

Congress of the United States
Washington, DC 20515

April 12, 2019

The Honorable Gene L. Dodaro
Comptroller General of the United States
U.S. Government Accountability office
441 G Street NW
Washington, D.C. 20548

Dear Mr. Dodaro,

On March 4, 2019, GAO issued a report entitled “Chemical Assessments: Status of EPA’s Efforts to Produce Assessment and Implement the Toxic Substances Control Act (GAO-19-270).” Though this report began as an analysis of EPA’s Integrated Risk Information System’s (IRIS’s) progress in addressing efficiency and transparency challenges, as identified by GAO and the National Academies of Sciences (NAS), it also outlined a pattern of political obstruction that may impact the effectiveness of the IRIS program for years to come. We are concerned that the actions taken by political leadership at the Agency, as summarized by GAO, are hindering the IRIS program’s ability to conduct vital chemical assessments and to disseminate these assessments to relevant stakeholders so they can be utilized to protect public health. To that end, we request that GAO conduct a follow-on review to supplement its earlier findings on EPA IRIS and address additional questions that have been introduced since the issuance of the March 4 report.

As of June 2018, there were 23 chemicals in IRIS’s workflow. By December 2018, IRIS’s program outlook included only 11 chemicals, with two additional chemicals in peer review.¹ We are interested in understanding more about the process by which chemicals were removed from the workflow.

The first drop-off appears to have been in May 2018. According to a draft memo obtained in the process of the GAO report, the IRIS program decided to discontinue the assessment process for four late-stage chemicals – HBDC, acrylonitrile, n-butyl alcohol, and phthalates.² GAO describes this memo as having evolved from routine communication between IRIS leadership and program and regional offices regarding the current needs of stakeholders. However, the Office of Research and Development (ORD) did not allow the public release of this memo, because political leadership in program and regional offices disagreed with the priorities listed.

¹ “IRIS Program Outlook – December 2018,” 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

In lieu of releasing the May 2018 memo, EPA leadership determined that a further prioritization process needed to take place before establishing the priority chemicals list. Documents obtained by the Science, Space and Technology Committee indicate EPA political leadership was concerned that IRIS and program office career staff priorities might conflict with their own.³ In June 2018, ORD leadership requested that IRIS officials prepare a survey of program and regional offices to reconfirm the needs for 20 assessments in development at the time. With this request came a directive that no new IRIS assessment could be released without a formal request from a program office. ORD issued this IRIS-developed survey on August 10, 2018 to program offices. The survey listed 22 chemicals for consideration and asked program offices to outline and justify their priorities within this list. This list did not include ethyl tert-butyl ether (ETBE) or tert-butyl alcohol (TBA), which were already in peer review, or RDX, which was in the final stages of review and was ultimately published in August of 2018. While the survey process was taking place, IRIS was prohibited by EPA leadership from publicly releasing any assessment documentation, meaning that any assessments ready to move beyond internal stages could not be distributed for public comment or agency or peer review. It is unclear why the survey process required a halt of IRIS activities, including the cancellation of a public meeting on naphthalene on August 23, 2018, without a makeup date.

Several program offices responded to the August survey with lengthy lists of priority chemicals. According to documents obtained by the Science, Space and Technology Committee, career staff in ORD planned to compile this information and present it to Administrator Wheeler, but political appointees intervened to initiate a second survey.⁴ Unlike the first survey, it does not appear to have been prepared by IRIS staff. In fact, IRIS staff were not aware of the existence of a second round until other program offices contacted them for guidance. GAO found that program and regional offices were not informed about what the Administrator's office was hoping to achieve from this second survey.

We have a number of concerns about this survey process. First, it is not clear why it was necessary to further reduce the list of chemicals in IRIS's workflow from the list that had been compiled for the unpublished May 2018 memo. It is our understanding that the May memo came from a deliberative process between IRIS and program offices. We do not know of any significant new scientific information that would justify a wholesale reevaluation of program priorities. Furthermore, we are concerned about the level of difficulty GAO met in trying to learn more about the second survey and why it was needed in addition to the first. It is unusual that a programmatic prioritization exercise be conducted without any written or emailed instructions from political leadership and without the participation of career IRIS staff.⁵

We have reviewed responses from both rounds of the survey. We are concerned that EPA program offices that have historically been heavily dependent upon IRIS assessments for their work neglected to fully respond. The Office of Air and Radiation (OAR) did not submit any chemicals. The Office of Chemical Safety and Pollution Prevention (OCSPP) did not submit any chemicals beyond those being reviewed under the Toxic Substances Control Act (TSCA). The Office of Children's Health Protection (OCHP) submitted a first round response, but, according to testimony by Principal Deputy Assistant Administrator

³ Document obtained by the Science, Space, and Technology Committee via the Government Accountability Office.

⁴ Ibid.

⁵ "EPA's IRIS Program: Reviewing Its Progress and Roadblocks Ahead," House Committee on Science, Space, and Technology, March 27, 2019, accessed here: <https://science.house.gov/hearings/epas-iris-program-reviewing-its-progress-and-roadblocks-ahead>

Jennifer Orme-Zavaleta at a March 27th Science, Space, and Technology Committee hearing, OCHP's second response was submitted on December 5th, one day after IRIS's program outlook was issued.⁶

On December 4, 2018, EPA released a memorandum listing its updated IRIS priority list of 11 chemicals.⁷ No reasoning was given for the chemicals on the list or those omitted. Notably missing from the memo is formaldehyde, which has been ready for release for over a year, as confirmed by former EPA Administrator Scott Pruitt in a January 2018 Senate hearing.⁸ At the hearing last week, Dr. Orme-Zavaleta indicated that formaldehyde may have been among OCHP's list of three to four priority chemicals – the list submitted one day too late for consideration. Then, on April 2, EPA announced that IRIS work on formaldehyde had been officially suspended.⁹ This is despite Dr. Orme-Zavaleta's assertion at the hearing that EPA had "not discontinued that work." Decisions about IRIS's work should come from a sincere, deliberative process inclusive of career scientists, and this disconnect makes it clear that Dr. Orme-Zavaleta – the highest-ranking career official at ORD – was not adequately involved in the decision-making process for this highly controversial chemical.

The IRIS program's productivity is being further undermined by the reassignment of staffers described in the GAO report. We are concerned that this reassignment is a means for political leadership to drain the IRIS program of resources in defiance of appropriations report language directing EPA to sustain IRIS funding remain at the Fiscal Year 2017 enacted level.¹⁰ Reassignment of IRIS staff to TSCA implementation functionally deprives IRIS of appropriated resources.

After more than a decade of Congressional oversight of the IRIS program, it is troubling to see that the progress made over the past few years is being undermined by political leadership. Just a few years of hindering IRIS's productivity could lead to an outsized impact on the program's long-term output. In your review, please address the following questions:

1. Why did IRIS career staff make the decision to discontinue work on a number of late-stage assessments as per the May 2018 draft memo, namely hexabromocyclododecane, acrylonitrile, n-butyl alcohol, and phthalates?
2. How was the decision made to conduct a survey of IRIS chemical priorities in August 2018, and why was such a survey considered necessary?
3. To whom was the survey disseminated, and who reviewed the responses? Please provide a complete list of individual recipients of the survey and a complete list of individuals who reviewed the responses.

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

⁷ "IRIS Program Outlook – December 2018," 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

⁸ 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>m=top>

⁹ "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

¹⁰ "Division G – Department of the Interior, Environment, and Related Agencies Appropriations Act, 2018," page 52, accessed here: <https://docs.house.gov/billsthisweek/20180319/DIV%20G%20INTERIOR%20SOM%20FY18%20OMNI.OCR.pdf>

4. How was the decision made to initiate a second survey? How was this survey distributed to program offices? What were the parameters of the second round? How was the existence of the survey communicated to IRIS?
5. Were career staff involved in the initiation and development of the first-round survey; the initiation and development of the second-round survey; the review of responses from each round; and the deliberation process that went into the December 2018 list of priority chemicals?
6. How do the program offices' survey responses and, in some cases, lack thereof align with their historical reliance on IRIS assessments?
7. What is the future of the IRIS prioritization process? Will these surveys be repeated annually? How can new chemicals be added to the IRIS priority list?
8. Why was the public forum for naphthalene cancelled? What are the plans to reschedule it?
9. Is the reassignment of 28 out of 30 IRIS staff to support OPPT's TSCA work consistent with Congressional appropriations report language providing that IRIS funding remain at FY 2017 levels? Is it an appropriate use of the specialized skill set of IRIS staff? Are IRIS staff able to meaningfully contribute to TSCA risk evaluations despite how they differ significantly from IRIS assessments?

We are also interested in further evaluation of IRIS's updated systematic review process and would like to ensure that implementation of the NAS recommendations does not have unintended consequences for IRIS's core competencies.

10. Is the systematic review software adopted by IRIS sufficiently inclusive of relevant studies in all appropriate academic disciplines? Is its data extraction tool sufficient and reliable? Is the review process conducted by individuals who are appropriately informed of the subject matter for any given chemical assessment?
11. What is the status of the IRIS Handbook, and when is it expected to be published?

To discuss this request in more detail please have your staff contact Sara Palasits or Priyanka Hooghan of the House Science, Space, and Technology Committee staff at (202) 225-6375 or Michal Freedhoff of the Senate Environment and Public Works Committee staff at (202) 224-8832. Your assistance in this matter is greatly appreciated.

Sincerely,



Eddie Bernice Johnson
Chairwoman
House Committee on Science, Space, and Technology



Tom Carper
Ranking Member
Senate Committee on Environment and Public Works



Lizzie Fletcher

Chair

Subcommittee on Environment

House Committee on Science, Space, and Technology



Mikie Sherrill

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House Committee on Science, Space, and Technology

Cc:

The Honorable Frank Lucas

Ranking Member

House Committee on Science, Space, and Technology