EDDIE BERNICE JOHNSON, Texas
CHAIRWOMAN

FRANK D. LUCAS, Oklahoma
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6301

(202) 225–6375
www.science.house.gov

July 18, 2019

The Honorable Andrew Wheeler
Administrator
Environmental Protection Agency
1301 Constitution Ave. NW
Washington, D.C., 20460

Dear Administrator Wheeler,

I write to follow up on the repeated requests the Committee on Science, Space, and Technology ("the Committee") has issued to EPA regarding the Integrated Risk Information System (IRIS) program. Over the past five months, EPA has stonewalled this Committee — preventing a coequal branch of government from conducting Constitutionally-mandated oversight. I am deeply troubled by this lack of cooperation with our efforts to evaluate a program so vital to ensuring the health and safety of the American people, and this behavior fits into a disturbing pattern of obstruction and disrespect of Congressional authority.

EPA's intransigence and continued disregard for Congressional oversight demands has made it clear that use of compulsory power by this Committee is in order.

Background on Committee Inquiries

EPA's IRIS program is responsible for characterizing the health hazards of chemicals, through hazard identification and dose response assessments, which are particularly important for understanding how chemicals impact children, pregnant women, the elderly, and the immunocompromised. IRIS last completed an assessment of formaldehyde in 1990, and since that time, significant new data has emerged. In 2009 researchers at the National Cancer Institute, the U.S. National Toxicology Program and the International Agency for Research on Cancer (IARC) all released study results linking formaldehyde to leukemia. At that same time, IRIS had already initiated work on a draft for an updated health hazard assessment for formaldehyde. The draft was released in June of 2010. In January 2018, your predecessor, Administrator Scott Pruitt, confirmed to the Senate that the formaldehyde assessment had been finalized, concluding that formaldehyde causes leukemia, but that it was being held up.[1]

[1] Annie Snider, "Sources: EPA blocks warnings on cancer-causing chemical," *Politico*, July 6, 2018, accessed here: https://www.politico.com/story/2018/07/06/epa-formaldehyde-warnings-blocked-696628

However, on December 19, 2018, EPA quietly removed formaldehyde and nine other chemical assessments from its program outlook, effectively stopping all efforts to finalize the reviews already in progress.[2] When pressed for an explanation by Members of Congress and the press, EPA defended its decision to reduce the IRIS workflow by nearly half by citing the need to conserve time and resources[3] and pointed to a newly-instituted prioritization process involving a two-part survey of EPA program offices. The Agency has rebuffed the Committee's attempts to understand the prioritization process and how the benefits of eliminating several late-stage chemical assessments, including formaldehyde, outweigh the harms to the public.

Committee Requests for Information from EPA

On February 5, 2019, Committee staff emailed EPA Congressional Affairs requesting a staff-level briefing on the IRIS program and its dropping on the formaldehyde review from its December 2018 program outlook. After a back-and-forth regarding scheduling, EPA Congressional Affairs requested that "all congressional requests for briefings [be] sent via a formal letter from the member."[4] This is highly unusual and constitutes an artificial barrier to information to which Committee staff is entitled in order to perform their role.

On March 4, 2019, I wrote with three of my colleagues in the Senate to EPA to request documents relating to EPA's elimination of the IRIS formaldehyde assessment.[5] My Senate colleagues were informed by EPA Congressional Affairs that EPA intended to treat the request as a Senate Minority request rather than a House Majority request, as my signature was not listed first.[6] We understand this as EPA's attempt to undermine the authority of a Chairwoman. The deadline for materials requested was April 5, but we have yet to receive any responsive documents.

On March 27, 2019, the Committee held a hearing entitled "*EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead*." At this hearing, we reviewed the Government Accountability Office's March 4 report on IRIS, wherein GAO found that political appointees within EPA are hindering the program's productivity, communication, and transparency. This included EPA's opaque process of selecting priority chemicals, its order that IRIS cease releasing documentation to the public, its undermining of the chronically understaffed IRIS program through staff reassignments, and the mysterious delay of the long-completed formaldehyde report. The Committee requested testimony from Dr. Kristina Thayer, head of the IRIS program. Instead, EPA sent Principal Deputy Assistant Administrator for Science, Dr. Jennifer Orme-Zavaleta. At the hearing, it became clear that Dr. Orme-Zavaleta was not involved in many of the decisions at

---

[2] "A Message from the IRIS Program," U.S. Environmental Protection Agency, December 19, 2018, accessed here: https://www.epa.gov/sites/production/files/2018-12/documents/iris_program_outlook_december_2018.pdf

[3] Testimony of Dr. Jennifer Orme-Zavaleta before the Committee on Science, Space, and Technology, p. 6, March 27, 2019, accessed here: https://science.house.gov/hearings/epas-iris-program-reviewing-its-progress-and-roadblocks-ahead

[4] Appendix Item 1

[5] Letter to Administrator Wheeler from Chairwoman Johnson and Senators Carper, Markey, and Whitehouse, March 4, 2019, accessed here: https://www.carper.senate.gov/public/_cache/files/d/8/d85d2332-eb76-457b-9357-0ca9287941d4/CAABAB95A210F123C71A45FA3DB8D84C.letter-to-administrator-wheeler-3-4-18.pdf

[6] Appendix Item 2

the core of the Committee's investigation of the program, and she was not prepared by the Agency to answer basic questions about relevant events from the past year.

At the hearing, Congressman Paul Tonko inquired about the Office of Children's Health Protection's (OCHP) response to the IRIS prioritization surveys. Dr. Orme-Zavaleta affirmed that OCHP did respond to the second-round survey. Congressman Tonko asked Dr. Orme-Zavaleta if formaldehyde was one of the priority chemicals listed and she responded:

> "I believe formaldehyde was one of the chemicals, but we can get back with you. I don't recall the full list."[7]

EPA has failed to remit OCHP's survey response to the Committee despite repeated reminders.

On April 3, the Committee sent a letter to you requesting a briefing on the announcement that EPA was officially discontinuing IRIS's work on formaldehyde.[8] The letter outlined specific questions that were asked in the hearing that Dr. Orme-Zavaleta was unable to answer. EPA has yet to offer a date for this briefing.

On April 11, the Committee followed up on our March 27 hearing with formal questions for the record. To date – four months after the hearing – the Committee has not received any response. This failure to respond to routine questions for the record is highly unusual.

On April 24, an EPA Congressional Affairs staffer returned the Agency's edits to the Committee transcript, which are supposed to be clarifications to clerical errors in the stenographer's record. But in that message the staffer suggested an edit to the transcript that would change the substance of Dr. Orme-Zavaleta's response to another question regarding OCHP. The staffer asked the Committee to omit her assertion that OCHP's response came a day after the December IRIS memo was released.[9] This is an outrageous attempt to change the record in order to circumvent Congressional oversight and improve public perception of EPA's actions.

During a staff-level phone call on May 3, EPA Congressional Affairs attempted to change course altogether, claiming that Dr. Orme-Zavaleta never told the Committee that the Agency would follow up about OCHP's response to the second-round IRIS survey, despite the clear exchange documented in the hearing transcript. In any event, the second-round IRIS survey is also part of the response we would expect to receive in response to our March 4 document request.

During the May 3 phone call, EPA Congressional Affairs also promised to deliver the following by May 10: responses to the March 4 bicameral letter, the OCHP second-round survey response, and responses to questions for the hearing record.[10] The Committee has yet to receive any of these items.

---

[7] "EPA's IRIS Program: Reviewing Its Progress and Roadblocks Ahead," Committee on Science, Space, and Technology, March 27, 2019, video accessed here and remarks at timestamp 1:10:50: https://science.house.gov/hearings/epas-iris-program-reviewing-its-progress-and-roadblocks-ahead

[8] Letter to Administrator Wheeler from Chairwoman Johnson and Chairwoman Sherrill, April 3, 2019, accessed here: https://science.house.gov/imo/media/doc/4.3.19%20Wheeler%20letter%20EPA%20IRIS.pdf

[9] Appendix Item 3

[10] Appendix Item 4

Your staff in Congressional Affairs has made every effort to obstruct the Committee's oversight, going so far as to attempt to change the substance of the record. At this point, the Committee has exhausted all non-compulsory means of conducting oversight over EPA. The Agency's obstruction of Congress is particularly disturbing considering the implications of the matter at hand for children's health.

EPA must provide to the Committee the following responsive materials by the accompanying deadlines:

- All documents responsive to the March 4, 2019 letter by August 1, 2019;
- The OCHP second-round IRIS survey response by close of business July 19, 2019;
- A date for the briefing requested in the April 3, 2019 letter must be agreed upon by July 22, 2019. The briefing must occur before August 7, 2019. David Dunlap, Kristina Thayer, and Tina Bahadori should be present and available for questions at the briefing;
- Answers to the questions for the record sent on April 11, 2019, by August 1, 2019.

Please respond in full by the provided deadlines or the Committee will be forced to use compulsory measures.

If you have any questions or would like to discuss compliance with requests made to date, please contact Ms. Janie Thompson at 202-225-6376.

Sincerely,

EDDIE BERNICE JOHNSON
Chairwoman
Committee on Science, Space, and Technology

CC: Ranking Member Frank Lucas, Committee on Science, Space, and Technology

APPENDIX

[redacted]

From: Moody, Christina [redacted]
Sent: Monday, February 11, 2019 1:08 PM
To: Hooghan, Priyanka
Subject: RE: Requesting an IRIS Update Briefing

Yes –

Going forward, all congressional requests for briefings will need to be sent via a formal letter from the member.

Thanks,

Christina J. Moody | Office of Congressional & Intergovernmental Relations
U.S. Environmental Protection Agency | 1200 Pennsylvania Ave NW (MC-1301A) | Washington DC | 20460
[redacted]

From: Hooghan, Priyanka
Sent: Monday, February 11, 2019 12:55 PM
To: Moody, Christina
Subject: RE: Requesting an IRIS Update Briefing

Hi Christina,

Just for my understanding, we will need to submit a letter in order to schedule a staff level briefing on the IRIS program?

Thanks,
Priyanka

Priyanka K. Hooghan
Staff Director - Subcommittee on Environment
Committee on Science, Space, and Technology
U.S. House of Representatives
2321 Rayburn House Office Building
Washington, DC 20515
[redacted]

http://science.house.gov/

From: Moody, Christina [redacted]
Sent: Monday, February 11, 2019 12:23 PM
To: Hooghan, Priyanka [redacted]
Subject: RE: Requesting an IRIS Update Briefing

Gm Priyanka,

Can you send a formal letter requesting the briefing and trip to the labs? We need it for tracking purposes.

Thanks, and feel free to call if you want to discuss further.

Christina J. Moody | Office of Congressional & Intergovernmental Relations
U.S. Environmental Protection Agency | 1200 Pennsylvania Ave NW (MC-1301A) | Washington DC | 20460
[redacted]

From: Hooghan, Priyanka [redacted]
Sent: Thursday, February 07, 2019 4:56 PM
To: Moody, Christina [redacted]
Cc: Schneider, Josh [redacted]; Palasits, Sara [redacted]
Subject: RE: Requesting an IRIS Update Briefing

Hi Christina,

I appreciate you checking for us, but we would prefer to have this briefing sooner rather than later. Can we still make the 21st work at 11 am? I can book a room for an hour and half to make sure we have ample time to get through everything.

Thanks,
Priyanka

From: Moody, Christina [redacted]
Sent: Thursday, February 07, 2019 4:45 PM
To: Hooghan, Priyanka [redacted]
Cc: Schneider, Josh [redacted]; Palasits, Sara [redacted]
Subject: Re: Requesting an IRIS Update Briefing

Hi Priyanka,

Apologies, but that date, nor week, works on this side due to prior obligations. We do have availability for March 7 @ 1pm.

Can we make that work?

Christina J. Moody
US Environmental Protection Agency
Office of Congressional and Intergovernmental Relations
[redacted]

On Feb 6, 2019, at 3:47 PM, Moody, Christina [redacted] wrote:

> I'm going to need to check.
>
> Christina J. Moody
> US Environmental Protection Agency
> Office of Congressional and Intergovernmental Relations
> [redacted]
>
> On Feb 6, 2019, at 2:46 PM, Hooghan, Priyanka [redacted] wrote:

Hi Christina – would staff be able to come in on the 22nd or during the last week of February?

Thanks,
Priyanka

From: Moody, Christina [redacted]
Sent: Wednesday, February 06, 2019 2:36 PM
To: Hooghan, Priyanka [redacted]
Cc: Schneider, Josh [redacted], Palasits, Sara [redacted]
Subject: Re: Requesting an IRIS Update Briefing

Priyanka,

Staff are available in 2.21 at 11am. Let me know if that time and date works.

Thanks!

Christina J. Moody
US Environmental Protection Agency
Office of Congressional and Intergovernmental Relations
[redacted]

On Feb 5, 2019, at 2:48 PM, Hooghan, Priyanka [redacted] wrote:

> Hi Christina,
>
> We wanted to set up a staff level briefing on the IRIS program. I saw the IRIS program update prior to the shutdown and noticed that there was no information on the status of the formaldehyde review or when the IRIS Handbook would be published. As such, we would like to get an update on the status of these two items, as well as an update on the status of ongoing assessments and how the shutdown may have impacted their projected dates for the "Next Anticipated Public Step(s)." Can you please let us know some times next week or later this month that IRIS and NCEA staff would be available to brief us in person in DC?
>
> Thanks,
> Priyanka
>
> Priyanka K. Hooghan
> *Democratic Professional Staff - Subcommittee on Environment*
> *Committee on Science, Space, and Technology*
> *U.S. House of Representatives*
> *394 Ford H.O.B.*
> *Washington, DC 20515*
> [redacted]
>
> *http://democrats.science.house.gov/*

From: Lyons, Troy [redacted]
Sent: Monday, March 04, 2019 5:14 PM
To: Plazza, John <[redacted]
Cc: [redacted] Obermann, Richard [redacted]; Hooghan, Priyanka [redacted]
Subject: Re: Joint SS&T EPW letters

Many thanks, John.

Sent from my iPhone

On Mar 4, 2019, at 4:17 PM, Plazza, John <[redacted]> wrote:

> Mr. Lyons,
> We have heard from our Senate counterparts that the EPA intends to handle the attached letters as "minority requests" rather than coming from a Committee Chair. I want to make clear that this letter is a joint request from the RM of EPW and the Chair of Science, Space, and Technology. The watermark on the top of the letter is irrelevant. Chairwoman Johnson expects this to be treated with the same attention and timeliness as any other request from the chair of a congressional committee.
>
> Please confirm receipt of this email and an acknowledgement that EPA will treat this request as having come from the chair of a congressional committee.
>
> Thank you for your attention to this matter,
>
> -John Plazza
> Chief Counsel
> Democratic Staff
> Committee on Science, Space, and Technology
>
> <03-04-19TC EBJ EM SW Wheeler Formaldehyde Letter FINAL.pdf>
> <03-04-19TC EBJ EM SW Grifo Formaldehyde Letter FINAL.pdf>

[redacted]

From: Thompson, Janie
Sent: Thursday, April 25, 2019 9:53 AM
To: [redacted]
Cc: Buchanan, Caitlin; Palasits, Sara; Hooghan, Priyanka; Schneider, Josh; Kovalovich, Aria; Knapp, Kristien
Subject: RE: Jennifer Orme-Zavaleta -- Thank You from the House Science, Space, and Technology Committee
Attachments: HSST IRIS Hearing Transcript Clarifications and Corrections 4-24-19.pdf

Travis,

Thanks for the reply. Caitlin is traveling so I'll close the loop.

We noticed the suggested correction on page 53 seeks to change the substance of Ms. Orme-Zavaleta's explanation on the OCHP memo, which isn't something we can do in clerical corrections of the transcript. The "day after" remark is important. Can we clear this up once and for all? When specifically was OCHP's second-round response returned, and to whom was it returned? We still have not received this memo as Dr. Orme-Zavaleta promised from the dais.

Janie
[redacted]

Page 53, Lines 1218-1219	Clarification/Correction. Change "but it came in the day after I released the December memo of the decisions" to "but it came in after the list and December memo had been finalized."

Begin forwarded message:

> **From:** "Voyles, Travis" [redacted]
> **Date:** April 24, 2019 at 3:00:49 PM GMT+2
> **To:** "Buchanan, Caitlin" [redacted]
> **Cc:** "Knapp, Kristien" [redacted]
> **Subject: RE: Jennifer Orme-Zavaleta -- Thank You from the House Science, Space, and Technology Committee**
>
> Hi Caitlin—Attached are our clarifications/corrections to the hearing transcript. Please call me if you have any questions! We will follow up soon with the responses to QFRs.
>
> Thanks,
>
> Travis
>
> Travis Voyles
> [redacted]

From: Buchanan, Caitlin [redacted]
Sent: Thursday, April 11, 2019 12:21 PM
To: Moody, Christina [redacted]; Voyles, Travis [redacted]
Subject: Jennifer Orme-Zavaleta -- Thank You from the House Science, Space, and Technology Committee

Dr. Orme-Zavaleta,

On behalf of the Committee on Science, Space, and Technology, I want to thank you for your participation at the March 27, 2019 hearing, "EPA'S IRIS Program: Reviewing Its Progress And Roadblocks Ahead." I have attached a verbatim transcript of the hearing for your review, as well as a thank you letter from Chairwoman Sherrill and Chairwoman Fletcher.

Please submit any transcript edits no later than Wednesday, April 24, 2019. Please let me know if you have any questions!

Caitlin Buchanan
Research Assistant, Subcommittee on Investigations & Oversight
Committee on Science, Space, & Technology
[redacted]
https://science.house.gov/

[redacted]

From: Voyles, Travis <[redacted]>
Sent: Wednesday, May 15, 2019 5:51 PM
To: Thompson, Janie
Cc: Palasits, Sara; Hooghan, Priyanka; Schneider, Josh; Freedhoff, Michal (EPW); [redacted]; Avenel Joseph [redacted]; Rodrick, Christian
Subject: RE: Recap of our call today - IRIS / formaldehyde

Hi Janie—Sorry I have been out of the office the past few days. We are still working on getting the response finalized with the program offices. I will try to provide an updated time frame in the next day if it looks like it will require further time.

Travis Voyles
O: [redacted]
C: [redacted]

From: Thompson, Janie
Sent: Monday, May 13, 2019 8:52 AM
To: Voyles, Travis ; Brazauskas, Joseph ; Rodrick, Christian
Cc: Palasits, Sara ; Hooghan, Priyanka ; Schneider, Josh ; Freedhoff, Michal (EPW) ; [redacted] Avenel Joseph [redacted]
Subject: RE: Recap of our call today - IRIS / formaldehyde

Travis,

We were expecting the doc response including OCHP 2nd round response last week. Can you please give a status update?

Thanks,
Janie

From: Voyles, Travis <[redacted]>
Sent: Friday, May 3, 2019 4:15 PM
To: Thompson, Janie <[redacted]>; Brazauskas, Joseph <[redacted]; Rodrick, Christian <[redacted]
Cc: Palasits, Sara <[redacted]; Hooghan, Priyanka <[redacted]; Schneider, Josh <[redacted]; Freedhoff, Michal (EPW) <[redacted] Avenel Joseph [redacted]
Subject: RE: Recap of our call today - IRIS / formaldehyde

Thanks Janie—We will keep you updated regarding the status of our response.

Have a good weekend!

Travis Voyles
O: [redacted]
C: [redacted]

From: Thompson, Janie <[redacted]
Sent: Friday, May 3, 2019 4:08 PM
To: Voyles, Travis <[redacted]; Brazauskas, Joseph <[redacted]; Rodrick, Christian <[redacted]
Cc: Palasits, Sara <[redacted]; Hooghan, Priyanka <[redacted]; Schneider, Josh <[redacted]; Freedhoff, Michal (EPW) <[redacted]; [redacted]; Avenel Joseph ([redacted]
Subject: Recap of our call today - IRIS / formaldehyde

Travis, Joe and Christian,

Thank you for taking the time to go through the outstanding SST requests with us. Below is a recap of what we discussed. Attached are associated documents.

- **Formaldehyde doc request in 03/04/19 letter to Administrator Wheeler:** We look forward to receiving these documents next week as you anticipated on the call. These were initially due on Friday, April 5, and you were granted an extension to Friday, April 19. Among the documents we expect to see are the surveys on IRIS priorities that went out to the EPA programs that use IRIS assessments (sent to OW, OLEM, OCHP, OAR, OCSPP, maybe others), as well as the responses from each of the programs for both rounds. That would include the Office of Children's Health Protection response to the second-round survey.
- **Ethics review in the 3/4/19 letter to Administrator Wheeler:** We asked for a determination on the Designated Agency Ethics official on Mr. Dunlap's recusal agreement related to formaldehyde and IRIS. We didn't really hear a commitment today as to whether the this request has been passed along to Justina Fugh. Can you confirm that it has and given an update on her consideration of this request?
- **03/04/19 letter to Dr. Francesca Grifo:** we would like to get a status update on the request for Dr. Grifo to determine whether EPA has violated its scientific integrity policy with regards to the delay in publishing the IRIS assessment of formaldehyde. You said you were in the process of analyzing the request.
- **04/03/19 letter to Administrator Wheeler:** We will touch base with you on scheduling a briefing after reviewing the docs we get under item 1.
- **OCHP round 2 response letter:** We would like to see OCHP's response to the second-round IRIS survey on program priorities. This is something we'd expect to be part of the response to the doc request above, but obviously no need to wait until next week to share it with us. The exchange with Dr. Orme-Zavaleta during our hearing is at 1:10:50 here: https://science.house.gov/hearings/epas-iris-program-reviewing-its-progress-and-roadblocks-ahead
- **QFRs from 03/27/19:** these were due on Wednesday, April 24. You said you were working to provide them next week so we will be on the lookout.

Thank you for your attention to all of the above. Please give us a call with any questions or updates. Have a good weekend --

Janie
[redacted]

United States Senate

WASHINGTON, DC 20510

March 4, 2019

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency (EPA)
1301 Constitution Ave. NW
Washington, DC 20460

Dear Administrator Wheeler:

We write to request information related to actions by EPA political appointees' that appear to have prevented the review and publication of the Environmental Protection Agency's (EPA's) Integrated Risk Information System (IRIS) program's formaldehyde health assessment. We also request that the EPA's Designated Agency Ethics Official determine whether Mr. David Dunlap has violated the terms of his recusal agreement by working on matters related to the formaldehyde health assessment.

Several Members of Congress have repeatedly[1] raised concerns with the long-delayed release of the formaldehyde health assessment, which has taken more than a decade and more than $10 million of taxpayer funds to undertake. The assessment, which has been ready to be peer reviewed for almost a year and a half and might have been ready for publication had EPA followed its typical review process and timelines, reportedly concludes that formaldehyde can cause nasopharyngeal cancer and leukemia, among other risks to human health.

While some of the efforts to delay the publication of this report by EPA political appointees have been publicly disclosed[2], a March 4, 2019 Government Accountability Office (GAO) report[3] further describes some of the circumstances surrounding EPA's decision not to finalize the formaldehyde health assessment, as well as other IRIS program delays, resource constraints and diversion of IRIS personnel to support other chemical safety efforts in the Agency. We have also obtained documents that indicate that Mr. Dunlap, who is recused from working on the formaldehyde health assessment, may have directed or participated in EPA's decision to reduce the number of chemicals that will be assessed under IRIS and cease work on the formaldehyde health assessment.

EPA's continued efforts to delay the publication of a report that describes the risk of cancer associated with exposure to formaldehyde will do nothing to eliminate or reduce that risk. Moreover, delaying this report only serves to further erode the public trust in the Agency whose mission is to protect human health and the environment. We urge you to immediately proceed to review, finalize and publish the formaldehyde health assessment without further delay, new studies, and taxpayer expense.

---

[1] https://www.markey.senate.gov/news/press-releases/senators-markey-whitehouse-and-carper-demands-epas-pruitt-stop-hiding-findings-of-key-study-on-health-impacts-of-toxic-formaldehyde

[2] https://www.politico.com/story/2018/07/06/epa-formaldehyde-warnings-blocked-696628

[3] GAO 19-270, "Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act," https://www.gao.gov/products/GAO-19-270

Efforts to delay the publication of EPA's formaldehyde health assessment date back at least since 2004. At that time, Senator Inhofe asked that[4] EPA not begin its planned update to its 1989 formaldehyde health assessment until the National Cancer Institute (NCI) completed an update of one of its own formaldehyde studies. This NCI study was not completed until 2009[5], and it provided more evidence of a link between exposure to formaldehyde and several types of cancer. In 2009, then-Senator Vitter refused[6] to allow the confirmation of an EPA nominee until EPA agreed[7] [8] to send its draft formaldehyde health assessment to the National Academy of Sciences (NAS) for review. The NAS review[9] took two more years to complete, and while it criticized some of EPA's methodologies, it did not refute[10] the linkage identified by EPA between exposure to formaldehyde and cancer. Efforts to refer other EPA IRIS health assessments and methodologies and delay their publication continued to be made through legislative provisions inserted into Congressional Appropriations bills[11] and oversight letters by then-Senator Vitter[12], Senator Inhofe and others.

In 2018, the NAS completed its most recent review[13] of the IRIS program, finding that "EPA has made 'substantial progress' in implementing recommendations outlined in past reports," saying in its press release that "the changes in the IRIS program over such a short period of time are impressive." The draft of the formaldehyde health assessment that has been stalled from being released for peer review and publication has incorporated applicable recommendations made by the NAS as well as any new scientific information that has been published during the lengthy delay.

After you were named Acting Administrator, several Members of the Environment and Public Works Committee asked you questions for the record at an August 1, 2018 hearing about the formaldehyde health assessment. You responded and wrote that EPA "is currently developing a new approach of soliciting program input on current and future IRIS assessments, to ensure IRIS assessment activities are focused on the highest priority needs. The formaldehyde assessment will be included in this activity, which will inform our next steps."

You were also asked several questions on this topic for the record of your January 16, 2019 confirmation hearing, and stated that "[b]ecause IRIS assessments are major investments in both time and resources, in an August 10, 2018 Memorandum to Agency program offices I requested an update of top priorities for IRIS assessments. Formaldehyde was not identified as a top priority."

Your response failed to fully describe the reason why formaldehyde was not identified as a top priority for the program offices. Specifically, the documents we obtained indicate that:

---

[4] https://s3.amazonaws.com/propublica/assets/docs/leavitt_inhofe_letter_041105.pdf
[5] https://www.propublica.org/article/study-reinforces-links-between-formaldehyde-and-cancer-518
[6] https://www.scientificamerican.com/article/vitter-formaldehyde-epa/
[7] https://www.nola.com/politics/2009/12/sen_david_vitter_and_epa_reach.html
[8] http://www.documentcloud.org/documents/1598-documents-related-to-sen-vitter-and-formaldehyde-regulation.html#document/p9
[9] https://www.nap.edu/read/13142/chapter/1
[10] https://www.nrdc.org/experts/jennifer-sass/national-academy-sciences-formaldehyde-still-causes-cancer-humans
[11] https://www.nrdc.org/experts/daniel-rosenberg/cancer-causing-chemicals-have-more-friends-congress-you-do-part-one
[12] https://www.americanchemistry.com/Policy/Regulatory-Reform/Senators-Vitter-Inhofe-Crapo-Letter-Requesting-Greater-Clarity-on-Process-to-Assess-Chemicals.pdf
[13] http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=25086

- A May, 2018 Draft EPA IRIS Program Outlook (attached) prepared by the program's Director indicated that the formaldehyde health assessment would be released for public comment (following inter- and intra-agency peer review) in the fourth quarter of FY 2019.
- An August, 2018 memo (attached) sent by Jennifer Orme-Zavaleta, Ph.D., the Principal Deputy Assistant Administrator in EPA's Office of Research and Development, requested that EPA Program offices describe their IRIS priorities, noting that the formaldehyde health assessment would be ready for review by other agencies by the fourth quarter of 2018. Her memo also noted that in the past, EPA's Office of Chemical Safety and Pollution Prevention, Office of Air and Radiation, Office of Water, Office of Children's Health Protection and Regions 2 and 5 all had expressed an interest in the completion of the formaldehyde health assessment.
- EPA's Office of Children's Health Protection, Office of Land and Emergency Management, Office of Water, and Region 4 all responded (attached) to Dr. Orme-Zavaleta's memo saying that they had a need for the formaldehyde health assessment. The Office of Chemical Safety and Pollution Prevention did not indicate such a need in its response and noted different priorities, while the Office of Air and Radiation did not indicate a need for any IRIS assessments to be completed at all.
- In October, 2018, EPA political officials made a second request for EPA program offices to indicate what their IRIS priorities were, and this time the program offices were told to select fewer chemicals for assessment. According to GAO's records of interviews with EPA staff, "they said that the Administrator has his own political agenda, and that will determine their priorities. The Administrator said that he needed to make a decision on formaldehyde one way or another – it couldn't just stay in limbo forever." Furthermore, "IRIS officials said that the "priority" survey in late October was actually a request made in person at a senior political meeting, and came from David Dunlap…They think Mr. Dunlap asked Assistant Administrators to give ORD lists of their top three priority assessments."
- EPA program offices then re-submitted new lists (attached) of priority chemicals for assessments, and this time, formaldehyde was not included on any office's priority list.
- On December 4, 2018, Jennifer Orme-Zavaleta, Ph.D., the Principal Deputy Assistant Administrator in EPA's Office of Research and Development, sent a new memo (attached) entitled "Updated Priorities for IRIS Assessments" that did not include formaldehyde.

So that we can further understand the extent to which EPA's political appointees may have engaged in efforts to suppress the completion of EPA's formaldehyde health assessment, we request the following materials to be provided no later than Friday April 5, 2019:

1. All documents (including comments, notes, emails, legal and other memoranda, white papers, scientific references, letters, telephone logs, text messages, meeting minutes and calendars, photographs, slides and presentations) prepared for or obtained by Trump Administration EPA political officials', or regarding Trump Administration EPA political officials, that are related to EPA's determination of whether and how to proceed with its formaldehyde health assessment (including documents related to the consideration of the use of EPA's TSCA authority to conduct a new 3-3.5 year long risk evaluation of formaldehyde).

We additionally request that EPA's Designated Agency Ethics Official determine whether Mr. Dunlap has violated his recusal agreement[14], which prevents him from working on EPA's formaldehyde risk assessment because of his past role[15] at Koch Industries (which has worked with other producers and

[14] https://www.eenews.net/assets/2018/12/27/document_gw_01.pdf
[15] https://www.eenews.net/stories/1060110585

users of formaldehyde to frequently criticize EPA's formaldehyde efforts). We note that Mr. Dunlap also planned to participate in a recent briefing on EPA's IRIS program and its formaldehyde health assessment that was requested by staff of the Environment and Public Works Committee. That briefing was postponed after the Committee staff asked whether Mr. Dunlap was permitted to participate, in light of his recusal from some of the subject matter of the briefing.

Thank you very much for your attention to this important matter. If you have any questions or concerns, please ask your staff to contact Michal Freedhoff of the Senate Environment and Public Works Committee staff at 202-224-8832, Priyanka Hooghan of the House Science, Space, and Technology Committee staff at (202) 225-6375, Avenel Joseph of Senator Markey's office at (202) 224-2742, or Dan Dudis of Senator Whitehouse's office at (202) 224-2921.

Sincerely,

The Honorable Tom Carper
Ranking Member
Environment and Public Works Committee
U.S. Senate

The Honorable Eddie Bernice Johnson
Chairwoman
Science, Space, and Technology Committee
U.S. House of Representatives

Edward J. Markey
United States Senator

Sheldon Whitehouse
United States Senator

EDDIE BERNICE JOHNSON, Texas
CHAIRWOMAN

FRANK D. LUCAS, Oklahoma
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6301

(202) 225–6375
www.science.house.gov

April 3, 2019

The Honorable Andrew Wheeler
Administrator
Environmental Protection Agency
1301 Constitution Ave. NW
Washington, D.C., 20460

Dear Administrator Wheeler,

We write to express our concern about the Program Outlook issued yesterday by the Environmental Protection Agency (EPA) regarding the upcoming workflow of the Integrated Risk Information System (IRIS).[1] The list issued is identical to that issued on December 19, 2018, but the message accompanying the list formally stated that the EPA is officially discontinuing IRIS's work on formaldehyde.

The formaldehyde assessment has been ready for public comment since at least the end of 2017, as confirmed by your predecessor, former Administrator Scott Pruitt, at a January 2018 Senate hearing.[2] Though the Agency has been successful in suppressing its release to the public, press reports indicate that the IRIS assessment concludes formaldehyde causes leukemia and other cancers.[3] It is unacceptable that the EPA is hiding information on a probable carcinogen from the American people.[4]

On March 20, 2019, the EPA announced that formaldehyde will be assessed under the Toxic Substances Control Act (TSCA).[5] It is absurd that formaldehyde can simultaneously be a high-priority chemical under TSCA and not be a priority at all for IRIS. These processes are not mutually exclusive, nor do they serve the same purpose, and it is unacceptable that the agency is apparently treating them as such by discontinuing IRIS's work. When asked about this discrepancy at a Science Committee hearing last week, Dr. Jennifer Orme-Zavaleta, the Principal Deputy Assistant Administrator for EPA's Office of Research and Development (ORD), said: "I wouldn't say that [formaldehyde is] not a priority for IRIS. We have

---

[1] "A Message from the IRIS Program," Environmental Protection Agency, April 2019, accessed here: https://www.epa.gov/sites/production/files/2019-04/documents/iris_program_outlook_apr2019.pdf
[2] Eric Levitz, "The EPA Is Hiding Proof That a Widely Used Chemical Causes Leukemia: Report," *New York Magazine*, July 6, 2018, accessed here: http://nymag.com/intelligencer/2018/07/the-epa-is-hiding-proof-that-formaldehyde-causes-leukemia.html?gtm=top&gtm=top
[3] Annie Snider, "Sources: EPA blocks warnings on cancer-causing chemical," *Politico*, July 6, 2018, accessed here: https://www.politico.com/story/2018/07/06/epa-formaldehyde-warnings-blocked-696628
[4] "Formaldehyde," International Agency for Research on Cancer, Volume 100F, 2012, accessed here: https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100F-29.pdf
[5] "Reaching Another TSCA Milestone, EPA Identifies 40 Chemicals to Prioritize for Risk Evaluation," U.S. Environmental Protection Agency, March 20, 2019, accessed here: https://www.epa.gov/newsroom/reaching-another-tsca-milestone-epa-identifies-40-chemicals-prioritize-risk-evaluation

not discontinued that work."[6] Dr. Orme-Zavaleta is the highest-ranking career official at ORD, and it appears she was unaware of EPA's plan to drop IRIS's formaldehyde assessment just one week before the decision was publicized. These decisions should come from a sincere, deliberative process that includes career scientists, but it appears political appointees at EPA left Dr. Orme-Zavaleta in the dark. Furthermore, the Agency allowed its principal deputy assistant administrator of ORD to come to the Science Committee hearing unprepared to answer questions on EPA's plans for a highly controversial chemical.

In order to understand the decision-making process behind formaldehyde's shift from IRIS's to TSCA's priority list, we request a staff-level briefing from relevant parties in the Office of Chemical Safety and Pollution Prevention (OCSPP), ORD, and any other office that participated in decisions related to formaldehyde. We request that the EPA send employees who are capable of fully answering questions on the issues outlined in this letter and discussed at last week's hearing. Please have your staff contact Janie Thompson or Sara Palasits at (202) 225-6375 to schedule the briefing.

The formaldehyde assessment has been years in the making. The National Academies of Sciences stands ready to review the assessment, already having entered a $500,000 contract with the EPA.[7] We urge EPA to allow the formaldehyde assessment to be released for review and to stop hiding the chemical's dangers from the American people, whose tax dollars paid for this work and whose well-being depends on the agency fulfilling its mandate to protect human health and the environment.

Sincerely,

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space & Technology

Mikie Sherrill
Chairwoman
Subcommittee on Investigations and Oversight

Cc:
The Honorable Frank Lucas
Ranking Member
Committee on Science, Space & Technology

---

[6] "EPA's IRIS Program: Reviewing Its Progress and Roadblocks Ahead," House Committee on Science, Space, & Technology, March 27, 2019, accessed here: https://science.house.gov/hearings/epas-iris-program-reviewing-its-progress-and-roadblocks-ahead

[7] Annie Snider, "Sources: EPA blocks warnings on cancer-causing chemical," *Politico*, July 6, 2018, accessed here: https://www.politico.com/story/2018/07/06/epa-formaldehyde-warnings-blocked-696628

EDDIE BERNICE JOHNSON, Texas
CHAIRWOMAN

FRANK D. LUCAS, Oklahoma
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6301

(202) 225–6375
www.science.house.gov

April 11, 2019

Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator for Science and EPA Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

Dear Dr. Orme-Zavaleta:

On behalf of the Committee on Science, Space, and Technology, Subcommittee on Investigations & Oversight, and Subcommittee on Environment, we want to express our sincere appreciation for your participation in the March 27, 2019 joint hearing entitled "*EPA'S IRIS Program: Reviewing Its Progress And Roadblocks Ahead.*"

We have attached a transcript of the hearing for your review. The Committee's rule pertaining to the printing of transcripts is as follows:

The transcripts of those hearings conducted by the Committee, when it is decided they will be printed, shall be published in substantially verbatim form, with the material requested for the record inserted at that place requested, or at the end of the record, as appropriate. Individuals, including Members, whose comments are to be published as part of a Committee document shall be given the opportunity to verify the accuracy of the transcription in advance of publication. Any requests by those Members, staff, or witnesses to correct any errors other than errors in the transcript, or disputed errors in transcription, shall be appended to the record, and the appropriate place where the change is requested will be footnoted. Prior to approval by the Chair of hearings conducted jointly with another Congressional Committee, a memorandum of understanding shall be prepared which incorporates an agreement for the publication of the transcript.

Transcript edits, if any, should be submitted by **Wednesday, April 24, 2019**. If no edits are received by the above date, we will presume that you have no suggested edits to the transcript.

We are also attaching questions submitted for the record by Members of the Committee. Please submit answers to all of the enclosed questions no later than **Wednesday, April 24, 2019**.

All transcript edits and responses to questions should be submitted to both of us and directed to the attention of Caitlin Buchanan. If you have any further questions or concerns, please contact Caitlin Buchanan at (202) 225-8500.

Sincerely,

Representative Mikie Sherrill
Chairwoman
Subcommittee on Investigations & Oversight
Committee on Science, Space, and Technology

Representative Lizzie Fletcher
Chair
Subcommittee on Environment
Committee on Science, Space, and Technology

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON INVESTIGATIONS & OVERSIGHT

"EPA'S IRIS Program: Reviewing Its Progress And Roadblocks Ahead."

Questions for the Record to:
Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator for Science and EPA Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency
Submitted by Subcommittee Chairwoman Mike Sherrill (D-NJ)

- In fall of 2018, David Dunlap assumed the role of deputy assistant administrator of ORD. Around the same time, ORD initiated the second round of the survey process, which you said you had no involvement in, though you had disseminated the first round. Did the process switch from your purview to David Dunlap's, and if so, when? What was his involvement in compiling the December 2018 and the April 2019 Program Outlook documents? What was yours? Was David Dunlap involved in decisions relating to formaldehyde prior to his December 2018 recusal?

- In the April 2019 Program Outlook, EPA lists some chemicals as "discontinued" and some as "suspended." What is the distinction between these classifications? What does it mean that assessments of suspended chemicals may be "restarted as Agency priorities change?" How does this differ from how work on a currently discontinued chemical may be picked up in response to changing priorities?

- According to your testimony, OCHP submitted its final list of priority chemicals for the IRIS survey exactly one day after ORD released a Program Outlook for the IRIS program in December 2018. As a result, ORD did not incorporate OCHP's priorities into the official IRIS Program Outlook. As it was compiling the December 2018 Program Outlook, did ORD make any effort to obtain OCHP's second-round survey response? What internal communications, written or oral, did OCHP receive regarding the timing and/or content of this second-round survey? Which EPA offices and officials communicated with OCHP regarding the IRIS survey, and to whom at OCHP were they communicating?

- In September 2018, the Director of OCHP was placed on Administrative Leave. Please identify the career employee or employees at OCHP who oversaw the compilation of OCHP's final list of priority chemicals for the IRIS survey. Please also identify the official who possessed the ultimate authority to approve OCHP's final list of priority chemicals before it was submitted to ORD.

- What chemicals did OCHP submit on its final priority list for the IRIS survey? Was formaldehyde one of the chemicals that OCHP identified as a priority?

- If OCHP had submitted its final list of priority chemicals for the IRIS survey before December 4, 2018, would its priorities have been included in the IRIS Program Outlook for December 2018? Since OCHP submitted its final list of priority chemicals too late to be considered as a part of the 2018 IRIS survey, will its priorities now be considered immediate nominations for the IRIS program, or as nominations for the next IRIS priority survey? Were these responses considered in ORD's April 2019 Program Outlook?

- According to Dr. Orme-Zavaleta's testimony, the IRIS priority survey will now occur annually. Please elaborate on how ORD plans to conduct the IRIS survey in 2019, and whether any procedures will differ from the process that occurred in 2018. When will the 2019 survey formally begin, and how will ORD ensure that every program office in EPA possesses the opportunity to submit its priorities in time to be considered?

- How much money has been spent over the years in preparing the draft formaldehyde assessment that is reportedly ready to be released for review?

Questions for the Record to:
Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator for Science and EPA Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency
Submitted by Representative Don Beyer (D-VA)

- The GAO report issued on March 4, 2019, stated that it was unclear what the IRIS prioritization process was meant to achieve. What was the purpose of the prioritization process? Who was involved in the decision to undertake each step of the prioritization process, from May 2018 through April 2019?

Questions for the Record to:
Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator for Science and EPA Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency
Submitted by Representative Bill Foster (D-IL)

Willowbrook Illinois in my district is home to a sterilization facility that used Ethylene Oxide to sterilize medical equipment. This community has unfortunately become an example of the important role the EPA plays in defending public health and what can happen when these systems do not work as they should. In the case of Ethylene Oxide, there was a 15-year gap between the publication of scientific papers that indicated that EtO was a far more powerful carcinogen than had been previously assumed, and the corrective actions and eventual shutdown of the facility in my district that was venting apparently unsafe amounts of EtO into nearby neighborhoods. See Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) and references therein.

- What were the reasons for a 15-year delay in this type of situation?
- How much of that delay could have been avoided if the EPA and other relevant regulators had been adequately and fully staffed and funded during this period?
- What is the best estimate of the number of people that will eventually get cancer, nationwide, because of that delay?