Message

From: Shams, Dahnish [Shams.Dahnish@epa.gov]
Sent: 11/2/2021 7:52:11 PM
To: Schlosser, Paul [Schlosser.Paul@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]
CC: White, Paul [White.Paul@epa.gov]; Kapraun, Dustin [Kapraun.Dustin@epa.gov]; Morozov, Viktor [Morozov.Viktor@epa.gov]
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

I can cancel if everyone is in agreement. I'll respond back to Hassan that he can finalize the report and deliver it to us.

- Dahnish

Chemical & Pollutant Assessment Division (CPAD)
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From: Schlosser, Paul <Schlosser.Paul@epa.gov>
Sent: Tuesday, November 2, 2021 3:43 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: White, Paul <White.Paul@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

I don't think there's anything in the report that needs further clarification from the reviewers. I can call in at 4 but would prefer to keep it short!

-Paul

From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, November 2, 2021 2:37 PM
To: Thayer, Kris <thayer.kris@epa.gov>
Cc: White, Paul <White.Paul@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

I added the clearance path as a topic for the SAD meeting with Samantha.

I think the only issue we need to discuss today is whether we are satisfied with the report or if we need to have Versar follow up on anything.

If not, I'll have Versar finalize the report and close out the peer review/task order.

- Dahnish

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From: Thayer, Kris <thayer.kris@epa.gov>
Sent: Tuesday, November 2, 2021 1:50 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Cc: White, Paul <White.Paul@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

I have a conflict for the check in. Is there anything specifically you need from me?

I think we are expecting comments from OGC/OMS on Thursday, then we want to whip this around ASAP for IOAA

Can you check with Ashlie on how to engage Samantha and CPHEA IO? Does she want to see it before IOAA, concurrent with all of IOAA, or concurrent with a slice of IOAA (e.g., Emma). Do we know if Tim wants to review before IOAA? Or all concurrent?

We are getting close to due date..

From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, November 2, 2021 11:29 AM
To: Thayer, Kris <thayer.kris@epa.gov>
Cc: White, Paul <White.Paul@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Kris – The edits are transferred over. I know we have a check-in this afternoon briefly. I'm hoping we can discuss finalizing the peer review and next steps just briefly.

- Dahnish

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From: Thayer, Kris <thayer.kris@epa.gov>
Sent: Tuesday, November 2, 2021 9:01 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Cc: White, Paul <White.Paul@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish – if not done already, do you mind transferring the edits in the email chain to the document?

From: Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Sent: Tuesday, November 2, 2021 8:17 AM
To: Schlosser, Paul <Schlosser.Paul@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Cc: White, Paul <White.Paul@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Also, I think maybe "specicity" is supposed to be "specificity".

Best,
Dustin

From: Schlosser, Paul <Schlosser.Paul@epa.gov>
Sent: Tuesday, November 2, 2021 8:01 AM
To: Thayer, Kris <thayer.kris@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Cc: White, Paul <White.Paul@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Poking at that a bit (see below):

From: Thayer, Kris <thayer.kris@epa.gov>
Sent: Tuesday, November 2, 2021 5:21 AM
To: Schlosser, Paul <Schlosser.Paul@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Cc: White, Paul <White.Paul@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Ex. 5 Deliberative Process (DP)

From: Schlosser, Paul <Schlosser.Paul@epa.gov>
Sent: Monday, November 1, 2021 5:08 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>

Cc: White, Paul <White.Paul@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,

Ex. 5 Deliberative Process (DP)

-Paul

From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Friday, October 29, 2021 12:32 PM
To: Schlosser, Paul <Schlosser.Paul@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Cc: White, Paul <White.Paul@epa.gov>
Subject: FW: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hi all – Dr. Smith provided his comments earlier this week. Do you all mind taking a quick look/read through of his comments before our meeting on Tuesday?

Also – Versar updated the table/matrix of comments.

- Dahnish

Chemical & Pollutant Assessment Division (CPAD)
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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Tuesday, October 26, 2021 8:22 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
Attached is the updated draft report and comment matrix. Let us know if you have any questions or comments as we get closer to the final report.

Hassan Husain

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, October 26, 2021 2:08 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Ok thanks Hassan! Appreciate the quick response.

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Tuesday, October 26, 2021 1:59 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
We got Dr. Smith's comments yesterday afternoon. We have incorporated the comments and are finalizing the report and matrix to send over to you. Should be there later today.

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, October 26, 2021 1:54 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hassan – Hope all is well. Quick question: do you have any updates on the final reviewers comments (Dr. Smith?)?

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Thursday, September 30, 2021 11:58 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
Are you looking for reviewer attribution? There is a specific section at the back end that has each reviewers comments organized together, we could certainly put this in a table if that helps. Give me a call when you get a chance, happy to discuss further.

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Wednesday, September 29, 2021 2:40 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hassan – Quick question: Is it possible to create a table at the front of the document that indicates which reviewers responded to each question? This would help us to review the document?

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Tuesday, September 21, 2021 9:03 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
Draft report attached here. Let me know if you have any questions or need anything clarified. We will add in Dr. Smith's responses to this same report when we wrap that up

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, September 21, 2021 10:16 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

OK great! Thanks Hassan. We do need his comments by late October to make sure we have the final report in hand before responding to the RFC.

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Tuesday, September 21, 2021 10:10 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
Will do, I can get that report into you today.
We'll also go ahead and get Dr. Smith initiated with the delivery date end of October.

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, September 21, 2021 9:44 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hi Hassan – Can we get the draft report without Dr. Smith's comments? We believe it might be too late for the RFC, but we would like his comments even if they come by late October.

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Monday, September 20, 2021 4:36 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Yes we have responses from everyone else
I'll keep a lookout for your response re: Dr. Smith

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Monday, September 20, 2021 4:31 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hi Hassan – See my responses in red below.

- Dahnish

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O: (202) 564-2758

From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Monday, September 20, 2021 4:23 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
Original comment deadline was September 7th. Did we get responses from everyone else?
Dr. Zhu submitted his comments on Friday. We are wrapping up the draft compilation report and can get that over.
In regards to the final reviewer:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

- Do you want us to send the compilation report with the current reviewer comments while we continue to look for the final reviewer? Yes please. A draft sometime this week would be great.
- Do you want to go forward with Dr. Smith/extend out the deadline? Let me check with Kris.

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Monday, September 20, 2021 4:17 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hassan – What was the deadline for comments to be received from the reviewers?

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Wednesday, September 15, 2021 1:04 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
I can talk after 3:30, I'll send you a Teams invite

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Wednesday, September 15, 2021 11:47 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hi Hassan – Can you talk at 2:30 PM ET today or after 3:30 PM ET?

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Tuesday, September 14, 2021 5:34 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
Quick update on the candidates:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

The five selected reviewers are:

Nan-Hung Hsieh, Ph.D.
California Department of Pesticide Regulation
Expertise: PBPK modeling; Statistics; Global sensitivity analysis; Metabolic rates *in vitro*

Kenneth M. Portier, Ph.D.
Independent Consultant
Expertise: Statistics; PBPK modeling; Global sensitivity analysis

Kan Shao, Ph.D.
Indiana University
Expertise: Statistics; Global sensitivity analysis

Raymond S. H. Yang, Ph.D.
Colorado State University
Expertise: PBPK modeling

Yiliang Zhu, Ph.D.
University of New Mexico School of Medicine
Expertise: Statistics; Global sensitivity analysis

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, September 14, 2021 10:25 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen,

Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hassan – All the candidates should likely be considered if available. Since we've been specifically trying to find someone with in vitro ADME experience, EPA would lean towards those with that type of lab experience. Knowledge of PBPK is a definite plus, but they all seem to have some of that.

Ex. 5 Deliberative Process (DP)

Let us know if you have any additional comments on this and if you make a selection from the candidates below.

- Dahnish

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Center for Public Health and Environmental Assessment (CPHEA)
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From: Shams, Dahnish
Sent: Thursday, September 9, 2021 11:56 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Thanks Hassan! Let me huddle with the team.

- Dahnish

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Center for Public Health and Environmental Assessment (CPHEA)
Office of Research and Development, U.S. EPA
O: (202) 564-2758

From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Thursday, September 9, 2021 11:05 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
See below:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Wednesday, September 8, 2021 12:02 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hassan – Do you have any background information on the individuals below? Particularly, the pharma folks. Given that Yan and Ashton have declined, there is no need to provide information on them.

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Tuesday, September 7, 2021 4:04 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Good afternoon Dahnish and Dustin,

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

We just wanted to run the names by you to perhaps get some initial insight on names that may raise COI flags or other issues. So far two people have declined (Drs. Ashton and Yan). The remaining candidates have not responded yet. In addition, we recontacted Dr. Jordan Smith from the original panel to ask if he would reconsider participating due to the timeline extension. He requested additional information regarding the level of effort and the new deadline; however, he has not responded after receiving that information.

Ex. 5 Deliberative Process (DP)

The five selected reviewers are:

Nan-Hung Hsieh, Ph.D.
California Department of Pesticide Regulation
Expertise: PBPK modeling; Statistics; Global sensitivity analysis; Metabolic rates *in vitro*

Kenneth M. Portier, Ph.D.

Independent Consultant
Expertise: Statistics; PBPK modeling; Global sensitivity analysis

Kan Shao, Ph.D.
Indiana University
Expertise: Statistics; Global sensitivity analysis

Raymond S. H. Yang, Ph.D.
Colorado State University
Expertise: PBPK modeling

Yiliang Zhu, Ph.D.
University of New Mexico School of Medicine
Expertise: Statistics; Global sensitivity analysis

As always let me know if you have any questions.

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