Message

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Sent: 4/5/2018 12:20:25 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
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Subject: Harmonizing TCE Efforts

Dr. Beck, good morning and I hope you are having a nice week.

In coordination with Andy Maier, Mike Dourson, Rod Thompson, and Ed Pfau, we would like to formally invite you to participate in a steering committee meeting and workshop (at a date to be determined soon, but hopefully in April) to develop a coordinated effort in connection with non-cancer endpoints for TCE.

We have prepared the following description to outline our thoughts, objectives, and path forward.

Harmonizing Efforts to Address the Non-Cancer Regulation of Trichloroethylene in the United States

Nationally, many science and science policy efforts are underway attempting to implement effective regulation of the non-cancer endpoints of trichloroethylene (TCE). These efforts have illustrated the need for an enhanced understanding of non-cancer toxicological assessment, exposure quantification and non-cancer risk characterization for purposes of risk management. For example, the practical application of non-cancer risk assessment science is being explored through a national effort to characterize a key aspect of U.S. EPA's Reference Concentration for TCE that includes "up to an order of magnitude uncertainty," which might define a "range" of acceptable remedial risk levels for risk management decisions. Efforts are also underway to verify the findings of the Johnson *et al.* (2001) study and to determine the implications of this study in the context of the existing non-cancer toxicology database. These efforts may more fully characterize the potential risk of fetal heart malformations, or confirm other studies that do not show this effect, through inhalation exposures to TCE in ambient air under different exposure scenarios.

In 2013, the Alliance for Risk Assessment (*ARA*) led an initiative to evaluate risk-based decision-making based on the Reference Concentration for TCE finalized by U.S. EPA in 2011 and published in IRIS. This effort resulted in a half-day webcast with international participation, and a guidance document on the risk management at TCE-contaminated sites.[1] The evaluation also resulted in a published manuscript (Dourson et al., 2016)[2] and many other national, regional and local efforts to address the problems associated with risk management of TCE. Five years after the *ARA* initiative, it appears that a renewal would support harmonizing ongoing TCE-related risk science efforts to better understand and regulate the risks of exposure.

A proposed first step in this effort is to convene a steering committee to plan future activities to support harmonizing TCE risk assessment and management. Such activities might include open workshops, education sessions, technical project development, and other outreach.

We solicit your involvement in this effort as a steering committee participant with an anticipated near term commitment of attending a planning meeting in the Law Offices of Barnes & Thornburg LLP in Washington D.C. (with a webinar option) and a half-day workshop. The main goal of this steering committee workshop is to share information on efforts underway among stakeholders, have a brief overview of the work currently being done, and form a steering committee action plan to help guide future efforts and avoid duplication.

We are looking at scheduling this planning meeting and workshop on the week of 4/16, 4/23, or 4/25. Please let us know your preferred date and time as soon as possible so we can sync our schedules. Once a date is confirmed, we will circulate a draft agenda for input.

[1] Alliance for Risk Assessment (ARA). Guidance for Contaminated Sites: Trichloroethylene (TCE) Risk Assessment Case Study. April 15, 2013.
[2] Dourson ML, Gadagbui BK, Thompson RB, Pfau EJ, Lowe J. Managing risks of noncancer health effects at hazardous waste sites: A case study using the Reference Concentration (RfC) of trichloroethylene (TCE). Regul Toxicol Pharmacol. 2016 Oct 80:125-33.

Thanks in advance for your time and willingness to participate.

dave

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