



U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

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February 26, 2003

Mr. Jeffrey Becker Wise
Policy Director
National Environmental Trust
1200 18th Street, NW, Suite 500
Washington, DC 20036

Re: Petition Requesting Ban of Use of Polyvinyl Chloride (PVC) in Products Intended for Children Five Years of Age and Under (**briefing package date corrected as noted in bold**)

Dear Mr. Wise:

As requested in your letter of November 19, 1998 I am communicating through you to advise the petitioners that on February 21, 2003, the Consumer Product Safety Commission voted 3-0 to deny the requests from the National Environmental Trust and eleven other organizations that the Commission:

- immediately ban polyvinyl chloride (PVC) in all toys and other products intended for children five years of age and under; and
- issue a national advisory on the health risks that have been associated with soft plastic vinyl toys to inform parents and consumers about the risks associated with PVC toys currently in stores and homes.

The submission from the petitioners gave as the primary reason for these requests the toxicity of diisononyl phthalate (DINP), a plasticizer in PVC, and the toxicity of lead and cadmium in PVC.

The requested ban on PVC in all toys and other products intended for children five years of age and under was docketed as a petition for rulemaking under section 3(j) of the Federal Hazardous Substances Act (FHSA) on December 7, 1998 (Petition No. HP 99-01). 15 U.S.C. §1262(j). The request that the Commission issue a national advisory on the health risks that have been associated with soft plastic vinyl toys was not docketed because it would not require rulemaking to implement.

To take the requested regulatory action, the Commission would have to declare under the FHSA that products containing PVC intended for use by children of five years old and younger were "hazardous substances." This would require the Commission to find that such PVC products met the FHSA's 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 handling or use, including reasonably foreseeable ingestion by children." 15 U.S.C. § 1261(f)(1)(A).

In making a decision whether to grant a petition and commence rulemaking, the Commission is to consider, *inter alia*, the following factors:

- Whether the product involved presents an unreasonable risk of injury
- Whether a rule is reasonably necessary to eliminate or reduce the risk of injury
- Whether failure of the Commission to initiate the rulemaking proceeding requested would unreasonably expose the petitioner or other consumers to the risk of injury which the petitioner alleges is presented by the product

16 CFR § 1051.9

The ban rulemaking would be conducted under section 3(a) of the FHSA.¹ Section 3(a)(2) of the FHSA requires that a rulemaking such as the one requested be conducted in accordance with section 701(e) of the Federal Food, Drug, and Cosmetic Act (FDCA).² Under section 701(e), for the Commission to proceed to rulemaking, the petition must set forth "reasonable grounds" for the requested action. The United States Court of Appeals for the District of Columbia Circuit has held that "reasonable grounds" for a petition under the FHSA "are grounds from which it is reasonable to conclude that the Commission would be able to make the findings required to issue the requested rule and to support those findings with substantial evidence on the record."³

The Commission considered the petition and the materials submitted with it; the June 15, 2001 final report of the Chronic Hazard Advisory Panel (CHAP) on DINP convened in accordance with sections 28 and 31 of the Consumer Product Safety Act, 15 U.S.C. §§ 2077, 2080; a CPSC staff behavioral observation study to determine how much time young children actually spend mouthing objects and the types of objects they mouth; the November 1997 Commission staff report entitled, *CPSC Staff Report on Lead and Cadmium in Children's Polyvinyl Chloride (PVC) Products*; the 488 public comments received on the petition; the staff briefing package dated **August 13, 2002**; information presented by the staff during an oral

¹ 15 U.S.C. § 1262(a).

² 21 U.S.C. § 371(e).

³ *Consumer Federation of America v. CPSC*, 883 F.2d 1073, 1076 (D.C. Cir. 1989).

briefing on November 8, 2002; comments received on the staff briefing package; and other information.

The staff briefing package recounts the extensive scientific and technical investigations that have been carried out by the CPSC and others on the issue of PVC in products intended for children and concludes as follows.

Based upon the scientific data presented in this briefing package, the staff believes that there is no demonstrated health risk posed by PVC toys or other products intended for children 5 years of age and under and thus, no justification for either banning PVC use in toys and other products intended for children five years of age and under or for issuing a national advisory on the health risks associated with soft plastic toys.

Memorandum from Marilyn L. Wind, Ph.D., Deputy Associate Executive Director, Directorate for Health Sciences, to the Commission, *Response to Petition HP 99-1*, August 13, 2002, at 16-17.

That conclusion is based in part on the finding of the DINP CHAP that, “[f]or the majority of children, the exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury.” *Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP)*, June 2001, Executive Summary item 17. The new data from the recent CPSC behavioral observation study reported in the staff briefing package, which was not available at the time of the CHAP’s deliberations, confirm this conclusion and demonstrate that children are exposed to DINP at even lower levels than the CHAP assumed when they reached their conclusion. Further, the recent survey of toys mouthed by children under the age of three also reported in the staff briefing package shows that not all soft plastic toys contain DINP. Therefore, exposure would be even less than the CHAP predicted because children mouth these toys for less time per day than the CHAP estimated, and the average amount of DINP in toys mouthed by children under the age of three is less than the CHAP estimated. If the risk to children under the age of three is not sufficient to warrant action, then based upon the data collected in the staff’s behavioral observation study, and the data available in published literature, which indicate that mouthing declines as children age, there is no basis for the findings necessary under the CPSC regulations governing grant or denial of petitions or the FHSA for the Commission to take the requested actions with respect to DINP in PVC toys and other products intended for children five years of age and under.

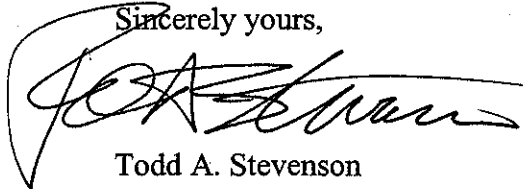
With respect to lead and cadmium, in November 1997, the Commission staff issued a report entitled, *CPSC Staff Report on Lead and Cadmium in Children’s Polyvinyl Chloride (PVC) Products*. That report detailed the results of testing the Commission staff conducted on children’s products that Greenpeace had alleged contained hazardous levels of lead and cadmium. Although some of the vinyl products identified by Greenpeace and tested by CPSC

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staff contained lead or cadmium, further testing and evaluation revealed that hazardous amounts of lead or cadmium were not released from the products. This means that children would not be exposed to hazardous levels. The report concluded that children would not be exposed to hazardous levels of lead or cadmium when the products are handled or used in a reasonably foreseeable manner. Thus, there is no basis for the findings necessary under the CPSC regulations governing grant or denial of petitions or the FHSA for the Commission to take the requested actions with respect to lead or cadmium in PVC toys and other products intended for children five years of age and under.

In sum, as a result of consideration of the extensive research and analysis summarized herein, the Commission has denied the petition and declined to issue the requested national health advisory.

Sincerely yours,



Todd A. Stevenson
Secretary

Copy to:

Nancy Chuda
Director
Children's Health Environmental Coalition

Mary Ellen Fise
General Counsel
Consumer Federation of America

Rick Hind
Legislative Director
Toxics Campaign
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U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

**STATEMENT OF THE HONORABLE MARY SHEILA GALL
ON VOTE TO DENY PETITION REQUESTING A BAN
OF POLYVINYL CHLORIDE IN TOYS AND PRODUCTS INTENDED
FOR CHILDREN FIVE AND UNDER**

February 20, 2003

Today I voted to deny a petition submitted by a group of organizations that asked the Commission to ban Polyvinyl Chloride (PVC) in all toys and other products intended for children aged five years and under. The Commission staff gave extensive consideration to the allegations of the petition and thoroughly examined all of the health effects alleged to be caused by children's mouthing of products made of PVC. The staff paid particular attention to products that used diisonyl phthalate (DINP) as a plasticizer. This thorough examination revealed that there is no risk posed by PVC that rises even remotely to that specified by the Federal Hazardous Substances Act (FHSA), the statute under which the Commission regulates this type of risk. Accordingly, the petition must be denied.

The Commission and its staff gave careful attention to the allegations of the petition, as they properly should when claims of detrimental health effects to children are made. A previous Commission staff risk assessment concluded that the lead and cadmium in PVC products posed no risk of injury to children and the petitioners submitted no evidence that called into question the results of that risk assessment. Assessing the risk posed by DINP in PVC involved work beyond that contained in the earlier risk assessment. The Commission went to great lengths to assess all the risks that might be posed by DINP. The staff used a method validated by two international interlaboratory studies of measuring the quantity of DINP that migrates from PVC products. The staff then used that method to estimate the amount of DINP that actually entered a child's body when a PVC product was mouthed. The Commission then convened a Chronic Hazard Advisory Panel (CHAP), which reviewed extensive toxicological data about DINP. The CHAP concluded that for the vast majority of children the exposure to DINP from PVC-containing products posed a minimal to non-existent risk of injury. Data from a subsequent Commission staff study of exposure times of children mouthing products revealed that children were exposed to even less DINP than the CHAP had assumed in making its finding. The chance that children are being injured from mouthing products made from PVC is *de minimus*. There is simply nothing in the record that remotely justifies any finding that PVC products intended for children constitute a hazardous substance within the meaning of the FHSA.

While the Commission has no legal authority to ban PVC products intended for use by children, there is toxicity data showing that it is a carcinogen in rodents, although it is a type of

cancer not usually associated with humans. As least partially in response to these toxicity findings, in 1998 the toy industry and large retail chain stores in the U.S. voluntarily agreed not to sell items made out of PVC designed to be placed in the mouth (e.g., teethingers, rattles and pacifiers). The European Union and Japan reached a similar result through their own regulatory processes.

Chronic hazards are among the most technically difficult product-safety problems that the Commission considers. Unlike acute hazards, where the effects occur very quickly and are easily observable, chronic hazards involve health effects that may occur many years after exposure and which may be difficult to trace to exposure to any particular substance. Considerable scientific expertise must be brought to bear on any allegations of chronic hazards and the result must always reflect a judgment call. This may be subject to revision if more is learned about the toxicity or exposure of a specific substance. In the case of PVC, however, consumers may have a high level of assurance that soft plastic products pose no risk to children.



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

STATEMENT OF THE HONORABLE THOMAS H. MOORE
ON THE PETITION TO BAN POLYVINYL CHLORIDE IN PRODUCTS INTENDED FOR
CHILDREN FIVE YEARS OF AGE AND UNDER
February 21, 2003

I am voting to deny the petition to ban polyvinyl chloride in products intended for children five years of age and under. The clear weight of the evidence produced by staff supports the conclusion that children are not at risk from mouthing products currently on the market that contain diisononyl phthalate (DINP). This evidence consists of new exposure studies showing how long children mouth various objects, the migration rates of phthalates from products on the market, an Acceptable Daily Intake that has an extremely large uncertainty/adjustment factor and a scientific consensus that DINP is nongenotoxic and that the cancer caused by peroxisomal proliferation by DINP in the liver of rodents is not relevant to humans. As these are the best and most current scientific opinions, I believe the Commission must bow to that judgment. Our staff has done extraordinary work on this petition—by far the most comprehensive work done to date anywhere in the world. I congratulate them on their achievement. Both their work, and the work of the scientists who participated in the Chronic Hazard Advisory Panel on DINP, should calm parents' fears about the potential harm to young children from children's products currently on the market that contain DINP.

I am concerned, however, that the staff's conclusions could be the basis for industry to use phthalates in products that they have voluntarily agreed not to use them in, namely rattles, teething rings and pacifiers. One area in which we do not have concrete information is the migration rate of DINP from these three types of children's products. Our assumption about the migration rate of phthalates from these products could prove to be too low. We also are not completely sure how much phthalates very young children are exposed to from other sources in their environment. This background exposure, coupled with the uncertainty of the rate of migration, made me consider voting to defer action on the petition until we see what happens in the marketplace as a result of the staff's conclusions. If phthalates were to be used in teething rings, rattles or pacifiers in the future, the uncertainties mentioned above could cause us to be petitioned again in this area. I decided that I would not vote based on speculation of what might happen. All I can vote on today is the current state of the marketplace and of scientific knowledge, both of which lead to the conclusion that the ingestion of DINP by young children from the children's products on the market poses no risk of harm to America's children.