Message

From: Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]
Sent: 4/10/2019 12:03:19 PM
To: Beck, Nancy [Beck.Nancy@epa.gov]
Subject: FW: NCEA TSCA Risk Evaluation Support-- Weekly Update

Leonid Kopylev and Tom Bateson are playing a key role in delivering an initial draft human health risk evaluation this Friday for asbestos

???

From: Dunn, Alexandra
Sent: Wednesday, April 10, 2019 5:45 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Kadeli, Lek <Kadeli.Lek@epa.gov>
Subject: Re: NCEA TSCA Risk Evaluation Support-- Weekly Update

Thank you Tina. This is helpful. Adding Lek who is helping on our staffing and resource plan.

Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, DC

Sent from my iPhone

On Apr 10, 2019, at 5:20 AM, Bahadori, Tina <Bahadori.Tina@epa.gov> wrote:

> Good Morning,
>
> Sharing progress for your information --
>
> **NCEA TSCA Risk Evaluation Support 04/10 Update.** Expert consultation on trichloroethylene (TCE) developmental toxicity regarding a new study and overall weight of evidence was provided to the Office of Pollution Prevention and Toxics (OPPT)/Risk Assessment Division (RAD) this week. Work on the weight of evidence and evidence integration for cancer and non-cancer sections for carbon tetrachloride is being finalized this week. Staff are also supporting methylene chloride, trichloroethylene, and perchloroethylene human health characterizations with consultation on analysis techniques including meta-analyses. Leonid Kopylev and Tom Bateson are playing a key role in delivering an initial draft human health risk evaluation this Friday for asbestos. Study evaluations and associated quality control continue. The schedule for the nine risk evaluations currently being drafted is: 1,4-dioxane hexabromocyclododecane (HBCD) expected in Agency review this week; the schedules for the six solvents and asbestos are broken into two groups with 1-Bromopropane, methylene chloride, N-methyl-2-pyrrolidone (NMP) and asbestos in group two, then TCE, perchloroethylene (PERC) and carbon tetrachloride in group three. HERO staff continue supporting risk evaluations and are planning for future needs.
>
> Tina

From: Bahadori, Tina
Sent: Wednesday, April 3, 2019 10:12 AM
To: Dunn, Alexandra <dunn.alexandra@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>
Subject: RE: NCEA TSCA Risk Evaluation Support-- Weekly Update

Good Morning,

Sharing for your information:

NCEA TSCA Support 04/03/19 Update. A small group of ORD experts from National Center for Computational Toxicology (NCCT), National Health and Environmental Effects Research Laboratory (NHEERL), and NCEA discussed trichloroethylene (TCE) and developmental toxicity with the Office of Pollution Prevention and Toxics (OPPT)/Risk Assessment Division (RAD) last week and are preparing some written comments. NCEA team provided work on 1,4-dioxane cancer mode of action and weight of evidence. Work on the weight of evidence and evidence integration for cancer and non-cancer sections for carbon tetrachloride continues. Staff are also supporting methylene chloride, trichloroethylene, and perchloroethylene human health characterizations. Support on the asbestos workgroup continues with NCEA staff an integral part of the human health team. Study evaluations and associated quality control continue. The schedule for the nine risk evaluations currently being drafted is: 1,4-dioxane and HBCD first going to Agency review at end of April; the schedules for the six solvents and asbestos are being adjusted.

Tina

From: Bahadori, Tina
Sent: Wednesday, March 27, 2019 5:40 AM
To: Dunn, Alexandra <dunn.alexandra@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>
Subject: NCEA TSCA Risk Evaluation Support-- Weekly Update

Good Morning,

Sharing for your information:

NCEA TSCA Risk Evaluation Support 03/27 Update. Staff have reviewed the exposure, environmental, and human health hazard, characterizations in the draft hexabromocyclododecane (HBCD) risk evaluation in advance of the expected rapid turn-around review for the full risk characterization likely to occur end of April-beginning of May. A small group of ORD experts from National Center for Computational Toxicology (NCCT), National Health and

Environmental Effects Research Laboratory (NHEERL), and NCEA discussed trichloroethylene (TCE) and developmental toxicity with the Office of Pollution Prevention and Toxics (OPPT)/Risk Assessment Division (RAD) last week and are preparing some written comments. NCEA teams continue to work on 1,4-dioxane cancer mode of action and weight of evidence/evidence integration and both cancer and non-cancer sections for carbon tetrachloride. Staff are also supporting methylene chloride, trichloroethylene and perchloroethylene human health characterizations. Support on the asbestos workgroup continues with NCEA staff an integral part of the human health team. Study evaluations and associated quality control continue. The schedule for the nine risk evaluations currently being drafted is: 1,4-dioxane and HBCD first going to Agency review at end of April; the six solvents going to Agency review mid-May and asbestos about a month later.

Please let Emma or me know if you have any questions or require more detailed information.

Tina

Tina Bahadori, Sc.D.
Director, National Center for Environmental Assessment (EPA/ORD/NCEA)
National Program Director, Human Health Risk Assessment (EPA/ORD/HHRA)
DC phone: 202-564-7903

From: Bahadori, Tina
Sent: Wednesday, March 20, 2019 10:55 AM
To: Beck, Nancy; Dunn, Alexandra; Bertrand, Charlotte
Cc: Dunlap, David; Lavoie, Emma; Orme-Zavaleta, Jennifer; Hartman, Mark
Subject: RE: follow up from this am

Hi Again,

Emma prepares pithy weekly summaries of NCEA TSCA support for ORD leadership. I pasted it here, thinking it might be useful to you as well. Just to give you a sense of proportion, with this level of support, NCEA is at maximum saturation right now until the current activities are completed.

March 20th Update of NCEA TSCA Support. In addition to work reported last week staff are reviewing the exposure, environmental, and human health hazard, characterizations in the draft hexabromocyclododecane (HBCD) risk evaluation in advance of the expected rapid turn-around review for the full risk characterization. NCEA teams continue to work on 1,4-dioxane cancer mode of action and weight of evidence/evidence integration and both cancer and non-cancer sections for carbon tetrachloride. Staff are also supporting methylene chloride,

trichloroethylene and perchloroethylene human health characterizations. Support on the asbestos workgroup continues with NCEA staff an integral part of the human health team. Study evaluations and associated quality control are also being supported. A small group of ORD experts including NCEA scientists are also preparing to discuss trichloroethylene (TCE) and developmental toxicity with Office of Pollution Prevention and Toxics (OPPT)/Risk Assessment Division (RAD) this week.

Tina

From: Bahadori, Tina
Sent: Wednesday, March 20, 2019 10:41 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>
Subject: RE: follow up from this am

On the matter of details, I believe the ball is in OPPT's court to start the paperwork. Perhaps that is in motion already?

On the matter of the staffing data – let's make it past the current intensity of meeting your immediate deadlines and we can have a deeper conversation on how to do the analysis to support your fee's rules decisions.

Tina

From: Beck, Nancy
Sent: Wednesday, March 20, 2019 9:57 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>
Subject: RE: follow up from this am

Thanks Tina.
Its great to hear the tracking is already happening. This will make our tracking for the fee's rule much easier.
On average, if we assume 2nd quarter was about 8 weeks (since we lost days to the shut down), we have 2000 hours across 30 people. It sounded very large to me (which is great) but then I was chatting with others who are more familiar with FTE hours per person etc. Looking at the math, 2000 hours and 30 people comes out to be about 67hours/per person, which comes out to about 8hours/per person/per week. So about a day a week for 30 people—on average. I recognize some people spend more time on TSCA support than others. Is that about right?

Having some dedicated detailee's will surely be helpful. We greatly appreciate the cooperation in that space!
Nancy

Nancy B. Beck, Ph.D., DABT
Principal Deputy Assistant Administrator, OCSPP
P: 202-564-1273
beck.nancy@epa.gov

From: Bahadori, Tina
Sent: Tuesday, March 19, 2019 11:12 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Subject: RE: follow up from this am

The majority of the NCEA scientists supporting TSCA also have primary responsibilities for the FY2019 IRIS assessments. They use project management tools to manage their own assessment responsibilities, even as they provide scientific support to TSCA. But we do track hours provided to any major Agency technical support activity, including TSCA. We are about to update the information for FY2019 second quarter. Not all the data are in, but it looks like NCEA has provided about 2000 hours of support to TSCA implementation in FY2019, across about 30 staff members.

Tina

From: Beck, Nancy
Sent: Tuesday, March 19, 2019 10:33 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Subject: RE: follow up from this am

Many thanks Tina. We appreciate all the great work ORD has done and will continue to do to support our program.
These updates are very helpful. To help us understand workload, it would be super helpful to know how much of their time each of your FTE are spending on the specific projects. I know someone was able to bundle it for GAO, so updates along those lines to help us understand where we have additional brain power on each chemical and how much time they are spending would be helpful. We also need to be tracking efforts for continued implementation of our fee's rule.

Many thanks again,
Nancy

Nancy B. Beck, Ph.D., DABT
Principal Deputy Assistant Administrator, OCSPP
P: 202-564-1273
beck.nancy@epa.gov

From: Bahadori, Tina
Sent: Tuesday, March 19, 2019 10:16 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Subject: RE: follow up from this am

Hi Nancy,

Just to clarify, the memo Jennifer forwarded to you yesterday summarized the work that was done by the end of CY 2018, in response to OPPT's September request. Post shutdown, we have been in a new engagement phase, with new tasks supporting assessment development. So, there has been no hiatus in NCEA's TSCA support. We plan to provide these updates regularly to OPPT.

Looking forward to a discussion with you, Alex, and Charlotte soon.

Tina

==========

Tina Bahadori, Sc.D.
Director, National Center for Environmental Assessment (EPA/ORD/NCEA)
National Program Director, Human Health Risk Assessment (EPA/ORD/HHRA)
DC phone: 202-564-7903

From: Bahadori, Tina
Sent: Monday, March 18, 2019 5:30 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>
Subject: RE: follow up from this am

Hi Nancy,

Right now, especially without the time extension on the TSCA risk evaluations, NCEA has made the progress of these first 10 RE's an absolute priority. Emma Lavoie (copied here) and our project management lead in NCEA have been meeting regularly with Stan/Cathy and OPPT's assessment leads to infuse appropriate resources as requested. I am sure you are aware that the needs and asks from OPPT evolve almost on a daily basis – understandably, given the

urgency of your current activities. Nonetheless, we have now reached a good point where our efforts are well-integrated with OPPT and the collaboration is fairly seamless. To be most effective in supporting these assessments through peer review, it would very beneficial for us to meet with Alex, Charlotte, and you to get a better understanding of your longer-range strategy for meeting these CY2019 deadlines.

Thank you,

Tina

From: Beck, Nancy
Sent: Monday, March 18, 2019 1:50 PM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>
Subject: RE: follow up from this am

Many thanks Jennifer.
I think this shows us how far along the specific tasks are to completion and it seems as though we should be finding more projects for ORD staff! Lots of accomplishments.

In addition, it would help us to know how much time each of your folks are spending to provide TSCA support- eg do we have them each 10 hrs a week or is it more like 40.

Nancy B. Beck, Ph.D., DABT
Principal Deputy Assistant Administrator, OCSPP
P: 202-564-1273
beck.nancy@epa.gov

From: Orme-Zavaleta, Jennifer
Sent: Monday, March 18, 2019 1:02 PM
To: Dunn, Alexandra <dunn.alexandra@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>
Subject: follow up from this am

HI all, and my apologies – this came to me earlier and got lost in the shuffle. See below and we can discuss further

MEMORANDUM

SUBJECT: Status of NCEA Support for OCSPP Request on TSCA Risk Evaluations

FROM: Tina Bahadori, NCEA Director
ORD National Center for Environmental Assessment (NCEA)

TO: Jennifer Orme-Zavaleta, Principal Deputy Assistant Administrator
Office of Research and Development

DATE: 4 February 2019

ORD/NCEA has completed the program support requested in September 2018 for the development of human health assessments for nine of the TSCA risk evaluations.

Specifically, we have provided:

1. Expert study quality assessment and quality control for approximately 150 animal and epidemiology studies for Perc, TCE, NMP, DCM, and HBCD;
2. During study quality assessments, provided expert feedback on the OCSPP tools for epidemiology and animal toxicology study evaluations;
3. Benchmark dose modelling and summaries for 1,4-dioxane and 1-bromopropane cancer endpoints;
4. Benchmark dose modelling and summaries for 1-bromopropane developmental toxicity endpoints;
5. PBPK modelling and summary for NMP;
6. Expert consultations on data integration for cancer for 1,4-dioxane and carbon tetrachloride;
7. Expert consultations on the incorporation of new data, e.g., Big Blue Mouse assay;
8. Expert consultations for development of technical direction for contractor support on TCE;
9. Help to refine data extraction forms and develop templates for data visualizations in tabular format and HAWC; and
10. Review of NCEA products in response to this OCSPP request through IRIS interdisciplinary workgroups for consistent expert engagement and expert opinion.

Most of this support was completed in December 2018. Several of the original requests, not listed here, did not need extensive assistance due to timing or further development of the evaluations after staff level discussions, e.g., data integration for some chemicals. Requests related to fate-exposure support are being led by ORD/NERL.

Other ongoing efforts:

1. Additional request for PBPK modelling scenarios for NMP that was ongoing prior to the government shut-down and will be completed in early March 2019;
2. NCEA asbestos experts' continued support for the asbestos evaluation via the asbestos human health sub-workgroup;
3. NCEA experts' support for the TSCA Tiger Teams for pre-prioritization process development and for alternatives to animal testing.

NCEA's TSCA support is being managed and documented in the SharePoint site developed specifically for this effort and shared with OPPT/RAD. Attached is a snapshot from the Project Management Tasks page that also lists the assessment staff assigned to each activity. It does not include other oversight and coordination support/resources provided programmatically and managerially across IRIS and NCEA.

March 13 update:

NCEA TSCA Support. On March 14th, the first drafts of 1,4-dioxane and hexabromocyclodecane (HBCD) risk evaluations are due. Additionally, NCEA teams have begun working on 1,4-dioxane cancer mode of action and weight of evidence/evidence integration and both cancer and non-

cancer sections for carbon tetrachloride. Staff are also supporting trichloroethylene and perchloroethylene, specifically supporting development of direction for meta-analyses of epidemiology data. Support on the asbestos workgroup continues with NCEA staff an integral part of the human health team.

Please let me know if you need more detailed information.

==========

Tina Bahadori, Sc.D.
Director, National Center for Environmental Assessment (EPA/ORD/NCEA)
National Program Director, Human Health Risk Assessment (EPA/ORD/HHRA)
RRB Room 71210; Telephone: 202-564-7903; Personal Privacy / Ex. 6

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
Office of Research and Development
US Environmental Protection Agency
Personal Privacy / Ex. 6
DC 202-564-6620
RTP 919-541-2283