

February 18, 2004

VIA HAND DELIVERY AND EMAIL: [tsac@committees.usgbc.org](mailto:tsac@committees.usgbc.org)

Nigel Howard  
Vice President  
U.S. Green Building Council  
1015 18th Street, NW, Suite 805  
Washington, DC 20036

RE: Registration for February 18, 2004 Public Meeting

Dear Mr. Howard:

The Phthalate Esters Panel (Panel) of the American Chemistry Council appreciates this opportunity to comment on the LEED3 TSAC PVC Task Group (Task Group) methodology for its PVC database. These comments pertain specifically to the Task Group's consideration of information on phthalate esters as part of its methodology. The Panel consists of the major U.S. manufacturers and some users of phthalate esters.<sup>1</sup>

#### Background on Phthalate Esters

Phthalate esters refers to a class of chemicals which have in common a benzene ring with two carboxylic acid groups that are esterified with an alcohol. The nature of the hydrocarbon "arms" of the molecule differentiates the various phthalate esters.

In terms of volume, the largest use of phthalate esters is to plasticize polyvinyl chloride (PVC). Flexible PVC products containing phthalates include wallpaper, vinyl flooring, carpet tile, shower curtains, and wire and cable insulation.

It is important to understand that not all phthalate esters are used with vinyl. In particular, to the Panel's knowledge, there is no use in vinyl of low molecular weight phthalates such as dimethyl phthalate (DMP), diethyl phthalate (DEP), and dibutyl phthalate (DBP).<sup>2</sup>

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<sup>1</sup> The members of the Panel are BASF Corporation, Eastman Chemical Company, ExxonMobil Chemical Company, Ferro Corporation, PolyOne Corporation, and Teknor Apex Company.

<sup>2</sup> Very small quantities of DBP were used in PVC for specialty applications in the 1970's and 1980's, but no such uses now exist.

Phthalates are not covalently bound to the PVC molecules, and it is therefore possible for them to migrate out of the PVC matrix. It is important to understand, however, that such migration occurs at a very low rate. Although there is not a covalent bond, there are other considerable physical and chemical forces that retain the phthalate within the PVC matrix. Indeed, if this were not so, phthalates would not be useful as plasticizers, because the flexibility of the PVC would not last long. The fact that flexible PVC products remain flexible for years testifies to the very low rate of migration of phthalate from the PVC. In addition, some PVC products have a surface treatment that acts as a barrier to phthalate migration.

The PVC Reports List Should Contain Authoritative Reviews of Phthalates rather than Attempt to List All Relevant Individual Studies

The proposed methodology involves generating a matrix with cells populated with relevant studies to consider in the context of the issue addressed by the cell. The Task Group is generating a PVC Reports List that apparently is to be the universe of studies for populating the cells.

The version of the list released for comment includes over 400 entries concerning phthalates. While this might be thought a large number already, it is but a minor portion of the available and pertinent studies. Phthalate esters are among the most studied compounds in the world. The National Toxicology Program Center for Evaluation of Human Reproductive Risks (NTP CERHR) reviewed over 1000 studies for its review of seven phthalates, and those studies related primarily to the endpoints of reproductive and developmental toxicity. Hundreds of other studies exist that relate to other endpoints.

It is unrealistic to expect that the Task Group could fairly review the relevant scientific literature on a study-by-study basis within a reasonable timeframe. Many of the studies on phthalates involve complex, cutting-edge science, such that high levels of expertise are needed to analyze the studies and draw an overall conclusion. Review panels with a number of scientific experts have taken months or even years to conduct reviews on phthalates. For example, the NTP CERHR Expert Panel, which was composed of 16 scientists from a wide variety of disciplines, took 15 months – including three intensive 2-day meetings – to complete its review and report.

Rather than try to replicate any such process, the Panel strongly urges that the Task Group rely on reviews of phthalates conducted by authoritative bodies. Several such in-depth reviews have been completed recently, as listed below. As these reviews are recent and comprehensive, they capture nearly all pertinent studies on phthalates, and as well provide a synthesis of what the overall weight of the evidence indicates about the potential risk posed by such phthalates.

- National Toxicology Program Center for Evaluation of Human Reproductive Risks (NTP CERHR) Review of Seven Phthalates. The first phase of this review of reproductive and developmental toxicity risks of phthalates consisted of the generation of reports by a panel of 16 independent scientists expert in wide array of relevant disciplines. The Expert Panel reports were published in October 2000. NTP CERHR accepted comments on those reports, reviewed studies that became available subsequent to the Expert Panel

review, and published final monographs for six of the seven phthalates in 2003 (the seventh monograph is expected within the next two months). In general, the NTP CERHR found minimal to negligible concern for human reproductive or developmental effects from exposures to phthalates. The Expert Panel reports and NTP CERHR monographs can be accessed at <http://cerhr.niehs.nih.gov/reports/index.html>.

- Consumer Product Safety Commission (CPSC) Assessment of DINP. The CPSC conducted an in-depth assessment of the potential hazards diisononyl phthalate (DINP). Part of the CPSC review process consisted of the convening of a Chronic Hazard Advisory Panel (CHAP), which consisted of seven independent experts in relevant scientific disciplines. The CHAP report was published in June 2000 and can be accessed at <http://www.cpsc.gov/LIBRARY/FOIA/Foia01/os/dinp.pdf>. The CPSC used the results of the CHAP plus its own analysis of the potential health risks of DINP-plasticized vinyl toys and other items to young children. The CPSC concluded there was no demonstrated health risk posed by PVC toys or other products intended for children. <http://www.cpsc.gov/library/foia/foia03/petition/Ageunder.pdf>. On this basis the Commissioners unanimously voted to deny a petition to ban such products. <http://www.cpsc.gov/library/foia/foia02/brief/briefing.html>
- European Union (EU) Risk Assessments. The EU has undertaken intensive and comprehensive risk assessments for several phthalates. Development of the risk assessments includes drafting of a report by scientists in the country designated as rapporteur for the chemical, extensive discussion of the data and conclusions by scientific experts from all EU member countries, and review of the draft risk assessment by the EU Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE). In August 2003, the European Chemicals Bureau published the final assessments for DINP and diisodecyl phthalate (DIDP), which find no need for risk reduction measures for any current use of these chemicals. Those assessments are available at <http://ecb.jrc.it/existing-chemicals/> (click on Risk Assessment tab, then risk assessment reports link in the fourth bullet). Risk assessments are also ongoing for butyl benzyl phthalate (BBP) and di(2-ethylhexyl) phthalate (DEHP).
- International Agency for Research on Cancer (IARC) Monographs. IARC, an agency of the World Health Organization, has reviewed the carcinogenicity data for DEHP and BBP and has found that neither is classifiable as to carcinogenicity to humans. IARC reviews consist of comprehensive analysis and discussion of the data by a panel of approximately 30 independent experts. The IARC summary for BBP can be accessed at <http://monographs.iarc.fr/htdocs/monographs/vol73/73-04.html>, and that for DEHP at <http://monographs.iarc.fr/htdocs/monographs/vol77/77-01.html>.

To the extent the Task Group wishes to include other studies on phthalates, it should strive to include all major relevant studies, representing the full weight of the evidence. At a minimum, it should include the primary studies relied upon in the above reviews. The Task Group should avoid drawing on the references lists of opinion or advocacy pieces, which may exclude relevant studies that do not support the position of the authors.

### The PVC Reports List Should Exclude News Articles and Opinion Pieces

Several of the phthalate items in the current PVC Reports List are simply news articles or editorials. While they may be published in a scientific journal, they represent the understanding and opinion of a reporter or an advocate, not the results of a scientific study. Even in scientifically-oriented journals, such items are not peer-reviewed, and they frequently are alarmist, biased, and/or inaccurate. It is therefore inappropriate to include such items in the Reports List.

Likewise, some reports on phthalates have been produced by individuals or groups with a stated position on PVC and/or phthalates. Although they may purport to be summaries of the available data, they are in essence opinion pieces that have not been peer reviewed. They may fail to discuss studies that do not support their position, or may provide interpretations that do not reflect the scientific consensus. The Panel therefore believes it also is inappropriate to include such reports in the PVC Reports List.

### The PVC Reports List Should Contain Only Reviews and Studies on the Higher-Molecular Weight Phthalates that are Used in Vinyl Building Products

Some of the studies included in the current PVC Reports List are on phthalates not used in vinyl. As discussed above, lower-molecular-weight phthalates such as DMP, DEP, and DBP are not used in vinyl products. Any studies or reviews of these phthalates therefore are not relevant for the Task Group's purposes and should be excluded from the PVC Reports List.

### The Task Group Should Exercise Caution in Extrapolating Results for a Given Phthalate to Other Phthalates

While phthalates possess some similarities, their physical, chemical and toxicological properties depend in large part on the hydrocarbon "arms" of the molecule, which vary with each phthalate. Indeed, a variety of phthalates are commercially produced because their varying properties make them suitable for a variety of uses.

In some cases, the properties of phthalates are on a continuum – for example, the solubilities of phthalates in water decrease with increasing molecular weight. In other cases, however, observation of an effect caused by one phthalate may be unique to that phthalate, or the effect may occur in some other phthalates only at much higher doses.

It is common to see claims that "phthalates" cause such-and-such an effect, when in fact the effect has been seen in tests of only one or two particular phthalates, and has not been observed in tests of other phthalates. The Task Group should scrutinize any such statement for its basis. An effect observed for one phthalate should not be ascribed to any other phthalate without a scientific basis for doing so.

### The PVC Task Group's Methodology Should Provide for Consideration of Risk, Not Just Hazard

In toxicological parlance, some of the studies on phthalates indicate a hazard – that is, at a given dose, the phthalate elicited an adverse effect in the study animal. The fact that a chemical poses a hazard to a study animal does not necessarily mean, however, that it poses a risk. In general, effects from phthalates are seen only at very high levels in rodent studies – levels to which humans would not realistically be exposed. In addition, studies in primates indicate that the effects seen in rodents may have no relevance to humans. Thus, while phthalates may pose a *hazard* of a given effect, the data may indicate they do not pose a significant *risk*.

Consideration of risk is particularly important for the comparison of alternatives. Chemical A may be more “hazardous” than Chemical B in the sense that a lower dose will elicit effects. But the relative exposures may be such that Chemical B may actually pose a greater risk.

It is not clear how the PVC Task Group's methodology will account for risk versus hazard. The results of any study indicating a hazard should be considered in the context of the dose level required to elicit an effect and likely levels of actual environmental exposure. This is an advantage of using the reviews that are discussed above – they each do consider the risks posed by phthalates, not just their hazards.

Consideration of phthalates' risk recently has been greatly facilitated by the availability of biomonitoring data from the Centers for Disease Control and Prevention (CDC). The CDC data for phthalate urinary metabolites can be converted to actual human exposures to phthalates; this shows that exposures to phthalates – especially the higher-molecular weight phthalates used in vinyl building materials – are well below government safety levels – levels which in turn are well below levels at which effects are actually seen in rodent studies.<sup>3</sup> The CDC biomonitoring report, “Second National Report on Human Exposure to Environmental Chemicals” is available at <http://www.cdc.gov/exposurereport/>. Table 1 provides phthalate exposure levels, for phthalates used in vinyl, calculated from the data in that report.

### The PVC Task Group Should Apply Precaution in Using a Precautionary Approach

The proposed methodology states that the Task Group will include use of a precautionary approach. Any precautionary approach should recognize that choosing an alternative to avoid a perceived hazard is not necessarily precautionary. As stated above, Chemical A may be more “hazardous” than Chemical B in the sense that a lower dose will elicit effects. But the relative

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<sup>3</sup> See McKee, R. et al. (2004). NTP center for the evaluation of risks to human reproduction reports on phthalates: addressing the data gaps. *Reproductive Toxicology* 18(1):1-22 (abstract available at <http://authors.elsevier.com/sd/article/S0890623803001254>; David, R. (2000). Exposure to phthalate esters. *Environmental Health Perspectives* 108:A440 and Kohn, M. et al. (2000). Human exposure estimates for phthalates. *Environmental Health Perspectives* 108:A 440-A 442 (both available at <http://ehpnet1.niehs.nih.gov/docs/2000/108-10/correspondence.html#exp>).

exposures may be such that Chemical B may actually pose a greater *risk*. Or it may be that Chemical B is less studied so that its hazards (and thus risk) are simply unknown.

As stated above, phthalate esters are among the best-studied compounds in the world. Good scientific methodology requires that toxicology studies involve doses sufficiently high to elicit an effect. This is necessary to obtain a measure of the risk posed by the test substance. Thus, because phthalates have been well-studied, they have been observed to produce effects at high doses in animal studies. This substantial body of studies and the observation of effect levels is an advantage, because it enables the derivation of acceptable levels of exposure.

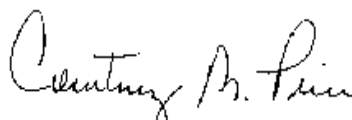
Because the existing data allow development of acceptable exposure levels for phthalates, it is possible to compare environmental levels of phthalates to those acceptable levels. As discussed above, this comparison shows that phthalate exposures (from all sources, not just building materials) are well below those safety levels (see Table 1). And, indeed, in over 50 years of use, there is no reliable scientific evidence that phthalate exposure has caused any adverse effects in humans.

In light of this, it would be ironic to advise shifting away from phthalates to materials that may not be as well studied, relying on a "precautionary" approach that concerns itself with speculation about potential hazards. The PVC Task Group precautionary approach should not penalize a phthalate ester for being better-studied than other alternatives, and should recognize the advantages such studies provide for using these materials in a beneficial manner.

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If you have any questions, please call Marian K. Stanley, Senior Director and Manager of the Phthalate Esters Panel, at (703) 741-5623 or email her at [Marian\\_St Stanley@americanchemistry.com](mailto:Marian_St Stanley@americanchemistry.com).

Sincerely yours,



Courtney M. Price  
Vice-President, CHEMSTAR

**Table 1**

**Phthalate Exposures Based on 2<sup>nd</sup> CDC National Exposure Report<sup>a</sup>  
 Expressed as Micrograms per Kilogram per Day<sup>b</sup>**

**Geometric Mean**

Phthalate	Total Sample	By Age Group			By Gender		By Race/Ethnicity <sup>c</sup>			RfD <sup>d</sup>
		6-11	12-19	20+	Men	Women	Mex-A	Black	White	
BBP	0.51	0.80	0.35	0.43	0.46	0.56	0.46	0.54	0.51	200
DEHP	0.63	0.57	0.28	0.61	0.58	0.67	0.63	0.62	0.62	20
DINP	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	120 <sup>e</sup>

<LOD = below limit of detection

**95<sup>th</sup> Percentile**

Phthalate	Total Sample	By Age Group			By Gender		By Race/Ethnicity <sup>c</sup>			RfD <sup>d</sup>
		6-11	12-19	20+	Men	Women	Mex-A	Black	White	
BBP	2.82	2.84	1.39	2.08	2.67	2.91	2.48	3.16	2.83	200
DEHP	3.71	4.62	1.33	3.51	4.33	3.27	3.15	3.69	4.01	20
DINP	0.68	0.52	0.17	0.73	0.67	0.68	0.56	0.68	0.79	120 <sup>e</sup>

a. Second National Report on Human Exposure to Environmental Chemicals, U.S. Centers for Disease Control and Prevention (<http://www.cdc.gov/exposurereport/>).

b. The urinary concentrations of phthalate monoesters reported by CDC were converted to daily intake of the parent phthalate using the methodology described in David, R. (2000). Exposure to phthalate esters. *Environmental Health Perspectives* 108(10):A440. The values given by this methodology are very similar to values derived by a separate methodology used by the CDC and the National Institute for Environmental Health Sciences. Kohn, M., et al. (2000). Human exposure estimates for phthalates. *Environmental Health Perspectives* 108(10):A440-442. Note, however, that the conversion equation in the David article was incorrectly formatted. The correct equation is as follows:

$$\text{daily intake } (\mu\text{g}/\text{kg}/\text{day}) = \left( \frac{\text{urine conc.} (\mu\text{g}/\text{g creatinine}) \times \text{creatinine excretion} (\text{g}/\text{kg}/\text{day}) \times \text{mol wt diester} (\text{g}/\text{mol})}{\text{mol w. monoester} (\text{g}/\text{mol}) \times \left( \frac{\text{mol monoester in urine}}{\text{mol diester ingested}} \right)} \right)$$

The values used for creatinine excretion were taken from Tietz, M., ed. (1986). *Textbook of Clinical Chemistry*. W.B. Saunders Co., Philadelphia, PA, p. 1821. Values for the ratio of monoester in urine to diester ingested were taken from Anderson, W. Castle, L., Scotter, M., Massey, R. and Springall, C. (2001). A biomarker approach to measuring human dietary exposure to certain phthalate diesters. *Food Additives & Contaminants* 18(12):1068-174.

c. Mex-A = Mexican Americans; Black = Non-Hispanic Blacks; White = Non-Hispanic Whites.

d. From the Integrated Risk Information System (IRIS) database maintained by the US Environmental Protection Agency ([www.epa.gov/ngispgm3/iris](http://www.epa.gov/ngispgm3/iris)).

e. EPA has not developed an RfD for DINP. The value given is the Acceptable Daily Intake from *Report to the US Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP)*, June 2001 (available at <http://www.epsc.gov/LIBRARY/FOIA/Foia01/os/dinp.pdf>).