Message

From: Keshava, Nagalakshmi [Keshava.Nagu@epa.gov]
Sent: 7/2/2013 7:53:34 PM
To: Gibbons, Catherine [Gibbons.Catherine@epa.gov]; Pratt, Margaret [pratt.margaret@epa.gov]; Keshava, Channa [Keshava.Channa@epa.gov]
CC: Chiu, Weihsueh [Chiu.Weihsueh@epa.gov]; Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]
Subject: FW: Formaldehyde assessment: Supplemental Information attached
Attachments: FormaldehydeAppendixdraft070113forREVIEW.docx

Here is the appendix that contains genotoxicity section.....

From: Cogliano, Vincent
Sent: Tuesday, July 02, 2013 3:20 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: Supplemental Information attached

Hello again, everyone – Attached you will find the Supplemental Information file for Formaldehyde. Please read Andrew's note below for information about the state of the file.

With respect to yesterday's message with what your review should cover, by "issues raised by the NRC review" we mean the specialized science issues and recommendations in chapters 3-6 of the NRC report (e.g. toxicokinetics, modes of action, portal-of-entry effects, systemic effects, RfCs and unit risks). The more general recommendations in chapter 7 will be addressed by a concurrent overall review of the entire assessment.

When your disciplinary workgroup has developed its recommendations, please send them to Barbara Glenn and Andrew Kraft, with copies to David Bussard, Gina Perovich, Charlie Ris, Bob Sonawane, and also to me so I can keep track of the progress of the section reviews.

Thank you again for your help in reviewing this assessment that is critical to the IRIS program.

-- Vince

From: Kraft, Andrew
Sent: Monday, July 01, 2013 8:16 PM
To: Glenn, Barbara; Cogliano, Vincent
Cc: Bussard, David; Perovich, Gina; Sonawane, Bob; Kraft, Andrew
Subject: RE:

Please find attached the file containing the Supplemental Information to the formaldehyde Toxicological Review. Similar to the TR, this document has numerous comment bubbles, including materials in process and yet to be inserted.

It is important to note that this document is quite preliminary as compared to the TR, in particular Appendix C and D (which will undergo substantial revisions over the coming weeks). Appendix D contains preliminary responses to NAS comments—as mentioned previously, we would prefer if the Specialty Groups reviewing the documents would first evaluate the documents' clarity and conclusions prior to considering whether the NAS critiques have been addressed. Note: Appendix D is currently being revised, as the current text is significantly outdated and may be inaccurate.

For both the TR and appendices, it would be useful to suggest the reviewers use the "Document Map" feature to "drive" around these large documents more quickly and effectively (this feature is located under the "View" tab in Word). In addition, in both the TR and Supplemental materials, the Table of Contents, Figures List, and Tables List should all be updated and active with (cntrl+click) links to the relevant text.

Regards,
Barbara and Andrew

PS: It remains unclear how the recent Endnote + Litciter updates pushed to all personnel will affect performance (as portions of both documents have been "HEROized")

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