Message

From: Vandenberg, John [Vandenberg.John@epa.gov]
Sent: 6/25/2018 2:01:28 PM
To: Holden, Bob [BHolden@joneswalker.com]
CC: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]; Yamada, Richard (Yujiro) [yamada.richard@epa.gov]; Fine, Steven [fine.steven@epa.gov]; Gray, David [gray.david@epa.gov]; Holloman, Vincia [Holloman.Vincia@epa.gov]; Idsal, Anne [idsal.anne@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]; Quality [Quality@epa.gov]; Kirby, Kevin [KIRBY.KEVIN@EPA.GOV]; Jorge-Lavastida@denka-pe.com; Henry, Elise [EHenry@joneswalker.com]; Brou, Kelly [KBrou@joneswalker.com]; Bahadori, Tina [Bahadori.Tina@epa.gov]; Rodan, Bruce [rodan.bruce@epa.gov]
Subject: RE: Chloroprene RFC #17002 and Chloroprene PBPK Model

Yes! Sorry about that - July 19, 2018.

From: Holden, Bob [mailto:BHolden@joneswalker.com]
Sent: Monday, June 25, 2018 10:00 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Fine, Steven <fine.steven@epa.gov>; Gray, David <gray.david@epa.gov>; Holloman, Vincia <Holloman.Vincia@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Quality <Quality@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Jorge-Lavastida@denka-pe.com; Henry, Elise <EHenry@joneswalker.com>; Brou, Kelly <KBrou@joneswalker.com>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Subject: RE: Chloroprene RFC #17002 and Chloroprene PBPK Model

Jon,

Thank you! Just to confirm, this is for July 19, correct?

Bob

From: Vandenberg, John <Vandenberg.John@epa.gov>
Sent: Monday, June 25, 2018 8:46 AM
To: Holden, Bob <BHolden@joneswalker.com>
Cc: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Fine, Steven <fine.steven@epa.gov>; Gray, David <gray.david@epa.gov>; Holloman, Vincia <Holloman.Vincia@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Quality <Quality@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Jorge-Lavastida@denka-pe.com; Henry, Elise <EHenry@joneswalker.com>; Brou, Kelly <KBrou@joneswalker.com>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Subject: RE: Chloroprene RFC #17002 and Chloroprene PBPK Model

Mr. Holden,

Thank you for your email of June 20 seeking to arrange a meeting to discuss the chloroprene PBPK workplan proposed by Ramboll on behalf of DPE.

I have surveyed the potential EPA participants and recommend the meeting occur from 1:00-3:00 PM in conference room B249 at the EPA facilities in Research Triangle Park, NC. We will arrange a teleconference line for those calling in remotely.

Once you have firm list of the Ramboll/DPE participants, please let me know who will be attending in person. We need the names and affiliations of visitors a few days in advance of the meeting (i.e., by July 17) so we can arrange for their entry into the EPA facility (a driver's license or other government identification will be required).

The EPA participants are anticipated to include Paul Schlosser, Dustin Kapraun, Kris Thayer and myself (in person) and Allen Davis, Alan Sasso and Tina Bahadori (by phone or video).

Please let me know if you have any questions.

John Vandenberg

From: Holden, Bob [mailto:BHolden@joneswalker.com]
Sent: Wednesday, June 20, 2018 12:06 PM
To: Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Fine, Steven <fine.steven@epa.gov>; Gray, David <gray.david@epa.gov>; Holloman, Vincia <Holloman.Vincia@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Quality <Quality@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Jorge-Lavastida@denka-pe.com; Henry, Elise <EHenry@joneswalker.com>; Brou, Kelly <KBrou@joneswalker.com>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Subject: Re: Chloroprene RFC #17002 and Chloroprene PBPK Model

Dear Dr. Vandenberg,

Thank you for your email of June 13th and for providing EPA's comments on the chloroprene PBPK workplan proposed by Ramboll on behalf of DPE. We are eager to meet with EPA's chloroprene risk assessment team to discuss the proposed PBPK model, and we agree to meet at the EPA facility in Research Triangle Park. We have conferred with DPE and its consultants, and the date that works best for our team is **July 19**. Please confirm that this date works for you and suggest a meeting time.

We are still determining who should attend, but at present DPE's team will include:

- Mr. Patrick Walsh, Manager of Safety, Health, and Environment at DPE's Pontchartrain Works Neoprene facility in LaPlace, Louisiana. And,
- With the Ramboll consulting firm, Dr. Harvey Clewell and Dr. Robinan Gentry (in person), and Dr. Sonja Sax, Ms. Cynthia Van Landingham, and Dr. Jerry Campbell (by phone).

We will keep you apprised of any changes or additions to the attendance list.

Please let us know who is likely to attend the meeting on behalf of EPA and how much time we should set aside for it.

Thank you again for accommodating our request to meet with you to discuss our PBPK modeling efforts.

Bob Holden

From: Vandenberg, John <Vandenberg.John@epa.gov>
Sent: Wednesday, June 13, 2018 11:41 AM
To: Holden, Bob <BHolden@joneswalker.com>
Cc: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Fine, Steven <fine.steven@epa.gov>; Gray, David <gray.david@epa.gov>; Holloman, Vincia <Holloman.Vincia@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Quality <Quality@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Jorge-Lavastida@denka-pe.com; Henry, Elise

<EHenry@joneswalker.com>; Brou, Kelly <KBrou@joneswalker.com>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Subject: RE: Draft Email to Dr. Vandenberg - Privileged and Confidential

Dear Mr. Holden,

Thank you for your letter of June 7 with potential dates for meeting with EPA regarding the development by Dr. Clewell and the Ramboll team of a PBPK model and its subsequent evaluation by EPA. Of the dates you identified, the July 16 and July 18-19 dates will work for us. The key participants are located in Research Triangle Park, NC and it would be most convenient for us to meet at the EPA facility in that location. Please let me know what dates and times work for you and I will arrange logistics for the meeting.

Attached to this email are EPA comments (dated June 13, 2018) on the DPE workplan to develop a PBPK model (dated March 23, 2018). This set of comments complements the document you received on May 30 from Tina Bahadori titled "An Umbrella Quality Assurance Project Plan (QAPP) for PBPK Models" (also attached). We have provided this information to support an informed discussion in July, and subsequently a more technical discussion, per your suggestion. Please let me know if there are preferred dates for a technical meeting (or, we can determine the need for a technical meeting during our July meeting).

Please contact me if you have any questions.

Best regards,

John

Attachments

From: Holden, Bob [mailto:BHolden@joneswalker.com]
Sent: Thursday, June 07, 2018 11:25 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Fine, Steven <fine.steven@epa.gov>; Gray, David <gray.david@epa.gov>; Holloman, Vincia <Holloman.Vincia@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Quality <Quality@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Jorge-Lavastida@denka-pe.com; Henry, Elise <EHenry@joneswalker.com>; Brou, Kelly <KBrou@joneswalker.com>
Subject: RE: Draft Email to Dr. Vandenberg - Privileged and Confidential

My apologies, but I hit send on the email below before adding all cc's.

Bob Holden

From: Holden, Bob
Sent: Thursday, June 7, 2018 10:21 AM
To: 'Vandenberg.John@epa.gov' <Vandenberg.John@epa.gov>
Cc: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Fine, Steven <fine.steven@epa.gov>; Gray, David <gray.david@epa.gov>; Holloman, Vincia <Holloman.Vincia@epa.gov>
Subject: FW: Draft Email to Dr. Vandenberg - Privileged and Confidential

Dear Dr. Vandenberg:

As you know, by letter to me dated May 30, 2018, Dr. Tina Bahadori said that I should contact you to arrange a meeting to discuss the path forward on the scientific studies being performed on behalf of Denka Performance Elastomer LLC ("DPE") concerning the development of a physiologically-based pharmacokinetic (PBPK) model to support a recalculation of the inhalation unit risk for chloroprene. Dr. Bahadori said that you would coordinate scheduling a meeting to discuss this, which meeting would include Dr. Kris Thayer and EPA's chloroprene risk assessment team.

Specifically, we would like to discuss the following:

1. The status of PBPK model work being undertaken by Dr. Harvey Clewell and the Ramboll team,

2. Quality assurance issues with the PBPK model,

3. Planned steps for publication and peer review of the PBPK model and underlying data, and

4. The next steps to allow EPA's Integrated Risk Information System (IRIS) to utilize the PBPK information, such as through a new Request for Correction (RFC), and peer review issues in connection therewith.

We would be happy to meet in person at a location of your choice. The first dates on which DPE and its key consultants with Ramboll, Dr. Harvey Clewell and Dr. Ken Mundt, are available would be June 20, 21, or 22 (Wednesday, Thursday or Friday).

Although we would prefer to schedule this meeting as soon as possible, the DPE team and its consultants are also available from July 11-13, and July 16-20.

Please let us know which of these dates would work from EPA's perspective and if EPA has additional objectives for this initial meeting. We will be happy to coordinate on the schedule and attendees in advance

Drs. Harvey Clewell and Jerry Campbell with Ramboll have suggested that it would be beneficial to hold a purely technical meeting with Dr. Paul Schlosser and his associates to discuss the proposed PBPK model for chloroprene. A representative of DPE would also attend to provide assistance as needed. This meeting would involve a discussion of in-depth details such as computer code and data validation.

We look forward to working with you and the chloroprene assessment team. Please feel free to contact me or Patrick Walsh, DPE's SHE Manager, patrick-walsh@denka-PE.com, 985-536-7573, to discuss this.

Sincerely,

Bob Holden

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