Message

From: Whalan, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB12B5D4BD5E4BD88CCDE4F514C56A8E-WHALAN, JOHN]
Sent: 7/9/2013 5:53:09 PM
To: Wolf, Doug C. [Wolf.Doug@epa.gov]
CC: Stanek, John [Stanek.John@epa.gov]; Burgoon, Lyle [Burgoon.Lyle@epa.gov]
Subject: FW: Formaldehyde assessment for review by the IRIS Disciplinary Workgroups
Attachments: FormaldehydeTRdraft070113forREVIEW.docx; Memo_HumanCancerQRA_Approaches_FormaldehydeTR.docx; Disciplinary Grps_Formaldehyde_062113.xlsx

Here is the second Email from Vince.

John

From: Cogliano, Vincent
Sent: Monday, July 01, 2013 6:38 PM
To: Bale, Ambuja; Ball, James; Christensen, Krista; Fox, John; Gehlhaus, Martin; Gibbons, Catherine; Guyton, Kate; Hogan, Karen; Hotchkiss, Andrew; Keshava, Nagalakshmi; Kraft, Andrew; Makris, Susan; Newhouse, Kathleen; Persad, Amanda; Schlosser, Paul; Stanek, John; Subramaniam, Ravi; Whalan, John
Cc: Glenn, Barbara; Kraft, Andrew; Burgoon, Lyle; Bussard, David; Chiu, Weihsueh; Cogliano, Vincent; DeSantis, Joe; Gatchett, Annette; Hammerstrom, Karen; Hawkins, Belinda; Perovich, Gina; Rieth, Susan; Ris, Charles; Ross, Mary; Sams, Reeder; Sonawane, Bob; Strong, Jamie; Troyer, Michael; Vandenberg, John; Walsh, Debra
Subject: Formaldehyde assessment for review by the IRIS Disciplinary Workgroups

Hello Disciplinary Workgroup Co-Chairs – Attached are the Tox Review for Formaldehyde, a memo describing approaches to the quantitative cancer assessment, and a "map" that identifies sections that pertain to each Disciplinary Workgroup. The Supplemental Information document will follow Tuesday.

We will discuss the process for reviewing this assessment at Tuesday morning's IRIS Management Council. Then the management liaisons can discuss the review process with their respective Co-Chairs. The Co-Chairs should select primary and secondary reviewers for the sections that are pertinent to their discipline, forward the assessment to their respective Workgroups, and determine how and when their Workgroup will meet to discuss the comments that you will send to the Assessment Managers (Barbara Glenn and Andrew Kraft).

Your review should cover:
1. Are the sections you reviewed clear, convincing, and objective?
2. Are the conclusions supported by the evidence presented?
3. Are the science issues addressed effectively, with alternative perspectives discussed where appropriate?
4. Are the issues raised by the NRC review of April 2011 addressed effectively?

You need not review the original literature. Begin with the evidence tables and see whether the synthesis follows logically and clearly. If not, that is a comment to take up within the Disciplinary Workgroup.

I will also welcome your feedback about how this process worked and how we might improve it in the future.

Thank you for your assistance in simulating the SAB and public reviews of this important assessment,
Vince

From: Glenn, Barbara
Sent: Monday, July 01, 2013 5:40 PM
To: Cogliano, Vincent
Cc: Bussard, David; Perovich, Gina; Sonawane, Bob; Kraft, Andrew
Subject:

The draft toxicological review for formaldehyde is attached. A file containing supplemental information will be sent later today (we have encountered problems inserting portions, complicated by the problems with Outlook that occurred today). We (the formaldehyde team) are looking forward to participating in the review process and anticipate a stronger product as a result.

The toxicological review contains the Front Matter, Hazard Identification and Dose-Response Analyses. The Supplemental Material is organized into appendices supporting the hazard identification, the derivation of toxicity values for several health systems, and the derivation of unit risks for cancer. In addition to the hazard syntheses for each health domain [non-cancer: 1.2; cancer: 1.3], each review group will want to look at the following parts of the assessment for background and documentation of the literature reviews and study methods evaluations:

- Preface materials [pre-Section 1], as well as Section 1.1-- review not required (feel free to do so), but will acclimate reader;
- Literature Review for health domain in Appendix B.3;
- Study Quality Tables for health domain in Appendix B.4;
- Hazard conclusion for the health domain [non-cancer: 1.4.1; cancer: 1.4.2];
- Mechanistic Information for the non-cancer health effects in Section 1.2;
- Dose-Response piece for the health domain [non-cancer: 2.1; cancer: 2.2].

The third attachment is a memo describing some possible approaches for organizing the dose-response section describing the calculation of extra risk using the NCI study results. This draft section is "under construction" and the team did not identify a single way to present this material. The thoughts of the Statistical Working Group will be very helpful in this regard.

The draft contains several comment bubbles throughout indicating items that the team/authors are aware of and revisions that they plan on making. Revisions to various parts of the document are ongoing. In particular, the documentation of dose-response analyses for cancer is in flux.

Instead of extensive track-changes in the files, providing editorial comments in comment bubbles will be more helpful for revisions because the document is not static at this point.

Regards, Barbara and Andrew