Message

From: Segal, Scott [scott.segal@bracewell.com]
Sent: 8/16/2017 6:16:17 PM
To: Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]
CC: Krenik, Edward [edward.krenik@bracewell.com]; Lee, John [john.lee@bracewell.com]
Subject: FW: RFC technical meeting

Richard – do you have a moment to discuss this? We are trying to get that staff meeting that we have discussed on the books as soon as possible. Thanks, ss/

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From: Krenik, Edward
Sent: Wednesday, August 16, 2017 11:01 AM
To: Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>
Cc: Holloman, Vincia <Holloman.Vincia@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; yamada.richard@epa.gov; Segal, Scott <scott.segal@bracewell.com>; Lee, John <john.lee@bracewell.com>
Subject: Re: RFC technical meeting

Hi Kevin,

This will respond to your email of July 24 below, advising us that the EPA does not believe an in-person meeting concerning this matter would be helpful. We would request you to reconsider and provide us with an opportunity to meet and discuss this matter as soon as possible.

As you know, on June 26, Denka Performance Elastomer ("DPE") submitted its Request for Correction ("RfC") concerning the EPA 2010 Toxicity Review of Chloroprene ("the 2010 Review"). The RfC presents an urgent petition to EPA for the correction of scientific conclusions on a very complex matter. DPE seeks the agency's urgent attention to this matter.

As we described in the RfC, based in part on the erroneous findings in the 2010 Review, EPA, the Louisiana Department of Environmental Quality ("LDEQ"), and the public are devoting extraordinary resources to scrutinizing DPE's chloroprene emissions from its Neoprene plant located in La Place, Louisiana. In addition, subsequent to the filing of the RfC on June 26, on June 28, 2017, a class action petition was filed against DPE concerning the same matter in a case styled, "Robert Taylor, Jr., et al. v. Denka Performance Elastomer LLC and DuPont de Nemours and Company," no. 70907, 40th Judicial District Court for the State of Louisiana. EPA's attention to this matter is urgent.

While DPE wishes to be respectful of the EPA Information Quality process, the toxicological and epidemiological information presented in the RfC is very complex. DPE believes that one or more in-person meetings could short-cut what might otherwise be a time consuming written exchange of questions and answers. Moreover, DPE has the only Neoprene production facility in the United States, and has devoted very substantial efforts into the preparation of the RfC and the review of underlying scientific efforts, as set out in the supporting report by Ramboll Environ. DPE believes that its resources could be extremely helpful to the EPA in understanding the scientific issues supporting the RfC.

Two sentences from your email below stand out and highlight the need for face-to-face meetings. You state, "Your submitted Request for Correction, although extensive and detailed, is well understood by EPA subject matter experts with whom you have already spoken. This information is not new. "

With respect to your statement that this information is well understood by EPA subject matter experts, we believe to the contrary. We would note that EPA's subject matter experts have praised the 2010 Review, notwithstanding its preparation prior to and deviations from the IRIS reform initiatives recommended by the National Research Council (NRC) of the National Academies of Sciences in 2011 and 2014, and which Congress and EPA have embraced. The 2010 IRIS Review needs to be corrected in accordance with these reforms.

With respect to your statement that "the information is not new," again we believe to the contrary. The RfC cites important post-2010 scientific information about chloroprene toxicity. The 2010 Review expressly states that its results would be improved with the use of physiologically based pharmacokinetic (PBPK) models to apply laboratory results from the most sensitive laboratory species to estimate potential applicability of the results to humans. The RfC provides the data and information needed to make PBPK adjustments to the 2010 laboratory animal findings. The new information cited and relied on in the RfC includes the following important new published chloroprene studies:

- Thomas RS, Himmelstein, MW, and Clewell HJ III, Yang Y, Healy E, Black MB, and Andersen ME. (2013). Cross-species transcriptomic analysis of mouse and rat lung exposed to chloroprene. *Toxicological Sciences* 131(2): 629–640. doi:10.1093/toxsci/kfs314.

- Yang Y, Himmelstein MW, and Clewell HJ. (2012). Kinetic modeling of b-chloroprene metabolism: Probabilistic in vitro–in vivo extrapolation of metabolism in the lung, liver and kidneys of mice, rats and humans. *Toxicology in Vitro* 26:1047–1055.

- Allen BC, Van Landingham C, Yang Y, Youk AO, Marsh GM, Esmen N, Gentry PR, Clewell III HJ, and Himmelstein MW. (2014). A constrained maximum likelihood approach to evaluate the impact of dose metric on cancer risk assessment: Application to b-chloroprene. *Regulatory Toxicology and Pharmacology* 70: 203–213.

In addition, the principal exhibit to the Request for Correction is the Ramboll Environ report entitled, "Basis for Requesting Correction of the US EPA Toxicological Review of Chloroprene," dated June 2017. Among other new information presented therein, the Ramboll Environ report provides a recalculated IUR of 3.2×10^{-6} $\mu g/m^3$, a value 156 times higher than the 2010 Review estimated, and the Ramboll Environ report performs a "reality

check" to show that the epidemiological data are inconsistent with the 2010 IUR but could be consistent with the Ramboll Environ recalculated IUR.

Moreover, the Ramboll Environ report identifies fundamental errors in the 2010 Review, including for example, the statistical flaws in the 2010 Review's analysis of subgroups of the epidemiological cohorts studied by Marsh, et al., and in the 2010 Review's unsupported determination that chloroprene might have a mutagenic mode of action.

DPE believes that in-person meetings concerning this matter are extremely important and may help EPA to understand these issues better. Please let us know if the agency will reconsider and meet with us.

Thank you. We look forward to meeting.

Ed

Sent from my Verizon, Samsung Galaxy smartphone

EDWARD KRENIK
Partner
Ext. 5877
Policy Resolution Group

-------- Original message --------
From: "Kirby, Kevin" <KIRBY.KEVIN@EPA.GOV>
Date: 7/24/17 4:11 PM (GMT-06:00)
To: "Krenik, Edward" <edward.krenik@bracewell.com>
Cc: "Holloman, Vincia" <Holloman.Vincia@epa.gov>, "Vandenberg, John" <Vandenberg.John@epa.gov>
Subject: Re: RFC technical meeting

Hi Ed,

Thanks for your kind offer to present your report with a technical team, supporting your submitted Request for Correction (RFC #17002). This won't be necessary nor expected as part of the Agency's Information Quality Guidelines.

Your submitted Request for Correction, although extensive and detailed, is well understood by EPA subject matter experts with whom you have already spoken. This information is not new. As you know, these EPA individuals are quite familiar with this and other information supporting the toxicological review of chloroprene as framed in the Integrated Risk Information System (IRIS).

As part of our IGG process, we are currently bringing these and other internal subject matter experts together to consider how best to assess the information presented in the RFC, review the IRIS information and respond to your data quality concerns. Should addition clarification material for this submitted RFR be needed, we'll certainly follow-up with the you via the requester's specific point of contact.

Should you have any additional materials to share with EPA relevant to this Request, please don't hesitate to send them to me at Quality@EPA.gov with reference to RFC #17002.

Thank you for your attention in helping us ensure quality information at EPA!

Kevin

Kevin Kirby, IQG Program Manager
Enterprise Quality Management Division
Office of Enterprise Information Programs
Office of Environmental Information
US Environmental Protection Agency

From: Krenik, Edward <edward.krenik@bracewell.com>
Sent: Monday, July 24, 2017 2:16 PM
To: Kirby, Kevin
Subject: RE: RFC technical meeting

Hi Kevin,

Checking back with you on some possible dates to have our technical people present our report and RFC. Let me know some possible dates and I will coordinate with our team.

Thanks,

Ed

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From: Vandenberg, John [mailto:Vandenberg.John@epa.gov]
Sent: Friday, July 14, 2017 12:39 PM
To: Krenik, Edward
Cc: Kirby, Kevin
Subject: RE: RFC technical meeting

Hi Ed,
I saw Bob Holder and the other Denka reps at a meeting yesterday in LaPlace, and I told Bob that the request for correction process has a lot of steps, and interactions with the requestor are handled by the Office of Environmental Information (OEI).
The lead there is Kevin Kirby, copied here.
John