October 17, 2016

Linda Birnbaum, Ph.D.
Director
National Institute of Environmental Health Sciences and the National Toxicology Program
PO Box 12233 (MD B2-01)
Research Triangle Park, NC 27709

Re: Request for Technical Report on Research Evaluating Potential Mechanism for Formaldehyde-Induced Leukemia in p53-Haploinsufficient Mice

Dear Dr. Birnbaum:

In August 2015, the American Chemistry Council's Formaldehyde Panel wrote to you seeking your assistance in the expeditious publication of formaldehyde research conducted by the National Institute of Environmental Health Sciences (NIEHS) which had been presented at 2014[1] and 2015[2] Society of Toxicology (SOT) meetings. While we appreciate your September 2015 reply indicating that this work would be published once finalized, now more than a year later and nearly two years since the findings of this study were initially presented, we recently learned from Dr. Morgan that the manuscript was submitted to two peer reviewed journals but not accepted for publication by either. We understand authors are currently working to revise the manuscript for a future submission and that they have no plans to generate a technical report on the study that could be released for public dissemination.

We certainly encourage NIEHS to continue to seek publication in a peer reviewed journal, but, due to the timeliness of this research and ongoing reviews by other chemical assessment agencies, it is essential that a technical report be provided so that we and other agencies, such as EPA, have the ability to fully understand the data presented during the SOT meetings. This is especially critical given the uncertainty of the eventual publication of the research. Technical reports have been issued by NIEHS in the past for short-term and long-term research studies conducted to characterize various toxicological endpoints. Specifically, in 2005, a technical report was issued on research conducted in genetically modified mice for Aspartame.[3] Notably,

[1] D. L. Morgan, D. Dixon, M. P. Jokinen, D. H. King, H. Price, G. Travlos, R. A. Herbert, J. E. French, M. P. Waalkes. 2014 Society of Toxicology Annual Meeting, Poster Board -129; Evaluation of a potential mechanism for formaldehyde-induced leukemia in C3B6.129F1-Trp53tm1Brd mice.
[2] D. L. Morgan, D. Dixon, M. P. Jokinen, D. H. King, H. Price, G. Travlos, R. A. Herbert, J. E. French, and M. P. Waalkes. 2015 Society of Toxicology Annual Meeting, Abstract #1637; Evaluation of a potential mechanism for formaldehyde-induced leukemia in p53-haploinsufficient mice.
[3] Toxicology Studies of Aspartame (CAS NO. 22839-47-0) in Genetically Modified (FVB Tg.AC HEMIZYGOUS) And B6.129-Cdkn2atm1Rdp (N2) Deficient Mice and Carcinogenicity Studies of Aspartame in Genetically Modified [B6.129-Trp53tm1Brd (N5) HAPLOINSUFFICIENT] Mice. Weblink: https://ntp.niehs.nih.gov/ntp/htdocs/gmm_rpts/gmm1.pdf

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this technical report provides an example of NIEHS developing technical reports on similar research parameters.

The important information that this research can provide to understanding the mode of action for leukemia and formaldehyde exposure makes it essential that NIEHS disclose its findings and the underlying data developed for this research effort. Therefore, in the spirit of transparency, we formally request that NIEHS release a technical report with the research data by November 30, 2016.

Thank you for your prompt response to this request and feel free to contact me with any questions (phone: 202-249-6707 or email: Kimberly_White@americanchemistry.com).

Sincerely,

Kimberly Wise White, PhD
American Chemistry Council (ACC)
Senior Director
Chemical Products & Technology Division

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