ExxonMobil Chemical Company
13501 Katy Freeway
Houston, Texas 77079-1398

Elissa P. Sturry
Vice President
Intermediates

ExxonMobil
Chemical

June 24, 2010

Honorable Cass R. Sunstein
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
1650 Pennsylvania Avenue, NW
Washington, D.C. 20503

RE: Follow up to EO 12866 Meeting - Chemicals of Concern Listing

Dear Administrator Sunstein,

I wanted to take an opportunity to thank the OIRA staff for the attention and time taken to listen to ExxonMobil's views on chemical management principles and EPA's proposal to list certain phthalates as Chemicals of Concern under TSCA.

As we discussed, DINP and DIDP[1] are two of the most well studied chemicals in commerce today. Prior assessments by other regulatory agencies in the United States and Europe have recognized the significant differences among phthalates, and have consistently found that DINP and DIDP do not present significant risks to human health or the environment. A proposal to list these chemicals under TSCA section 5(b)(4) will have a significant impact on public and industry perceptions and would send a signal to the marketplace that these substances are the highest priority for elimination through regulation and/or voluntary actions. It is therefore critical that EPA not exercise this authority lightly, that purposes for listing are clearly articulated, that listing criteria be defined, that each individual substance proposed for listing be supported by strong scientific evidence, that careful consideration be given to *all* of the available scientific evidence, and that each listed substance in fact be a high priority for regulatory action.

ExxonMobil believes that a comprehensive review of the available scientific data for DINP and DIDP will lead to the conclusion that neither should be included in a list of "chemicals of concern" under TSCA section 5(b)(4). Further, it is our belief that such a listing may offer no improvement to health and environmental protection; and would be costly to U.S. businesses, lead to a competitive disadvantage with other industrial countries, and have a detrimental effect on U.S. exports and jobs. We hope that EPA will be encouraged not to proceed with any section 5(b)(4) proposal for these two compounds until a comprehensive assessment of all the evidence has occurred.

We regret that you were unable to join us personally for this discussion, but appreciate the opportunity to meet with your staff. We are preparing additional materials on the DINP and DIDP science for EPA and will copy your office.

Best regards,

Elissa Sturry

cc: Kevin Neyland
David Rostker

[1] Di-isononyl Phthalate and Di-isodecyl Phthalate

From: angela.rollins@exxonmobil.com
To: Beck, Nancy
Cc: Steve Risotto; Roetker, David
Subject: Followup to ACC meeting with OMB -- 2001 CHAP Report
Date: Tuesday, June 22, 2010 5:49:41 PM
Attachments: 2003.01.23 CPSCStaffResponse to follow up questions full.pdf

---

Nancy,
It was nice meeting you last Wednesday at the meeting between OMB and ACC regarding EPA's Phthalate Chemical Action Plan and its proposed TSCA 5(b)(4) listing. As follow-up, attached is a link to the Consumer Product Safety Commission (CPSC) Chronic Hazard Advisory Panel (CHAP) Report on DINP. I've also provided links to a few key documents of relevance to this topic, which includes the CPSC reports associated with the CHAP report as well as the CPSC Commission's Q&As and responses to petitions. I tried to use website links where possible rather than sending the documents, but if you would prefer the documents, I'd be happy to send them. There is quite a bit of information below; however, the first ~20 pages of the first link provides a good introduction: the CPSC executive summary and briefing memo.

Because the last public document from CPSC regarding toys and DINP is dated 2007, I'm also including a recently prepared "Review of Recent Scientific Data on DINP and Risk Characterisation for its use in Toys and Childcare Articles" from the European Council for Plasticizers and Intermediates (ECPI). This contains the latest science on DINP since the CHAP and subsequent CPSC reviews.

CPSC Reports: Petition Requesting Ban of Use of PVC in Products - Intended for Children Five Years of Age (HP 99-1) (Parts 1-7) -- http://www.cpsc.gov/library/foia/foia02/brief/briefing.html
Report of the Chronic Hazard Advisory Panel on Diisononyl Phthalate, June 2001 (169 pgs) -- http://www.cpsc.gov/LIBRARY/FOIA/Foia01/os/dinp.pdf
2003 CPSC Staff Responses to Commission's follow up questions (21 pgs) -- (See attached file: 2003.01.23 CPSCStaffResponse to follow up questions full.pdf)
2003 Commission Denial of Petition Requesting Ban of Use of Polyvinyl Chloride (PVC) (8 pgs) -- http://www.cpsc.gov/library/foia/foia03/petition/Ageunder.pdf
2003 Summer CPSC Newsletter (see pgs 3-5) -- http://www.cpsc.gov/cpscpub/pubs/cpsr_nws29.pdf
2007 CPSC Letter to Senator Runner (position unchanged) (2 pgs)-- http://www.americanchemistry.com/s_phthalate/sec.asp?CID=1907&DID=8777
2009 Review of Recent Scientific Data on DINP and Risk Characterisation for its use in Toys and Childcare articles (59 pgs) -- http://www.cpsc.gov/about/cpsia/comments/DINPToysExxon062009.pdf

Also, ECHA has recently posted the database for REACH registered substances on their website. http://apps.echa.europa.eu/registered/registered-sub.aspx (CAS #: DINP - 68515-48-0, DIDP - 68515-49-1)

Sincerely,
Angela Rollins
Oxo Americas Regulatory Affairs Advisor
ExxonMobil Chemical Company

Bus Phone: 281-870-6439
angela.rollins@exxonmobil.com

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: JAN 27 2003

TO : The Commission

THROUGH: Todd A. Stevenson, Secretary
W.H. DuRoss, III, General Counsel
Patricia M. Semple, Executive Director

FROM : Jacqueline Elder, for Acting Assistant Executive Director
Office of Hazard Identification and Reduction
Marilyn L. Wind, Ph.D., Deputy Associate Executive Director MLW
Directorate for Health Sciences

SUBJECT : Response to Follow-Up Questions from Chairman Stratton and Commissioner Moore from Briefing on Petition HP 99-1, Request to Ban Polyvinyl Chloride in Toys and Other Products Intended for Children Five Years of Age and Under

Attached are the staff responses to the follow-up questions posed by Chairman Stratton and Commissioner Moore from the briefing on Petition HP 99-1, the request to ban polyvinyl chloride in toys and other products intended for children five years of age and under.

NOTE: This document has not been reviewed or accepted by the Commission.
Initial MLW Date 1/27/03

CPSA § 6(b)(1) Cleared 1/27/03
Mfrs, Pvt Lblr or Prdcr Identified
Excepted
Firms Notified.
Comments Processed.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: January 16, 2003

TO : Marilyn L. Wind, Ph.D., Project Manager, Petition HP 99-1

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director for Health Sciences
Lori Saltzman, M.S., Director, Division of Health Sciences

Susan Ahmed, Ph.D., Associate Executive Director for Epidemiology
Russell H. Roegner, Ph.D., Director, Division of Hazard Analysis

FROM : Michael A. Babich, Ph.D., Chemist, Division of Health Sciences
Michael A. Greene, Ph.D., Mathematical Statistician, Division of Hazard Analysis

SUBJECT : Response to Chairman Stratton's Follow-Up Questions to the Public Briefing on Petition HP 99-1

1. *Is it possible that children spend very little time mouthing soft PVC toys because soft PVC mouthing toys are virtually unavailable in stores?*

   Staff does not believe that the reason that children spend very little time mouthing soft PVC toys is because "soft PVC mouthing toys are virtually unavailable in stores." Although phthalates are no longer being used in teethers and rattles, there are still soft PVC mouthing toys in the stores. Some of these contain DINP, while others contain a different plasticizer. In our survey of the types of toys mouthed by children in the observational study, we found about 60 percent of soft plastic toys were made of PVC and about 42 percent contained DINP. There are also soft plastic toys, teethers and rattles that are made from plastics such as polypropylene and polyethelene.

   Even if soft plastic toys are less available than a few years ago, children in the observational study still had access to them. Our data show that 42 percent of children under 1 year of age mouthed soft plastic toys on the days that they were observed, as did 57 percent of children between 1 and 2 years, and 47 percent of children over 2 years of age.

2. *Would greater availability of soft PVC mouthing toys cause some children to reach the ADI?*

   To address this question the staff calculated the hypothetical DINP exposure based on a scenario where all soft plastic toys, soft plastic teethers and soft plastic rattles contained

DINP. (Our current estimate is that 42 percent of soft plastic toys contain DINP, and following CPSC's agreement with toy manufacturers in 1999, we know that no teethers or rattles contain DINP.) Because teethers and rattles do not currently contain DINP, we are unable to determine how much DINP would migrate from them. We assumed that teethers and rattles would have the same migration rates as the soft plastic toys that we tested. In this hypothetical case, the estimated 95th percentile exposure for 3-12 month olds, the age group with the highest exposure, would be 2.2 µg/kg-d, which is well below the ADI of 120 µg/kg-d (briefing package, p. 381).

We also calculated the hypothetical DINP exposure based on a second scenario where all toys, teethers and rattles contained DINP. Mouthing times were taken from the data for non-PVC toys, cloth and hard plastic teethers and other such objects in addition to the objects in the previous paragraph. This represents a situation of greater availability of PVC toys, teethers and rattles. In this hypothetical case, the estimated 95th percentile exposure for 3-12 month olds was 10.7 µg/kg-d. This represents greater DINP intake than the previous scenario, but it is still considerably below the ADI.

This conclusion and the conclusion in the next question are subject to the assumption that migration rates of teethers and rattles would be the same as toys. Since DINP intake is a multiple of the migration rate, large increases in migration rates would be necessary to bring intake close to the ADI.

Therefore, based on the results of the staff risk assessment in these hypothetical cases, representing both the greater availability of PVC teethers, rattles, and toys containing DINP *and the unavailability of toys that did not contain DINP*, children would still not ingest DINP at levels near the ADI.

3. *Assuming that the Commission denies the ban on PVC in toys and other products intended for children under five years, and that industry withdraws its voluntary ban on DINP, is it likely that children will mouth products containing PVC for significantly longer periods of time than our study currently shows?*

The hypothetical cases in question 2 represent an estimate of DINP exposure that could occur if (1) all soft plastic toys, soft plastic teethers, and soft plastic rattles and (2) all toys, teethers and rattles were to contain DINP. The estimated 95th percentile exposures are well below the ADI.

We would then conclude that if the industry withdraws its voluntary ban on DINP, overall DINP exposure could increase, but still remain well below the ADI.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: January 17, 2003

TO : Marilyn L. Wind, Ph.D., Project Manager, Petition HP 99-1

THROUGH: Susan Ahmed, Ph.D., Associate Executive Director for Epidemiology

Russell H. Roegner, Ph.D., Director, Division of Hazard Analysis

FROM : Michael A. Greene, Ph.D.
Mathematical Statistician
Division of Hazard Analysis

SUBJECT : Response to Commissioner Moore's Follow-Up Questions to the Public Briefing on Petition HP 99-1

The purpose of this memo is to respond to questions raised by Commissioner Moore. Questions are in italics, followed by the responses.

1. The observational study was designed to have 50% of the participants from Chicago and 50% from Houston. The actual distribution was 61% from Chicago and 39% from Houston. How does that affect our ability to draw national conclusions from the data? Did this skew the data in terms of rural versus urban? What was the percentage of children from rural areas in the observational study?

The first part of the answer addresses the Houston/Chicago proportions and the second part addresses the urban/rural proportions.

Houston/Chicago proportions

In the briefing package, we identified 61% of the sample from Chicago and 39% from Houston. This breakdown referred to the 551 children recruited in the telephone survey. The observational study contained 169 children with a slightly different demographic breakdown. In the observational study 57% of the children were from the Chicago area and 43% from the Houston area. While this deviated from the planned 50/50 distribution, staff doubts that it had much effect because the mouthing times from the two areas were fairly close. These are shown in table 1 below.

Table 1
Hourly Mouthing Time (mins/hr) for Soft Plastic Toys
by Metropolitan Area

	All			Chicago Area			Houston Area		
Age	N	Mean	Median	N	Mean	Median	N	Mean	Median
0-12	54	0.13	0.00	32	0.16	0.00	22	0.08	0.00
12-24	66	0.18	0.01	36	0.24	0.06	30	0.12	0.00
24-36	49	0.07	0.00	29	0.10	0.00	20	0.03	0.01

Note: N is the sample size.

In making estimates of DINP intake, we pooled mouthing data from the two areas. Table 2 shows that the children from Illinois had slightly higher mouthing times than children from Houston. If we had more children from Houston and that pattern remained consistent, we would likely have reported a slightly lower DINP intake than was in the briefing package. This would have indicated an even larger difference between the amount of DINP ingested and the ADI.

The urban and rural proportions

The technical definition of "rural" refers to areas that are incorporated or unincorporated places with fewer than 2,500 residents and open territory.[1] The counties in the study fall into two categories, either (1) central counties of metro areas of 1 million population or more or (2) fringe counties in metro areas of 1 million population or more. Both types of counties are defined as "urban." Table 2 below shows the distribution of the study sample by metropolitan area and county. The central counties in the Chicago and Houston metropolitan areas are Cook, DuPage, Lake, Kane and Harris. Despite the low population density, all other counties in table 2 below are classified as fringe counties.[2] There are no rural counties in the study and as a result, there are no rural children in our study.

[1] This definition is from the Economic Research Service of the U. S. Department of Agriculture. See www.ers.usda.gov/briefing/rurality whatisrural/.
[2] See www.ers.usda.gov/briefing/Rural/Data/Codes/ruc.htm. Data based on the 1990 census.

Table 2
Distribution of Study Children by County

County	Number of Children	Percent of Sample	County Population	Land Area (square miles)	Persons per square mile
Cook	36	21%	5,350,269	946	5,656
DuPage	1	1%	912,044	334	2,731
Lake	5	3%	661,111	448	1,476
Kane	2	1%	425,545	520	818
Kendall	17	10%	58,227	321	181
DeKalb	12	7%	89,743	634	142
Grundy	24	14%	38,331	420	91
Total Chicago area	97	57%			
Harris	52	31%	3,460,589	1,729	2,001
Montgomery	11	7%	315,418	1,044	302
Waller	5	3%	33,591	514	65
Chambers	4	2%	26,859	599	45
Total Houston area	72	43%			
Total	169				

Source: Residence information provided in the demographic file (demogra). Population, and land area from U.S. Census Bureau, 2001 estimates.

Drawing National Conclusions

First, there is no reason to believe that the Chicago/Houston imbalance made any important difference in the DINP risk assessment. If we weighted the data to correct for the imbalance, it would show lower soft plastic toy mouthing times than was reported in the briefing package.

Second, our data is drawn only from urban areas. This represents about three-quarters of the U. S. population.[3] Accordingly, we have the ability to draw conclusions about three-quarters of the nation. There are, however, no theoretical reasons to believe that there are substantial differences in urban and rural children's mouthing times for soft plastic objects, or that there are differences among areas of the country.

[3] According to the Economic Research Service, in 1990, 187 million people lived in urban areas and 62 million lived in rural areas. See footnote 1 for the reference. These are the newest data available.

2. After making several comments about the limitations of the observational study, the ORC Macro Telephone Study Implementation Report makes the following statement on page 97 of the briefing package: "Given this sampling approach, it is not safe to make statistical inferences with respect to the larger population of families and children throughout the United States. That is, statistics based on these data may be used to make formal statistical inferences regarding the overall population of families with children in the selected study areas within Chicago and Houston SMSAs. It is possible to make generalizations based on these data to the broader U.S. population of families with children, albeit not in a formal statistical sense. While caution should be used in making such generalizations, and formal statistical tests are unavailable, these data should paint a reasonable picture of mouthing behaviors among children nationwide." Is this a fair assessment of the usefulness of the observation study?

Answering this question requires describing the reasons for selecting the sample and then describing the demographic composition of our sample.

The Sample Selection Process

Macro's comment "... given this sampling approach..." refers to purposive (purposeful, rather than random) sampling of Chicago and Houston. In studies when units are not randomly sampled, without other information, the analysis does not have the ability to generalize beyond the sampled units when there is substantial regional variation in the measurements. However, there is no reason to believe that there are such variations. All previous studies on mouthing, although conducted at a single study site have been accepted as being representative.[4] The Netherlands study was used by the European Commission in their DINP risk assessment covering countries in the European Union, while the other two studies were published in refereed journals. The information that allows local studies to be generalized is that there are no theoretical reasons to believe that mouthing behavior has regional variation.

Our study was designed to improve on these studies. Our design involved the following:

- Two cities, rather than one, to incorporate any possible geographic or regional variation in mouthing behavior.
- The sample of children should approximate the demographic characteristics of the U.S.
- Within the two cities, the children should be sampled randomly. We required the use of random digit dialing.
- We required that the children would be observed in their homes by trained observers rather than parents because we wanted accurate records of mouthing times and descriptions of the type of objects mouthed. This last part was especially important because we wanted to know mouthing times associated with soft plastic toys.

[4] The first published mouthing study was conducted in a university town in the Netherlands (Groot, Lekkerkerk and Steenbekkers, 1998), the Fisher Price study was in western New York state (Juberg, Thompson, Alfano and Coughlin, 2001) and the most recent study was in the Pacific northwest (Tulve, Suggs, McCurdy, Cohen Hubal, and Moya, 2002).

This design improved on previous studies. All previous studies used a single study area, and no study has published demographic characteristics of the children. No previous study has broken down mouthing time into the detailed categories found in our study. No previous study provides the ability to identify mouthing times for soft plastic toys.

The design required a contractor who would train observers, schedule visits and then observe the children in their homes. Selection of the two cities was up to the contractor and subject to CPSC approval. Our criteria for approval were that the cities taken together had demographic characteristics similar to the U. S. and that the cities were geographically distant. We believed that the contractor would select one city in his home area, to minimize travel costs, and the second city would be selected for demographic balance.

Sample Demographic Characteristics

Except for the urban/rural characteristic discussed in question 1, the sample was designed to have the demographic characteristics of the U. S. population. Table 3 shows that the study sample had a lower proportion of children in low income families than the U. S. population and Table 4 shows a smaller proportion of Black children. Aside from underrepresentation of these groups, the sample approximately matched the demographics of the U. S. population.

Table 3
Income Distribution in the Study Sample and the U. S. Population

Income	Count in Mouthing Study	Percent in Mouthing Study	Percent in U. S. Population with at least one child under six years of age
0-20,000	16	11	21
20,000-39,999	36	24	24
40,000-49,999	26	17	10
50,000-74,999	45	30	21
75,000 or more	29	19	23
Don't Know/Refused	17		-
Total	169	100	

Notes: Count and percent in mouthing study from Briefing Package. "Don't Know/Refused allocated in proportion to known sample. Percent in U.S. Population from U. S. Census Bureau, "Current Population Survey, Annual Demographic Survey March 2000 Supplement," Table FINC-03. Totals may not add due to rounding.

Table 4
Distribution of Study Sample and U.S. Population by Race

Race	Count in Mouthing Study	Percent in Mouthing Study	Percent in U. S. Population with at least one child under six years of age
White	142	84	83
Black	17	10	14
Asian	6	4	4
Multi-Racial	4	2	-
Total	169	100	100

Notes: Count and percent in mouthing study from Briefing Package. Asian includes Filipino, Indian, and Arabic. When respondents indicated membership in more than one race category, they were shown as Multi-Racial.. U. S. data from the Census Bureau.

One reason for underrepresentation of the low income stratum was because children were recruited for the study by telephone. Low income people are believed to be less likely to have telephones.[5]

[5] While 6 percent of the total U. S. population does not have a telephone, about 25 percent of households with incomes under $5,000 annually lack phones. See Giesbrecht, Kulp and Starer (1999).

Given this underrepresentation, what effect did it have on overall mouthing times? Table 5 compares the mouthing time distributions of the two underrepresented groups, low income and Black children, with the entire study sample.

Table 5
Hourly Mouthing Times (minutes per hour) for Soft Plastic Toys
For the Entire Sample, Black Children and Low Income Children

	All			Black Children			Low Income Children		
Age	N	Mean	Median	N	Mean	Median	N	Mean	Median
0-12	54	0.13	0.00	11	0.07	0.00	9	0.05	0.00
12-24	66	0.18	0.01	2	0.02	0.02	3	0.29	0.00
24-36	49	0.07	0.00	4	0.03	0.00	4	0.03	0.01

Note: See Briefing Package. Low income means an annual of less than 20,000.

Table 5 shows that the mean mouthing times in minutes per hour for Black and low income children in the lowest age group (0-12 months) were lower than the sample taken as a whole. Sample sizes for the other age groups make generalization less accurate. If the sample were weighted to account for the lower representation of Black and low income children, it would not alter the conclusion that there is no risk to children under the age of three years.

Conclusion

Staff does not agree with ORC-Macro's assessment, that "... it is not safe to make statistical inferences with respect to the larger population of families and children throughout the United States..." The sample design improves on the studies in the literature. The sample has reasonably good demographic characteristics. Moreover, where the sample departs from national demographics, there did not seem to be any meaningful impact on the risk assessment.

3. The following sentence appears on page 231 of the briefing package: "Ordinary confidence intervals rely on the normal distribution (or some other distribution), but with these particular data, the data did not seem to follow the normal distribution nor any known distribution." What would cause the data to be so irregular in its distribution?

In the data, while many children have zero or very low mouthing times for soft plastic toys, a few children have mouthing times that are several times larger than the mean. We saw this asymmetry in the Dutch data in our 1998 analysis and were not surprised to see it here in our data. The asymmetry is also shown in Juberg et al (2001, figures 1 and 2). That study used mouthing data from a study conducted by Fisher Price in western New York state.

The statistical procedures for estimating DINP intake in the risk analysis incorporated the asymmetry in the mouthing data in the estimation of upper percentiles. For example, the 95th percentile DINP intake for children 12-24 months was 0.53 micrograms per kilogram per day, while both the median and 5th percentile DINP intake were less than 0.01 micrograms per kilogram per day. The confidence intervals are also asymmetric, for example, the estimate for

the mean DINP intake for children 12-24 months was 0.08 micrograms per kilogram per day (95% confidence interval 0.04-0.14).

4. On page 231, in describing the bootstrap procedure, the statement is made: "Since there is a weak relationship between age and mouthing times, we define the age groups as the year of age. This means for a child who is between 3 months and a year old, we would select a mouthing time from any child who is in that age group." On page 242 of the Green report where he is looking at two studies examining the relationship between age and mouthing times, he notes in his conclusion that "Age was a significant predictor in both analyses.... There is no reason to believe that this pattern would change for children over 36 months." Also see page 305: "As with any risk assessment, this risk assessment includes assumptions and sources of uncertainty. In applying the Monte Carlo procedure, it was assumed that the hourly mouthing duration, exposure duration, and body weight are dependent on the age in months." There seems to be an inconsistency: Is there a weak relationship between age and mouthing times which allows for a fudge factor within each year of age, or is it a significant predictor of mouthing times such that a child's age in months is important?

DINP intake was computed using hourly mouthing time, daily exposure time, children's weight and PVC object migration rates. There is a strong correlation between age and daily exposure time (time awake and able to mouth objects) and between age and children's weight. There is a weaker correlation between age and mouthing time, however there is a significant downward trend in mouthing time with increasing age. The following discussion describes in detail how these conclusions were reached.

Risk assessment for children 36 months and younger

Hourly mouthing times. Within an age group, all the hourly mouthing times were pooled independently of age.[6] We pooled hourly mouthing times because within an age group there was no practically meaningful relationship between age and mouthing time. This conclusion was based on a regression model relating mouthing time to age.[7] While the regression was statistically significant, it predicted that differences in mouthing times were small between children who were close in age. For example, children a month apart were predicted to have hourly mouthing times that differed by 0.0046 minutes and children 10 months apart would have predicted differences of 0.046 minutes. With predicted differences that small, it did not seem appropriate to distinguish mouthing times by age within an age group.

Exposure and daily mouthing times. Daily mouthing time was calculated from hourly mouthing time by multiplying hourly mouthing time by daily exposure time. Exposure time estimates involved another regression equation. We used a model for exposure time for two reasons. First, we needed a statistical model to fill in exposure times for 60 of the 169 children whose parents had not provided exposure time. Second, we had exposure time data from almost

[6] Age groups used in the briefing package were 3–12 months, 12-24 months and 24-36 months.
[7] Soft Plastic Mouthing Time is measured in minutes per hour and age is expressed in months. These are the same units for mouthing time as found in table 2 above. Statistics were ($F = 5.44$ on 1 and 166 df, $p < 0.0208$), $r = 0.16$. The regression equation was Soft Plastic Toy Mouthing Time = 0.209 – 0.0046 Age

all the children in the Phase I study, so exposure time would be based on a larger sample than the observational study (n=483). This sample spanned ages between 3 months and 6 years.

Like the mouthing equation, the regression equation was statistically significant. However, the correlation between exposure time and age was higher than the correlation between hourly mouthing time and age.[8]

Weight. The calculation for DINP intake was completed by multiplying daily mouthing time by migration rates and then dividing by body weight. Weight was also related to age. In the risk analysis, we used age-based tables for the distribution of children's weight (U. S. Environmental Protection Agency, 1997). Weight in itself is not thought to affect DINP intake, but the ADI and risk are stated in intake per unit body weight. Heavier children can ingest the same amount of some chemical as lighter children but will have a lower risk.

To summarize, there was a weak relationship between age and hourly mouthing time, and a stronger relationship between age and body weight and age and exposure time. Assembling these factors led to a relationship between the child's age and DINP intake for children between 3 and 36 months. The results were grouped by age.

Extrapolating DINP risk for children over 36 months

The issue then arose about what to do about estimating DINP intake and risk for children over 36 months of age (page 242 cited in the question above). As a result of problems with the telephone survey, staff had no mouthing data for these children to be used in a risk analysis. Staff looked at data we had collected and other studies to determine if we could safely conclude that the DINP risk for older children was no higher than children under 36 months.

We considered the following:

1. We had exposure time data and body weight data for children over 36 months. These were both components of the intake equation with exposure time in the numerator and weight in the denominator. The data showed that both variables increased with increasing age. We looked at the ratio of exposure divided by weight and found that the ratio decreased with increasing age. This meant that if children 36 months and older had mouthing times that were the same as children under 36 months, the DINP intake in dose per body weight would be lower.

2. We had no data on hourly mouthing times for children over 36 months. Since we had a downward sloping curve with age up to 36 months, we suspected that this pattern would continue for older children. Also at the time, we had data from Juberg et al (2001) which also showed mouthing time decreased with increasing age up to 36 months.[9]

---

[8] $F(1,481) = 166.01$, $p < 0.001$. The correlation, r, was 0.51. The regression equation was Exposure time = 9.46 + 0.0375 Age, with exposure time in hours and age again in months.

[9] The Juberg study and our study are "the two studies" noted in the question.

3. Additionally, we had one study on mouthing time for children over 36 months. This was data collected by Smith and Kiss (1998), which showed that mouthing time decreased with increasing age between 1 and 4 years, then stabilized for the older children. Recently we received a second study that included older children (Tulve et al, 2002). This study shows a negative relationship between age and mouthing frequency for children between 10 months and 60 months.

This information led staff to recommend that an observation study not be conducted for older children because it appeared very unlikely that such children would have higher DINP intake than younger children.

5. Assuming that children were mouthing what was available in their respective homes, how do we know how representative that is of the totality of children's products on the market? And unless we know that, how can we give an estimate of how long a particular product category is mouthed by children and how can we be confident that our migration analysis was truly representative?

The sample of toys involved in the migration rate analysis was based on the toys the professional observers described that study children mouthed. The process we used to obtain the toy sample for migration rate estimation was as follows:

- Human Factors staff examined the record of every mouthing observation (more than 20,000 separate incidents) in the data provided by the observation contractor. Staff then classified the objects mouthed as "soft plastic toys," or something else based on the descriptions provided in the data. Contractor staff had also classified objects as "soft plastic" but this was reviewed and edited by Human Factors staff.
- Hazard Analysis staff provided a list of soft plastic objects in decreasing order of total mouthing time to the CPSC lab staff. The descriptions did not usually include brand names, but were enough to allow lab staff to shop and purchase items.
- Using this list, lab staff purchased soft plastic toys that were available at local stores. These toys were then used for the migration rate studies. The list of objects purchased was in the briefing package.

In view of the sample demographics described in answer to question 1 and in the briefing package, and the process above, we believe the sample of soft plastic objects is representative of such objects in children's homes.

References

Giesbrech LH, Kulp DW, Starer AW (1999), *Telephone Survey Design*. Joing Program in Survey Management Course Manual. University of Maryland, College, Park, MD.

Groot ME, Lekkerkerk MC, Steenbekkers LPA (1998), "Mouthing Behavior of Young Children: an Observational Study," Wageningen Agricultural University, Wageningen, Netherlands.

Juberg DR, Thompson KM, Alfano K, Coughlin RJ (2001), "An Observational Study of Object Mouthing Behavior by Young Children," *Pediatrics, 107(1)*, pages 135-142.

Smith T, Kiss C (1998), "Empirical Observations of Children's Mouthing Behaviors: Frequencies and Durations," U. S. Consumer Product Safety Commission, Washington, DC.

Tulve NS, Suggs JC, McCurdy T, Cohen Hubal EA, Moya J (2002), "Frequency of Mouthing Behavior in Young Children," *Journal of Exposure Analysis and Environmental Epidemiology*. 12, 259-264.

U.S. Environmental Protection Agency (1997), "Exposure Factors Handbook, Volume 1." Office of Research and Development, National Center for Environmental Assessment, Washington, DC.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: January 16, 2003

TO : Marilyn L. Wind, Ph.D., Project Manager, Petition HP 99-1

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director for Health Sciences
Lori Saltzman, M.S., Director, Division of Health Sciences

FROM : Michael A. Babich, Ph.D., Chemist, Division of Health Sciences

SUBJECT : Response to Commissioner Moore's Follow-Up Questions to the Public Briefing on the Petition Requesting a Ban of the Use of PVC in Products Intended for Children Five Years of Age and Under (HP 99-1). Questions 6-10.

6. *When you add in the exposure to phthalates that a child could be receiving through other sources in the home/environment, you can have some children potentially over the ADI. Do we know how far over the ADI you have to go before there is cause for concern?*

In responding to this question, it is important to note that, at present, only about 42 percent of soft plastic toys and no teethers, rattles, or pacifiers, contain DINP. The estimated 95th percentile oral exposure from mouthing soft plastic toys is 0.53 µg/kg-d, which is two orders of magnitude below the ADI of 120 µg/kg-d (briefing package p. 381). Background exposure to total dialkyl phthalates has been estimated to be as great as 23 µg/kg-d (briefing package p. 387). Thus, even if the background exposure is added, the total exposure (23.5 µg/kg-d) is still well below the ADI.

The staff also estimated the exposure that could occur if all soft plastic toys, teethers and rattles contained DINP. In this hypothetical case, the estimated 95th percentile exposure for 3-12 month olds, the age group with the highest exposure, would be 2.2 µg/kg-d. Again, even if the background exposure is added, the total exposure (25.2 µg/kg-d) is still well below the ADI.

Therefore, even if exposure to total phthalates from other sources is considered, children mouthing soft plastic toys, teethers, and rattles are not likely to exceed the ADI.

The ADI is an estimate of the amount of DINP that one may be exposed to over a lifetime with a negligible risk of harm. In the present case, the ADI is based on a study in which animals were fed DINP over a lifetime. The ADI is 125 times below the dose at which no adverse health effects were observed in the animals. At a dose 1,250 times the ADI, there was an increase in the incidence of spongiosis hepatis, which appeared relatively late in life. If an individual exposure were to exceed the ADI, this would not necessarily result in harm. We cannot say exactly at what dose or duration of exposure, if any,

harmful effects would occur. We can only say that exposure up to the ADI for up to a lifetime of exposure is considered to present a negligible risk of harm.

7. *Given that some few children might approach or even slightly exceed the ADI, and that migration rates were not obtained for pacifiers, are we sure that the voluntary removal of DINP from pacifiers is sufficient? Do pacifiers tend to be made domestically? Do we periodically test pacifiers for DINP?*

   Pacifiers are generally made of either latex or silicone. Neither latex nor silicone products contain DINP. The staff tested children's products for the presence of phthalates three times between 1998 and 2002. In 1998, only one brand of pacifier was found to contain phthalates, but it is no longer made. In 1999 and 2002 we found no phthalate-containing pacifiers. To our knowledge, no pacifiers sold in the U.S. contain DINP. Some pacifiers are manufactured domestically, but substantial numbers are imported. Since no pacifiers contain DINP and staff knows of none made of PVC, the voluntary agreement appears to be working.

8. *We have a recent request to docket a petition to ban phthalates in polymer clay. Is the data from soft plastic toys likely to be sufficient to make a determination on this proposed ban or could this be a case where more information on dermal exposure could be needed?*

   The staff has not received a petition on polymer clay for review. However, polymer clay is a different product that contains different dialkyl phthalates. Polymer clay is intended for children over the age of three and adults. It is not intended for mouthing. Therefore, this is a separate issue that is not related to the discussion on soft plastic teethers, rattles, and toys.

9. *On pages 356-357 of the package is the following: "No data on the relative susceptibility of children or immature animals to DINP are available.... as noted by the CHAP, the lack of data on the effects of DINP in children or immature animals is a potentially significant source of uncertainty." Are you confident that the ADI is sufficiently low to take this into account?*

   Yes. The ADI is 125 times below the dose at which no adverse health effects were observed in the animals. In deriving the ADI, the CHAP included two 10-fold uncertainty factors—the first for the possibility that humans may be more sensitive to DINP than animals and the second to protect sensitive populations, including children.

10. *The CHAP concluded that DINP is not genotoxic and that the mechanism by which it causes liver cancer in rats is not readily induced in humans. Do these same conclusions apply to DEHP which was removed from pacifiers, rattles and some other children's products in the 1980's? Given the more definitive scientific information that we have about the chronic hazards associated with exposure of DINP and what we now know about children's mouthing behavior, would we be likely to come to the same conclusion about DEHP that we came to back in the 1980's?*

In the 1980's, the concern about DEHP was its ability to induce liver tumors in animals. At the present time, our knowledge of the mechanisms by which DEHP, DINP, and other peroxisome proliferators induce liver tumors in animals has increased greatly. The CHAP's conclusions regarding the potential carcinogenicity of DINP would likely apply to DEHP as well.

The CPSC staff has not recently reviewed the health effects of DEHP or derived an ADI value. However, DEHP is known to induce non-cancer health effects in animals, including spongiosis hepatis and developmental effects. The European Union has set a tolerable daily intake (TDI) (similar to an ADI) of 37 μg/kg-d for DEHP, based on developmental effects in animals. Because we have not conducted a toxicity review or risk assessment for DEHP, the staff cannot comment on the TDI set by the European Union.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

OFFICE OF SECRETARY
2003 FEB 13 A 10:24

Memorandum

Date: FEB 13 2003

TO : The Commission

THROUGH: Todd A. Stevenson, Secretary
W.H. DuRoss, III, General Counsel
Patricia M. Semple, Executive Director
Jacqueline Elder, Acting Assistant Executive Director
Office of Hazard Identification and Reduction
Mary Ann Danello, Ph.D., Associate Executive Director,
Directorate for Health Sciences

FROM : Michael A. Babich, Ph.D., Chemist, Division of Health Sciences
Marilyn L. Wind, Ph.D., Deputy Associate Executive Director
Directorate for Health Sciences
Lowell Martin, Office of the General Counsel

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 ___ Date 2/13/03

CPSA & FHSA Cleared
No Mfrs/Privlblrs 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.