



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 19 2019

OFFICE OF CONGRESSIONAL
AND INTERGOVERNMENTAL RELATIONS

The Honorable Eddie Bernice Johnson
Chairwoman
Committee on Science, Space, and Technology
U.S. House of Representatives
Washington, D.C. 20515

Dear Madam Chairwoman:

On behalf of the U.S. Environmental Protection Agency, I am writing in response to your November 15, 2019, letter regarding the Agency's Integrated Risk Information System (IRIS) program formaldehyde assessment.

On July 19, 2019, the EPA provided the first of many responses to the Committee. This response detailed at length the Agency's prioritization process for the IRIS program and the process for assessing formaldehyde under the Toxic Substances Control Act (TSCA) program within the EPA's Office of Chemical Safety and Pollution Prevention (OCSPP). In light of this explanation, the Agency was surprised when your November 15, 2019 letter indicated that the Agency had only provided "useless information" and had not provided any "information to the Committee which could actually inform the Committee's inquiry." As a result, it seems necessary to again articulate the reasoning and details behind the effort to identify IRIS program priorities and move forward with a risk evaluation for formaldehyde under TSCA.

Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, Office of Research and Development Principal Deputy Assistant Administrator Jennifer Orme-Zavaleta, at the direction of then-Acting Administrator Wheeler, in a request dated August 10, 2018, established a more formal, structured process for identifying IRIS program priorities. Through this new process, EPA programs can formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. This process included a requirement that all IRIS program priorities be approved by the program's Assistant Administrator. This initial formalized prioritization process was completed in December 2018, and it is bringing further stability and responsiveness to the IRIS program. An added benefit of this new process is that it should result in a reduction in the length of time it takes to produce assessments because each assessment should be tailored to the program needs—called fit-for-purpose assessments.

As detailed in the December 4, 2018 memorandum from Principal Deputy Assistant Administrator Orme-Zavaleta, ORD consolidated the program input on high priority assessment needs and presented this to the Agency's Assistant Administrators and Deputies. Based on that input, the prioritization process identified eleven priority chemicals: hexavalent chromium, inorganic arsenic, mercury salts, methylmercury, polychlorinated biphenyl (PCBs), five per- and polyfluoroalkyl substances (PFAS), and vanadium.

As the Agency stated in the July 19, 2019 response to the Committee, the IRIS program will conduct a similar formal, structured process for identifying IRIS program priorities annually. Additionally, programs are still able to identify and nominate chemicals at any time. As Administrator Wheeler stated during his recent testimony before the Committee, the Agency has already initiated another formal request and prioritization process. On September 9, 2019, ORD Principal Deputy Assistant Administrator Orme-Zavaleta sent out a memorandum to all Assistant Administrators and Deputies initiating ORD's annual solicitation for input on program office priorities for development of future IRIS program assessments.

The recent changes to TSCA have also led the Agency to reexamine the most appropriate programs for efficient and effective assessment of chemicals through its statutory obligations and other methods. On March 20, 2019, the EPA published a list of 40 chemicals for which the Agency initiated the prioritization process, a new process through which the EPA designates chemical substances as high priority or low priority for risk evaluation under the amended TSCA. One of the chemicals identified as a candidate for high-priority designation is formaldehyde. Moving forward with a risk evaluation for formaldehyde under TSCA does not mean that the formaldehyde work done under IRIS will be lost. In fact, all the work done by the IRIS program will inform the Agency as it evaluates formaldehyde under TSCA.

The benefit to conducting a risk evaluation under TSCA is that the Agency will be able to take subsequent regulatory steps if the EPA determines that the chemical will present an unreasonable risk of injury to health or the environment under its conditions of use. The IRIS program was not mandated by Congress and does not provide authority to take these regulatory steps. As noted earlier, IRIS is only half of a risk assessment (no exposure or risk characterization) and thus a risk assessment has no immediate impact on minimizing or eliminating risk until applied in a regulatory context. Under TSCA, when prioritization is complete, chemicals designated as high priority will begin a risk evaluation process to determine if the chemical, under its conditions of use, presents an unreasonable risk to health or the environment. If unreasonable risk is found under TSCA, the EPA is then required to take steps, by issuing a proposed regulation within one year (subject to extension), to mitigate the unreasonable risk.

The EPA has been entirely transparent in our production of documents and information to the Committee in the issues raised in letters, questions during testimony, and numerous conversations with Committee staff. The details discussed in this response and the information the Agency has previously provided the Committee show the EPA has been responsive to the Committee and has reasonably accommodated its requests for information. Despite the Committee's claims, the Agency strongly believes that the over 2,500 pages of responsive document productions, in addition to providing multiple senior Agency officials to testify at hearings and provide briefings, and numerous letter responses, demonstrates that the Agency is being responsive to the Committee's request. In the

Committee's initial March 4, 2019 letter, you requested extensive materials "prepared for or obtained by Trump Administration political officials" regarding "EPA's determination of whether and how to proceed with [the] formaldehyde health assessment." Every document produced to the Committee to date has been responsive of this request, and while the Agency understands the Committee disagrees with this assessment, the Committee has yet to provide the Agency any details on how the Agency's production has not been responsive to the broad scope of the Committee's request nor provided any input on narrowing the scope of the request.

The Committee's subpoena demands production of an internal Agency document relating to the EPA's Office of Children's Health Protection (OCHP). The Agency has determined that the document is confidential, deliberative, and should not be released beyond the Agency. The Agency has determined that releasing this document will have a chilling effect on internal Agency deliberations and will also affect the ability of Agency staff to conduct future deliberations. On November 5, 2019, in order to accommodate the Committee's request for this specific information, the EPA offered to provide the Committee the opportunity to review the document *in camera*. However, the Committee chose to completely ignore this effort by the Agency to accommodate this request, and instead hastily issued a subpoena to the Agency for this document on November 15, 2019. Despite the Agency's view that this subpoena is unwarranted and unnecessary, in order to comply with the Committee's subpoena, the Agency is enclosing the requested document.

The Agency is only releasing this document to comply with the Committee's subpoena. In order to provide the Committee with the clearest understanding of the document, the Agency wants to ensure that the Committee is aware that OCHP identified this chemical as one that was potentially going to be selected to begin risk evaluation in 2019 under TSCA. As you are aware, and has been detailed numerous times to the Committee, in early 2019 the EPA published a list of 40 chemicals for which the Agency initiated the prioritization process. One of the chemicals identified as a candidate for high-priority designation is formaldehyde. In conducting a risk evaluation for formaldehyde under TSCA, all the work performed by the IRIS program will inform the Agency in this evaluation.

The EPA recognizes the potential risk that is posed by formaldehyde and has prioritized assessing this chemical under TSCA in order to most efficiently and effectively fulfill the Agency's mission of protecting human health and the environment.

Please note that this production contains documents that reveal internal Agency information. Therefore, we have added a header and footer to these documents that reads "Deliberative, Confidential, Internal Document of the U.S. EPA; Disclosure Authorized Only to the U.S. House Committee on Science, Space, and Technology in Response to Committee Subpoena." Through this accommodation, the EPA does not waive any confidentiality interests in these documents or similar documents in other circumstances.

The EPA respectfully requests that the Committee and staff protect the document and the information contained in it from further dissemination. Should the Committee determine that its legislative mandate requires further distribution of this confidential information outside the Committee, we request that such need is first discussed with the EPA to help ensure the Executive Branch's confidentiality interests are protected.

As discussed with Committee staff today, we understand the Committee's desire to obtain additional information from ORD Deputy Assistant Administrator David Dunlap. We are encouraged by the prospect that the Committee would withdraw the subpoena that was issued to Deputy Assistant Administrator Dunlap on the condition that he attends a transcribed interview before the Committee on December 13, 2019. We appreciate the Committee's willingness to resolve both matters raised in the November 15, 2019 subpoenas. The EPA recognizes the importance of the Committee's need to obtain information necessary to perform its legitimate oversight functions and is committed to continuing to work with your staff on how best to accommodate the Committee's interests.

Sincerely,



Joseph A. Brazauskas, Jr.
Associate Administrator

Enclosure

cc: The Honorable Frank Lucas, Ranking Member