

United States Senate

WASHINGTON, DC 20510

May 17, 2018

The Honorable Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Administrator Pruitt:

We write regarding the status of the Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS) program's formaldehyde assessment, which appears to have been significantly delayed.

The IRIS program helps EPA accomplish its mission of protecting human health from exposure to environmental contaminants by providing high quality, publicly available information on the toxicity of chemicals to which the public might be exposed. Although IRIS assessments are not regulations, they provide a critical part of the scientific foundation for decision-making across EPA. During the last administration, utilizing recommendations provided by the National Academy of Sciences (NAS) National Research Council, the IRIS program began a reassessment of the human health impacts of formaldehyde.

Based upon our review of publicly available documents, internal EPA documents, and conversations with former EPA employee(s) with knowledge of the formaldehyde assessment's progress, it is our understanding that IRIS completed its revised draft assessment during the fall of 2017. We further understand that this draft assessment found formaldehyde to be carcinogenic, presenting evidence for nasopharyngeal cancer and leukemia, among other risks to human health.

EPA has contracted with the NAS to conduct the external peer review of the revised draft IRIS formaldehyde assessment once it has been finalized. However, before this peer review process can even begin, the draft assessment must undergo an agency review process, where it is reviewed internally by different offices within the EPA before it is shared with other relevant federal agencies for interagency review and feedback. Each of these steps (agency and interagency review) typically takes 60-90 days for completion. After interagency review has been completed, EPA then publishes the assessment for public comment. The final step in the process is delivery to the NAS for peer review.¹

¹ IRIS Process for Developing Human Health Assessments. U.S. Environmental Protection Agency, <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process>
EPA's Integrated Risk Information System (IRIS) Program, Report to Congress, January 2018
https://www.epa.gov/sites/production/files/2018-02/documents/iris_report_to_congress_2018.pdf

Given this timeline, EPA by now should have published the assessment for public comment. We have learned, however, that multiple political appointees within EPA have expressed reluctance to move the assessment through the agency review process, have repeatedly set up briefings on the assessment only to later cancel them, and/or have insisted that IRIS first set up briefings for industry stakeholders before completing agency review. These political appointees have been reported to include your Deputy Chief of Staff Byron Brown, your Chief of Staff Ryan Jackson, the Assistant Administrator for the Office of Air and Radiation, Bill Wehrum, Deputy Assistant Administrator for the Office of Air and Radiation, Clint Woods, and Deputy Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, Nancy Beck.

We have also learned that, at the same time as EPA political appointees' requests were delaying the formaldehyde assessment's movement through the agency review process, the American Chemistry Council (ACC) as well as interested corporations such as ExxonMobil have been pressuring EPA not to release the assessment for public comment as drafted. ACC, ExxonMobil, and other industry actors are said by the individuals we have communicated with to particularly object to findings related to leukemia.

Our offices have made numerous unsuccessful efforts to ascertain what is holding up the publication of the formaldehyde assessment. For example, Senator Markey questioned you about it at your appearance before the Senate Environment and Public Works Committee on January 30, 2018:

Senator Markey: Mr. Pruitt, it's my understanding that the EPA has finalized its conclusion that formaldehyde causes leukemia and other cancers and that [the] completed new assessment is ready to be released for public review, but it is still being held up. Can you give us a status update as to the EPA's handling of the formaldehyde issue and the conclusion that it in fact does cause leukemia and other cancers?

Administrator Pruitt: You know, my understanding is similar to yours, but I will confirm that and provide the information to you from the program office.

Senator Markey: Will you commit to releasing that report which is already completed in a short period of time once you have reviewed it if it in fact meets the standards which your EPA staff has already established in terms of assessing that it does cause leukemia.

Administrator Pruitt: Senator, I will commit to looking into that and making sure that your office is aware of what we have and when we can release it.

Senator Markey: Can you get me an answer within 10 days?

Administrator Pruitt: Yes.

Senator Markey's staff has followed up on this matter with your program staff roughly every two to three weeks since the January hearing.

Additionally, Senator Carper sent you the following two as-yet unanswered post-hearing questions in February:

Questions from Senator Carper

1. EPA's February 1, 2018 Report to Congress on the Integrated Risk Information System (IRIS) states that EPA has already contracted with the National Academy of Sciences for peer review of the formaldehyde human health assessment.
 - a. I have been informed that the human health assessment for formaldehyde was completed by IRIS staff months ago. Is that accurate?
 - b. If so, why has the health assessment not yet been released i) for intra-agency review, ii) inter-agency peer review, iii) for public comment and iv) to the NAS for peer review, and when will each such step occur?
 - c. If not, please describe precisely what work remains to be completed before each step described above can occur, along with time estimates for each step.
 - d. Please provide me with an un-redacted copy of the current draft of the IRIS human health assessment for formaldehyde.

2. From January 20, 2017 until the present, please provide information regarding all meetings (including conference calls) related to the formaldehyde human health assessment, including the date, attendee names (and for non-EPA employees, their affiliations) and copies of any materials prepared for or obtained from each such meeting. Please also provide the same information for meetings EPA staff may have attended related to formaldehyde more generally.

As of the date of this letter, neither you nor your staff has answered these Senators' questions, provided an explanation as to why the agency review process has stalled, or given any information regarding a new timeline for completion of this assessment. In light of EPA's seeming inability to explain to us why the formaldehyde assessment has not yet been published for public comment and moved to peer review, in addition to providing responses to the Senators' pending requests, and based on the information we have learned, we are asking for written responses to the following questions by June 6, 2018:

1. Please provide the timeline and agenda items that will allow the EPA to complete the remaining steps in the review process for the draft formaldehyde assessment. When do you plan on completing the agency review process? When do you expect to release the document for interagency review? When will you release the IRIS formaldehyde assessment for public comment and peer review?

2. What are the reason(s) why the formaldehyde assessment has not advanced out of the agency review process in more than five months? Please provide us with all communications and documentation (including emails, letters, memos, meeting minutes, text messages, or other communications) where the = formaldehyde assessment was mentioned by yourself, Byron Brown, Ryan Jackson, Bill Wehrum, Clint Woods, or Nancy Beck.

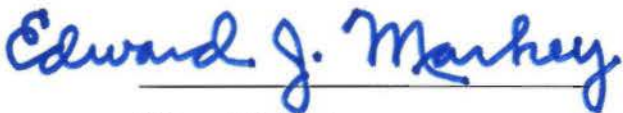
3. Please provide us with all communications and documentation (including emails, letters, memos, meeting minutes, text messages, white papers, or other communications) since

January 2017 between EPA and ACC, ExxonMobil, or any other corporation or industry group related to the formaldehyde assessment. Please also include any meetings between EPA personnel and these organizations in which the issue of formaldehyde or the IRIS assessment was discussed.

Since you became EPA Administrator, you have been fond of saying that your mission at EPA is “back to basics.” We note that EPA’s official mission is “to protect human health and the environment.”² In our opinion, assessing chemicals for their effects on human health is a basic part of EPA’s mission to protect human health. Unfortunately, it appears that the agency may be succumbing to pressure from industry in its attempt to delay or block the publication of the formaldehyde health assessment. This is exceptionally disturbing, and lends further credence to the belief, already widely held, that EPA has been captured by industry.³ We urge you to ensure there are no further efforts to delay or block the publication of this assessment that has serious implications for public health.

Should you have any questions, please do not hesitate to contact Avenel Joseph of Senator Markey’s staff at avenel_joseph@markey.senate.gov or Dan Dudis of Senator Whitehouse’s staff at dan_dudis@whitehouse.senate.gov.

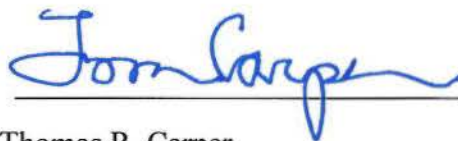
Sincerely,



Edward J. Markey
United States Senator



Sheldon Whitehouse
United States Senator



Thomas R. Carper
United States Senator

² Our Mission and What We Do, U.S. Environmental Protection Agency, <https://www.epa.gov/aboutepa/our-mission-and-what-we-do>

³ Lindsey Dillon et al. “The Environmental Protection Agency in the Early Trump Administration: Prelude to Regulatory Capture,” *American Journal of Public Health* 108, no. S2 (April 1, 2018): pp. S89-S94.