Message

From: Husain, Hassan [USA - EMP] [hhusain@versar.com]
Sent: 9/22/2021 1:02:57 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
Attachments: 9.21.21 Draft Follow up Chloroprene PBPK Comment Report.docx

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

Hassan Husain
Senior Program Manager
Environmental Services Group
VERSAR
Your Needs. Our Mission.
hhusain@versar.com
Direct Office: 240-252-2304
Mobile: Ex. 6 Personal Privacy (PP)
www.versar.com

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

Chemical & Pollutant Assessment Division (CPAD)
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: 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.

Hassan Husain
Senior Program Manager
Environmental Services Group

hhusain@versar.com
Direct Office: 240-252-2304
Mobile: Ex. 6 Personal Privacy (PP)
www.versar.com

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

Chemical & Pollutant Assessment Division (CPAD)
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: 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

Hassan Husain
Senior Program Manager
Environmental Services Group
hhusain@versar.com
Direct Office: 240-252-2304
Mobile: Ex. 6 Personal Privacy (PP)
www.versar.com

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

Chemical & Pollutant Assessment Division (CPAD)
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: 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:

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- 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.

Hassan Husain
Senior Program Manager
Environmental Services Group
VERSAR
hhusain@versar.com
Direct Office: 240-252-2304
Mobile: Ex. 6 Personal Privacy (PP)
www.versar.com

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

Chemical & Pollutant Assessment Division (CPAD)
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: 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

Hassan Husain
Senior Program Manager
Environmental Services Group
VERSAR
Your Needs. Our Mission.
hhusain@versar.com
Direct Office: 240-252-2304
Mobile: Ex. 6 Personal Privacy (PP)
www.versar.com

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

Chemical & Pollutant Assessment Division (CPAD)
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: 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:
We continue to search for an in-vitro expert. To date we have contacted a total of 31 potential candidates for this expertise slot. At this point we are running into an issue of candidates with expertise are too closely related to the COI issues to be viable. I wanted to discuss with you further if you have some time Wednesday for a quick call.

On 9/3 we contacted the seven candidates listed below as well as sent a reminder earlier this week to those that hadn't replied yet:

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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

Hassan Husain
Senior Program Manager
Environmental Services Group
VERSAR
hhusain@versar.com
Direct Office: 240-252-2304
Mobile: Ex. 6 Personal Privacy (PP)
www.versar.com

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.

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

- Dahnish

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

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

Chemical & Pollutant Assessment Division (CPAD)
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)

Hassan Husain
Senior Program Manager
Environmental Services Group
VERSAR
hhusain@versar.com
Direct Office: 240-252-2304
Mobile Ex. 6 Personal Privacy (PP)
www.versar.com

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

Chemical & Pollutant Assessment Division (CPAD)
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: 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,

I am writing to provide another update. We continue to search for an in-vitro expert. To date we have contacted a total of 31 potential candidates for this expertise slot. On Friday (9/3) we identified and contacted the seven additional candidates listed below:

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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)

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The five selected reviewers are:

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

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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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Senior Program Manager
Environmental Services Group
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hhusain@versar.com
Direct Office: 240-252-2304
Mobile: Ex. 6 Personal Privacy (PP)
www.versar.com

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