The Chemical Company

Steven J. Goldberg
Vice President & Associate General Counsel

January 20, 2012

Michael Babich
Directorate for Health Sciences,
Consumer Product Safety Commission
Bethesda, MD 20814

RE: Failure to Consider Industry Data on Phthalates and Phthalate Substitutes
Chronic Hazard Advisory Panel (CHAP) on phthalates and phthalate substitutes

Dear Dr. Babich:

Thank you for your December 19, 2011 letter, written in response to BASF Corporation's (BASF's) concerns that the CHAP may fail to fully consider certain toxicological and other information on Hexamoll® DINCH™ ("DINCH") and dipropylheptyl phthalate (DPHP) in its review of potential health effects of phthalates and phthalate alternatives. As stated in my November 29, 2011 letter to you, robust summaries in the NICNAS, EFSA, and SCENIHR reports on Hexamoll® DINCH™ and the oral risk assessment by NSF International on DPHP were developed by these organizations from their independent reviews of the full study reports provided by BASF SE, and so should be duly considered by the CHAP. In your letter, you responded that "[D]uring the July 20 I0 CHAP meeting, Dr. Rainer Otter, Head of Regulatory Toxicology, BASF, denied the CHAP's request to provide copies of the underlying toxicity studies on which your company's summary submissions on DINCH and DPHP are based. Because the summaries lacked sufficient detail on the methods used and data results, the CHAP requested the underlying studies so that they could independently assess and draw conclusions concerning DINCH or DPHP."

As Dr. Otter probably explained, BASF is not able to publicly disclose the underlying study reports without compromising their commercial value to BASF Corporation (and to BASF SE, its corporate parent) in support of their REACH registrations of these two substances. BASF remains primarily concerned that the public disclosure of these study reports would provide an opportunity for non-European manufacturers to circumvent their responsibility under REACH to compensate BASF for access to the studies and unlawfully gain access to the European market. The commercial harm to BASF, should that scenario unfold, could be significant. That said, we want to provide the CHAP members with every opportunity to review the underlying studies and assure themselves that the conclusions presented in the robust summaries are technically valid. We offer two options:

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Option 1: We would offer to have BASF's toxicologists meet with the CHAP to go through each of the studies in detail, providing complete copies of the study reports to the CHAP members for use during that meeting. The study reports would be returned to the BASF participants at the end of the meeting and would not remain in the CHAP's possession.

Option 2: We would submit copies of the underlying reports to the CHAP with the understanding that they would be considered "commercial information" protected from disclosure to the public by the US Freedom of Information Act (5 U.S.C. §552). While we understand that the CHAP's practice is to post all documents considered during its review on http://www.cpsc.gov/about/cpsia/chap0710.html , its website, we would submit that the CHAP would be required to manage such commercial information received from a manufacturer in the confidential manner proposed by BASF, as discussed below. Should the CHAP elect this option, BASF would submit copies of the study reports accompanied by the information required at 16 CFR § 1015.18(c).[1] We would also continue to make BASF's toxicologists available by phone to clarify any aspect of these reports.

We believe that Option 2 is available to the CHAP for the following reasons: Given:

(i) that REACH registration is required of each legal entity manufacturing DINCH and/or DPHP (or products containing thereof) in the EU or importing into the EU,
(ii) the commercial value of these study reports to BASF Corporation in support of its REACH registration (through its Only Representative) of relevant BASF products, and
(iii) that other EU or non-EU manufacturers would need lawful access to these studies to support their own REACH registration(s),

it is clear that these study reports qualify as "commercial information" protected from disclosure by the US Freedom of Information Act (5 U.S.C. §552(b)(4)).

Notwithstanding CHAP policy to post all information received on its website, the CHAP would be required to manage the confidential information proposed to be shared by BASF in the manner described. As noted at Section 6 of the Consumer Product Safety Improvement Act of 2008 (Public Law 110-314, codified at 15 U.S.C. § 2055), "Nothing contained in this Act shall be construed to require the release of any information

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[1] 16 CFR § 1015.18(c) Each request for exemption from disclosure under 5 U.S.C. 552(b)(4) as a trade secret or privileged or confidential commercial or financial information must:
(1) Specifically identify the exact portion(s) of the document claimed to be confidential;
(2) State whether the information claimed to be confidential has ever been released in any manner to a person who was not an employee or in a confidential relationship with the company;
(3) State whether the information so specified is commonly known within the industry or is readily ascertainable by outside persons with a minimum of time and effort;
(4) State how release of the information so specified would be likely to cause substantial harm to the company's competitive position; and
(5) State whether the submitter is authorized to make claims of confidentiality on behalf of the person or organization concerned.

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described by subsection (b) of section 552 of title 5 or which is otherwise protected by law from disclosure to the public." Moreover, "All information reported to or otherwise obtained by the Commission or its representative under this Act which information contains or relates to a trade secret or other matter referred to in section 1905 of title 18 or subject to section 552(b)(4) of title 5 shall be considered confidential and shall not be disclosed." As noted at 15 USC §2077(g) (Chronic Hazard Advisory Panels, Requests for and disclosures of information): "Each Panel shall request information and disclose information to the public, as provided in subsection (h) of this section, only through the Commission." In summary, the disclosure of information submitted to the CHAP is subject to requirements protecting commercial information from public disclosure.

Moreover, it would appear unlawful for the CHAP to disregard or discount the information in the robust summaries on DINCH and DPHP, provided it finds the methods used to be valid and the data results appropriately interpreted. As noted at 15 USC §2057c(2)(B)(iv), "The panel shall ... review all relevant data, including the most recent, best-available, peer-reviewed, scientific studies of these phthalates and phthalate alternatives that employ objective data collection practices or employ other objective methods." (Emphasis supplied.) The robust summaries cover information that clearly falls within the scope of "all relevant data" which shall be reviewed by the CHAP and, if found to be technically valid, duly considered.

We appreciate your and the CHAP's consideration of these options and look forward to hearing how it would like to proceed. We recognize that the CHAP is operating under a defined timeline and so are prepared to proceed with urgency in satisfying either option. Please contact me at 973 245-6057 should you like to discuss this matter. In addition, if you or any of the panel members have questions about the underlying studies, again please contact Dr. Raymond David, Manager of Toxicology (973 245-6858), or Dr. Patrick Harmon, Industry Manager for Industrial Petrochemicals (713-759-3087).

Sincerely yours,

Steven J. Goldberg

cc: Raymond David
Patrick Harmon

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