COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
SUBCOMMITTEE ON ENVIRONMENT
U.S. HOUSE OF REPRESENTATIVES

HEARING CHARTER

EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead

Wednesday, March 27, 2019
10:00 a.m.
2318 Rayburn House Office Building

PURPOSE

The purpose of this hearing is to assess the current state of the EPA's Integrated Risk Information System (IRIS) program in light of the findings published in the March 4, 2019, Government Accountability Office (GAO) report, "Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act." Additionally, witnesses will provide their expert perspectives on the EPA's current status on implementing recommendations for the IRIS program provided by the GAO and the National Academies of Science, Engineering, and Medicine (NAS), as well as the unique value of IRIS assessments.

WITNESSES

Panel 1:

- **Dr. Jennifer Orme-Zavaleta (OR-may Zah-vah-let-ah),** *Principal Deputy Assistant Administrator for Science for the Office of Research and Development, and EPA Science Advisor, Environmental Protection Agency (EPA)* – Dr. Orme-Zavaleta has been with the EPA since 1981 and is currently the highest level career staff in the EPA's Office of Research and Development (ORD). Dr. Orme-Zavaleta's previous experience at EPA includes numerous roles in the Offices of Toxic Substances, Water, and Research & Development.[1]

- **Mr. Alfredo Gomez (GO-mez)**, *Director, Natural Resources and Environment, Government Accountability Office (GAO)* – Mr. Gomez has been with GAO for a combined tenure of 23 years. His subject matter expertise includes: toxic chemicals, air quality, climate change, water quality, and hazardous waste.[2] Mr. Gomez is the principal author of the March 4, 2019 GAO report on IRIS.

[1] Environmental Protection Agency, "Jennifer Orme-Zavaleta," March 20, 2019, accessed here: https://www.epa.gov/aboutepa/principal-deputy-assistant-administrator-science-office-research-and-development-and-epa.
[2] Government Accountability Office, "Alfredo Gomez," March 20, 2019, accessed here: https://www.gao.gov/about/contact-us/find-an-expert/alfredo-gomez.

Panel 2:

- **Dr. Bernard D. Goldstein (GOLD-steen)**, *Professor Emeritus and Dean Emeritus at University of Pittsburgh Graduate School of Public Health* – Dr. Goldstein has an extensive scientific career spanning nearly 50 years. He is a board-certified physician in Internal Medicine, Hematology, and Toxicology, and has published nearly 200 peer-reviewed papers. From 1983 to 1985, Dr. Goldstein served as the EPA's Assistant Administrator for Research and Development.[3]

- **Dr. Ivan Rusyn (ROO-sin),** *Professor, Department of Veterinary Integrative Biosciences, Texas A&M University; Chair, Interdisciplinary Faculty of Toxicology; Director, Texas A&M Superfund Research Center* – Dr. Rusyn is a professor and toxicologist at Texas A&M University, specializing in the relationship between chemical exposures and adverse health effects such as cancer.[4] Dr. Rusyn participated as a member of the review committee for the 2011 NAS review of the IRIS formaldehyde assessment and an independent reviewer for the NAS 2014 follow-up review of IRIS.[5]

- **Dr. Julie E. Goodman,** *Principal, Gradient* – Dr. Goodman is an expert toxicologist and epidemiologist and a principal at Gradient, an environmental and risk sciences consulting firm, with a focus on workplace and environmental chemicals.[6]

- **Ms. Wilma Subra (SOO-bra),** *President, Subra Company; Technical Advisor, Louisiana Environmental Action Network* – Ms. Subra is the founder and president of Subra Company, Inc., the technical advisor to the non-profit Louisiana Environmental Action Network, and a recipient of the MacArthur Foundation Fellowship Award in 1999.[7] Subra Company is an environmental consulting firm that provides technical assistance and expert guidance to communities at risk of exposure to toxic chemicals.[8] Ms. Subra has extensive experience with the use of IRIS toxicity assessments in her work.

[3] University of Pittsburgh, "Bernard Goldstein," March 20, 2019, accessed here: https://www.publichealth.pitt.edu/home/directory/bernard-goldstein.
[4] Texas A&M University, "Laboratory of Environmental Genomics," March 20, 2019, accessed here: http://rusynlab.org/.
[5] National Academies of Sciences, Engineering and Medicine, "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," 2011, accessed here: https://www.nap.edu/catalog/13142/review-of-the-environmental-protection-agencys-draft-iris-assessment-of-formaldehyde.
[6] Gradient, "Julie E. Goodman," March 20, 2019, accessed here: https://gradientcorp.com/bio/Goodman.
[7] MacArthur Foundation Fellows Program, Class of 1999, "Wilma Alpha Subra," January 1, 2005, accessed here: https://www.macfound.org/fellows/625/.
[8] Louisiana Environmental Action Network, "Wilma Subra," April 7, 2011, accessed here: https://leanweb.org/uncategorized/wilma-subra/.

BACKGROUND

Overview of EPA's IRIS Program

EPA created the IRIS program in 1985 to provide consistency in the evaluation of chemical toxicity across the Agency. IRIS develops toxicity assessments that measure the human health impacts of chemicals to which the general public could be exposed. IRIS is located within EPA's non-regulatory Office of Research and Development (ORD) to ensure that IRIS's scientific review process remains distinct from the regulatory programs of EPA program offices. IRIS is not a program office itself and does not issue its own regulations. Rather, IRIS toxicity assessments are intended to support EPA program and regional offices as they implement Agency policies, along with other considerations (e.g., statutory and legal requirements including cost-benefit information, technological feasibility, and economic factors). IRIS assessments establish the health outcomes associated with exposure to a chemical and the relationship between the level of exposure and the health impact so program offices can use the data for the remaining steps of the risk assessment and risk management processes.[9] As of March 2019, IRIS's database contains 568 finalized assessments.[10]

IRIS utilizes a 7-step process to complete its toxicity assessments. In the first step, IRIS writes a draft toxicity assessment by conducting a comprehensive search and review of relevant scientific literature regarding the impacts of exposure to a given chemical. IRIS then submits the assessment for agency review within EPA (step two) and inter-agency review within the executive branch (step three). After incorporating comments, IRIS releases the assessment for public comment and external peer review (step four). The assessment returns to IRIS for revision based on public comments and peer review (step five) and is subsequently evaluated one final time within EPA and the executive branch (step six). After the completion of these steps, IRIS finalizes the assessment and posts it to the IRIS website (step seven).[11]

IRIS assessments are considered by many stakeholders both within and outside of the EPA to be the "gold standard" for assessing the human health impact of chemical exposure. Within EPA, IRIS assessments are the preferred source of chemical toxicity values for program and regional offices. Beyond EPA, IRIS assessments constitute an important resource for risk assessors and environmental and health agencies from state, tribal, and local governments that often lack EPA's resources. International organizations use IRIS assessments for their own work as well.

[9] Environmental Protection Agency, "Basic Information about the Integrated Risk Information System," March 20, 2019, accessed here: https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system.
[10] Environmental Protection Agency, "IRIS Assessments," March 20, 2019, accessed here: https://cfpub.epa.gov/ncea/iris_drafts/atoz.cfm?list_type=alpha.
[11] Environmental Protection Agency, "Basic Information about the Integrated Risk Information System," March 20, 2019, accessed here: https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system.

External Reviews of the IRIS Program

Government Accountability Office Reviews of the IRIS Program

The Government Accountability Office (GAO) is the independent, nonpartisan agency that provides Congress with information on government programs. Every two years GAO publishes a High Risk List, which outlines programs and operations within the federal government that are most vulnerable to "fraud, waste, abuse, and mismanagement, or that need transformation."[12] In 2009, GAO first placed the IRIS program on its High Risk List due to its inability to "complete timely, credible assessments or decrease its backlog of 70 ongoing assessments."[13] The IRIS program has remained on the High Risk List ever since, including the most recent version published on March 6, 2019, which noted a decrease in "leadership commitment" to IRIS over the preceding two years due to "limited information for completing chemical assessments and proposed budget cuts."[14] However, GAO has also documented notable progress for IRIS in a number of areas since 2009, including a more efficient inter-agency review process, an accelerated timeline for less challenging reports, and enhanced transparency regarding inter-agency comments and external peer review.[15] GAO's evaluation of IRIS improved in the metrics that correspond to these areas between 2009 and 2019.[16]

In addition to its biennial High Risk List, GAO undertook a separate review of EPA chemical assessment programs and published a report on March 4, 2019. The report, entitled "Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act," noted that decisions made by ORD leadership prevented IRIS from releasing toxicity assessments publicly between June and December 2018.[17] According to the report, ORD leadership instructed IRIS in June 2018 not to release any assessment materials without a formal request from a program office. The report also found that ORD leadership, at the request of then-Acting Administrator Andrew Wheeler, initiated a survey in August 2018 for program and regional offices to submit their own priority chemicals for IRIS assessment. ORD leadership followed up in October 2018 with another request to program and regional offices for further prioritization, asking for no more than 3-4 priority chemicals from each office. In December 2018, ORD issued a memo identifying 11 chemicals for IRIS program assessment. While the survey was occurring, ORD instructed IRIS not to release any of its toxicity assessments. GAO further noted that the ORD December memo did not include several IRIS assessments that had already advanced to later stages, such as formaldehyde and polycyclic

[12] Government Accountability Office, "High Risk List," March 20, 2019, accessed here: https://www.gao.gov/highrisk/overview.
[13] Government Accountability Office, "High-Risk Series: An Update," January 2009, accessed here: https://www.gao.gov/assets/290/284961.pdf.
[14] Government Accountability Office, "High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas," March 2019, accessed here: https://www.gao.gov/assets/700/697245.pdf.
[15] Government Accountability Office, "High-Risk Series: An Update," February 2011, February 2013, and February 2015, accessed here: https://www.gao.gov/new.items/d11278.pdf; https://www.gao.gov/assets/660/652133.pdf; https://www.gao.gov/assets/670/668415.pdf.
[16] Government Accountability Office, "High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others," February 2017, accessed here: https://www.gao.gov/assets/690/682765.pdf.
[17] Government Accountability Office, "Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act," March 2019, accessed here: https://www.gao.gov/assets/700/697212.pdf.

aromatic hydrocarbon (PAH), and did not provide any update or guidance concerning their status. According to GAO, the absence of the late-stage assessments "could create confusion for stakeholders interested in them." Finally, GAO detailed that in October 2018, 28 out of 30 IRIS employees dedicated between 25 and 50 percent of their time in support of the Office of Pollution Prevention and Toxics (OPPT) as it conducted risk evaluations under the Toxic Substances Control Act (TSCA).[18]

National Academies Reviews of the IRIS Program

In 2011, the National Research Council of the National Academy of Sciences (NAS) released a review of the IRIS formaldehyde assessment.[19] In addition to evaluating the assessment itself, NAS identified areas for improvement within the IRIS assessment process and offered a roadmap to achieve the improvements. NAS recommended steps to improve the standardization of IRIS's assessment procedures. NAS also recommended actions to increase the "transparency and efficiency" of the IRIS assessment process and urged IRIS to amend its procedures regarding weight-of-evidence determinations.[20] Congress directed EPA to incorporate NAS's suggestions as appropriate and requested a follow-up review from NAS.

In 2014, NAS released its follow up review of IRIS's implementation of the recommendations from the 2011 review.[21] NAS asserted that EPA had "embraced" its IRIS recommendations and commended the Agency for "substantive new approaches, continuing commitment to improving the [IRIS] process, and successes to date." While NAS offered further recommendations to consolidate the improvements, the review stated that "the committee found that appropriate revisions of all elements of the IRIS assessment process were underway or planned," noting in particular the progress towards "'user friendliness' and transparency."[22] NAS recommended continuous updates to IRIS assessment methods, a systematic review of delays in the assessment process, evolving competencies as necessary among IRIS employees, and the creation of a strategic plan to ensure that IRIS's methodology would continue to improve in the future.

At EPA's request, NAS returned to IRIS in 2017 to review its progress. After an evaluation process that included a public workshop to discuss the IRIS program, NAS released its review in April 2018.[23] NAS determined that EPA "has instituted even more substantive changes in the IRIS program" and described itself as "impressed with the changes being instituted" since 2014. The review highlighted the advent of systematic review as a foundation for the IRIS assessment

[18] Government Accountability Office, "Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act," March 2019, accessed here: https://www.gao.gov/assets/700/697212.pdf.
[19] National Academies of Sciences, Engineering and Medicine, "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," April 2011, accessed here: https://www.nap.edu/catalog/13142/review-of-the-environmental-protection-agencys-draft-iris-assessment-of-formaldehyde.
[20] *Id.*
[21] National Academies of Sciences, Engineering and Medicine, "Review of EPA's Integrated Risk Information System (IRIS) Process," May 2014, accessed here: https://www.nap.edu/catalog/18764/review-of-epas-integrated-risk-information-system-iris-process.
[22] *Id.*
[23] National Academies of Sciences, Engineering and Medicine, "Progress Toward Transforming the Integrated Risk Information System (IRIS) Program," April 2018, accessed here: https://www.nap.edu/catalog/25086/progress-toward-transforming-the-integrated-risk-information-system-iris-program.

process. NAS noted the need for ongoing implementation of reforms, such as the release of an IRIS handbook to provide guidance for the assessment process and allow for greater transparency among stakeholders. NAS concluded that EPA had achieved "substantial progress" regarding the implementation of NAS recommendations for the IRIS assessment process.[24]

EPA Science Advisory Board Praise of the IRIS Program

EPA's Science Advisory Board (SAB) provides scientific advice to the Administrator and Agency, reviews the quality and relevance of the scientific information used by the EPA, and reviews EPA research programs. On September 1, 2017, after receiving an update regarding IRIS's implementation of the NAS recommendations, the SAB voted unanimously to praise the IRIS program's progress in a letter to then-EPA Administrator Scott Pruitt:[25]

> *"The SAB has observed significant enhancements in the IRIS program over the past few years, with impactful changes over the past year, and marked progress over the past six months. The changes are so extensive and positive that they constitute a virtual reinvention of IRIS. For example, it is now standard practice for the program to engage stakeholders in an early scoping and problem formulation phase, thereby allowing stakeholders to provide important input at the very beginning of the process. The program has fully adopted the principles of systematic review, and incorporated automation and publicly available software platforms to modernize the process. Finally, the IRIS documents are now more modular and structured to enhance transparency and readability."*

Ongoing Challenges for IRIS

Despite the improvements in the IRIS toxicity assessment process documented by NAS, IRIS faces serious near-term challenges. At the public workshop conducted by NAS in February 2018 as a part of its review, high-ranking officials overseeing IRIS articulated concerns about limited resources to implement the full extent of NAS's recommendations and complete assessments on the desired timeline.[26] The officials expressed anxiety regarding a wave of staff retirements that threatened to deplete the IRIS program of valuable experience and expertise.[27] IRIS also confronts a decline in leadership support within the EPA, as documented by GAO in its High Risk List. Agency budgets have proposed funding cuts for IRIS, and in October 2018, most of the IRIS staff was instructed to dedicate 25 to 50 percent of their time in support of a different

[24] National Academies of Sciences, Engineering and Medicine, "Progress Toward Transforming the Integrated Risk Information System (IRIS) Program," April 2018, accessed here: https://www.nap.edu/catalog/25086/progress-toward-transforming-the-integrated-risk-information-system-iris-program.
[25] Environmental Protection Agency, "Science Advisory Board comments on EPA's response to recommendations on the Information Risk Information System," September 1, 2017, accessed here: https://yosemite.epa.gov/sab/sabproduct.nsf/95eac6037dbee075852573a00075f732/a9a9acce42b6aa0e8525818e004cc597/$FILE/EPA-SAB-17-008.pdf.
[26] Environmental Protection Agency, "Workshop to Review Advances Made to the IRIS Process," February 2018, accessed here: https://www.epa.gov/iris/workshop-review-advances-made-iris-process-feb-2018.
[27] *Id*.

EPA program.[28] Additionally, Agency officials issued directives that prevented IRIS from releasing any toxicity assessments during the second half of 2018.[29] These issues present obstacles to the IRIS program moving forward.

[28] Government Accountability Office, "Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act," March 2019, accessed here: https://www.gao.gov/assets/700/697212.pdf.
[29] *Id*.