Message

**From**: Chalfant, Katherine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C340D89F94584F1DA6BCD101B2FAD166-CHALFANT, KATHERINE]
**Sent**: 2/2/2021 12:45:13 PM
**To**: Wells, Jeffrey [Wells.jeffrey@epa.gov]
**Subject**: RE: RFR 17002A Chloroprene

Thank you Jeff!

*Katherine*

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Katherine Chalfant
U.S. Environmental Protection Agency
Acting Director, Enterprise Quality Management Division
Office of Enterprise Information Programs, WJCW Ex. 6 Personal Privacy (PP)
Office of Environmental Information
1200 Pennsylvania Ave, NW
Washington, DC 20460
Phone: (202) 564-1511
Cell: Ex. 6 Personal Privacy (PP)

**From:** Wells, Jeffrey <Wells.jeffrey@epa.gov>
**Sent:** Tuesday, February 02, 2021 7:42 AM
**To:** Chalfant, Katherine <Chalfant.Katherine@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
**Cc:** D'Amico, Louis <DAmico.Louis@epa.gov>; Gray, David <gray.david@epa.gov>; Grimm, Patrick <Grimm.Patrick@epa.gov>; Tallent, Robert <Tallent.Robert@epa.gov>; Sheppard, Tracy <Sheppard.Tracy@epa.gov>
**Subject:** RE: RFR 17002A Chloroprene

I will check with Vaughn Noga this morning at 8 to see if he would like to be involved or not, but regardless, yes please include me in the internal meeting.

**Ex. 5 Deliberative Process (DP)**

Thanks,
Jeff

**From:** Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Sent:** Tuesday, February 2, 2021 7:15 AM
**To:** Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
**Cc:** D'Amico, Louis <DAmico.Louis@epa.gov>; Gray, David <gray.david@epa.gov>; Wells, Jeffrey <Wells.jeffrey@epa.gov>; Grimm, Patrick <Grimm.Patrick@epa.gov>; Tallent, Robert <Tallent.Robert@epa.gov>; Sheppard, Tracy <Sheppard.Tracy@epa.gov>; Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Subject:** RE: RFR 17002A Chloroprene

**Ex. 5 Deliberative Process (DP)**

Thank you both and we look forward to your email!

*Katherine*

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**From:** Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
**Sent:** Tuesday, February 02, 2021 7:11 AM
**To:** Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Cc:** D'Amico, Louis <DAmico.Louis@epa.gov>; Gray, David <gray.david@epa.gov>; Wells, Jeffrey <Wells.jeffrey@epa.gov>; Grimm, Patrick <Grimm.Patrick@epa.gov>; Tallent, Robert <Tallent.Robert@epa.gov>; Sheppard, Tracy <Sheppard.Tracy@epa.gov>
**Subject:** RE: RFR 17002A Chloroprene

Thanks Katherine, I think it would be good to have a call and talk through how best to follow up with Denka. Ex. 5 Deliberative Process (DP)

**Ex. 5 Deliberative Process (DP)**

Lou, can you help get something scheduled? In the mean time, I'll draft an email response back to Patricka and get your review before sending

thanks

Jennifer Orme-Zavaleta, PhD
Acting Assistant Administrator, and
Principal Deputy Assistant Administrator
Office of Research and Development
US Environmental Protection Agency

DC 202-564-6620
Cel Ex. 6 Personal Privacy (PP)

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**From:** Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Sent:** Monday, February 1, 2021 5:29 PM
**To:** Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
**Cc:** D'Amico, Louis <DAmico.Louis@epa.gov>; Gray, David <gray.david@epa.gov>; Wells, Jeffrey <Wells.jeffrey@epa.gov>; Grimm, Patrick <Grimm.Patrick@epa.gov>; Tallent, Robert <Tallent.Robert@epa.gov>; Sheppard, Tracy <Sheppard.Tracy@epa.gov>; Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Subject:** RE: RFR 17002A Chloroprene

# Ex. 5 Deliberative Process (DP)

Please let us know if you would like to discuss further. I'm in all week.

Thank you!

*Katherine*

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**From:** Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
**Sent:** Monday, February 01, 2021 4:51 PM
**To:** Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Cc:** D'Amico, Louis <DAmico.Louis@epa.gov>; Gray, David <gray.david@epa.gov>
**Subject:** RE: RFR 17002A Chloroprene

HI Katherine, got a call/voice message from Patrick this afternoon. He indicated he still has questions on the process going forward and wants me to call him back. Might be good if we could have a quick check in before anyone connects back with him. Let me know when you have some time, thanks

Jennifer Orme-Zavaleta, PhD
Acting Assistant Administrator, and
Principal Deputy Assistant Administrator
Office of Research and Development
US Environmental Protection Agency

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Cel Ex. 6 Personal Privacy (PP)

**From:** Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Sent:** Monday, February 1, 2021 2:08 PM
**To:** Walsh, Patrick <patrick-walsh@denka-pe.com>
**Cc:** Noga, Vaughn <Noga.Vaughn@EPA.GOV>; Wells, Jeffrey <Wells.jeffrey@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Grimm, Patrick <Grimm.Patrick@epa.gov>; Tallent, Robert <Tallent.Robert@epa.gov>; Sheppard, Tracy <Sheppard.Tracy@epa.gov>; Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Subject:** RFR 17002A Chloroprene

Patrick,

Thank you for your email. The Request for Reconsideration (RFR) #17002A, Chloroprene, is an anomaly from EPA's Information Quality Guidelines (IQGs) process driven by a request from your company, Denka. While we followed the RFR outlined in the IQGs in preparation for the Executive Panel, in October 2018, Denka requested a Stay of Review of the RFR. An agreement was then made between the EPA and Denka to stay the RFR process. This was to allow the development and peer review of the PBPK model for its inclusion with the original material submitted for the RFR. Again, this was a special case to enable Denka to submit new material and for the EPA to fully consider it to enable a thorough scientific assessment of the RFR. This action is now complete. It is time to continue the RFR process.

Please understand my office manages the RFR process and has no input into the scientific validity or analysis of material submitted. At this point in the process, a team of EPA technical experts and information owners will assemble all the material. Per the IQGs, the Assistant Administrator (AA) information owner will present this material in total to the Executive Panel along with a scientific assessment. The Executive Panel will make an independent, well-considered decision. You will then be notified of the decision. This is how the process will work to bring RFR 17002A to a resolution.

I appreciate the effort your company has made, the stakes involved for its interests as well as the concerns of your community. I can assure you that we will consider this RFR very carefully.

Regards,

Katherine
*Katherine*

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**From:** Walsh, Patrick <patrick-walsh@denka-pe.com>
**Sent:** Friday, January 22, 2021 2:03 PM
**To:** Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Cc:** Noga, Vaughn <Noga.Vaughn@EPA.GOV>; Wells, Jeffrey <Wells.jeffrey@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Grimm, Patrick <Grimm.Patrick@epa.gov>; Tallent, Robert <Tallent.Robert@epa.gov>; Sheppard, Tracy <Sheppard.Tracy@epa.gov>
**Subject:** Re: RFR 17002A Chloroprene - Ramboll/DPE Response to Peer Reviewer Recommendations

Hi Katherine,

Thanks for the quick response. It's good to know that the Executive Panel will be considering all the work we have done with ORD over the last couple of years.

Since I got your email, I have looked at the links you provided and everything else I could find about the RFR process, and I couldn't find anything that discusses a situation like this – where an Executive Panel will be reviewing a major new scientific development like the PBPK model and before any EPA office has passed judgement on it. It sounds like the Scoping Team will play an important role, but I couldn't find anything about it. Would it be

possible to set up a call with you to discuss all this? These issues are of enormous importance to our company and the community around us, and we would just like to understand how the process will actually work.

I would be grateful to have the chance to talk with you and will adjust my schedule so that I can be available any time that would work for you.

Thanks,

Patrick

Patrick A. Walsh, CIH
SHE Manager
Denka Performance Elastomer, LLC
Sent from my phone--please excuse typos

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**From:** Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Sent:** Tuesday, January 19, 2021 12:17:41 PM
**To:** Walsh, Patrick <patrick-walsh@denka-pe.com>
**Cc:** Noga, Vaughn <Noga.Vaughn@EPA.GOV>; Wells, Jeffrey <Wells.jeffrey@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Grimm, Patrick <Grimm.Patrick@epa.gov>; Tallent, Robert <Tallent.Robert@epa.gov>; Sheppard, Tracy <Sheppard.Tracy@epa.gov>
**Subject:** RFR 17002A Chloroprene - Ramboll/DPE Response to Peer Reviewer Recommendations

**THINK SECURE**. This email has come from an **external source**. Do not click on links or open attachments unless you recognize the sender.
Hi Patrick,

Now that the independent peer review of the Denka/Ramboll PBPK Model has been completed, all parties within the EPA feel that enough information has been gathered to move forward with the Request for Reconsideration (RFR) process.

Consideration will be given to all information and concerns raised in the original RFR submission, the PBPK model that Ramboll has developed, reaction to the peer review report from Denka/Ramboll, and input from the Office of Research and Development. This information in total will be presented to the RFR Executive Panel for their consideration and decision.

There comes a time in the process when the EPA must take the information it has and proceed with the RFR process and we have reached that point. The purpose of the RFR process is to have an independent, objective review by the RFR Executive Panel of all the pertinent information. Whatever their ultimate decision, it will be clearly explained.

From here on we will follow the RFR process (https://www.epa.gov/sites/production/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf ) outlined in our Information Quality Guidelines.

Know that we appreciate your position. There has been a voluminous amount of information gathered relevant to this RFR with many resources and hours contributed by all concerned. We at the EPA take very seriously our duty to reach carefully considered, scientifically justified decisions in these matters.

Regards,

*Katherine*

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**From:** Walsh, Patrick <patrick-walsh@denka-pe.com>
**Sent:** Thursday, January 14, 2021 12:55 PM
**To:** Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Cc:** Noga, Vaughn <Noga.Vaughn@EPA.GOV>; Wells, Jeffrey <Wells.jeffrey@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Grimm, Patrick <Grimm.Patrick@epa.gov>; Tallent, Robert <Tallent.Robert@epa.gov>; Sheppard, Tracy <Sheppard.Tracy@epa.gov>
**Subject:** RE: RFR 17002A Chloroprene - Ramboll/DPE Response to Peer Reviewer Recommendations
**Importance:** High

Hi Katherine,

Thank you for your quick response, and I'm glad the agency is keeping this a high priority.

I do have a number of follow up questions and concerns that I hope you and others copied on this email will be able to address.

First and foremost, we were surprised and concerned to hear that EPA has unilaterally decided to reactivate the RFR process. We have invested enormous amounts of time and resources to develop a PBPK model that is acceptable to ORD. And for almost two years now, we have worked closely with ORD to develop a rigorous, scientifically sound model that experts from ORD and Ramboll can agree on (and that has been published in a peer-reviewed scientific journal). Yet as outlined in EPA's IQA guidelines, the RFR process is an adversarial appeals process under which an outside party asks the Executive Panel to overrule a decision made by an EPA "information owner," which in this case would be ORD. Ramboll's experts believe that they are close to reaching an agreement with ORD experts on an approach that would allow ORD to replace the current IUR with one that is based on better science.

The most important question I had was, if there is to be an RFR process, will it focus on the concerns that we raised in our original RFR or will it consider the PBPK model that Ramboll has developed, with input from ORD, over the last 2 years?

Combined with the issues that we had at the beginning of the peer review panel meeting when it appeared Ramboll was being deliberately excluded from the discussion, this sudden change in direction leaves me with grave concerns about the transparency and objectivity of this process and how it moves forward.

I think it would be most efficient if we could have a teleconference in the next few days to discuss my question above as well as a few other concerns rather than sending emails back and forth. What is your availability in the next few days to have a chat with me? I'm busy but can move things around to accommodate your schedule. Thanks.

Patrick A. Walsh, CIH | SHE Manager
Denka Performance Elastomer LLC
560 Highway 44 | LaPlace, LA 70068
Office: 985-536-7573 | Cell: 251-321-5989
patrick-walsh@denka-pe.com

**From:** Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Sent:** Tuesday, January 12, 2021 9:58 AM
**To:** Walsh, Patrick <patrick-walsh@denka-pe.com>
**Cc:** Noga, Vaughn <Noga.Vaughn@EPA.GOV>; Wells, Jeffrey <Wells.jeffrey@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Grimm, Patrick <Grimm.Patrick@epa.gov>; Tallent, Robert <Tallent.Robert@epa.gov>; Sheppard, Tracy <Sheppard.Tracy@epa.gov>
**Subject:** RFR 17002A Chloroprene - Ramboll/DPE Response to Peer Reviewer Recommendations

Patrick,

The IRIS Program is evaluating Ramboll's responses to the peer reviewer comments. Their evaluation will be considered by EPA as it reaches a determination on the Request for Reconsideration (RFR).

The RFR process is described in the EPA Information Quality Guidelines at https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information. The information provided here states that "The Assistant Administrator (AA) or Regional Administrator (RA) information owner presents to an Executive Panel. The Executive Panel would be comprised of the Science Advisor/AA for the Office of Research and Development (ORD), Chief Information Officer/AA for Mission Support, and the Economics Advisor/AA for the Office of Policy (OP). The 3-member Executive Panel would be chaired by the Chief Information Officer/AA for Mission Support. When the subject of the RFR originated from a member office, that Panel member would be replaced by an alternate AA or RA. While the Executive Panel is considering an RFR, the decision made on the initial complaint by the information owner office or region remains in effect. The Executive Panel makes the final decision on the RFR."

A Scoping Team will convene in the upcoming weeks. The Scoping Team will gather all material related to the RFR and prepare a presentation for delivery to the Executive Panel. The Executive Panel will be scheduled at that point based on the availability of the Panel members. This entire process could take a few months for presentation preparation and the unpredictability of administration transition activities.

Please know that the resolution of RFR 17002A is a high priority of the EPA and will be handled as expediently as possible.

Regards,

Katherine

**From:** Walsh, Patrick <patrick-walsh@denka-pe.com>
**Sent:** Monday, January 11, 2021 4:22 PM
**To:** Chalfant, Katherine <Chalfant.Katherine@epa.gov>
**Cc:** Noga, Vaughn <Noga.Vaughn@EPA.GOV>; Wells, Jeffrey <Wells.jeffrey@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Grimm, Patrick <Grimm.Patrick@epa.gov>; Tallent, Robert <Tallent.Robert@epa.gov>; Sheppard, Tracy <Sheppard.Tracy@epa.gov>
**Subject:** RE: RFR 17002A - Chloroprene - Ramboll/DPE Response to Peer Reviewer Recommendations

Hi Katherine,

Thanks for the update. I do have a few questions I hope you'll be able to answer:

1. My understanding was that Ramboll's responses would be evaluated by IRIS technical staff. Has that changed? If it's not IRIS staff, who will be completing the review?
2. Can you expand a bit on what "re-initiating the RFR process" means? My understanding was that the RFR process had been suspended while IRIS deliberated on this issue. Does this signal that their deliberation is complete? What was the outcome of that deliberation?
3. Can you give me a timeframe for this "re-initiation" and the steps involved? We have been dealing with this for years at this point and there are many people in the community around my plant that are needlessly concerned for their health. I'm eager to relieve that if it's possible to do so.

I (and a great many others) look forward to your prompt response. Thanks very much.

Patrick A. Walsh, CIH | SHE Manager
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