Message

From: Orme-Zavaleta, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C5A111DC377411595E5B24B5D96146B-ORME-ZAVALETA, JENNIFER]
Sent: 3/24/2021 11:52:32 AM
To: Starfield, Lawrence [Starfield.Lawrence@epa.gov]
CC: Gray, David [gray.david@epa.gov]
Subject: RE: Reopening FY2021 Call for Nomination of Chemicals for Developing or Updating IRIS Assessments

Morning and sorry for the delay – having ORD leadership mtgs
Here's the latest I have from Kris Thayer on this

Ex. 5 Deliberative Process (DP)

Happy to talk thru further if you'd like.

jennifer

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
Cell Ex. 6 Personal Privacy (PP)

From: Starfield, Lawrence <Starfield.Lawrence@epa.gov>
Sent: Monday, March 22, 2021 6:07 PM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: Gray, David <gray.david@epa.gov>
Subject: FW: Reopening FY2021 Call for Nomination of Chemicals for Developing or Updating IRIS Assessments

Jennifer,

Ex. 5 Deliberative Process (DP)

Larry

This message is CONFIDENTIAL, and may contain legally privileged information. If you are not the intended recipient, or believe you received this communication in error, please delete it immediately, do not copy, and notify the sender. Thank you.

From: Bhandari, Pradnya <Bhandari.Pradnya@epa.gov> **On Behalf Of** Orme-Zavaleta, Jennifer
Sent: Thursday, March 11, 2021 11:02 AM
To: Leadership_Assistant_Administrators <Leadership_Assistant_Administrators@epa.gov>; Leadership_Regional_Administrators <Leadership_Regional_Administrators@epa.gov>; Leadership_Deputy_Assistant_Administrators <Leadership_Deputy_Assistant_Administrators@epa.gov>; Leadership_Deputy_Regional_Administrators <Leadership_Deputy_Regional_Administrators@epa.gov>
Cc: Frey, Christopher <Frey.Christopher@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Miller, Gregory <Miller.Gregory@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Stedeford, Todd <Stedeford.Todd@epa.gov>; Barone, Stan <Barone.Stan@epa.gov>; Benson, Amy <Benson.Amy@epa.gov>; Raffaele, Kathleen <raffaele.kathleen@epa.gov>; Murphy, Deirdre <Murphy.Deirdre@epa.gov>; Hoyer, Marion <hoyer.marion@epa.gov>; Vasu, Amy <Vasu.Amy@epa.gov>; Saili, Katerine <saili.katerine@epa.gov>; Dockins, Chris <Dockins.Chris@epa.gov>; Dzubow, Rebecca <Dzubow.Rebecca@epa.gov>; Lloyd, Christine <Lloyd.Christine@epa.gov>; Cassidy, Meghan <Cassidy.Meghan@epa.gov>; Olsen, Marian <Olsen.Marian@epa.gov>; Gehlhaus, Martin <Gehlhaus.Martin@epa.gov>; Adams, Glenn <Adams.Glenn@epa.gov>; Koporec, Kevin <Koporec.Kevin@epa.gov>; Frederick, Tim <Frederick.Tim@epa.gov>; Sundar, Bhooma <sundar.bhooma@epa.gov>; Milburn, Anna <Milburn.Anna@epa.gov>; Schumacher, Kelly <Schumacher.Kelly@epa.gov>; Benson, Bob <Benson.Bob@epa.gov>; Small, Matthew <Small.Matthew@epa.gov>; Stralka, Daniel <Stralka.Daniel@epa.gov>; Kissinger, Lon <Kissinger.Lon@epa.gov>; Lead Region Coordinators HQ <Lead_Region_Coordinators_HQ@epa.gov>; ORD-OSAPE-RSL <ORD-OSAPE-RSL@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Trentacoste, Emily <trentacoste.emily@epa.gov>; Robbins, Chris <Robbins.Chris@epa.gov>
Subject: Reopening FY2021 Call for Nomination of Chemicals for Developing or Updating IRIS Assessments

Agency Leadership,

The purpose of this memorandum is to reinitiate the call for nominations for developing IRIS assessments.

In September 2020, the Office of Research and Development (ORD) issued the annual call for nominations for the development of Integrated Risk Information System (IRIS) hazard and dose-response assessments. ORD received formal nominations for three chemicals from OLEM as priorities in the most recent process – naphthalene, ethylbenzene, and PAH mixtures. Learning of several issues with the FY21 nomination process, ORD did not complete this process. To reach closure, ORD is "redoing" the FY21 process with the intent to focus on science-based decisions and increase transparency, allowing for ORD to be more responsive to Agency needs and where ORD is also a stakeholder in the process.

Therefore, I am asking program and regional offices to review and prioritize the attached input we received for IRIS assessments as well as identify other chemicals ORD should consider. In your response, please be sure to indicate information on whether the nomination focuses on a specific route of exposure, and whether the cancer and/or noncancer assessment is required. If submitting more than one chemical, it would be helpful to have a sense of priority. Responses should be sent directly from your offices to the IRIS Program Director, Dr. Kris Thayer (thayer.kris@epa.gov), in ORD's Center for Public Health and Environmental Assessment, by **April 9, 2021**.

Once ORD receives this updated information, the IRIS Program will evaluate their capacity and resources to add additional chemicals to the IRIS agenda, taking into account ongoing assessments by other Offices and any statutory/regulatory deadlines to meet Agency needs. The IRIS program will propose new assessments to ORD leadership for decision, then brief program and regional offices on decisions and next steps. We anticipate finalizing the FY21 nominations 1 month after receiving updated information from the program and regional offices.

Moving forward, we will be revamping the nomination process for next year. The ORD IRIS program will be engaging our partner program and regional IRIS program contacts before we initiate the FY22 process. The goal of the updated nomination process will be to ensure transparency and full engagement of Agency offices so that we can identify IRIS assessments that meet Agency needs.

I also want to note that ORD will unsuspend the IRIS assessment of formaldehyde and will add formaldehyde to the current IRIS agenda. The next step for this assessment is agency review. In addition, IRIS staff will be updating the literature to be included in the assessment since suspension in 2018. The IRIS formaldehyde assessment will then be a resource for our colleagues in OCSPP, as well as other program offices, for use under their own statutory requirements.

I encourage your staff to reach out to Dr. Kris Thayer to address any questions. Shortly after transmittal of this memorandum, the IRIS Program will be setting up a call to discuss any questions related to the previous round of nominations and provide further details moving forward.

I recognize the importance of the IRIS Program to decisions made across the Agency, and ORD is committed to ensuring that IRIS assessments provide timely, transparent, rigorous, and high-quality evaluations of the hazard and dose-response data to inform risk assessment decisions. I appreciate your flexibility and willingness to help us resolve issues in the FY21 nomination process, and I look forward to engaging with you as we develop a more transparent, sustainable, and durable approach to identify assessment needs across the Agency in the years to come.

Jennifer