Message

From: Hubbard, Joseph [Hubbard.Joseph@epa.gov]
Sent: 3/24/2021 1:25:28 PM
To: Mitchell, David [dmitchell@theadvocate.com]
CC: Durant, Jennah [Durant.Jennah@epa.gov]
Subject: RE: Denka Performance Elastomer News Release & Background Information

Hi David, the names are on the first page of this document: Final Chloroprene Post-Meeting Peer Review Summary Report (PDF)
It was on the materials page of that first link we shared. This document has a lot of information and should be useful.

I'm checking on a background interview with one of our experts.

Best,

Joe Hubbard
U.S. Environmental Protection Agency
OFFICE: 214-665-8476
Hubbard.joseph@epa.gov

From: Hubbard, Joseph
Sent: Wednesday, March 17, 2021 4:55 PM
To: Mitchell, David <dmitchell@theadvocate.com>
Cc: Durant, Jennah <Durant.Jennah@epa.gov>
Subject: Re: Denka Performance Elastomer News Release & Background Information

Hi David,

Thanks for working with us. Here's the revised statement with an update to number 4.

Hey David,

Here's our response to your follow-up. Attribution to an EPA Spokesperson.

Here is a link to the peer review and other related materials: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=349015

1. **Can you tell me what uncertainties were identified in the PBPK model?**

The independent external peer reviewers identified a number of limitations in the materials submitted by Denka Performance Elastomers for peer review. The model requires application of a number of parameters, and for some of the parameters there are significant uncertainties in the available data. For example, an in vitro system was used to estimate rates of metabolism of chloroprene, and the fate of the metabolites, which are important to the model estimates of cancer risk. The peer reviewers were critical of the approach used to estimate these parameters. Further, chloroprene exposure in key animal studies demonstrate it is a multi-site carcinogen, yet the PBPK model does not provide estimates of overall cancer risk, including cancers in tissues other than the lung.

2. **Who were the people who did the external peer review?**

For this peer review, nine experts with experience and expertise in one or more of the following areas were selected to peer review: physiologically based pharmacokinetic (PBPK) modeling, statistics, mass transport fluid dynamics and molecular diffusion, and metabolic rates *in vitro*. Note the above link to the peer review materials identifies the peer reviewers.

3. **Was the earlier version of this study something EPA looked at as part of its 2010 decision on cancer risk from chloroprene?**

No, the "earlier version of this study" was published in 2012, after the 2010 IRIS assessment chloroprene was published.

a. **Does this revised finding change the agency's view on chloroprene toxicity level? See attached.**
The attached study by Marsh et al was not submitted as part of the Request for Correction nor Request for Reconsideration and the Agency has not reviewed this study.

4. **How does the agency square the risk estimates for chloroprene and the average to below-average cancer incidence rates found around Denka, per the La. Tumor Registry? Shouldn't the registry's findings suggest the risk is too high or, if not, what other factors countervail against that type of inference?** EPA has not done a formal analysis of the Louisiana Tumor Registry.

Regards,

Joe Hubbard
U.S. Environmental Protection Agency
OFFICE: 214-665-8476
Hubbard.joseph@epa.gov

On Mar 12, 2021, at 1:57 PM, Mitchell, David <dmitchell@theadvocate.com> wrote:

Great

Sent from my iPhone

On Mar 12, 2021, at 12:34 PM, Hubbard, Joseph <Hubbard.Joseph@epa.gov> wrote:

Hi David,

We are getting close on this one. Should have something soon.

Regards,

Joe Hubbard
U.S. Environmental Protection Agency
OFFICE: 214-665-8476
Hubbard.joseph@epa.gov

On Mar 10, 2021, at 2:51 PM, Mitchell, David <dmitchell@theadvocate.com> wrote:

I'm flexible at this point as this has gone down into the weedy grasses. I'd like to turn this week if possible. So early Friday?

Also I got this clarification from Denka today. Does it seem accurate?

"Below is some additional background that we hope can clarify the status of the model and the nature of the process DPE has been working through with the agency to date.

DPE identified flaws in the 2010 IRIS study mentioned in your message with EPA back in 2016 and submitted a Request for Correction (RFC) based on those flaws. Despite this not being in agency rules, the EPA representative managing DPE's

RFC told the company that its RFC could not identify errors with the study and request the agency to address them, but rather the RFC had to actually contain new information for EPA to consider it. After he told DPE that, the company put in a Request for Reconsideration (RFR) on the denied RFC while it worked simultaneously to generate this new information in the form of a major update to an existing PBPK model.

Note that the 2010 IRIS study actually states that their assessment of health risk would be more accurate using a PBPK model. EPA had already identified questions/work to be done on a PBPK model that was partially produced as long ago as 2004, so DPE contracted scientists with Ramboll to update it based on EPA's previous critiques. Ramboll completed the model, which includes hundreds of parameters to facilitate a more complete understanding of metabolism of the chemical, and DPE submitted it to EPA for review. EPA reviewed it internally, then oversaw an external peer review of the model all while DPE had its RFR filed with the agency.

The peer review panel was composed of a group of scientists from various research backgrounds. The panel was charged with reviewing the scientific process of the model and raising questions for clarification. It provided questions to Ramboll (noted as "uncertainties" in the email below) and the group then worked with EPA's scientists to develop answers to those questions and provide additional clarification. DPE and Ramboll are working to complete that process and will discuss the results with EPA to ensure that the agency's standards are met prior to submitting a new RFC.

As a result of all these changes, EPA indicated it would be more appropriate to submit the model as a new RFC rather than part of the existing RFR. Following agency suggestion, DPE withdrew its RFR and is preparing to submit a new RFC (as described in our release) with the reviewed and revised model as new information. EPA is aware of DPE's intention and expecting the RFC. DPE hopes to have the new RFC submitted by the end of April.

THE ADVOCATE

BATON ROUGE · NEW ORLEANS · ACADIANA

David J. Mitchell

River Parishes reporter

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10705 Rieger Road, Baton Rouge, LA 70809

From: Hubbard, Joseph <Hubbard.Joseph@epa.gov>
Sent: Wednesday, March 10, 2021 2:16 PM
To: Mitchell, David <dmitchell@theadvocate.com>
Subject: RE: Denka Performance Elastomer News Release & Background Information

Okay, thanks David, I received the message about the external review committee.

What is your new deadline?

Best,

Joe Hubbard
U.S. Environmental Protection Agency
OFFICE: 214-665-8476
Hubbard.joseph@epa.gov

From: Mitchell, David <dmitchell@theadvocate.com>
Sent: Wednesday, March 10, 2021 1:40 PM
To: Hubbard, Joseph <Hubbard.Joseph@epa.gov>
Subject: RE: Denka Performance Elastomer News Release & Background Information

I sent you another about who was on the external review committee. And this question here, what were the uncertainties the led to the review committee's decision.

Also, while we're talking, I was provided a copy of this study of industrial workers that kind of took a second look at their well-being years later and their cancer deaths and didn't find any elevated rates.
Was the earlier version of this study something EPA looked at as part of its 2010 decision on cancer risk from chloroprene?
Does this revised finding change the agency's view on chloroprene toxicity level. See attached.

Finally, how does the agency square the risk estimates for chloroprene and the average to below-average cancer incidence rates found around Denka, per the La. Tumor Registry? Shouldn't the registry's findings suggest the risk is too high or, if not, what other factors countervail against that type of inference? This is a point frequently made in defense of Denka and other industries in Miss. River region.

The tracts around Denka missing data on specific cancers because of low population but are mixed on overall cancer incidences.

See cancer registry data. https://sph.lsuhsc.edu/wp-content/uploads/2020/12/04_Appendix-A1-A15.pdf

THE ADVOCATE

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From: Hubbard, Joseph <Hubbard.Joseph@epa.gov>
Sent: Wednesday, March 10, 2021 11:26 AM
To: Mitchell, David <dmitchell@theadvocate.com>
Subject: RE: Denka Performance Elastomer News Release & Background Information

David,

Do you have any additional follow-ups? I want to get them to you all at one time.

Best,

Joe Hubbard
U.S. Environmental Protection Agency
OFFICE: 214-665-8476
Hubbard.joseph@epa.gov

From: Mitchell, David <dmitchell@theadvocate.com>
Sent: Wednesday, March 10, 2021 10:58 AM
To: Hubbard, Joseph <Hubbard.Joseph@epa.gov>
Subject: RE: Denka Performance Elastomer News Release & Background Information

Can you tell me what uncertainties were identified in the PBPK model?

THE ADVOCATE

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From: Hubbard, Joseph <Hubbard.Joseph@epa.gov>
Sent: Wednesday, March 10, 2021 7:03 AM
To: Mitchell, David <dmitchell@theadvocate.com>
Cc: Durant, Jennah <Durant.Jennah@epa.gov>
Subject: RE: Denka Performance Elastomer News Release & Background Information

Hi David,

One quick update: The scope of work for each grant are partially complete and both grants are in compliance with federal requirements.

Best,

Joe Hubbard
U.S. Environmental Protection Agency
OFFICE: 214-665-8476
Hubbard.joseph@epa.gov

From: Hubbard, Joseph
Sent: Tuesday, March 9, 2021 3:16 PM
To: Mitchell, David <dmitchell@theadvocate.com>
Cc: Jennah Durant (Durant.Jennah@epa.gov) <Durant.Jennah@epa.gov>
Subject: RE: Denka Performance Elastomer News Release & Background Information

Hi David,

Thanks for your flexibility. Here's our response:

Q1 Also, how does this grant relate to the CRISP report recently issued by the La. Tumor Registry and LSU Health Sciences? LSU says this grant didn't go to them. If so, who is doing this work? When did it start? When will it finish? Is this grant related to the CRISP report recently issued by the La. Tumor Registry and LSU Health Sciences?

A1 Yes, this grant relates to the CRISP report. Both the Louisiana Department of Environmental Quality and the Louisiana Department of Health and Hospitals have separate multipurpose grants from EPA, but the work for this project is connected. LSU was working with LDH on the study. The scope of work for each grant are partially complete and both grants are in compliance with federal requirements. The performance period is from October 1, 2019 through September 30, 2021.

Q2 Can any of you shed light on this process? Denka says they previously filed for a request for reconsideration and withdrew it and now have filed a request for correction. They also say that EPA had peer-reviewed this new Denka risk model for chloroprene, "which suggests the agency's previous assessment could overstate cancer risk from chloroprene exposure by as much as 130 times." Help me understand this process, both generally and in reference to chloroprene.

A2 Chloroprene was identified in the 2010 EPA Integrated Risk Information System (IRIS) assessment as a likely human carcinogen. In June 2017, DPE submitted a Request for Correction (RFC) of the IRIS assessment under EPA's Information Quality Guidelines (IQGs) stating that the assessment does not reflect the "best available science." This request was denied primarily because the issues raised by DPE were previously considered during the external peer review of the IRIS

assessment. ORD also conducted an updated literature search and concluded no new evidence was published that would alter the 2010 IRIS conclusions. A physiologically based pharmacokinetic (PBPK) model for chloroprene had been published but EPA identified several limitations in the model that would preclude its application in an assessment.

In July 2018, DPE submitted a Request for Reconsideration (RFR) of EPA's denial of the RFC. In their request, DPE proposed to update the PBPK model for chloroprene to address the limitations raised by EPA. DPE subsequently updated the PBPK model and documentation and submitted it to EPA. EPA organized an independent expert peer review of this updated model. In December2020, the external peer reviewers identified uncertainties in the model that would preclude its application by EPA to update the IRIS chloroprene assessment. DPE decided to withdraw the RFR on March 1, 2021.

EPA has not received a new RFC from DPE concerning Chloroprene as of today. Once the document is received, we will assign an RFC number and process it in accordance with our Information Quality Guidelines (IQG). For more information on IQG, please visit: https://www.epa.gov/sites/production/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf.

Best,

Joe Hubbard
U.S. Environmental Protection Agency
OFFICE: 214-665-8476
Hubbard.joseph@epa.gov

From: Mitchell, David <dmitchell@theadvocate.com>
Sent: Tuesday, March 9, 2021 1:18 PM
To: Hubbard, Joseph <Hubbard.Joseph@epa.gov>
Subject: RE: Denka Performance Elastomer News Release & Background Information

You have time. I realize the weeds are deep on this one.

THE ADVOCATE

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From: Hubbard, Joseph <Hubbard.Joseph@epa.gov>
Sent: Tuesday, March 09, 2021 1:04 PM
To: Mitchell, David <dmitchell@theadvocate.com>
Subject: RE: Denka Performance Elastomer News Release & Background Information

Hey David, we are working on this and should have something soon.

Will you be able to update your story?

Best,

Joe Hubbard
U.S. Environmental Protection Agency
OFFICE: 214-665-8476
Hubbard.joseph@epa.gov

From: Hubbard, Joseph
Sent: Monday, March 8, 2021 4:33 PM
To: Mitchell, David <dmitchell@theadvocate.com>
Subject: RE: Denka Performance Elastomer News Release & Background Information

We may need additional time, but will aim to meet your deadline.

Best,

Joe Hubbard
U.S. Environmental Protection Agency
OFFICE: 214-665-8476
Hubbard.joseph@epa.gov

From: Mitchell, David <dmitchell@theadvocate.com>
Sent: Monday, March 8, 2021 4:30 PM
To: Hubbard, Joseph <Hubbard.Joseph@epa.gov>
Subject: Re: Denka Performance Elastomer News Release & Background Information

Tomorrow at noon.

Sent from my iPhone

On Mar 8, 2021, at 4:00 PM, Hubbard, Joseph <Hubbard.Joseph@epa.gov> wrote:

What's your deadline?

On Mar 8, 2021, at 3:26 PM, Mitchell, David <dmitchell@theadvocate.com> wrote:

Resent you that in separate email.

THE ADVOCATE

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From: Hubbard, Joseph <Hubbard.Joseph@epa.gov>
Sent: Monday, March 08, 2021 3:13 PM
To: Mitchell, David <dmitchell@theadvocate.com>
Subject: RE: Denka Performance Elastomer News Release & Background Information

Also, Can you resend me your questions regarding the recent La. Tumor Registry report in connection with Denka and chloroprene?

Best,

Joe Hubbard
U.S. Environmental Protection Agency
OFFICE: 214-665-8476
Hubbard.joseph@epa.gov

From: Mitchell, David <dmitchell@theadvocate.com>
Sent: Monday, March 8, 2021 2:55 PM
To: R6Press <R6Press@epa.gov>; Durant, Jennah <Durant.Jennah@epa.gov>; Hubbard, Joseph <Hubbard.Joseph@epa.gov>; Harwood, Jackie <Harwood.Jackie@epa.gov>
Subject: FW: Denka Performance Elastomer News Release & Background Information

Can any of you shed light on this process?

Denka says they previously filed for a request for reconsideration and withdrew it and now have filed a request for correction.
They also say that EPA had peer-reviewed this new Denka risk model for chloroprene, "which suggests the agency's previous assessment could overstate cancer risk from chloroprene exposure by as much as 130 times."

Help me understand this process, both generally and in reference to chloroprene.

Also you still haven't responded to me regarding my questions about the recent La. Tumor Registry report in connection with Denka and chloroprene.

THE ADVOCATE

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From: Schleifstein, Mark <mschleifstein@theadvocate.com>
Sent: Monday, March 08, 2021 2:12 PM
To: Mitchell, David <dmitchell@theadvocate.com>
Subject: FW: Denka Performance Elastomer News Release & Background Information

Mark Schleifstein
Environment reporter
mschleifstein@theadvocate.com
The Times-Picayune | The New Orleans Advocate
840 St. Charles Ave.
New Orleans LA 70130

Mobile: 504.717.1157
Home: 504.887.5331

<image001.png>

From: Jim Harris <jharris@hdaissues.com>
Sent: Monday, March 8, 2021 1:29 PM
To: Schleifstein, Mark <mschleifstein@theadvocate.com>
Cc: David Laplante <dlaplante@hdaissues.com>
Subject: Denka Performance Elastomer News Release & Background Information

Mark,

Please find **attached** a news release from Denka Performance Elastomer. You may quote me as spokesperson if you decide to use this information. Below are some basic points on what it's about. I hope you received the background information on DPE that I sent you a week or so go. I hope everything is going well.

Best,
Jim Harris
On behalf of Denka Performance Elastomer

Background

• DPE is submitting a formal Request for Correction to the U.S. EPA that includes a new scientific model of chloroprene metabolism as part of the company's continued work with the agency to improve its understanding of chloroprene. A response or action on the request from EPA could take months.

• The model has been reviewed by the agency, undergone external peer review as part of being published in a prestigious scientific journal last year, a testament to the scientific community's confidence in its methods.

• The new model shows previous suggestions by the EPA's Integrated Risk Information System about chloroprene greatly overestimated potential risks to more than 130 times higher than reality.

• DPE's new request to EPA will take the place of a Request for Reconsideration, which the company withdrew as part of EPA's standard process for reviewing agency actions. EPA has suggested that this is a more appropriate process for incorporating the new model into EPA's risk assessment. A final decision and action by EPA on DPE's request could take several months. DPE will continue to work with EPA throughout this process.

• As you know, while DPE has been working with EPA throughout the scientific review process, the company spent over $35 million on emissions reduction projects, installing new equipment and improvements to reduce its environmental footprint. This investment has resulted in a similar decrease in concentrations of chloroprene measured in the air near the facility.

Jim Harris
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