Message

From: Sonawane, Bob [Sonawane.Bob@epa.gov]
Sent: 4/2/2013 3:47:13 PM
To: Glenn, Barbara [Glenn.Barbara@epa.gov]
Subject: FW: follow up to Feb 27 meeting
Attachments: 2013_ACCletter_Ravi_final.pdf; 2013_Ravi_attach1_4_c.pdf; 2013_Ravi_attach5poster_c.pdf

Hi Barbara,

FYI.

Bob

From: Mason, Ann [mailto:Ann_Mason@americanchemistry.com]
Sent: Monday, April 01, 2013 5:39 PM
To: Subramaniam, Ravi; Bussard, David; Olden, Kenneth; Sonawane, Bob; Starr, Tom; James A. Swenberg (jswenber@email.unc.edu)
Cc: Brust, Laura; Risotto, Steve
Subject: follow up to Feb 27 meeting

Extracted text from attached Letter

April 1, 2013

Ravi Subramaniam, Ph.D.
National Center for Environmental Assessment
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Follow-Up to February 27, 2013, Meeting
EPA-HQ-ORD-2010-0396

Dear Dr. Subramaniam,

Thank you for arranging the February 27 meeting between Drs. Thomas Starr, James Swenberg, and EPA staff to respond to EPA's questions about the biological data and to allow Dr. Starr to further describe the "bottom-up" approach to characterizing potential human cancer risks from inhaled formaldehyde exposure.

During the February 27 meeting, EPA staff questioned Dr. Swenberg about the methods and conduct of the research. All of his papers have been critically reviewed and published in the peer reviewed literature and subjected to scrutiny by scientific experts internationally.

The need to accommodate endogenous exposures is not a new topic. Scientists and risk assessors have long grappled with the problem of how to incorporate endogenous exposures in chemical assessments. Reviewers of the draft formaldehyde IRIS document and previous IRIS Toxicological Reviews of other endogenous chemicals have criticized EPA for not incorporating the potential contributions of endogenous levels into low level risk values.

The use of the bottom-up approach and these uniquely sensitive biological data provide a vehicle for describing and characterizing the possible inherent risks associated with endogenous formaldehyde. By using conservative default assumptions that assume that all background risk is from endogenous levels of formaldehyde, the bottom-up approach serves to bound possible endogenous risks and provides EPA with a way of characterizing possible added risks associated with exogenous formaldehyde exposure. Thus, the bottom-up approach can provide a 'reality check' of the top-down approach that EPA typically takes.

As I stated at the end of the meeting, there is much more to discuss on these critical issues. ACC continues to believe that EPA's assessment would benefit from additional in-depth scientific discussions on key issues, including the significance of the dG adduct data and the implications of the bottom-up approach to EPA's risk assessment, are urgently needed.

We look forward to continuing this dialogue on these important topics.

Sincerely,
Ann M. Mason
Senior Director

Attachments:
1: Slides from Dr. Swenberg
2: Slides from Dr. Starr
3: Spreadsheet of control animal data from Dr. Swenberg
4: List of relevant manuscripts
5: 2013 SOT Poster by Dr. Ben Moeller
6: 2013 SOT Poster by Dr. Genna Andrews-Kingon
7: 2013 SOT Poster by Dr. Bahar Edrissi
8: 2013 SOT Poster by Dr. Julia Rager
9: 2013 SOT Poster by Dr. Rui Yu

cc: K. Olden, D. Bussard, B. Sonawane, T. Starr, J. Swenberg

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