEHP's monoester metabolite in urine represents only about one tenth of the ingested dose during the previous 24 hours. Do we know what the similar amount ingested would have been for DINP?

Yes, it is possible to estimate the amount of DINP ingested from the urinary level. This is discussed in the response to question 2a.

c. The CDC study on page 81 suggests that the debate over whether peroxisomal proliferation is relevant in humans is an on-going one. I had the impression this was pretty well settled. Is it?

There is scientific consensus about whether cancer caused by peroxisomal proliferation in the liver of rodents is relevant to humans. The staff concluded that DINP, which is a

[2] Raymond M. David, Ph.D., Chairman, Phthalates Ester Panel, Toxicology Research Task Group

peroxisome proliferator, is not likely to present a cancer risk to humans. This conclusion is based, in part, on the findings of the Chronic Hazard Advisory Panel (CHAP). In addition, the staff has participated in a more recent, international advisory panel on peroxisome proliferation convened by the International Life Sciences Institute (ILSI) for the U.S. Environmental Protection Agency. The ILSI panel reviewed the latest available information on peroxisome proliferators, including DINP, and reached essentially the same conclusion as the CHAP. The ILSI panel report will be available later this year.

d. Is there anything in the CDC report that would alter your conclusions about DINP?

No, there is nothing in the CDC report that would alter the staff conclusions about DINP. The CDC report is consistent with our current understanding of DINP exposure.