# EPA'S IRIS PROGRAM: REVIEWING ITS PROGRESS AND ROADBLOCKS AHEAD

## JOINT HEARING

BEFORE THE

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

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# C O N T E N T S

**March 27, 2019**

# EPA'S IRIS PROGRAM: REVIEWING ITS PROGRESS AND ROADBLOCKS AHEAD

**WEDNESDAY, MARCH 27, 2019**

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
JOINT WITH THE SUBCOMMITTEE ON ENVIRONMENT,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
*Washington, D.C.*

The Subcommittees met, pursuant to notice, at 10:01 a.m., in room 2318 of the Rayburn House Office Building, Hon. Mikie Sherrill [Chairwoman of the Subcommittee on Investigations and Oversight] presiding.

**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.

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[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.

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[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

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[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.*

Chairwoman SHERRILL. This hearing will come to order.

Without objection, the Chair is authorized to declare recess at any time.

Good morning, and welcome to the Investigations and Oversight Subcommittee's first hearing of the 116th Congress. I'm pleased to work alongside Ranking Member Norman of South Carolina and look forward to a productive and collaborative relationship.

This is also a joint Subcommittee hearing with the Environment Subcommittee, and I'm very pleased to welcome my fellow Chair Mrs. Fletcher, who's on her way, and her counterpart in the minority, Representative Marshall of Kansas. I expect this is just the beginning of the cooperative partnership that our Subcommittees will enjoy during this Congress, and I look forward to continuing to work closely with you in the weeks and months ahead.

In this first hearing, we are focusing on a subject that directly impacts the state of public health in this country. The EPA's (Environmental Protection Agency's) Integrated Risk Information System, or IRIS, is tasked with developing impartial, science-based assessments on toxicity of chemicals. It is considered the gold standard for chemical toxicity assessments in the United States, and note that IRIS is not itself a risk management program or a regulator. Instead, its findings are used by other branches of the EPA and State and local governments to inform guidelines and regulations about what levels of human exposure to a given chemical are acceptable.

IRIS has produced toxicity assessments for a multitude of dangerous chemicals, including asbestos, mercury and ethylene oxide, to name a few. Unfortunately, we have learned in recent weeks that IRIS is being undercut by political leadership at the EPA. America needs a strong, empowered IRIS to provide EPA, States, tribes, municipalities, and communities everywhere with the best-available science regarding chemical toxicity.

When IRIS is prevented from doing its work, the public is less informed, and therefore less safe. The public needs IRIS to be independent of outside influence, but the GAO report we will discuss today outlines troubling facts about political interference with IRIS. Political appointees at EPA have blocked the release of IRIS assessments, imposed new bureaucratic hurdles, and reduced the number of priority chemicals for IRIS to evaluate with no explanation.

The formaldehyde assessment in particular has been ready to be released for over a year. Then-EPA Administrator Scott Pruitt said so himself in a January 2018 hearing before the Senate. Press reports indicate that IRIS has determined a connection exists between formaldehyde and leukemia. It is unacceptable for political considerations to suppress IRIS' findings. I fail to see any credible reason why findings of fact on chemical risks should be withheld from the public. EPA must release the IRIS formaldehyde assessment as soon as possible.

EPA's management of the IRIS Program has prompted concern as well. In October 2018, 28 out of roughly 30 IRIS employees spent 25 to 50 percent of their time working on risk evaluations for a different EPA office. This kind of staff reassignment distracts

IRIS from its core mission and deprives IRIS of the resources it needs to address its own work in a timely fashion.

I'm very pleased to welcome the distinguished witnesses appearing here today. And in our two panels, we have government officials, eminent scholars, and community advocates who see the real-world impact of IRIS assessments. We appreciate your willingness to appear before our Subcommittees today.

Protecting the public from toxic chemicals is a core function of the EPA, and IRIS is vital to the EPA's ability to accomplish its mission. I'm pleased to have the opportunity to continue this Committee's work to ensure that IRIS is allowed to do its job for the sake of public health.

[The prepared statement of Chairwoman Sherrill follows:]

U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON
**SCIENCE, SPACE, & TECHNOLOGY**

Opening Statement

**Chairwoman Mikie Sherrill (D-NJ)**
**Subcommittee on Investigations and Oversight**

Joint Subcommittee Hearing:
*EPA's IRIS Program: Reviewing Its Progress and Roadblocks Ahead*
March 27, 2019

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Chairwoman SHERRILL. The Chair now recognizes Mr. Norman for an opening statement.

Mr. NORMAN. Thank you so much, Chairwoman Fletcher and Chairwoman Sherrill. Thank you all for convening this meeting. I want to thank the witnesses for taking your time to come. It's very important what you're doing.

We're here today to examine the EPA's Integrated Risk Information System program, which is also called IRIS. This hearing provides an opportunity to review the issues and challenges that burden the IRIS Program, steps that IRIS has taken toward addressing these issues, and challenges that remain today. I'm hopeful that our expert panel of witnesses will paint a detailed picture of how to improve the IRIS Program and remedy issues that have burdened us for years.

As Ranking Member of the Investigations and Oversight Committee, I approach this issue from an oversight perspective, focused on how to improve IRIS. With a background in business and real estate, I've learned how burdensome and costly, onerous regulations have become.

My experience in the real estate business has also taught me a thing or two about construction. For example, one of the primary tenets of construction is that your foundation is critical. If you build atop a faulty foundation, the entire structure is at risk and likely ruined where it stands.

As I understand it, IRIS assessments are analogous to a structural foundation. In preparing chemical assessments, IRIS conducts the first two steps of the risk assessment process: First, a hazard identification; second, a dose-response assessment. EPA's program and regional offices then rely on IRIS assessments and the foundation for conducting the last two steps of the risk assessment process, including an exposure assessment and a risk characterization.

As with a structural foundation, if an IRIS assessment is based on flawed information, or is itself faulty, then it jeopardizes all subsequent work that builds atop a faulty foundation. As a result, faulty assessments can lead to bad regulations and unnecessary public health scares. The IRIS Program must continue to address transparency issues that have plagued it over the past decade because Americans need assurance that sound science forms the foundation for government regulations.

The U.S. Government Accountability Office (GAO) added IRIS to its list of government programs that are highly vulnerable to risk of waste, fraud, abuse, and mismanagement in 2009. IRIS was added to GAO's "High-Risk List" because actions were needed to streamline and increase the transparency and the dependency of IRIS assessments. Despite attempts at improvement and efforts to remedy its challenges over the past decade, IRIS remains on the High-Risk List today.

In addition to its High-Risk List, GAO recently published a report that examined IRIS' efforts to improve its chemical assessment process and implement outstanding recommendations. While GAO commended IRIS for its efforts to address identified challenges, it also appropriately recognized that there remained much room for much improvement, especially with respect to issues of timeliness and transparency.

I want to thank the GAO for its great work. However, I was puzzled by certain findings regarding EPA leadership. In both reports, GAO seemed to fault EPA's leadership for delaying IRIS' progress. It also appeared that EPA leadership was chastised for failing to publicly commit to making IRIS a top priority, as was done by a previous Administrator, under a prior Administration.

I would suggest that a brief pause may have been necessary to adequately address the issues and challenges that IRIS faces and develop a plan of action for future progress. For example, think about repairing a rollercoaster. If you don't try to fix a malfunctioning rollercoaster while it's rolling around full of people. Instead, you suspend operations, you pull the cars off the track for evaluation, which makes for a better ride and safer in the end. Perhaps delays due to EPA leadership deliberation and assessment of IRIS should be handled in a similar fashion.

Despite its issues and challenges, the IRIS Program must still serve a critical function. And everyone here today recognizes the importance of ensuring Americans are protected from the dangers and hazards that IRIS aims to combat. It is for this reason that we must ensure IRIS' work is transparent, scientifically sound, and carried out in a timely and an efficient manner.

I look forward to a productive and insightful discussion with our distinguished witnesses about the issues and challenges that the IRIS Program faces and the efforts that IRIS has made in remedying them, and what remains to be done to ensure that IRIS lives up to its potential.

Thank you, Madam Chairwoman. I yield back.

[The prepared statement of Mr. Norman follows:]

COMMITTEE ON
SCIENCE, SPACE, AND TECHNOLOGY
REPUBLICANS Frank Lucas, Ranking Member

Subcommittee on Investigations & Oversight and Subcommittee on Environment
Hearing - EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead

**Opening Statement of Investigations and Oversight Subcommittee Ranking Member Ralph Norman**

March 27, 2019

Thank you, Chairwoman Fletcher and Chairwoman Sherrill, for convening this important hearing, and thank you to the witnesses for your testimony this morning.

We are here today to examine the EPA's Integrated Risk Information System Program – also called the IRIS Program or IRIS. This hearing provides an opportunity to review the issues and challenges that burden the IRIS Program, steps that IRIS has taken toward addressing these issues, and challenges that remain. I am hopeful that our expert panel of witnesses will paint a detailed picture of how to improve the IRIS Program and remedy issues that have burdened it for years.

As Ranking Member of the Investigations and Oversight Subcommittee, I approach this issue from an oversight perspective, focused on how to improve IRIS. With a background in business and real estate, I've learned how burdensome and costly onerous regulation can be.

My experience in the real-estate business has also taught me a thing or two about construction. For example, one of the primary tenets of construction is that your foundation is crucial. If you build atop a faulty foundation, the entire structure is at risk and likely ruined where it stands.

As I understand it, IRIS assessments are analogous to a structural foundation. In preparing chemical assessments, IRIS conducts the first two steps of the risk assessment process: First, a hazard identification; and second, a dose-response assessment. EPA's program and regional offices then rely on IRIS assessments as the foundation for conducting the last two steps of the risk assessment process, including: an exposure assessment; and a risk characterization.

As with a structural foundation, if an IRIS assessment is based on flawed information, or is itself faulty, then it jeopardizes all subsequent work that builds atop this faulty foundation. As a result, faulty assessments can lead to bad regulation and unnecessary public health scares.

The IRIS Program must continue to address transparency issues that have plagued it over the past decade, because Americans need assurance that sound science forms the foundation for government regulations.

The U.S. Government Accountability Office (GAO) added IRIS to its list of government programs that are highly-vulnerable to risk of waste, fraud, abuse, and mismanagement in 2009. IRIS was added to GAO's "High-Risk List" because actions were needed to streamline and increase the transparency and dependability of IRIS assessments. Despite attempts at improvement and efforts to remedy its challenges over the past decade, IRIS remains on the High-Risk List today.

In addition to its High-Risk List, GAO recently published a report that examined IRIS' efforts to improve its chemical assessment process and implement outstanding recommendations. While GAO commended IRIS for its efforts to address identified challenges, it also appropriately recognized there remained room for much improvement, especially with respect to issues of timeliness and transparency.

I want to thank GAO for its great work. However, I was puzzled by certain findings regarding EPA leadership. In both reports, GAO seemed to fault EPA leadership for delaying IRIS' progress. It also appeared that EPA leadership was chastised for failing to publicly commit to making IRIS a top priority—as was done by a previous administrator, under a prior administration.

I would suggest that a brief pause may have been necessary to adequately address the issues and challenges that IRIS faces and develop a plan of action for future progress. For example, think about repairing a roller coaster. You don't try to fix a malfunctioning roller coaster while it's rolling around full of people. Instead, you suspend operation and pull the cars off the track for evaluation, which makes for a better ride in the end. Perhaps delays due to EPA leadership deliberation and assessment of IRIS should be handled in a similar fashion.

Despite its issues and challenges, the IRIS Program must still serve a critical function. And everyone here today recognizes the importance of ensuring Americans are protected from the dangers and hazards that IRIS aims to combat. It is for this reason that we must also ensure IRIS' work is transparent, scientifically sound, and carried out in a timely and efficient manner.

I look forward to a productive and insightful discussion with our distinguished witnesses about the issues and challenges the IRIS Program faces, efforts IRIS has made in remedying them, and what remains to be done to ensure that IRIS lives up to its potential.

Thank you, Madam Chair. I yield back.

Chairwoman SHERRILL. Thank you, Mr. Norman.

The Chair now recognizes the Chairwoman for the Subcommittee on the Environment, Mrs. Fletcher, for an opening statement.

Mrs. FLETCHER. Thank you, Madam Chairwoman. Good morning. I would like to join the Chairwoman and Ranking Member Norman in welcoming all of our witnesses on both panels here today.

The EPA's IRIS Program conducts human health assessments that look at the health effects of chemical exposures in the environment. IRIS assessments are unique in providing information on chemical exposures and environmental hazards that may affect the general population, including children and the elderly, and that can occur over a lifetime. IRIS assessments follow a thorough process that includes internal and external peer review, as well as opportunity for public input.

While the IRIS Program suffered from timeliness and transparency issues earlier this decade, the program has incorporated many recommendations from the GAO and the National Academies of Sciences that have improved its processes. The IRIS Program was intentionally placed in EPA's Office of Research and Development, a nonregulatory program office at the Agency, to ensure that only credible science guided the development of its impartial assessments, which are not regulatory in nature.

There are many Federal, State, and local stakeholders, however, that rely on IRIS assessments to help make regulatory decisions that protect public health. Program and regional offices within the EPA routinely rely on IRIS assessments to guide their risk-management decisions. IRIS assessments are not only considered to be—are not considered to be duplicative of other Federal chemical assessments like those carried out under the EPA's *Toxic Substances Control Act*, or TSCA.

This is why the recent series of announcements by the EPA removing the chemical formaldehyde from its IRIS workflow and adding it to its TSCA workflow is concerning. It appears to reset the clock on a late-stage IRIS assessment. Non-Federal stakeholders, including community groups and State, local, and tribal agencies, rely on IRIS assessments not only because of their rigor and thoroughness, but also because many of these entities do not have the capacity to conduct such thorough toxicity assessments on their own. The values derived in IRIS assessments are routinely the top choice of State regulatory bodies in their standard-setting work because they are the most thoroughly developed and vetted values available.

Because of its rigorous process and the reliance of both Federal and non-Federal stakeholders of IRIS assessments to use them to direct risk-management decisions relating to public health, the program plays a unique role that is complementary to other review processes like TSCA.

Given this background, the findings of the GAO's March 4 report detailing political interference in the publication of IRIS assessments raise serious concerns. The EPA is responsible for protecting public health and the environment through the application of sound science and should not be creating internal roadblocks to performing this critical mission.

That is why I am glad we will be hearing from witnesses on both of our distinguished panels today, hearing from the EPA and GAO on the findings of this recent the GAO report and gaining a better understanding of the need for and importance of IRIS assessments, the improvements the program has made over the years, and the critical role these assessments play in protecting public health.

And with that I yield back.

[The prepared statement of Chairwoman Fletcher follows:]

U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON
**SCIENCE, SPACE, & TECHNOLOGY**

Opening Statement

**Chair Lizzie Fletcher (D-TX)**
**Subcommittee on Environment**

Joint Subcommittee Hearing:
*EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead*
March 27, 2019

Good morning, and I would like to join Chairwoman Sherrill in welcoming all of our witnesses on both panels for being here today.

The EPA's IRIS program conducts human health assessments that look at the health effects of chemical exposures in the environment. IRIS assessments are unique in providing information on chemical exposures and environmental hazards that may affect the general population, including children and the elderly, and that can occur over a lifetime.

IRIS assessments follow a thorough process that includes internal and external peer review, as well as opportunity for public input. While the IRIS program suffered from timeliness and transparency issues earlier this decade, the program has incorporated many recommendations from the GAO and the National Academies of Sciences that have improved its processes.

The IRIS program was intentionally placed in EPA's Office of Research and Development, a non-regulatory program office at the agency, to ensure that only credible science guided the development of its impartial assessments, which are not regulatory in nature.

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This is why the recent series of announcements by the EPA removing the chemical formaldehyde from its IRIS workflow, and adding it to its TSCA workflow, is concerning; it appears to reset the clock on a late-stage IRIS assessment.

Non-federal stakeholders, including community groups and state, local, and tribal agencies, rely on IRIS assessments not only because of their rigor and thoroughness, but also because many of these entities do not have the capacity to conduct such thorough toxicity assessments on their own. The values derived in IRIS assessments are routinely the top choice of state regulatory

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That is why I am glad we will be hearing from witnesses on both of our distinguished panels today; hearing from the EPA and GAO on the findings of this recent GAO report, and gaining a better understanding of the need for and importance of IRIS assessments, the improvements the program has made over the years, and the critical role these assessments play in protecting public health.

And with that I yield back the balance of my time.

Chairwoman SHERRILL. Thank you, Madam Chairwoman.

And the Chair now recognizes Mr. Marshall for an opening statement.

Mr. MARSHALL. Thank you, Chairwoman Fletcher and Chairwoman Sherrill, for holding this hearing, and thank you to the witnesses for being here today.

The EPA's IRIS Program was established to identify and characterize the health hazards of chemicals found in the environment. The program conducts chemical hazard identification and dose response assessments, which serve as a source of toxicity information for EPA program and regional offices as well as State and local agencies.

As a physician, I understand the importance of chemical toxicity assessments and their role in protecting the environment and advancing public health, particularly for sensitive populations such as children, pregnant women, and the elderly. Accordingly, it should be our top priority to ensure the underlying science that goes into these assessments is of the highest quality. Unfortunately, the IRIS Program has a poor track record in this department, and despite some recent progress by EPA leadership, many issues remain.

Two of the most troublesome problems for the IRIS Program are its inability to produce final products in a timely manner and an unexplained lack of scientific transparency in the assessment process. Both the National Academy of Sciences (NAS) and the Government Accountability Office (GAO) have recently published reports that criticize the program and make recommendations for improvement.

The National Academy of Sciences has published three reports detailing similar problems while making suggestions for reform and improvement of the program. The NAS reports in 2011 and 2014 found serious problems with IRIS and proposed sweeping recommendations to overhaul the program. If those recommendations had been fully implemented within the last 8 years, the program would be operating in a more functional manner and able to produce chemical assessments in a way that is timely, transparent to the public, and reflective of the best current scientific methodologies. Instead, we continue to live report to report, looking at incremental progress and an overall lack of tangible results.

The 2018 NAS review commends IRIS for its progress to implement systematic review of chemical assessments. And while I agree that IRIS' progress is commendable, several other critical products and recommendations remain unaddressed and incomplete. Publication of a robust handbook that details internal process, incorporation of mode-of-action information, and utilization of a weight-of-evidence framework are a few examples of simple objectives that have not been accomplished despite recommendations to do that. I hardly find the 2018 NAS review consequential in its praise of the program. In fact, I think it is a clear indication that a lot of work remains.

Likewise, the GAO has issued ongoing criticism of the program. In 2009, GAO added the IRIS Program to its High-Risk List, which identifies Federal programs with heightened vulnerabilities to fraud, waste, abuse, and mismanagement. Even with clear deficiencies pointed out and the EPA seemingly taking steps toward a

few of the recommendations for improvement, the program continues to appear on the High-Risk List to this day.

Separate of the High-Risk List, GAO recently issued a report that was largely critical of current EPA leadership and its efforts to manage and update the IRIS Program. Democrats and environmental groups continue to point to this report as evidence that the Trump Administration is trying to stifle science. On the contrary, I think these efforts are critical to overhauling a flawed program so it's responsive to program and regional office needs and best serve EPA's core mission. The program has many issues that need to be addressed, and EPA leadership is taking necessary steps to do just that.

One of the most troubling issues with IRIS is the publication of misleading or questionable information that can create confusion for Americans regarding the health risks associated with a given chemical. The 2016 IRIS assessment for ethylene oxide is a prime example. Naturally produced by the human body and plants, ethylene oxide is produced commercially to sterilize medical equipment. OSHA (Occupational Safety and Health Administration) set a safety standard of 1 part per million for workers exposed 8 hours a day, 5 days a week. This seems to be a reasonable value given that high, long-term exposure may increase cancer risks.

EPA's IRIS Program, however, set a lower risk value at 100 parts per quadrillion. And I think that's about a difference of 10 to the 9th. That value is 19,000 times lower than naturally occurring levels of ethylene oxide in the human body. Essentially, this assessment correlates to a normal human metabolism, and breathing ambient air is enough to cause cancer.

It is clear that much work remains before IRIS assessments can be tabbed as the gold standard review that the program was established to be. Meeting objective and transparent standards for evaluating chemical risks will require substantial changes and improvements to the program. I'm hopeful that one day soon the IRIS Program will be able to produce high-quality, scientifically sound chemical assessments that are widely accepted by the scientific community, and I look forward to working with my colleagues to ensure this happens.

Thank you, and I yield back.

[The prepared statement of Mr. Marshall follows:]

COMMITTEE ON
SCIENCE, SPACE, AND TECHNOLOGY
REPUBLICANS Frank Lucas, Ranking Member

Subcommittee on Investigations & Oversight and Subcommittee on Environment
Hearing - EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead

**Opening Statement of Environment Subcommittee**
**Ranking Member Roger Marshall**

*As Prepared for Delivery*

March 27, 2019

Thank you, Chairwoman Fletcher and Chairwoman Sherrill, for holding this hearing, and thank you to the witnesses for being here today.

The EPA's IRIS Program was established to identify and characterize the health hazards of chemicals found in the environment. The program conducts chemical hazard identification and dose response assessments, which serve as a source of toxicity information for EPA program and regional offices as well as state and local agencies. As a physician, I understand the importance of chemical toxicity assessments and their role in protecting the environment and advancing public health – particularly for sensitive populations such as children, pregnant women, and the elderly.

Accordingly, it should be our top priority to ensure the underlying science that goes into these assessments is of the highest quality. Unfortunately, the IRIS program has a poor track record in this department, and despite some recent progress by EPA leadership, many issues remain.

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If those recommendations had been fully implemented within the last eight years, the program would be operating in a more functional manner and able to produce chemical assessments in a way that is timely, transparent to the public, and reflective of the best current scientific methodologies. Instead, we continue to live report to report, looking at incremental progress and an overall lack of tangible results.

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Likewise, the GAO has issued ongoing criticism of the program. In 2009, GAO added the IRIS Program to its High-Risk List, which identifies federal programs with heightened vulnerabilities to fraud, waste, abuse, and mismanagement. Even with clear deficiencies pointed out and the EPA seemingly taking steps towards a few of the recommendations for improvement, the program continues to appear on the high-risk list to this day.

Separate of the High-Risk List, GAO recently issued a report that was largely critical of current EPA leadership and its efforts to manage and update the IRIS program. Democrats and environmental groups point to this report as evidence that the Trump Administration is trying to stifle science. On the contrary, I think these efforts are critical to overhauling a flawed program so that it is responsive to program and regional office needs and best serves EPA's core mission. The program has many issues that need to be addressed, and EPA leadership is taking necessary steps to do just that.

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It is clear that much work remains before IRIS assessments can be tabbed as the gold standard review that the program was established to be. Meeting objective and transparent standards for evaluating chemical risks will require substantial changes and improvements to the program.

I'm hopeful that one day soon the IRIS program will be able to produce high quality, scientifically sound chemical assessments that are widely accepted by the scientific community, and I look forward to working with my colleagues to ensure this happens.

Chairwoman SHERRILL. Thank you, Mr. Marshall.

We are pleased to have the Full Committee Ranking Member, Mr. Lucas, with us today, so the Chair now recognizes the Ranking Member for an opening statement.

Mr. LUCAS. Thank you, Madam Chair, and thank you to all the witnesses for being here today to discuss EPA's IRIS Program.

Over the last 10 years, numerous reports have been issued criticizing the IRIS Program for its lack of transparency, improper scientific processes, and ineffectiveness in addressing the needs of EPA regional and program offices. The flaws are well-documented. Current EPA leadership is taking positive steps to address these issues, and I laud their progress. However, we have yet to see a completed assessment of the IRIS Program that fully incorporates all of the recommendations made in the last decade.

Unfortunately, that means there are numerous IRIS assessments in the database that are questionable, unreliable, and in some instances just plain incorrect. Take IRIS' assessment of ethylene oxide, which is used to sterilize medical equipment. In fact, some medical equipment can't be sterilized by any other chemical. In 2016, IRIS set an absurd risk value that is 19,000 times lower than the levels of this chemical that naturally occur in the human body. Assessments like this can have disastrous effects on the economy and human health if relied upon by government agencies in crafting regulation.

Accordingly, today's hearing raises an important theme: How we characterize the chemicals in the environment. Unfortunately, there are too many government agencies, both national and international, that mischaracterize risk associated with chemicals. These agencies, just like the IRIS Program, have a history of identifying extremely conservative, even paranoid levels of exposure that can be classified as carcinogenic.

Another program with a poor track record of assessing risk is the International Agency for Research on Cancer, IARC. Unlike IRIS, IARC's problems go beyond bad science. IARC is plagued by a severe lack of transparency and accountability, as well as significant conflicts of interest. But other parallels with IRIS exist. IARC assessments have led to the classification of things like red meat and coffee as being carcinogenic. States like California adopt these assessments at face value and slap a warning on every product imaginable. The public promptly ignores these warnings because they know coffee will not give them cancer. In the end, we are left with useless and ineffective regulations that only serve to waste taxpayer money.

Although the IRIS Program does not have regulatory authority, it is important to note the consequences of when government agencies miscategorize risk. As I said, I'm pleased the current Administration is taking a thoughtful and meaningful look at how we characterize I should say, chemical risk. I'm hopeful these efforts will bear fruit. In the meantime, we will remain vigilant in ensuring that programs like IRIS are useful, transparent, and effective in meeting EPA's core mission of protecting human health and the environment.

I yield back, Madam Chairwoman. Thank you.

[The prepared statement of Mr. Lucas follows:]

COMMITTEE ON
SCIENCE, SPACE, AND TECHNOLOGY
REPUBLICANS Frank Lucas, Ranking Member

Subcommittee on Investigations & Oversight and Subcommittee on Environment
Hearing - EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead

**Opening Statement of Ranking Member Frank Lucas**

March 27, 2019

Thank you, Madam Chair, and thank you to all the witnesses for being here today to discuss EPA's IRIS program.

Over the last 10 years, numerous reports have been issued criticizing the IRIS program for its lack of transparency, improper scientific processes, and ineffectiveness in addressing the needs of EPA regional and program offices. The flaws are well documented.

Current EPA leadership is taking positive steps to address these issues, and I applaud their progress. However, we have yet to see a completed assessment from the IRIS program that fully incorporates all the recommendations made in the last decade. Unfortunately, that means there are numerous IRIS assessments in the database that are questionable, unreliable, and in some instances just plain incorrect.

Take IRIS' assessment of ethylene oxide, which is used to sterilize medical equipment. In fact, some medical equipment can't be sterilized by any other chemical.

In 2016, IRIS set an absurd risk value that is 19,000 times lower than the levels of this chemical that naturally occur in the human body. Assessments like this one can have disastrous effects on the economy and human health if relied upon by government agencies in crafting regulation.

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Like I said, I am pleased the current administration is taking a thoughtful and meaningful look at how we characterize chemical risk. I'm hopeful these efforts bear fruit. In the meantime, we will remain vigilant in ensuring that programs like IRIS are useful, transparent, and effective in meeting EPA's core mission of protecting human health and the environment.

Chairwoman SHERRILL. Thank you, Mr. Ranking Member.

If there are Members who wish to submit additional opening statements, your statements will be added to the record at this point.

[The prepared statement of Chairwoman Johnson follows:]

U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON
**SCIENCE, SPACE, & TECHNOLOGY**

Opening Statement

**Chairwoman Eddie Bernice Johnson (D-TX)**

Joint Subcommittee Hearing:
*EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead*
March 27, 2019

Thank you Madam Chair, and I would like to join you in welcoming our witnesses this morning. This Committee has a long history of oversight of the EPA's IRIS program. I have been able to witness the progress made over the years, including the great strides the IRIS program has made in addressing recommendations made by the National Academies. These improvements have been applauded by the National Academies, EPA's Science Advisory Board, and members of this Committee.

It is because of this progress that I am particularly concerned about the GAO report released earlier this month. It appears that political leadership at the EPA is suppressing IRIS's ability to complete its invaluable chemical assessments and to communicate with stakeholders who are reliant on IRIS's toxicity values. I am concerned that this will lead to a backsliding in IRIS's progress. For example, in this year's High Risk List, GAO stated that leadership commitment to the program decreased from meeting GAO's standard in the last report, to only partially meeting the standard this year.

Insufficient commitment to the IRIS program is insufficient commitment to ensuring the health and safety of Americans. As my colleague Ms. Sherrill pointed out, IRIS is the gold standard for toxicity assessments, providing crucial information on which federal, state, and local governments can base their regulations and guidelines to keep air and water free of harmful contamination. IRIS assessments also empower communities by informing them of their exposure risks. In Willowbrook, Illinois, for example, residents began to develop mysterious symptoms related to their exposure to ethylene oxide emitted by a nearby factory. As IRIS had issued an assessment of ethylene oxide in 2016, residents were able to educate themselves on their risk, and with IRIS values to support their case, Willowbrook residents were able to push the Illinois state government to ban the use of ethylene oxide at the factory.

It is imperative that IRIS not be impeded in conducting chemical assessments and disseminating its conclusions to the public. Communities all across the United States – particularly communities that are poorer, more urban, and less white – are needlessly suffering due to contaminants in the air they breathe and the water they drink.

In my years on the Committee, an ongoing issue of controversy has been IRIS's assessment of formaldehyde. By many accounts, the assessment is ready to be reviewed, but is being held up and ultimately was dropped from IRIS's list of priority chemicals – a decision that appears to be politically, rather than scientifically, motivated. Currently, there are two outstanding letters – one to Administrator Wheeler and one to Dr. Francesca Grifo – that I and three of my Senate colleagues sent to the EPA inquiring about the decision to suppress this report and whether this delay violates the agency's scientific integrity policy. We look forward to reviewing the documents requested in this letter, which we expect the Agency to submit to us by April 5.

Thank you, and I yield back to Chairwoman Sherrill.

Chairwoman SHERRILL. At this time I would like to introduce the witnesses for our first panel: Dr. Jennifer Orme-Zavaleta, the Principal Deputy Assistant Administrator for Science with the Office of Research and Development and the Science Advisor for the Environmental Protection Agency, the EPA; and Mr. Alfredo Gomez, Director of the Natural Resources and Environment team with the Government Accountability Office, the GAO. Mr. Gomez is also the principal author of the March 2019 GAO report on the Integrated Risk Information System, IRIS, which is the basis of our hearing today.

As our witnesses should know, you will each have 5 minutes for your spoken testimony. Your written testimony will be included in the record for the hearing. When you all have completed your spoken testimony, we will begin with the questions, and each Member will have 5 minutes to question the panel. We will start with Dr. Orme-Zavaleta.

**TESTIMONY OF DR. JENNIFER ORME-ZAVALETA, PRINCIPAL DEPUTY ASSISTANT ADMINISTRATOR FOR SCIENCE AND SCIENCE ADVISOR, OFFICE OF RESEARCH AND DEVELOPMENT, EPA**

Dr. ORME-ZAVALETA. Thank you, and good morning, Chairwomen Fletcher and Sherrill, Ranking Members Marshall and Norman, and other distinguished Members of the two Subcommittees. My name is Jennifer Orme-Zavaleta, and I'm the Principal Deputy Assistant Administrator for Science in EPA's Office of Research and Development (ORD). I also act as the Agency's Science Advisor. My responsibility as the career lead for ORD is to ensure that we provide solid and robust science to inform Agency decisions.

I have worked for EPA since 1981 in the areas of human health and ecological risk, research, policy development, strategic planning, and program implementation. Of these nearly 38 years, I've spent 26 in ORD, which is the parent office of the Integrated Risk Information System, commonly called IRIS. I appreciate the opportunity to talk with you today about IRIS. I was at EPA when IRIS was created, and I've seen it grow into the rigorous scientific program it is today.

ORD's highly trained IRIS staff helped the program's regions, States, and others assess the risk of potential exposures to chemicals and nonchemical contaminants. IRIS assessments are a key part of this, providing the first two steps of the risk-assessment process: Hazard identification and dose-response assessment. This information informs risk assessments that are conducted by EPA programs, regions, States, and others, though some EPA programs conduct their own hazard and dose-response assessments.

IRIS assessments provide a scientific foundation for decision-making under an array of environmental laws. The IRIS assessment process ensures transparency, scientific rigor, and provides opportunities for public, stakeholder intra- and interagency engagement. This process also includes robust independent scientific peer review.

In 2011 and 2014, the National Academy of Sciences issued reports outlining recommendations to improve the IRIS Program by adopting systematic review, and this is known for transparency

and scientific rigor. In 2017, IRIS began to implement systematic review across its assessments, and since then, IRIS has made assessment plans and protocols available to the public earlier in the assessment development process, providing more time to consider scientific complexities.

In a report published in April 2018, the National Academies concluded that IRIS has made substantial progress. GAO has also provided input to improve the IRIS Program, which has included suggestions to increase timeliness, transparency, and process challenges. In a recent audit report, GAO found that IRIS has made improvements and has demonstrated the impacts of actions that we've taken. IRIS has made these improvements by incorporating project and program management by moving away from a one-size-fits-all assessment to a mixed portfolio of chemical evaluation products. In addition, IRIS has optimized systematic review software tools, which are increasing the efficiency and promoting greater transparency by making information more accessible to the public.

With these changes, a large segment of the assessment portfolio can now be completed in 1 to 3 years instead of 3 to 10. The GAO report noted this, indicating that the preparation of several recent draft assessments has taken months, not years. To ensure that these new and improved processes are successful, IRIS has extensively trained its staff and is extending this training across the Agency and to the stakeholder community as well.

Another major challenge—change in how IRIS operates is in how EPA programs request and prioritize IRIS assessments. Because IRIS assessments play such a critical role, the EPA Administrator requested a formal process signed off at the Assistant Administrator level, through which programs identify what IRIS assessments are a priority, when they are needed, and why they are needed. This process was completed in December and identified 11 priority chemicals. This formal process is a great improvement, as it brings further stability and responsiveness to the IRIS Program while also reinforcing accountability between the requesting program office and the IRIS Program. We will continue to conduct this process annually, though programs may nominate a new assessment at any time.

Now that the prioritization process is complete, the public and stakeholders can expect to see IRIS assessments move forward. Last week, IRIS released a systematic review protocol for hexavalent chromium, and we plan to release other assessment materials soon. The formal prioritization process, along with the improvements in IRIS, has made—has helped us to address the NAS and GAO recommendations, and this will continue to make IRIS more efficient and a more effective program.

We recognize that we still have work to do, but I am confident that as we move forward and address these open—we will address these open recommendations and concerns identified by the GAO.

So thank you for the opportunity to appear before you today, and I look forward to answering your questions.

[The prepared statement of Dr. Orme-Zavaleta follows:]

**Testimony of**
**Jennifer Orme-Zavaleta, Ph.D.**
**Principal Deputy Assistant Administrator for Science and Science Advisor**
**Office of Research and Development**
**U.S. Environmental Protection Agency**

**Hearing on EPA's Integrated Risk Information System (IRIS) Program**
**Before the**
**Committee on Science, Space, and Technology**
**Subcommittee on Investigations and Oversight**
**and Subcommittee on Environment**
**U.S. House of Representatives**
**March 27, 2019**

Good morning, Chairwoman Fletcher, Chairwoman Sherrill, Ranking members Marshall and Norman, and other distinguished members of the two Subcommittees. My name is Jennifer Orme-Zavaleta, and I am the Principal Deputy Assistant Administrator for Science in the U.S. Environmental Protection Agency's Office of Research and Development. I also act as EPA's Science Advisor. My responsibility as the career lead for ORD is to ensure that we provide solid and robust science to inform Agency decisions.

I have worked at EPA since 1981 in the areas of human health and ecological research, risk assessment, policy development, strategic planning, and program implementation. Of the nearly 38 years I've been at EPA, I've spent 26 years in the Office of Research and Development (ORD), which is the parent office of the Integrated Risk Information System program – commonly called IRIS.

I appreciate the opportunity to talk with you today about IRIS. I was at EPA when IRIS was created in 1985, and I've seen the program grow into the rigorous scientific program it is today.

**Background and Overview of IRIS Program**

A significant part of what ORD does is help the Programs, Regions, States, and others assess the risk of potential exposures to chemicals, as well as nonchemical contaminants, whether encountered in commerce or in the environment. There are approximately 40,000 chemicals in commerce, and 'legacy' chemicals can be found in Superfund sites. In order for risk assessment to meet the current demands to protect the environment and public health a significant transformation is needed. And this has been our focus in ORD, and my focus in my role as Science Advisor over the past year and a half.

There are four main components of risk assessment: hazard identification, dose-response assessment, exposure assessment, and risk characterization. IRIS assessments include the first two steps of the risk assessment process: hazard identification and dose-response. Hazard identification tells you which health outcomes are associated with the chemical. Dose-response assessment characterizes the quantitative relationship between chemical exposure and health hazards and is used to derive, when appropriate, toxicity values. The information provided by IRIS can be combined with exposure assessments to inform risk assessments conducted by EPA Programs, Regions, and others including States. IRIS assessments are not regulations, but they can provide, whole or in part, a scientific foundation for decision making to protect human health across EPA under an array of environmental laws.

IRIS was created in 1985 to provide consistent hazard conclusions and toxicity values across the Agency. Housing IRIS in ORD affords EPA a scientifically-focused evaluation of hazard and toxicity information, which can be used to inform policy making. IRIS staff are highly trained experts and being concentrated in ORD facilitates their capacity to quickly address the needs of its agency partners. This is especially important considering that some of the users of IRIS assessments, such as the Office of Land and Emergency Management (OLEM) and EPA's regional offices, do not have the capacity to fully meet all of their assessment needs. Some EPA programs conduct their own hazard and dose-response assessments, such as the Office of Pesticide Programs. It is important to note that in 2016, when the Lautenberg Chemical Safety Act was passed, the IRIS program made assisting with Toxic Substances Control Act (TSCA) implementation a high priority.

The IRIS program utilizes a multi-step process that provides structured opportunities for public, stakeholder, and intra- and inter-agency engagement throughout the assessment development process – from concept to completion. The assessments are complex and involve multidisciplinary evaluations of scientific information, developed through a transparent and systematic process including robust, independent peer review. As such, IRIS assessments have traditionally been considered a top-tier product for use in some EPA Programs and Regions as the basis for their programmatic decisions. IRIS staff also provides assistance outside of the assessments themselves, including technical support, training, and scientific translation to help the Programs, Regions, and States implement their governing statutes and regulations to ultimately protect public health and the environment. Recent science and technical assistance provided by IRIS surrounding the potential public health concerns from exposures to perchlorate, chloroprene, and ethylene oxide highlight the critical importance of IRIS.

**GAO and NAS Recommendations and Implementation**

In 2011 and 2014, the National Academy of Sciences (NAS) issued reports outlining recommendations to improve the IRIS program by adopting systematic review, a method of conducting a standardized literature-based assessment and quality review known for the transparency and rigor it brings to the process. Since then, IRIS has been working diligently to implement these recommendations. And in April 2018, the NAS issued a consensus report on the progress of the IRIS program. In its overall conclusions, the committee reported, "The committee is encouraged by the steps that EPA has taken, which have accelerated during the last year under new leadership. It is clear that EPA has been responsive and has made substantial progress in implementing National Academies recommendations."

Systematic review methods provide clarity on the strategies used to search and select literature, objectively evaluate the strengths and weaknesses of individual studies, provide structured frameworks to guide integrative weight-of-evidence evaluation, and provide clearer rationale for selecting the studies that are advanced for consideration in calculating toxicity values.

Over the last several years, the IRIS program has been exploring how to practically implement systematic review into chemical assessment. During FY 2017, and with the arrival of the new IRIS Director, who is a global leader in systematic review, IRIS began to implement systematic review pragmatically across its assessments. As IRIS has operationalized systematic review, assessment plans and protocols have been made available for public review and comment earlier in the assessment development process, providing more time for consideration of the scientific complexities before the assessment is drafted.

GAO has also provided input to improve the IRIS program. This input included suggestions to address timeliness, improve transparency, and address process challenges. In their recent audit report, GAO found that IRIS has made improvement and has demonstrated the impact of the corrective actions on IRIS workflow, productivity, and impact.

IRIS has modernized its process and workflows by incorporating project and program management to better manage staff and resource commitments. In addition, it has moved away from one-size-fits-all assessments to a mixed portfolio of chemical evaluation products. It has also optimized the use of a variety of specialized systematic review software tools to increase efficiency and promote greater transparency by making the underlying assessment information more accessible to the public. With these changes, a large segment of the assessment portfolio can be completed in 1-3 years instead of 3-10 years for the one size-fits-all model. As the GAO audit report indicates, preparation of several recent draft assessments has taken months, not years. These are significant improvements that have helped address GAO's input regarding the timeliness, transparency, and process of IRIS assessments.

I would like to note that, even as IRIS modernizes, it has continued to adhere to the "IRIS Process," which includes intra- and inter-agency review, public comment, and rigorous peer review. The IRIS process has been carefully negotiated with its stakeholder communities inside and outside the federal government.

IRIS has also invested in extensive staff training across its organization to energize this culture of change and ensure new processes are successful. Continuous staff training has been incorporated into the workflow, and the use of specialized software tools make it possible to bring more of the work in-house using existing FTEs with reduced reliance on contract and extramural resources. It allows us to stabilize the quality of work products and prepare for

fluctuating workload scenarios. This training is being extended across the Agency and to the stakeholder community, including industry stakeholders.

**IRIS Prioritization**

Another major change in how IRIS operates is in how EPA programs request and prioritize IRIS assessments. Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, the EPA Administrator requested a more formal, structured survey of IRIS priorities signed at the Assistant Administrator level. This formalized prioritization process was completed in December 2018, and it is bringing further stability and responsiveness to the IRIS program.

Through this new process, programs formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. Not only does this improve the scope of IRIS assessments and help IRIS prioritize its activities, it also reinforces accountability between the requesting program and IRIS.

This process has identified eleven priority chemicals: hexavalent chromium, inorganic arsenic, mercury salts, methylmercury, polychlorinated biphenyl (PCBs), five per- and polyfluoroalkyl substances (PFASs), and vanadium. The IRIS program will conduct this same formal request and prioritization process annually, although programs are able to nominate at any time.

**Conclusion**

EPA recognizes that the IRIS program still has work to do, and we are committed to addressing the recommendations made by the NAS and GAO. Now that the formal request and prioritization process is complete, the public and stakeholders can expect to see IRIS assessments

move forward. Just last week, the IRIS program released a systematic review protocol for the hexavalent chromium assessment for public comment. We anticipate releasing other assessment materials in the coming weeks. As the IRIS program moves forward to develop assessments, I am confident that we will be able to address the open recommendations and concerns identified by the GAO.

The formal request and prioritization process, along with the improvements IRIS has made in the past few years to address NAS and GAO recommendations, will make IRIS an even more efficient and effective program that provides the Agency's IRIS users with the science needed to help fulfill their statutory mandates to protect human health and the environment.

Thank you again for the opportunity to appear before you today. I am happy to take any questions you may have.

**Jennifer Orme-Zavaleta**

**Principal Deputy Assistant Administrator for Science for the Office of Research and Development, and EPA Science Advisor**

Jennifer Orme-Zavaleta, Ph.D., is the Principal Deputy Assistant Administrator for Science for the Office of Research and Development and the EPA Science Advisor. Dr. Orme-Zavaleta has been with EPA since 1981, working in the areas of human health and ecological research, risk assessment, policy and regulation development, strategic planning, and program implementation. The focus of her experience includes the evaluation of risks to human and ecosystem health, and the influence of environmental change on human health in response to a variety of stressors including synthetic organic and inorganic chemicals, radionuclides, microorganisms, and vector-borne disease.

Dr. Orme-Zavaleta received her B.A. in Zoology from Ohio Wesleyan University, M.S. in Zoology and Toxicology from Miami University, and Ph.D. in Wildlife Science and Public Health from Oregon State University.

Jennifer has held a number of positions within EPA in the Offices of Toxic Substances, Water and Research and Development. Most recently she served as the Director of EPA's National Exposure Research Laboratory. She also served as the Interim National Program Director for Safe and Sustainable Water Resources, where she led the development of research to achieve safe, resilient and sustainable solutions to the increasingly complex water challenges facing US regions, states, tribes, cities and rural areas.

Chairwoman SHERRILL. Thank you, Dr. Orme-Zavaleta.
And now, I would like to recognize Mr. Gomez for his testimony.

**TESTIMONY OF ALFREDO GOMEZ,**
**DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT,**
**GOVERNMENT ACCOUNTABILITY OFFICE**

Mr. GOMEZ. Chairman—Chairwomen Sherrill and Fletcher, Ranking Members Norman and Marshall, and Members of the Subcommittees, good morning. I'm pleased to be here today to discuss our work on EPA's efforts to address toxic chemicals.

As has been noted, EPA is responsible for reviewing chemicals in commerce and for those entering the marketplace. EPA's ability to effectively implement its mission of protecting public health and the environment depends on its credible and timely assessments of the risks posed by these chemicals. The Agency's Integrated Risk Information System program, which is under the Office of Research and Development, identifies and characterizes the health hazards of chemicals and produces human health toxicity assessments. EPA program and regional offices rely in part on these assessments to make risk management decisions.

My statement today summarizes our March 2019 report on EPA's efforts to produce IRIS assessments. I will discuss the extent to which the IRIS Program has made progress in addressing identified challenges and in producing chemical assessments. And as has already been noted by the Committee, we also recently issued our High Risk update, which includes transforming EPA's process for assessing and controlling toxic chemicals.

Just as a matter of background, I wanted to mention that the IRIS Program uses a seven-step process to produce assessments, so there's a lot of review that's built into the process. First, EPA has to determine the scope and the questions that the assessment will cover, and these are released for review and public comment. The draft assessment is then developed using systematic review. After the full draft is developed, it goes through agency review, interagency review, and external peer review and public comment. After staff make revisions to address the comments, the draft then goes through another round of internal and interagency review. Then the program finalizes and posts the assessments to the IRIS website.

So historically, developing IRIS assessments has been a lengthy process and typically takes several years to complete. The IRIS Program has made progress addressing timeliness and transparency challenges in the assessment process. So, for example, the IRIS Program is now employing project management principles and specialized software to better plan assessments and utilize staff. In addition, the program has begun assessments that are more limited in scope and targeted to specific program and regional office needs.

The IRIS Program has implemented systematic review, which provides a structured and transparent process for identifying relevant studies, reviewing their methodological strengths and weaknesses, and integrating these studies as part of weight-of-evidence analysis.

In early 2018, EPA made progress on assessments that were in development. However, EPA leadership deliberations delay the release of some assessments by 6 months. So in June 2018, the Administrator's office told IRIS officials that they could not release any IRIS documentation without a formal request from EPA program office leadership. In August 2018, the Office of Research and Development asked program offices through a survey to reconfirm which of the 20 ongoing chemical assessments they needed. Several program offices responded confirming their needs for these assessments.

Then in late October 2018, prior to releasing the results of the initial survey, these offices were asked to limit their chemical requests further to the top three or four assessments. EPA leadership did not provide them a reason for the limit or guidance on prioritizing assessments.

Then finally in December 2018, as has been noted, EPA publicly issued its IRIS Work Plan, which provided an updated list of 13 assessments. Eleven of the 13 chemicals on the IRIS Work Plan were requested by two EPA program offices. The two remaining assessments were already at external peer review. EPA gave no indication of when additional assessments could be requested or what the IRIS Program's workflow would be in the future.

While the program's work was delayed, EPA directed 28 of approximately IRIS staff to support implementation of TSCA with 25 to 50 percent of their time according to officials. It is unclear if this is a temporary workforce shift or if TSCA will require this level of support moving forward.

So, Chairwomen Sherrill and Fletcher, Ranking Members Norman and Marshall, and Members of the Subcommittees, this concludes my statement. I'd be pleased to answer questions.

[The prepared statement of Mr. Gomez follows:]

United States Government Accountability Office

GAO

Testimony

Before Subcommittees on Investigations and Oversight and Environment, Committee on Science, Space, and Technology, House of Representatives

For Release on Delivery
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# CHEMICAL ASSESSMENTS

## Overview of EPA's Efforts to Produce Assessments

Statement of J. Alfredo Gómez, Director,
Natural Resources and Environment

Chairwomen Sherrill and Fletcher, Ranking Members Norman and Marshall, and Members of the Subcommittees:

Thank you for the opportunity to be here today to discuss our recent report on the status of the Environmental Protection Agency's (EPA) efforts to produce assessments of the potential human health effects that may result from exposure to various chemicals in the environment. This is part of our body of work on the agency's efforts to address toxic chemicals.[1] EPA's ability to effectively implement its mission of protecting public health and the environment depends on its credible and timely assessments of the risks posed by chemicals. The agency's Integrated Risk Information System (IRIS) Program identifies and characterizes the health hazards of chemicals and produces chemical assessments that contain this information.

The National Academy of Sciences (NAS) and we have made recommendations on many topics related to IRIS.[2] In 2009, we added EPA's process for assessing and controlling toxic chemicals to our list of agencies and program areas that are high risk because of their vulnerabilities to fraud, waste, abuse, and mismanagement or that are in most need of transformation.[3] This high-risk area has evolved since 2009, which we discuss in our two most recent high-risk reports.[4]

[1]GAO, *Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act*, GAO-19-270 (Washington, D.C.: Mar. 4, 2019). While several areas of EPA carry out chemical risk assessments, this report focused on the IRIS Program and EPA's implementation of the Toxic Substances Control Act (TSCA), as amended.

[2]National Research Council of the National Academies, *Review of EPA's Draft IRIS Assessment of Formaldehyde* (Washington, D.C.: National Academies Press, 2011); *Review of EPA's Integrated Risk Information System (IRIS) Process* (Washington, D.C.: National Academies Press, 2014); and *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation* (Washington, D.C.: National Academies Press, 2018). GAO, *Chemical Assessments: An Agencywide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessments*, GAO-13-369 (Washington, D.C.: May 10, 2013); and *High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others*, GAO-17-317 (Washington, D.C.: Feb. 15, 2017).

[3]GAO, *High-Risk Series: An Update*, GAO-09-271 (Washington, D.C.: January 2009). This area was added to the High Risk List as a government program in need of broad-based transformation.

[4]GAO, *High-Risk Series: Substantial Efforts needed to Achieve Greater Progress on High-Risk Areas*, GAO-19-157SP (Washington, D.C.: March 2019) and GAO-17-317.

My statement today discusses the extent to which the IRIS Program has made progress in (1) addressing identified challenges and (2) producing chemical assessments. This statement summarizes our March 2019 report on EPA's efforts to produce IRIS assessments.[5] We reviewed program documentation from 2012 through 2019 and applicable EPA guidelines and program management practices. We interviewed IRIS officials, the leadership (as of October 2018) in EPA's Office of Research and Development (ORD), and officials from EPA program and regional offices that request or use IRIS assessments on a regular basis. We interviewed representatives from an environmental stakeholder organization and an industry stakeholder organization that both have been involved in chemical regulatory policy and worked with or followed the IRIS Program for the past several years. Our March 2019 report contains a detailed overview of our scope and methodology.

We conducted the work on which this statement is based in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## Background

EPA uses risk assessments to provide information on potential health or ecological risks.[6] A number of program and regional offices at EPA prepare chemical risk assessments, and these risk assessments provide the foundation for EPA's risk management decisions, such as whether EPA should establish air and water quality standards to protect the public from exposure to toxic chemicals. In preparing risk management decisions, some EPA program and regional offices rely in part on chemical assessments that the IRIS Program prepares. IRIS assessments generally include hazard identification and dose-response assessment. Hazard identification identifies credible health hazards associated with exposures to a chemical, and dose-response assessment characterizes the quantitative relationship between chemical exposure

[5]GAO-19-270.

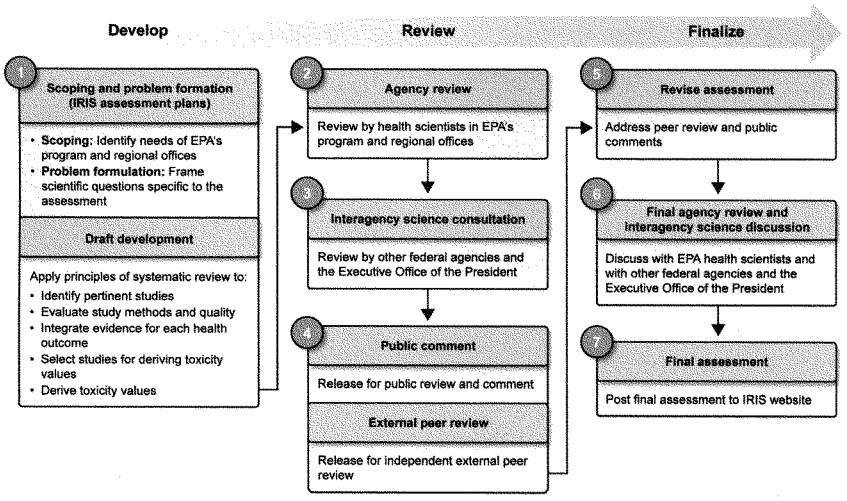
[6]Environmental Protection Agency, *Risk Characterization Handbook* (Washington, D.C.: December 2000), accessed January 7, 2019, https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.

and each credible health hazard. The IRIS Program derives toxicity values through this quantitative relationship. These toxicity values are combined with exposure assessments, produced by other offices within EPA, to produce a risk assessment.

EPA created the IRIS Program in 1985 to help develop consensus opinions within the agency about the health effects from lifetime exposure to chemicals. The IRIS database of chemical assessments contains EPA's scientific positions on these health effects, and, as of November 2018, it included information on 510 chemicals. Based on our body of work on the IRIS Program, the program's importance has increased over time as EPA program offices and regions have increasingly relied on IRIS chemical assessments in making environmental protection and risk management decisions. In addition, state and local environmental programs, as well as some international regulatory bodies, rely on IRIS chemical assessments in managing their environmental protection programs.

The IRIS Program uses a seven-step process to produce chemical assessments, as shown in figure 1.

**Figure 1: Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Chemical Assessment Development Process**




Source: EPA. | GAO-19-454T

The first step in the assessment development process includes a wide range of efforts by program staff, such as determining the scope and initial problem formulation of an assessment in consultation with EPA program and regional offices; obtaining agency and public feedback on the result, called the IRIS Assessment Plan; selecting and extracting relevant data; analyzing and integrating the evidence into a draft assessment; and deriving chemical toxicity values. After these efforts, depicted in step 1 of figure 1, the draft assessment goes through internal agency and interagency review, public comment, and peer review as shown in steps 2 through 4. After staff make revisions to address comments received (step 5), the draft assessment goes through another

round of internal and interagency review, and then the program finalizes and posts the assessment to the IRIS website.[7]

## The IRIS Program Has Made Progress in Addressing Identified Process Challenges

As detailed in our report, the IRIS Program has made progress toward addressing process challenges related to timeliness and transparency that governmental, industry, academic, and non-governmental stakeholders identified in recent years.[8] In our report, we identified the key actions the IRIS Program has taken to address lack of timeliness in producing assessments and lack of transparency in how it produces assessments.

### The IRIS Program Has Made Changes to Address Timeliness

As discussed in our report, developing IRIS assessments has historically been a lengthy process. Because of the rigor of the IRIS process and the amount of literature that program staff must search and consider, producing an assessment typically takes several years, as we found in December 2011.[9] For our March 2019 report, officials from several program and regional offices told us that despite the length of time it takes for the IRIS Program to complete its assessments, they prefer these assessments as sources of information over other agencies' toxicity assessments.

The IRIS Program is striving to address the length of time it takes to produce assessments in three key ways. First, IRIS is utilizing project

[7]The IRIS Program has not changed the process steps since 2013, but the types of documents produced during step 1 have evolved from preliminary assessment materials (before 2017) to IRIS Assessment Plans and protocols (after 2017) to better integrate systematic review approaches into the existing process.

[8]National Research Council of the National Academies, *Review of EPA's Draft IRIS Assessment of Formaldehyde* (Washington, D.C.: National Academies Press, 2011); *Review of EPA's Integrated Risk Information System (IRIS) Process* (Washington, D.C.: National Academies Press, 2014); *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation* (Washington, D.C.: National Academies Press, 2018). GAO, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*, GAO-08-440 (Washington, D.C.: Mar. 7, 2008; *Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program*, GAO-12-42 (Washington, D.C.: Dec. 9, 2011); GAO-13-369; and GAO-17-317. *Making EPA Great Again, Before the H.R. Comm. On Science, Space, and Technology*, 115th Cong. (2017) (Statement of Kimberly W. White, Ph.D., American Chemistry Council).

[9]GAO-12-42.

management principles and new software that enable the program to better plan assessment schedules and utilize staff. IRIS officials said that by using these tools, IRIS staff are able to view project tasks, timelines, and milestones to manage their individual tasks and assessment work. Additionally, according to IRIS officials, the recent adoption of specialized systematic review software also enables program staff to more quickly perform literature searches and to efficiently filter search results to the most relevant information for an assessment.

Second, the IRIS Program is tailoring assessments to program and regional office needs, called fit-for-purpose assessments. IRIS officials said the idea is that instead of producing a wide-ranging assessment, the program can produce assessments that are more limited in scope and targeted to specific program and regional office needs, reducing the amount of time IRIS staff need to search for information; synthesize it; and draft, review, and issue an assessment. The program began employing this model in 2017.

Third, the IRIS Program is streamlining the peer review process as much as possible. EPA guidelines require peer review of all IRIS assessments. Smaller, less complex assessments may be peer reviewed through a contractor-led letter review or panel; more complex assessments are usually reviewed by a full Scientific Advisory Board or a NAS panel, though IRIS leadership determines the most appropriate method of peer review based on Office of Management and Budget and EPA Peer Review Handbook guidelines. IRIS officials said that as they try to produce more fit-for-purpose assessments that are smaller in scope, they plan to utilize letter reviews, as appropriate, to streamline the peer review process.

## The IRIS Program Has Made Changes to Address Lack of Transparency

As detailed in our report, another major category of NAS recommendations that the IRIS Program has addressed is the need for greater transparency in how the program conducts assessments. In response, the IRIS Program has in the past several years implemented systematic review and increased outreach efforts with stakeholders and the public.

The IRIS Program began addressing the need for greater transparency by implementing systematic review as a basis for every assessment and has been doing so for several years. By using systematic review, the IRIS Program can demonstrate that it considered all available literature in forming conclusions and deriving toxicity values. Utilizing the new

software tools described above allows program staff to search more widely than before and to identify the most relevant results faster and more accurately.

The IRIS Program also furthered transparency by increasing the frequency, structure, and content of communications with EPA program and regional offices about overall program priorities and individual assessments. When new leadership joined the IRIS Program in early 2017, they began reaching out to individual program and regional offices to reconfirm their needs and priorities. IRIS officials said this effort was in part to ensure that the IRIS Program was delivering what the program offices needed, as well as to help the IRIS Program keep its priorities up to date and ensure that resources (primarily staff) were aligned with EPA-wide priorities.

Since 2013, the IRIS Program has released preliminary assessment materials—including IRIS Assessment Plans and assessment protocols—so that EPA and interagency stakeholders and the public could be aware of scoping and problem formulation for each assessment. Since 2017, according to EPA, these documents have had a new structure and better demonstrate the application of systematic review, and they continue to convey EPA's need for each assessment and frame questions specific to each assessment. Officials in several program and regional offices that use IRIS assessments told us that the release of IRIS Assessment Plans and protocols was very helpful because it allowed them to offer early input to the IRIS Program about the scope of an assessment, when it could affect the direction of the assessment.

## EPA Leadership Deliberations Delayed Progress on Producing Assessments

EPA made progress in early 2018 on assessments in development. However, the release of documents related to IRIS assessments was delayed for nearly 6 months because EPA leadership instructed the IRIS Program not to release any assessment documentation pending the outcome of EPA leadership deliberations concerning IRIS Program priorities.

### The Program Made Progress in Early 2018 on Assessments in Development

During calendar year 2018, the IRIS Program planned to release documents or hold meetings for 15 of the 23 ongoing chemical assessments in development, as well as for the IRIS Handbook and a template for assessment protocols. From January through May 2018, the IRIS Program met each of its internal deadlines for work on nine different

chemical assessments and released the template for assessment protocols for agency review.

## IRIS Program Assessment Production Was Delayed by EPA Leadership Deliberations about Priorities

As we described in our report, EPA leadership deliberations about the program's priorities that took place from June through December 2018 delayed the program's assessment production. IRIS officials told us that in early June 2018, EPA leadership in ORD informed them that the IRIS Program could not release an assessment without a formal request for that assessment from the current leadership of a program office.[10] At the request of the EPA Administrator, IRIS officials prepared a survey of program and regional offices, asking them to reconfirm their needs for 20 assessments that were in development.[11] This survey was sent by memorandum in August 2018. Program office responses were to be signed by the Assistant Administrator of each program office to ensure that the reconfirmations were consistent with the priorities of EPA program office leadership.[12] While survey responses were being compiled, EPA leadership in ORD instructed the IRIS Program not to publicly release any assessment documentation. As a result, any assessment or subsidiary assessment document (e.g., an IRIS Assessment Plan or protocol) that was ready for agency review, public comment, or peer review was unable to proceed through the IRIS assessment development process.

According to documents we reviewed, by mid-September 2018, several program offices had submitted responses to the survey to ORD. Three program offices confirmed their needs for the majority of chemicals on the survey list: the Office of Water confirmed needs for 15 of 20, the Office of Land and Emergency Management confirmed needs for all 20 chemicals,

[10]For example, IRIS officials said that the IRIS Assessment Plan for naphthalene had been ready for release since May 25, 2018, but EPA leadership in ORD refused to sign off on the release because no other EPA leadership in program offices had formally requested the assessment. The IRIS Assessment Plan for naphthalene was eventually released for public comment on July 5, 2018. Additionally, a May 2018 statement prepared by the program outlining changes to the program's workflow and an updated list of assessments in development was not approved by EPA leadership in ORD for posting to the IRIS website because current EPA leadership in program and regional offices had not formally requested these assessments.

[11]The survey did not include two assessments, ethyl tertiary butyl ether (ETBE) and tert-butyl alcohol (TBA), because they were out for public comment and external peer review.

[12]Regional offices were told that their submissions would be included as part of a program office request.

and the Office of Children's Health Protection confirmed needs for 18 of 20 chemicals. The Office of Policy also emailed ORD to add its concurrence with the list of ongoing assessments. The Office of Chemical Safety and Pollution Prevention did not confirm needs for any of the 20 chemicals but did nominate nine new chemicals. The Office of Air and Radiation did not submit a reply to ORD.

In late October 2018, prior to releasing results of the initial program and regional office survey, EPA leadership in ORD made a second request of program offices for a prioritized list of assessments. According to officials from the IRIS office, who were queried for advice by officials from some program offices, ORD's second request was made verbally at a meeting and included direction to the program offices to limit their requests to no more than three to four chemicals. ORD's request did not provide information on the basis for selecting priorities or the reason for the limit of three or four chemical assessments from the original survey submissions. The calls for advice from program office officials represented the first time the IRIS Program heard about the requests for a prioritized list, according to IRIS program officials. Furthermore, since neither the program and regional offices nor the IRIS Program had information from the EPA Administrator's office about what the prioritization was meant to achieve, the IRIS Program was unable to provide guidance about which chemicals might be considered a priority or how many the program might be able to continue work on.

When EPA leadership completed its deliberations about the program's priorities, it issued a memorandum on December 4, 2018, that listed 11 chemical assessments that the IRIS Program would develop. This was a reduction of the program's workflow from 22 assessments, but the memorandum announcing the reduced workflow gave no reason for the reduction. The memorandum accompanying the list of 11 chemicals gave no indication of when more assessments could be requested or if IRIS's workflow would remain at 11 chemicals for the foreseeable future. According to the memorandum, the 11 chemicals were requested by two EPA program offices (the Office of Water and the Office of Land and Emergency Management). We received this memorandum at the end of our review and did not have the opportunity to review the prioritization process that led to its drafting.

Two weeks after the issuance of the memorandum, the IRIS Program publicly issued a program outlook, which included two additional

assessments that were not included in the memorandum for a total of 13 assessments.[13] The two assessments, ethyl tertiary butyl ether (ETBE) and tert-butyl alcohol (TBA), were not included in the memorandum because they were out for public comment and external peer review. Furthermore, four assessments that were in the later stages of development but had not yet been issued were not included in the 13 assessments listed in the December 2018 Outlook. The four assessments were: acrylonitrile, n-Butyl alcohol, formaldehyde,[14] and polycyclic aromatic hydrocarbon. The absence of these four assessments from the December 2018 Outlook could create confusion for stakeholders interested in them. EPA provided no information on the status of these four assessments or whether it planned to discontinue working on them or restart them at another time. As we have previously reported, an overarching factor that affects EPA's ability to complete IRIS assessments in a timely manner is that once a delay in the assessment process occurs, work that has been completed can become outdated, necessitating rework throughout some or all of the assessment process.[15] Thus, it remains to be seen when these assessments can be expected to move to the next step in the IRIS process or be completed. From June through December 2018, the IRIS Program was unable to release any work while it waited for feedback from the Administrator's office regarding whether its assessment workflow was consistent with agency priorities.

The thirteen assessments that were included in the December 2018 Outlook and their statuses as of December 19, 2018 were:

- **External Peer review:** ETBE and TBA.
- **Draft Development:** arsenic, inorganic; chromium VI; polychlorinated biphenyls (PCBs; noncancer); perfluorononanoic acid (PFNA); perfluorobutanoic acid (PFBA); perfluorohexanoic acid (PFHxA);

[13]For more information on the assessments released in the IRIS 2018 IRIS Program Outlook, see: https://www.epa.gov/iris/iris-program-outlook.

[14]As we have previously reported, EPA began an IRIS assessment of formaldehyde in 1997 because the existing assessment was determined to be outdated. Formaldehyde is a colorless, flammable, strong-smelling gas used to manufacture building materials, such as pressed wood products, and is used in many household products, including paper, pharmaceuticals, and leather goods. See GAO-08-440.

[15]GAO-08-440.

perfluorohexane sulfonate (PFHxS); and perfluorodecanoic acid (PFDA).[16]

- **Scoping and Problem Formulation:** Mercury salts; methylmercury; vanadium and compounds.

IRIS officials told us that staff continued whatever draft development work that they could do internally, but several IRIS staff had been working increasingly for a single office responsible for risk management—the Office of Pollution Prevention and Toxics (OPPT)—to support its work preparing risk evaluations under the Toxic Substances Control Act (TSCA), as amended.[17] ORD reported to us that in September 2018—3 months after IRIS assessments were stopped from being released because of ongoing EPA leadership deliberations—five of approximately 30 IRIS staff were supporting OPPT with 25 to 50 percent of their time. In October 2018—4 months after IRIS assessments were stopped from being released—28 of approximately 30 IRIS staff were supporting OPPT with 25 to 50 percent of their time. According to IRIS officials, this was occurring primarily because OPPT has a significant amount of work to do to meet its statutory deadlines, and OPPT needed IRIS staff expertise to help meet those deadlines.

As we reported, EPA's proposed budget cuts have caused IRIS officials concerns about whether they will have sufficient resources to expand assessment work in the future. For example, over the past 3 years, EPA's budget justification for human health risk assessment work, of which IRIS's budget makes up about half, was reduced to about $22 million from its fiscal year 2017 budget of $40.5 million. This led, in part to a decrease in the rating for leadership commitment for the IRIS Program from met in our February 2017 High-Risk Report to partially met in our March 2019 High-Risk Report.[18] In February 2017, we reported that the EPA Administrator demonstrated leadership commitment to the IRIS

[16]PFNA, PFBA, PFHxA, PFHxS and PFDA are members of a class of man-made chemicals known as PFAS—a groups that also includes PFOS, PFOA, GenX, and many others.

[17]In 2016, Congress enacted the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA to expand EPA's authority and responsibility related to regulating toxic chemicals, and established specific deadlines to promulgate new rules, conduct risk evaluations for existing chemicals, and review and make determinations on new chemical submissions, among other responsibilities. For more information on EPA's implementation of TSCA, see GAO-19-270.

[18]GAO-17-317 and GAO-19-157SP.

Program by identifying action on toxics and chemical safety as one of her top seven priorities for the agency—priorities that included the IRIS Program. However, current EPA leadership has not made a similar statement and has proposed significant cuts to the program's budget. Congress did not support these reductions.

Chairwomen Sherrill and Fletcher, Ranking Members Norman and Marshall, and Members of the Subcommittees, this completes our prepared statement. We would be pleased to respond to any questions that you may have at this time.

## GAO Contacts and Staff Acknowledgments

If you or your staff have any questions about information in this testimony or the related report, please contact J. Alfredo Gómez, Director, Natural Resources and Environment, at (202) 512-3841 or gomezj@gao.gov. Key contributors to this statement include Diane Raynes (Assistant Director), Summer Lingard-Smith (Analyst-in-Charge), and Alisa Carrigan. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony.

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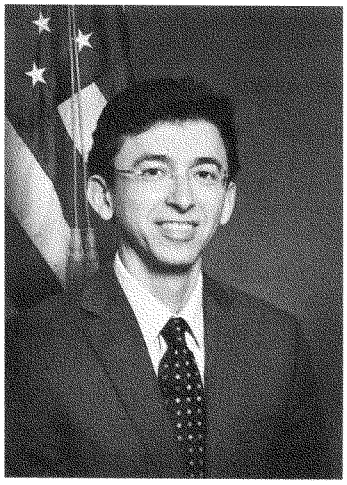

J. Alfredo Gómez serves as a Director in the Natural Resources and Environment team of the U.S. Government Accountability Office (GAO). He manages the team's work in environmental protection issues. His portfolio includes work in cleanup of hazardous substances, drinking and clean water issues, ecosystem restoration, pesticides, toxic chemicals, climate change, and EPA-wide management issues. Mr. Gómez has produced numerous reports and testimonies addressing a wide range of environmental, natural resource, agency management, and food safety issues. Mr. Gómez began his GAO career in the Chicago Regional Office in 1991, working on environmental protection issues. He left GAO to work for the Honolulu City Council where he audited local government agencies, and subsequently returned to GAO in 1998. Mr. Gómez holds a bachelor's degree in Chemical Engineering from Rice University and a master's degree in Public Policy Studies from the University of Chicago.

Chairwoman SHERRILL. Thank you, Mr. Gomez.

At this point we will begin our first round of questions. The Chair recognizes herself for 5 minutes.

First of all, Mr. Gomez, I want to commend you and your colleagues at the GAO on your thorough and meticulous work in the report that was published on March 4. The Subcommittee appreciates your efforts to help us better understand the status of the IRIS Program.

Can you summarize the GAO's findings regarding the recent EPA's leadership decisions that hindered IRIS' ability to complete its toxicity assessments?

Mr. GOMEZ. Maybe I can just provide another summary of the—as our audit documented, the steps. As I mentioned earlier, it started in August with ORD sending out a survey to all of the program offices to reconfirm whether the 20 ongoing assessments were still needed. And so offices then responded to that. In fact, there were three offices, program offices, that responded that they needed the majority of those assessments. In fact, it was the Office of Land and Emergency Management which requested that all 20 of those chemical assessments were needed. The Office of Water requested 15 of those, and the Office of Children's Health Protection requested 18. Also, the Office of Policy did confirm all of them.

And as I also noted, then in October the—sorry, there was then—there was then a request in mid-October, a second time, for offices to reprioritize and to further reduce the number of assessments to three or four.

Chairwoman SHERRILL. And so you had mentioned also in releasing the reports that I believe it was August—it was in 2018. A new policy came out that you had to ask leadership to release the reports or get authorization——

Mr. GOMEZ. Yes, so essentially before an IRIS assessment could be issued, it had to be requested by an Assistant Administrator or even if you needed an assessment, that it needed to be at that level.

Chairwoman SHERRILL. OK. And before that, how did it work?

Mr. GOMEZ. The IRIS officials, the offices would just work with the program offices at EPA and ask them what——

Chairwoman SHERRILL. Determine——

Mr. GOMEZ [continuing]. They needed.

Chairwoman SHERRILL. And then we've been talking a bit about the 2011 National Academies' review of IRIS' draft formaldehyde assessment, and it identified areas for IRIS to improve. Much has changed since then, so can you also—and you spoke a little bit about timeliness and transparency, but can you also provide an overview of the progress that IRIS has made since 2011 in improving its assessment process?

Mr. GOMEZ. Sure. So that's also something that we discussed in our High Risk update report where we lay out the areas in which—and I think it's been mentioned by a number of the Members of the Committee already that there are a number of areas in the IRIS Program where there have been improvements in terms of them using systematic review, in terms of them trying to improve the timeliness process, and so there have been a variety of areas that we covered in terms of building the capacity of the program, mak-

ing sure that they have an action plan in place. And so those are the areas that we highlight, and we gave the program a rating of partially met in all of those areas because we do see a lot of progress. And, as has been noted, this is a program that historically has taken a long time to do chemical assessments, and so we see that there's a lot of improvement that's been taking place.

Chairwoman SHERRILL. And yet now some of the timeliness problems are because leadership is holding up the ability to release the assessments?

Mr. GOMEZ. So, as we noted in our report, in that 6-month period, there was a delay while these deliberations were taking place, and so that's what we were calling attention to.

Chairwoman SHERRILL. And finally, can you detail the IRIS staff reassignments in support of the Toxic Substances Control Act that occurred in October 2018?

Mr. GOMEZ. Sure. So as we noted in the report and as I noted in my statement, there—EPA directed 28 of their 30 IRIS staff to support implementation of TSCA, and they were providing anywhere from 25 to 50 percent of their time.

Chairwoman SHERRILL. Thank you very much.

I will now recognize Mr. Norman for 5 minutes.

Mr. NORMAN. Thank you, Chairwoman Sherrill.

In the 2014 report, the National Academy of Sciences specifically recommended that EPA finalize and release a handbook that outlines the IRIS assessment evaluation process. This recommendation was reiterated in 2018. The NAS evaluation of IRIS which stated that the EPA would complete the handbook in 2018.

Mr. Gomez, in preparing the recent reports, was the GAO provided a copy of the IRIS handbook?

Mr. GOMEZ. Yes, we have it. It's a draft copy because it has not been finalized yet. And that is something that we are also tracking, and so we've been looking to see when EPA is going to release that.

Mr. NORMAN. OK. Dr. Orme-Zavaleta, have you reviewed the IRIS handbook?

Dr. ORME-ZAVALETA. And please feel free to call me Jennifer.

Mr. NORMAN. I'll call you doctor.

Dr. ORME-ZAVALETA. I know my name's a mouthful. So we have a draft IRIS handbook that has gone through Agency review; it was initiated last summer. We received comments all the way through to December. We had our 5-week hiatus with the shutdown. We are still in the process of addressing some of the comments that came in and will continue to work toward completing that document.

Mr. NORMAN. When will it be ready for publication in your opinion?

Dr. ORME-ZAVALETA. So we're—conversations with some of the commenters are still ongoing. Some of the questions are not as easily identified, and in my opinion was going to extend into a broader conversation across the Agency, so we'll have to see how we can complete the document. And for those issues that need further work, what will be the process for addressing those.

Mr. NORMAN. Can you identify this morning what the hold up is exactly, and I guess when it will be completed with where you are, where you see it?

Dr. ORME-ZAVALETA. So some of the conversation is around how we evaluate hazard and how we identify or categorize areas of hazard, and these are conversations that involve more than one office, and so this is something that I'm looking to engage other parts of the Agency through our risk assessment forum to address whether that holds up this document or not. I think that's something that we still have to determine. So my hope is that we complete this soon, but this is a process that we are continuing. I've raised with the Administrator, and hopefully, we'll have a path forward on how to address.

Mr. NORMAN. Well, I mean, in my world—I mean, I'm a real estate developer. I look on a handbook as a blueprint to go by on projects. If you don't have a handbook, you really can't move forward. And the excuses I've heard—am I right? It hasn't been completed in 8 years?

Dr. ORME-ZAVALETA. What hasn't been completed in 8 years?

Mr. NORMAN. The handbook.

Dr. ORME-ZAVALETA. So I don't know when the handbook was initiated. I came into this role over this past year. But elements of the handbook are being captured in some of our systematic review protocols, and those documents are moving forward. So the document we just released last week on hexavalent chromium incorporates elements of that handbook. So we are utilizing that blueprint, and we're able to move forward on our assessments. The particular handbook is an internal guide for us, and just completion of that is something that we're still working through comments.

Mr. NORMAN. But it's very important to have the handbook——

Dr. ORME-ZAVALETA. Absolutely.

Mr. NORMAN [continuing]. As a guide so you can adequately move forward.

Dr. ORME-ZAVALETA. And we are utilizing that internally and running it through our assessment so that we keep those assessments moving.

Mr. NORMAN. Thank you. Mr. Gomez, the GAO has reviewed the IRIS Program over many years and multiple Administrations. In the GAO's review of the IRIS Program, has it found that the IRIS Program has regularly produced timely assessments for you all?

Mr. GOMEZ. No, sir. One of the findings is that it takes a long time, many years, to produce assessments, and so, as has been noted and discussed, we and the National Academies have made recommendations to improve the timeliness of those assessments.

Mr. NORMAN. Well, with that, then, do you think the IRIS Program should remain high on the GAO's High-Risk List?

Mr. GOMEZ. So we—we have it on a High-Risk List because we do see that it needs improvement to produce those assessments that are needed by other EPA program offices and folks outside of EPA, so until we see demonstrated progress in the program, it's going to remain on the list, yes.

Mr. NORMAN. Well, I would stress the importance of getting it in. In my world we're on penalties if we don't make something in a timely response. I can't just say to our tenants, you know, we're trying. It gives you an ending and a beginning date. Eight years to me is out of the question. Thank you all so much.

Chairwoman SHERRILL. Thank you. I now recognize Chairwoman Fletcher for 5 minutes.

Mrs. FLETCHER. Thank you, Madam Chairwoman. Thank you to the witnesses this morning. Your testimony has been helpful.

My first question is directed at Dr. Orme-Zavaleta. According to the EPA, the role of the Office of Science Advisor, or OSA, is to provide leadership on science and technology issues and policy to facilitate the integration of the highest quality science into the Agency's policies and decisions. As the current acting EPA Science Advisor can you discuss the OSA's role in EPA's strengthening transparency in regulatory science proposed rule? Was the OSA consulted during the drafting of this proposed rule before it was submitted to the Federal Register?

Dr. ORME-ZAVALETA. So the answer to that is no. The science—the STPC (Science and Technology Policy Council) was given a briefing once the proposal was out and has been aware of the next steps. The Agency received a number of comments. We're still going through and synthesizing those comments, and then we'll determine our next steps forward.

Mrs. FLETCHER. OK. And on a related note, the EPA ostensibly bases its environmental and public health protection regulations on robust science. How often do you engage with regulatory program offices within the Agency and provide scientific input on new regulatory actions? For example, how often are you consulted on the Agency's deregulatory actions?

Dr. ORME-ZAVALETA. So the—in the regulatory process, the Agency establishes an ADP (Action Development Process) workgroup, which is a—I don't remember the specific acronym, but it engages representatives across the Agency and is overseen by the lead office with the particular regulatory action. So our office and our staff are engaged when they have these workgroups formed and working through the different regulatory efforts.

Mrs. FLETCHER. How often do you meet with Administrator Wheeler to provide scientific input into decisionmaking at the highest levels of the EPA?

Dr. ORME-ZAVALETA. So I have a regular monthly meeting with the Administrator. I also see him weekly for—he meets with our—the senior leadership across the Agency. And then if there are specific rulemaking activities or issues to be addressed and there will be a meeting convened for briefing and either I or my staff will be involved in those discussions.

Mrs. FLETCHER. And how often did you or your predecessor meet with Administrator Pruitt for the same purpose?

Dr. ORME-ZAVALETA. So less. Each Administrator has their own style and approach, and with Administrator Pruitt he participated in senior staff meetings periodically, but I did not have an opportunity to meet with him as a representative of ORD.

Mrs. FLETCHER. Thank you, Dr. Orme-Zavaleta.

One other question relating to the GAO report is the GAO found that by October 2018 that more than 90 percent of IRIS staff were spending up to half their time supporting risk evaluation under TSCA, is that correct? And so——

Mr. GOMEZ. That is correct, yes.

Mrs. FLETCHER. OK. So, Dr. Orme-Zavaleta, since Congress has clearly expressed its intent that the IRIS Program remain within ORD, how could EPA justify diverting staff hired for the sake of implementing IRIS to other program offices within the Agency?

Dr. ORME-ZAVALETA. So just to be clear, the staff remained in ORD, and within the Agency, ORD is a partner with a number of our program offices working through different scientific issues, whether it's helping with implementation of TSCA or working with the Office of Water on some of their science issues or OLEM (Office of Land and Emergency Management) or others. So we take a one-EPA approach in leveraging the expertise and experience across the Agency for the different types of scientific disciplines. Some offices may not have as many types of scientists that ORD has, and so we work with them collaboratively in trying to sort through these different issues.

Mrs. FLETCHER. OK. And I want to follow up on one other question that one of my colleagues asked about the publication of the IRIS handbook. I know that we've already discussed it a little bit, but can you give us any insight into what has caused the delays in its publication?

Dr. ORME-ZAVALETA. So, again, we submitted the handbook for Agency review toward the end of last summer. We had comments come in through the course of the fall, some as late as December, and then with the shutdown that set us behind, so we are doing catch up and we are working through some of the issues that have been raised.

Mrs. FLETCHER. OK. Thank you. I yield back the remainder of my time.

Chairwoman SHERRILL. Thank you. The Chair now recognizes Representative Biggs.

Mr. BIGGS. Thank you, Madam Chair, and thank you, panelists, for being here today.

I think it's no secret to anybody who's watched my performance on this Committee that I've been a longtime critic of the IRIS Program. In the last Congress, while serving as the Chairman of the Environment Subcommittee, I sponsored legislation to effectively eliminate IRIS in its current form and return chemical assessments to the appropriate program offices of EPA. That bill, the *Improving Science in Chemical Assessments Act*, was voted out of the full SST Committee last July. I've reintroduced this bill the current Congress, but I doubt for some reason that it'll be reported out of this Committee again anytime soon. And I'm disappointed with that of course, that the chemical assessments process at EPA has not received a complete structural overhaul despite years' and years' worth of criticism and observations by the NAS and GAO.

That said, apparently, there have been few glimmers of hope at EPA over the last couple of years, and I'm happy about that, but clearly, there are at least some high-level officials at the Agency who generally believe that: One, chemical assessments should rely on good, transparent, publicly available science, and that's true. And two, chemical assessments should be carefully tailored to serve program and regional office needs, and I'm happy about that.

And I want to hear more from your perspective, Mr. Gomez. The most recent GAO report on the IRIS Program reiterates yet again

that EPA should develop an action plan that, among other reforms, places primary responsibility for chemical assessments in the relevant program offices. Is that a fair characterization?

Mr. GOMEZ. No, sir.

Mr. BIGGS. Please state how would you characterize it?

Mr. GOMEZ. So, the way IRIS came about, it was because there were many different program offices doing their own chemical assessments, sometimes different values were generated, and so this was an effort to centralize and to come up with Agency consensus on these assessments. And I'm sure that Jennifer can also talk about that history and evolution of the IRIS Program. So that is our understanding of it.

And our reports on the High-Risk List on IRIS are looking to improve the IRIS Program to make it more timely, to make it more transparent, as you said, so that it is using the best available studies that are out there, and it's going through the proper levels of review both internal and external peer review.

Mr. BIGGS. Well, can you explain why the EPA leadership has been criticized for beginning to do what GAO has been requesting?

Mr. GOMEZ. So and—again, in our current report we focus on—we do talk about the progress that EPA is making, which we've been chatting about, but we also talk about other challenges that the program is facing. And so we were drawing attention to the delays in issuing the assessments. As we've said, these assessments take a long time, sometimes years to do, so that's what we've been focusing on. And there is a lot of progress, and we do note that in the ratings that we do for the IRIS Program, but yet there's still challenges ahead.

Mr. BIGGS. Well, one of the interesting pieces of testimony that I'm taking from this today, is this notion of the handbook, the handbook that may have been ordered 8 years ago, recommended 8 years ago, certainly recommended 4 years ago, and yet I think it just takes a lot of moxie to come in here today and say, well, the reason we don't have this done is because we had a 35-day government shutdown this year. That's incredible moxie and doesn't get at the heart of this, but I think it does get at the heart of what the ultimate problem with IRIS is, and that is a bogged-down bureaucratic system that needs to be streamlined and fixed. And I hope that you take that into consideration. It's meant as positive feedback. I hope that it's criticism that requires and produces some real self-evaluation because I'm still disappointed at the IRIS Program, and I'm disappointed at the almost glacial pace that we see in change in that program.

I yield back.

Chairwoman SHERRILL. Thank you. I'd now like to recognize Representative Bonamici for 5 minutes.

Ms. BONAMICI. Thank you very much. Thanks to the Chairs and Ranking Members and to our witnesses.

The Environmental Protection Agency should rely on the best available independent science to inform Federal policy, and the EPA mandate is to protect public health and the environment, and that can only be achieved if the EPA is acting on the basis of science that's independently verifiable and free from political influ-

ence, bias from ideology and conflicts of interest, and that certainly includes credible assessments of the risks posed by chemicals.

And I've been on this Committee for about 7 years now and of course have sat in many hearings, as have many of my colleagues, about IRIS over the years. There's no question that there is a need for improvement, but what I am hearing today and what I am seeing in the recent GAO report I do not consider improvement.

The EPA's Integrated Risk Management System, or IRIS, remains distinct from the regulatory programs of the EPA intentionally. It's striking that the EPA would consider moving away from the robust science and preventing IRIS from disclosing its findings to the public. Continued efforts to sideline science from the policymaking process at the EPA will have chilling consequences for every person in this country who benefits from clean air and water and particularly and disproportionately young children, seniors, and the health-impaired.

Mr. Gomez, in the March 4 GAO report entitled "Chemical Assessment Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act," it outlines that in June 2018 EPA leadership in the Office of Research and Development instructed the IRIS Program to not release an assessment without a formal request from the current leadership of a program office. And then ORD instructed the IRIS Program to not publicly release any assessment documentation for public comment, agency, or peer review while the responses to a survey of program and regional offices needs were being compiled. And the list then of that—so it's 20 assessments was then reduced to three or four chemicals. I'm obviously concerned.

David Dunlap, a former Koch Industries lobbyist, now serves as a Deputy Assistant Administrator for Research and Development. These findings of the increased role of ORD in the IRIS assessment processes are very concerning.

So, Mr. Gomez, prior to June 2018, had political leadership at ORD ever limited the release of IRIS assessments?

Mr. GOMEZ. That is not our understanding.

Ms. BONAMICI. Did the GAO find any other changes to the seven-step process that IRIS uses to complete toxicity assessments?

Mr. GOMEZ. No, we are not aware of any changes at this point.

Ms. BONAMICI. Thank you. I want to point out there's just a section in the GAO report, page 25, that talks about the calls for advice from program office officials represented the first time the IRIS Program heard about requests for a prioritized list according to the IRIS Program officials since neither the program and regional offices nor the IRIS Program had information from the Administrator's office about what the prioritization was meant to achieve. The IRIS Program was unable to provide guidance about what chemicals may be considered a priority or how they might be able to continue to work on. And then the reduction with no apparent reason, those things are documented in the GAO report, very concerning.

Dr. Orme-Zavaleta, it's my understanding that you oversaw the August 2018 survey of program and regional office needs for 20 assessments. Did you and any other career staff at ORD and IRIS have any role during the second round of survey in October?

Dr. ORME-ZAVALETA. So once we received some initial responses from the programs in response to the August memo, there was a conversation the Administrator had with his leadership where there was conversation about further prioritizing. There was concern that the number of responses that came back, which was around 50 or so chemical requests, was too large.

Ms. BONAMICI. And what was the basis—did—was that explained? What does too large mean?

Dr. ORME-ZAVALETA. I wasn't involved in those discussions, so I can't say.

Ms. BONAMICI. Did you ever see the findings from the first survey, and are they publicly available?

Dr. ORME-ZAVALETA. So I did receive memos from the response of the survey from each of the program offices that responded, so yes, I have those, and I believe GAO received those from some of them.

Ms. BONAMICI. And the second survey from what I can tell from the GAO report was fairly informal, maybe even verbally sent. What factors determine the chemicals that were selected as priorities from the second survey?

Dr. ORME-ZAVALETA. So for the second survey there was a template that was returned back to me that was signed off by the Assistant Administrator for those offices. And, again, they were asked to respond what were their needs, how are they to be used, and when were they needed, and so that was the information that was provided back to me, and that included 11 compounds.

Ms. BONAMICI. My time is expired. I yield back. Thank you, Madam Chair.

Chairwoman SHERRILL. Thank you. And now the Chair yields 5 minutes to Dr. Marshall.

Mr. MARSHALL. Thank you so much, Chairwoman.

I think all my questions are directed to Dr. Orme-Zavaleta, so thank you so much for being here. Does IRIS assessment include any consideration of actual human exposure or making any determination of actual human risk?

Dr. ORME-ZAVALETA. So the—as noted earlier, the IRIS Program involves the first two steps of the risk assessment process, so it focuses on hazard and then dose response. That provides that scientific foundation, which then moves to a program office, and their program offices will apply other statutory considerations for the programs they implement that include exposure and risk characterization.

Mr. MARSHALL. I would suppose when you were doing your studies—you have four or five studies going at a time on one particular substance?

Dr. ORME-ZAVALETA. So in looking at hazard and dose response, we look at all available literature that is available for that particular chemical, and that can include animal information, human information. This is where our systematic review process comes into play where it helps to organize and synthesize that——

Mr. MARSHALL. What do you do when there's conflicting data, which I see all the time as a physician. I'll see 20 studies on a particular issue and there's usually lots of conflict between the studies that I'll read.

Dr. ORME-ZAVALETA. There's a lot of conversation, there's a lot of judgment that's employed in going through these evaluations, and that's why it's so critical that we have the levels of review that we have. So as we look through all of the information available in making determinations and judgments about hazard and dose response that forms those toxicity——

Mr. MARSHALL. And do you share with others, here's the studies we looked at and this is why we chose this one over that one——

Dr. ORME-ZAVALETA. Yes.

Mr. MARSHALL [continuing]. So that's a transparent process?

Dr. ORME-ZAVALETA. Absolutely.

Mr. MARSHALL. OK. It looks like to me that sometimes IRIS assessments set levels for a chemical below levels that are found naturally in the environment, which little Kansas common sense to me that doesn't make sense. Do you agree that sometimes you set numbers down that are lower than naturally occurring in the environment?

Dr. ORME-ZAVALETA. So depending on the chemical and what information is available—and so I don't know if you have a specific compound in mind, but we'll look at all of the available information, and that will feed into our dose-response assessments that could give a risk level that incorporates various levels of uncertainty as well.

Mr. MARSHALL. So if we're sitting in this room and we were packed here together and whether it's ethylene oxide or formaldehyde, whichever one it is, if you're setting levels lower than what we measure—do you ever measure what's just commonly occurring in the environment and—it just doesn't make sense to me.

Dr. ORME-ZAVALETA. So the measurement information is not part of the hazard dose-response evaluation. That's what comes in with the program offices in looking at exposure and determining what the final risk assessment will be. Keep in mind IRIS just provides the hazard and dose response and will give us a level—a toxicity level for either a cancer or a noncancer. Then that goes to a program office who will complete the risk assessment process by factoring in exposure and risk characterization information and then moves into that regulatory context.

Mr. MARSHALL. So, you know, as a scientist, do you think it would be OK to set a hazard level lower than what occurs naturally in the environment at times?

Dr. ORME-ZAVALETA. It's going to be data-driven, and it's not going to be done in an ad-hoc way. These assessments go through rigorous review within the Agency, between Federal agencies.

Mr. MARSHALL. Right.

Dr. ORME-ZAVALETA. It opens up for public comment. It goes through a rigorous external peer review. And then, as Mr. Gomez noted, once we come through and incorporate those comments, it goes back through another round of review within the Agency and between agencies.

Mr. MARSHALL. You know, as a physician, I have to take lots of data but eventually have to take some common sense every once in a while as well. When I see a study that just makes no sense at all to me and they come to a conclusion that I do an experiment

on that particular medication or treatment plan with my patients, so I do hope there's some common sense every once in a while.

Are IRIS assessment cancer classifications representative of actual human health risk?

Dr. ORME-ZAVALETA. I'm sorry, can you clarify——

Mr. MARSHALL. Yes.

Dr. ORME-ZAVALETA [continuing]. That again?

Mr. MARSHALL. Yes. Are IRIS assessment cancer classifications representative of actual human health risk?

Dr. ORME-ZAVALETA. So the Agency has cancer risk assessment guidelines, and those were last developed in 2005, and that lays out different levels of carcinogenicity classification based on available information, so—that will include whatever information we have from human data as well as animal data or other supporting data, and those go into those cancer classifications.

Mr. MARSHALL. OK. Thank you. And I yield back.

Chairwoman SHERRILL. Thank you. And now the Chair recognizes Representative Tonko.

Mr. TONKO. Thank you to the Chairs and Ranking Members for an important hearing.

The process—or processes through which science is conducted, reviewed, or communicated to the public and incorporated into policymaking must be transparent. It must be free from inappropriate political, ideological, and financial and other undue influence. We have seen a disturbing trend at EPA lately where science is being sidelined. I'm extremely concerned by the actions that have suppressed information and kept results hidden from the general public. I am also disappointed by recent efforts to hurt the IRIS Program.

The IRIS Program has reviewed hundreds of chemicals and supports programs across our entire Agency. This is an important program that keeps us safe. We should not be gutting it. We should be ensuring that it has the resources and staff to thrive and continue to provide for toxicity information. Instead, some here in Congress and in the Administration want to give an even louder voice to industry interests that would replace unbiased expertise. This would hurt public health and is a dangerous endeavor. EPA's priority must be to protect public health and our environment.

So, Dr. Orme-Zavaleta, according to GAO, the Office of Children's Health Protection, or OCHP, submitted a lengthy set of priority chemicals for the first round of the IRIS survey but did not see any of its priorities reflected in the December program outlook due to its lack of response during the second round. OCHP is a critical EPA office that focuses on the unique vulnerabilities facing children from environmental dangers. Our children's health should always be a priority, top priority for EPA.

So my question is, was OCHP asked to participate in the second round of the IRIS survey along with the other program offices?

Dr. ORME-ZAVALETA. They did receive that information to participate in the second round and in fact did submit their priorities, but it came in after the list and December memo had been finalized. You know, that said, as we noted in our process, an office can identify or nominate a new assessment need at any time, and we'll have another formal round of requests coming later this summer.

Mr. TONKO. Can you explain the timing? And was it a coincidence that OCHP submitted its list precisely when it was too late to include them?

Dr. ORME-ZAVALETA. So I was not involved in the further, the second phase of that prioritization process. I'm not aware of what particular timeframe was identified. Again, I was informed of here was the list and then I released memos and——

Mr. TONKO. But there was no—no one shared a prior history with you about——

Dr. ORME-ZAVALETA. I was not involved in those conversations.

Mr. TONKO. What chemicals did OCHP include on its second round priority list of three to four chemicals? And was formaldehyde one of those chemicals?

Dr. ORME-ZAVALETA. I believe formaldehyde was one of those chemicals, but we can get back with you. I don't recall the full list.

Mr. TONKO. And does ORD consider the protection of children's health a priority? And if so, why did it not make more of an effort to include OCHP's request in the final list of IRIS chemicals?

Dr. ORME-ZAVALETA. So we consider—so we are a supplier of science to the Agency's programs that use that information, and so as far as children's health programs, yes, we do consider it vitally important, and we help to sponsor some research at the children's health centers, along with NIEHS. Again, with the particular process I was not involved in that and did not receive the final input until early December.

Mr. TONKO. Can you imagine how they could have made more of an effort to include OCHP's request?

Dr. ORME-ZAVALETA. I think that's something that we can think about going forward.

Mr. TONKO. But nothing constructive that you would offer this panel today?

Dr. ORME-ZAVALETA. No, not at this point.

Mr. TONKO. Mr. Gomez, GAO's findings reveal a disturbing level of political interference with IRIS. If political appointees inside EPA are excluding the EPA career staff from key decisions, it raises a host of concerns about whether those appointees can be trusted to do the right thing for IRIS and the public. Was GAO able to determine who inside EPA made the decision to conduct a second round of the IRIS priority survey? And who decided to limit that round to three to four chemicals per program office?

Mr. GOMEZ. So that's something we do not have clear information on, so as we reported it was our understanding that something was done early to limit them, but we don't know. What we do know, though, is that we do have responses from some of the offices that did submit it in the second round saying these are our three and four chemicals.

Mr. TONKO. OK. I am out of time, so I will yield back, Madam Chair.

Chairwoman SHERRILL. Thank you. The Chair now recognizes Representative Bird—Baird, sorry.

Mr. BAIRD. Thank you, Madam Chair. I appreciate the witnesses being here today.

My question really goes to Dr. Orme-Zavaleta, and that has to do with the fact that Mr. Gomez mentioned a seven-step process for

chemical assessment development recognition, and so in that process there's a draft of IRIS assessments, and they're circulated internal to the EPA and to the region for review. So how are those comments and concerns resolved? And then once they've been submitted for review, then how do they resolve those concerns and questions?

Dr. ORME-ZAVALETA. So the IRIS Program has regular communications with program and regional representatives. I think they may meet even monthly. And as comments and questions come in, there are conversations with the full group to sort through and resolve those particular comments, and then that moves onto the next phase.

Mr. BAIRD. So I guess you're saying as those come in, if they're valid and reviewed, then they are incorporated in with the process and——

Dr. ORME-ZAVALETA. And there is a conversation between the IRIS staff and the program representatives, as well as regional representatives on addressing those comments.

Mr. BAIRD. A second part of that question, I understand the interagency science review formally was coordinated by the OMB (Office of Management and Budget), but how is that review currently coordinated?

Dr. ORME-ZAVALETA. The interagency science review process was revised in 2009 to be entirely managed and coordinated by EPA. OMB is a participant in the interagency science review process, along with other agencies and White House offices.

Mr. BAIRD. OMB? OK. Mr. Gomez, I have a couple of questions for you. It was noted that the IRIS officials have implemented systematic review. Do we have any current documentation that would suggest guidance on how this systematic review takes place on this process?

Mr. GOMEZ. So—and this is also something that Dr. Orme-Zavaleta can elaborate on. But systematic review is something that's been in place in EPA for a while. They have started also to use the software that allows them actually to do this faster. So, yes, we are aware that this is something that the IRIS Program is using. It is something that—that's good. In fact, I think maybe on your second panel there's someone that is even an expert on systematic review or knows a lot more about it.

Mr. BAIRD. Thank you. One more question in that regard. To your knowledge, what specific IRIS assessments completed since 2014 have demonstrated full of implementation of the EPA IRIS system review process, any idea?

Mr. GOMEZ. So, I'm sorry, you're asking how many have been released and went through the whole process?

Mr. BAIRD. And completed the whole process——

Mr. GOMEZ. Yes.

Mr. BAIRD [continuing]. Since 2014.

Mr. GOMEZ. Perhaps Dr. Orme-Zavaleta might know. I don't think there's been many. I think there was one that was released recently.

Dr. ORME-ZAVALETA. While RDX was released recently (August, 2018) it does not represent full implementation of the IRIS systematic review process. Because the assessment was already in devel-

opment when the 2011 NAS recommendations were released, the final assessment reflects early implementation in the programmatic adoption of the NRC recommendations.

Mr. BAIRD. Thank you, and I yield back my time.

Chairwoman SHERRILL. Thank you, Mr. Baird. The Chair now recognizes Representative McAdams.

Mr. MCADAMS. Thank you, Madam Chair.

I have a question for Dr. Orme-Zavaleta. Press reports and Senate testimony from then-EPA Administrator Scott Pruitt indicate that the IRIS formaldehyde assessment has been ready for public release since 2017, since the end of 2017, and that the assessment establishes a link between formaldehyde exposure and leukemia. Formaldehyde did not appear on the December 2018 list of IRIS priority chemicals, and the GAO report indicated that its future is unknown. So my question is what is the status of the formaldehyde assessment, and when can we expect it to be released for public comment?

Dr. ORME-ZAVALETA. So we do have a draft formaldehyde assessment, and with TSCA recently announcing that formaldehyde is in their top 20, we're going to be having conversations with our Office of Chemical Safety and Inclusion Prevention to determine next steps in going forward. We feel that the assessment that we have will be—will help with that TSCA determination, and we need to determine next steps for supporting the other Agency needs.

Mr. MCADAMS. So along those lines, why was the formaldehyde—why was formaldehyde left off the list of—the new list of IRIS priority chemicals, and who made that decision to leave it off?

Dr. ORME-ZAVALETA. So each program office made their decisions on what were their priorities, how they were going to use it, and when they needed it, and so I wasn't involved in those conversations. Again, the programs help provide the priorities, and then our responsibility is implementing those priorities and providing the best science available.

Mr. MCADAMS. So who would've made the decision to not include formaldehyde on that list?

Dr. ORME-ZAVALETA. So that was through the program offices, and the requests that I received were signed off at the Assistant Administrator level.

Mr. MCADAMS. So—and just last week EPA announced that it would designate formaldehyde a high-priority chemical under the Toxic Substances Control Act. How can formaldehyde be simultaneously a high-priority chemical under TSCA and not a priority at all for IRIS?

Dr. ORME-ZAVALETA. So I wouldn't say that it's not a priority for IRIS. We have not discontinued that work, and that information is going to be leveraged in helping to support TSCA moving forward, but there's going to be more conversations to follow on our next steps.

Mr. MCADAMS. Thank you. One question for Mr. Gomez. Can you explain what you meant when you wrote in your testimony that the absence of the formaldehyde assessment, quote, "could create confusion for stakeholders?"

Mr. GOMEZ. Right, so I think that there are stakeholders that were expecting to see that assessment and may in fact have use

for it, and so now that it's not on the final list, I think there are questions about what happened to it, as you were asking, and where—when is it going to be released.

Mr. MCADAMS. All right. Thank you. I yield back.

Chairwoman SHERRILL. Thank you, Mr. McAdams. Now, the Chair recognizes Representative Babin.

Mr. BABIN. Sure, thank you. Thank you, Madam Chair.

Mr. Gomez, in your review of the IRIS Program, you rely in part on the 2018 NAS report to find that the IRIS Program has made significant progress. This 2018 NAS review was simply, if I understand it, a check-the-box exercise organized by career program officials confirming that changes have been made to the program. In other words, the NAS review did not examine any IRIS products to ensure proper scientific rigor. It did not identify any tangible outcomes as a result of the changes made to the program. Did GAO identify any of these shortcomings after using the 2018 NAS review as a primary source for praise of the program?

Mr. GOMEZ. So perhaps what I can do is just explain the approach that we take in looking at the progress that the IRIS Program is making. So while we do look at other reports that are out there like the NAS study that you mentioned, we're looking at a couple of criteria, so we're looking at whether there is leadership commitment, you know, does the program have the capacity to do the work, do they have a plan in place to do the work, are they monitoring how well they're doing, and are they also demonstrating progress? So we look at all of those elements to then come up with a rating, and for the IRIS Program in particular, as we've been discussing, they have made some progress, so we are giving them the rating of partially met, so they're not fully met, and that is why it's still on the High-Risk List for GAO, and we're continuing to look at it.

But we are concerned, as others, about the length of time that it takes to issue these assessments, and so timeliness is an area that has a lot of attention.

Mr. BABIN. OK. Thank you. And then, Dr. Orme-Zavaleta, I see the Administration has taken steps to prioritize chemicals for assessment in the IRIS Program. Would you classify this as a positive step for IRIS?

Dr. ORME-ZAVALETA. I do. I think we have always gone out to programs in helping to identify what their needs are, but this new process raises it to the Assistant Administrator level, and that's going to help provide greater stability to the program, as well as greater accountability not only to the program offices and reminding them that they made this request but also in helping us in meeting those particular requests.

Mr. BABIN. OK. Thank you, and I yield back, Madam Chair.

Chairwoman SHERRILL. Thank you. The Chair now recognizes Representative Beyer.

Mr. BEYER. Thank you, Madam Chair.

Mr. Gomez, one of the main concerns I have reading the GAO report is that, you know, the IRIS, which we've talked about for many years on this Committee, is just far too important to allow chemical assessments to be decided by anything short of a trans-

parent, collaborative process that listens to the voices of the career staff.

So in reading the GAO report, you talked about how the ORD's second request is made verbally at a meeting, including direction to the program offices to limit their request to no more than three to four chemicals. Did ORD explain to you why it was appropriate to do this directive verbally and with no prior consultation and not through a documented process?

Mr. GOMEZ. No, sir, we don't have any additional information as to any additional guidance that was provided as to how they should further limit those assessments.

Mr. BEYER. OK. And then, Dr. Orme-Zavaleta, I know you've read all this carefully. Does it make any sense to you that ORD proceeded to a second round of the survey with no involvement from IRIS leadership?

Dr. ORME-ZAVALETA. So the conversation that took place was a meeting that the Administrator has weekly with his senior leadership, the Assistant Administrators, and so I was not there, I was not involved in that particular conversation. I don't know how the request was made. I don't know the conversation that ensued.

Mr. BEYER. Mr.—thank you. Mr. Gomez, did GAO—you know, we talked a lot about how the shrinking from 22 subject chemicals down to 11, and this is part of the prioritization process. Was there any evidence that IRIS was incapable of handling the previous largest—larger workflow?

Mr. GOMEZ. As we understand it, the IRIS Program was able to handle that workload given their current resources.

Mr. BEYER. And we certainly heard from—based on the questions from any of the other people on the panel that there were chemicals left out of that.

Dr. Orme-Zavaleta, and again, I know this wasn't in your decisionmaking, but when did ORD decide to reduce the number of priority chemicals by so much? And, you know, one of the criticisms again that shows up in the GAO report was there was—there's no information at the EPA Administrator's office about what the prioritization was meant to achieve.

Dr. ORME-ZAVALETA. So, again, I wasn't involved in that conversation. I don't know that it was requested by the ORD representative or by the Administrator.

Mr. BEYER. You know, the suspicious part of me wonders if the prioritization wasn't simply used as a way to eliminate chemicals that are controversial within industry and focus on ones that are easy, low-hanging fruit, for example, formaldehyde, which raises the prospect that this is not science driving it but rather politics and money, so——

Dr. ORME-ZAVALETA. So, again, I wasn't there, but if you'd like further information, we can go back to staff and respond back.

Mr. BEYER. OK. Great. Thank you very much. Mr.—Madam Chair, I yield back.

Chairwoman SHERRILL. Thank you. The Chair now recognizes Dr. Foster.

Mr. FOSTER. Thank you. I appreciate it, and I appreciate being allowed to serve on this—in this hearing, although I don't actually serve on the Committee.

I'd like to bring up the issue of ethylene oxide. Willowbrook, Illinois, in my district is home to a sterilization facility that's used ethylene oxide for decades to sterilize medical equipment. And this community has unfortunately become an example of the important role that the EPA plays in defending public health and what can happen when these systems don't do as well as they should.

In the case of ethylene oxide, there was roughly a 15-year gap between the publication of scientific papers that indicated ethylene oxide was a far more powerful carcinogen than had previously been assumed and the corrective actions and eventual shutdown of that facility in my district that was venting apparently unsafe amounts of ethylene oxide into nearby neighborhoods.

And I request unanimous consent to insert into the record the Executive Summary of the EPA's Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide into the record.

Chairwoman SHERRILL. Without objection.

Mr. FOSTER. Thank you. And so Dr.—oh, boy—Orme-Zavaleta——

Dr. ORME-ZAVALETA. Jennifer.

Mr. FOSTER. Jennifer, you know, what would the reasons have been for a 15-year delay in the scientific findings and the actual actions? You know, are these things limited by just a shortage of manpower? You've got tens of thousands of chemicals and you have to prioritize your effort and you just don't have enough people on this, or is this a situation where there's a lot of pressure from industry that's delaying—causing a 15-year delay of this kind?

Dr. ORME-ZAVALETA. Yes, so I'm not exactly clear on—you're thinking of the timeframe. IRIS provided an assessment for ethylene oxide in 2016.

Mr. FOSTER. Correct. And all the references in that were scientific papers dating from the late 1990s, early 2000s.

Dr. ORME-ZAVALETA. So, you know, I think that that's something I can take back to staff and we can get further information on how additional information can be incorporated, but the assessment that was published in 2016 went through—it's a very complex chemical, a lot of intricacies in trying to evaluate those risks.

Mr. FOSTER. Simple chemical but with complex biological effects.

Dr. ORME-ZAVALETA. There you go. And so in going through the reviews, it went through two rounds of review with our Scientific Advisory Board, which is not always common, but a very rigorous, thorough review, as well as reviewed through the different Federal agencies and within EPA, so it's a very solid assessment, and it's one that we continue to support, and that's part of our responsibility——

Mr. FOSTER. I understand. It just would have been nice if it would have been faster——

Dr. ORME-ZAVALETA. Yes.

Mr. FOSTER [continuing]. Than 15 years. And I was just wondering if this is a—I guess the point of my question is if this is a manpower-limited thing, then I think there is an argument to be made to just increase the manpower available so this situation doesn't happen because you can mess up either way. You know, there are people panicked selling their houses, and if it turns out the best scientific indications are that is unnecessary, then, you

know, mistakes have been made in that direction. And of course there's the danger of damage to human health.

And so if you could actually have a look at that specific case and see to what extent if you had—were not manpower limited——

Dr. ORME-ZAVALETA. Yes, we'll be glad to follow up.

Mr. FOSTER [continuing]. Whether—what that timescale could have been compressed to be.

Dr. ORME-ZAVALETA. Sure.

Mr. FOSTER. And also if you could come up with a best estimate of the number of people, you know, who will—you know, assuming that the report stays valid, a best estimate of the number of people, additional cancer cases nationwide due to that delay and particularly the avoidable part that might be avoided with more investment in manpower.

And just more generally does the EPA or any third party maintain estimates of the cumulative number of lives saved by EPA actions?

Dr. ORME-ZAVALETA. So I think that's something I'll also have to follow up on. There are evaluations that are not necessarily conducted within ORD but other parts of the agency that looks at impact analyses, and so that's something we can follow up on.

Mr. FOSTER. Yes. It would be a very good thing to do. Also, the cumulative costs because your actions impose costs on industry, and they save human lives, and seeing those two numbers side-by-side, both cumulatively and for specific actions, I think would clarify a lot of the thinking that—and certainly we tend to talk past each other when we are only looking at one side of it in this Committee in the past——

Dr. ORME-ZAVALETA. OK.

Mr. FOSTER [continuing]. And that would allow you of course to look at the number of lives saved per dollar of cost, which is a very tough thing to talk about in politics, but really, you know, that's I think one of the lenses that we have to look at this through. And particularly in cases where the actions are delayed because of manpower limitations that might allow us to think about whether an investment here—to quantify whether an investment in increased manpower would save a, you know, roughly quantifiable number of human lives. So if you do get back with those. And if it turns out that you don't have those estimates, come up with a scope of a congressional request to get those numbers reported. I think it would clarify our thinking greatly.

And thank you. I see my time is up, and I yield back.

Chairwoman SHERRILL. Well, thank you very much. Thank you to Dr. Orme-Zavaleta and Mr. Gomez for your testimony today. We'll now have a short break while we seat our next panel of witnesses. Thank you, everyone.

[Recess.]

Chairwoman SHERRILL. Welcome back. At this time I would like to introduce our second panel of witnesses. Dr. Bernard D. Goldstein is a Professor Emeritus and Dean Emeritus at the University of Pittsburgh, Graduate School of Public Health; Dr. Ivan Rusyn, a Professor with the Department of Veterinary Integrative Biosciences at Texas A&M University, and the Chair for the Inter-

disciplinary Faculty of Toxicology. He also serves as the Director of the Texas A&M Superfund Research Center.

Dr. Julie E. Goodman is a principal at Gradient, an environmental and risk sciences consulting firm with a focus on workplace and environmental chemicals.

And our final witness, Ms. Wilma Subra. Ms. Subra is the Founder and President of Subra Company, Inc., an environmental consulting firm in New Iberia, Louisiana. She also serves as a Technical Advisor to the Louisiana Environmental Action Network.

Dr. Goldstein, you are recognized for 5 minutes.

**TESTIMONY OF DR. BERNARD D. GOLDSTEIN, PROFESSOR EMERITUS AND DEAN EMERITUS, UNIVERSITY OF PITTSBURGH GRADUATE SCHOOL OF PUBLIC HEALTH**

Dr. GOLDSTEIN. Chairwoman Sherrill, Chairwoman Fletcher, and distinguished committee Members, I appreciate the opportunity to speak in front of this Committee again. To keep the time, I will focus on the core principles of why IRIS was developed and its relevance to today. It's not just my age that permits me to look back this far. I was Assistant Administrator for Research and Development appointed by President Reagan working under Administrators Ruckelshaus and Lee Thomas as IRIS was under development.

My conclusion regrettably is that rather than streamlining, disemboweling is really what is happening here. We are destroying the current long-term scientific basis for how EPA functions. My background is detailed in my written testimony. I want to emphasize that through the years, I've worked closely with industry. In my current consultant work in toxic tort cases I have about equally an expert defending an industry as I am an expert for the plaintiff side suing the industry, and it depends upon the facts of the case.

So why was IRIS developed? In 1983, soon after the NAS Red Book was released, I became EPA's Assistant Administrator for Research and Development. First, generally not known now, but EPA was already doing risk assessments. The problem was that the silo structure that characterized the EPA then and now made risk assessments a shambles. Now, this will occur again if assessments are removed from EPA's science offices to program offices. Different default assumptions were a key issue.

Administrator Ruckelshaus recognized that for risk assessment to be useful, it needed to be sufficiently standardized and transparent so that, in his words, it would not be like beating a spy to get whatever answer you wanted. External transparent peer review is recognized as being crucial.

And yet another reason for centralized ORD-led approaches, which I haven't heard discussed, is the obvious budgetary consequences because risk became—assumed a major role in assigning agency priorities. The program offices might want to increase the risk for air as opposed to water or water as opposed to air if, in fact, they are the ones allowed to have a say in what the basic approaches were.

Subsequently, other important roles for IRIS have been recognized. The local purposes, which I'm glad to hear both Chairwomen describe—I recently had a paper—a document from the Allegheny

County Health Department responding to a concern of local community, gentrifying community about some old industries there. It relied heavily on the IRIS process. It relied heavily on IRIS numbers, which were duplicated in this document.

There's also a need to be responsive to national concerns that in a sense help us with world trade issues. We have something that's recognized worldwide in IRIS. If we politicize it, we will no longer be able to look back and expect other countries to use it because it'll be seen as a politicized effort rather than the science that it now is.

And we need a centralized science—we need a centralized IRIS within ORD to decide whether and how to incorporate new science. And there is much new science related to hazard, related to dose response that has to be incorporated.

It should be clear, Administrator Wheeler's decision to cut IRIS' budget, withhold its assessments from peer review, and move the formaldehyde issue is quite a contradiction of these founding principles.

So let me conclude by saying that I have the deepest respect for Dr. Orme-Zavaleta—and I do call her Jennifer. I think she's doing really extremely well under the circumstances. But as the appointee of President Reagan confirmed by the U.S. Senate, I would have resigned had Administrator Ruckelshaus or Administrator Thomas tried to do the things that are happening now.

I cannot recommend that the current AA of ORD resign; there is none, nor in the third year of this Administration even are rumors to whose name might be sent to the Senate. And it is unlikely that any reputable scientist would accept such a nomination.

I would welcome answering questions about my overall written testimony, including transparency, about which I have previously testified in front of this Committee and about formaldehyde, which, as a hematologist and toxicologist, I've long been involved with. Thank you.

[The prepared statement of Dr. Goldstein follows:]

# Disemboweling is not the Same as Streamlining:
# Administrator Wheeler's Attack on EPA's IRIS Program

**Presentation to the Joint Hearing**

**of the**

**Subcommittee on Investigations & Oversight**

**and the**

**Subcommittee on Environment**

**of the**

**House Committee on Science, Space and Technology**

**"EPA's IRIS Program: reviewing its Progress and Roadblocks Ahead"**

**March 27, 2019**

**Bernard D. Goldstein, MD**

**Professor Emeritus**

**University of Pittsburgh Graduate School of Public Health***
**bdgold@pitt.edu**

*For identification purposes only

Chairwoman Sherrill, Chairwoman Fletcher, Committee Members

I am Bernard Goldstein MD, Professor Emeritus and Dean Emeritus of the University of Pittsburgh Graduate School of Public Health. In my testimony today I plan to focus on why IRIS was developed and on the specific issue of formaldehyde. I also will briefly put the IRIS issue in the context of other issues related to science at EPA

I began my involvement in environmental protection in 1966-68 as a Commissioned Officer in the US Public Health Service Division of Air Pollution, an organization that in 1970 was moved by President Nixon into the newly formed EPA.

My relevant background includes in 1983-85 serving as President Reagan's appointee as EPA Assistant Administrator for Research and Development, confirmed by the US Senate. I served under EPA Administrators William Ruckelshaus and Lee Thomas. I had previously been appointed under Administrator Anne Gorsuch to be head of the Clean Air Scientific Advisory Committee. I am also an elected member of the National Academy of Medicine and of the American Society for Clinical Investigation, and am Past President and Fellow of the Society for Risk Analysis. In relation to formaldehyde leukemogenesis, I began my medical career as a specialist in hematology, have performed research on leukemogenesis and have taken care of patients with leukemia. I have been board certified in both Hematology and in Toxicology. I have also served as a voting expert member of working groups on two occasions when the leukemogenesis of formaldehyde was considered by the World Health Organization's International Agency for Research on Cancer (IARC).

Through the years I have worked closely with industry. Examples include service on the Board of the Chemical Industry Institute for Toxicology and of the International Life Science Institute (ILSI), including ILSI's Risk Science Institute; receipt of research funding or donations to our programs in New Jersey from the American Petroleum Institute and a variety of chemical and petrochemical companies; and service on industry-based committees or on other committees which have active industry representatives. In my consultant work in toxic tort cases, depending upon the facts of the case I have about equally been an expert defending an industry as I have been an expert on the plaintiff's side suing industry.

My relationship with industry has not always been smooth. For example, our research funding from the American Petroleum Institute on benzene was not continued after we concluded that benzene was a cause of human leukemia; funding was also cut to our center in New Jersey because of our findings on the gasoline additive MTBE; and I resigned from ILSI because of actions that I disagreed with. However, I maintain great respect for the scientific and technical skills of the US chemical and petrochemical industry in general, and the ability of some individual companies to appropriately couple scientific advances with protection of the public, and to consider issues such as sustainability.

What I plan to tell you today is based on more than half a century of highly active involvement in issues related to the scientific basis for environmental protection. I have seen many ups and downs in American industry's willingness to subsume their interests in immediate profits to the goal of appropriate use of science in environmental decision making – which in the long term is in their best interests. There is no question that today we are at the lowest point ever since the formation of EPA. There can no longer be any doubt that EPA's leadership, at the behest of large portions of the American chemical, petrochemical and fossil fuel industries, is out to destroy EPA's carefully developed consensus processes to insure that science contributes its appropriate share to providing the most effective and

most efficient regulation of the American environment permitted under our laws. While I previously held out hope that EPA leadership would not be captured by its rhetoric, its current actions related to CASAC and to IRIS go well beyond my worst fears.

**Why IRIS was developed**

I arrived at EPA in 1983 soon after the NAS Red Book had laid out the principles that led to standardization of risk assessment. EPA was already doing risk assessments, as was FDA and other federal agencies. In fact, many of the principles on which risk assessment is built came originally from EPA, particularly its Carcinogen Assessment Group, and from FDA. But the silo structure that characterized EPA then, and still persists, made risk assessment at EPA in 1983 a shambles. As examples, each silo had different default assumptions that were used in extrapolating from animals to humans, or from high doses to low doses. This led to unacceptable differences in the risk assessments for the same chemical depending upon which part of the agency was regulating it. (Note that some differences are appropriate, e.g., based on different toxicokinetics due to different routes of exposure). We spent much effort, with the help of the external scientific community and the National Academies of Science, to address the appropriate default assumptions to be used – a process that needs to continue as newer toxicological and epidemiological methods are developed.

A related issue greatly concerned Administrator Ruckelshaus. For risk assessment to be useful, it needed to be sufficiently standardized and transparent so that, as in his words, it would not be like beating a spy to get whatever answer you wanted.

Yet another reason for a centralized ORD-led approach to risk assessment is that risk plays a major role in assigning agency priorities. As budget follows priority ranking for regulatory activities, questions might be raised as to the rationale for inconsistencies

We recognized another very important role for IRIS, one that is often overlooked inside the Beltway. I am reasonably certain, with no data, that by far the most frequent use of IRIS is for local purposes. A recent example in my experience is responding to a gentrifying community within Pittsburgh concerned about whether emissions from some of the older industrial plants are causing adverse health effects. Pressure from community groups led local authorities to perform fenceline measurements of chromium, manganese and lead. The report of the Allegheny County Health Department describing the measured levels leans heavily on comparison with IRIS data, including direct copies of risk factor tables from IRIS. Other uses by local authorities include deciding on how to advise a community after a buried drum of chemicals is discovered in an empty lot. This is a recommendation that is best given quickly without leaving the neighbors in limbo while health concerns increase and their property values go down. The current decrease in funding of IRIS to evaluate additional chemicals is not at all responsive to local community needs. It contradicts the Trump Administration's focus on having Washington serve states and local areas, as well as contradicting Congressional direction.

IRIS is also important to another area of great emphasis by President Trump. IRIS is currently respected and accepted throughout the world, as I have observed in my work in Southeast Asia and in the EU. Having a standardized approach recognized as authoritative world-wide helps protect US trade products from being unfairly treated through other countries developing biased ad hoc approaches to risk.

Destroying the reputation of IRIS as being independent of the political process does not help the administration's goal of reducing trade barriers.

It seemed obvious then, as it is still obvious now, that there is more than ample justification for a standardized transparent approach to risk analysis useful to help moving forward decisions about regulation at the national and local levels. Further, to achieve this goal it is necessary to have a science-based organizational structure that can independently assess the scientific literature pertinent to risk, using appropriate external peer reviews. This is what we set out to do in forming IRIS under Administrators Ruckelshaus and Thomas. Administrator Wheeler's decision to move the formaldehyde issue from IRIS to the TSCA staff is a compete contradiction of the founding principles of IRIS that have sustained this organization as a world authority. This would be true even if understanding the risk of formaldehyde was not pertinent to decisions being made by other program offices under different laws.

**Formaldehyde.**

The formaldehyde saga has become a poster child for the intentional failure of an industry to find out whether its products are causing harm, and to do so by any means at its disposal.

I was an expert voting member of the IARC panel that reviewed formaldehyde in 2006. We voted for formaldehyde to be considered a known human carcinogen based upon causation of nasal cancer. My belief then was that that formaldehyde was unlikely to be a leukemogen, a belief that persisted until shortly before the 2010 IARC meeting which reconsidered the issue.

The reasons for my initial skeptical response to epidemiological evidence linking formaldehyde with leukemia included the observation that bone marrow damage was caused by all other known external causes of leukemia (benzene, ionizing radiation, chemotherapy). But there was then no evidence of formaldehyde producing bone marrow damage.

Just prior to the 2010 IARC meeting which reconsidered formaldehyde, a paper was published showing low blood counts and chromosome abnormalities in Chinese workers exposed to formaldehyde as compared to those working in a factory without formaldehyde (Zhang et al, 2010). The Zhang et al paper was instrumental in swinging the IARC expert vote to in essence calling formaldehyde a known cause of human leukemia. At this 2010 IARC meeting I voted with the minority for the evidence being limited. I did so because the study needed to be repeated. My reasoning on this and other formaldehyde- related issues was detailed in a published paper (Goldstein, 2011) and was directly communicated to the formaldehyde industry. Since then the original authors of the Zhang et al paper have expanded and confirmed their findings, but industry has steadfastly refused to fund such a study in a different formaldehyde-exposed group.

Rather than repeat the Zhang et al study, industry has spent much money on consultants to attack the findings. I do not completely disagree with all of the resulting science. For example, Dr Swenberg and his colleagues have produced convincing evidence that little if any inhaled formaldehyde gets into the blood of rodents. But, as I have pointed out previously, it is only in formaldehyde-exposed humans that there is evidence of chromosomal abnormalities in circulating blood – in rats virtually all the studies of such abnormalities are negative. This suggests the possibility of a species difference that, once again, could be resolved by further studies in formaldehyde-exposed humans which industry has obstinately

refused to support. Further, the issue of species differences is one that has been addressed by IRIS scientists for more than thirty years. It is in IRIS that further understanding and resolution should occur – not in a program office.

My published letter describing the fallacious science in one of the industry consultant-generated papers also contains their reply. Their response claiming that I partially agreed with them is simply an obvious mis-statement of what I wrote, more befitting a legal brief than a scientific response. A more detailed response to Mundt et al by some of the authors of the original paper is at http://cebp.aacrjournals.org/content/27/1/120.long.

I make the point about the legal brief because I believe that a brief summary of what is happening to EPA's use of science is the replacement of processes that lead to obtaining the consensus of the scientific community with confrontational approaches that are more appropriate to law or to politics.

The ACC press release trumpeting Mundt et al is part of the longstanding effort, in which this Committee was previously involved, aimed at obtaining raw data so that paid industry consultants can find blemishes in studies which they can then claim to be scars (https://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/New-Study-Challenges-Formaldehyde-Cancer-Findings.html.) Their claims for transparency are based on the erroneous assumption that EPA is FDA. For FDA regulatory approval of a new drug, the usual requirement is a double blind randomized study in which one half of volunteers with a disease are given a potentially valuable new medication and the other half are given placebo – and neither the patient nor the treating physician is aware of which until the code is broken. This approach cannot be used for testing a pollutant. Would you agree to be randomly chosen to be exposed to a potentially harmful pollutant? Instead, in environmental health for replication we primarily depend on evaluation and synthesis of studies in which different investigators ask the same question in different populations using different methodologies. Instead of doing so, the formaldehyde industry continues to pay consultants to find the potential confounders that are less likely to be present in an FDA double blind placebo study.

I also note that EPA leadership's insistence on full transparency is not consistent with its holding secret the draft IRIS report on formaldehyde

**Why EPA particularly needs strong science-based approaches that are independently reviewed.**

The founding year for EPA and for OSHA was 1970. It is almost as if the US decided to experiment in how it would organize its scientific activities in a regulatory agency. OSHA is led by an Asst. Secretary of Labor. It has a completely separate scientific component, NIOSH, which is administratively light years away from OSHA and is led by someone not subject to Senate confirmation. In contrast, EPA has the Office of Research and Development within its organizational structure. The AA/ORD is intended to be a political appointee at the same level as the Asst Administrators who head policy offices.

EPA clearly has been more successful than OSHA in developing science-based regulations, in part reflecting the close proximity of its scientific arm to program offices, and the more efficient congressional and executive branch oversight that ensures this close working relationship. But an inherent disadvantage of the EPA organizational structure is that the close proximity of ORD allows more pressure to be developed to conform to political objectives. This has led to Congress and to EPA

requiring extensive independent review processes that have evolved over decades. Mr Wheeler's abrupt dismantling of these processes, without any believable problem statement, without test runs and without the extensive consultations inside and outside EPA that have characterized the previous evolution of EPA's science-based processes, is unforgiveable. It changes what had been a relatively successful organizational structure based on the value of proximity between science and policy development into a failure. As a scientist who has been heavily involved in the evolution of this process, I find the current actions of EPA's leadership to be incredibly shortsighted – at best.

**Conclusion**

I begin my concluding remarks by commending EPA's professional scientific career staff leadership of the Office of Research and Development for having stayed the course in these difficult times, despite the need to compromise. I would have resigned as Asst Administrator of ORD had either Administrator Ruckelshaus or Administrator Thomas tried to make the changes now being insisted on by Administrator Wheeler. I cannot recommend that the current AA/ORD resign. There is none, nor in the third year of this administration even a rumor as to whose name might be sent to the Senate. I can understand why Administrator Wheeler does not want a Presidential appointee confirmed by the US Senate to be able to stand up for science at EPA. But he can be reassured that it is unlikely that any reputable scientist would be willing to allow him or herself to be nominated

Administrator Wheeler claims that his goal in changing the IRIS process is to streamline inefficient management practices. Certainly any complex process such as IRIS can be improved, and among many others I also have made suggestions as to how to do it. But it is poor management to choose the most challenging example to experiment with process changes, particularly with a longstanding process that has been so central to environmental progress. The choice of formaldehyde as a test for management changes in IRIS is as inappropriate as the choice of particulates to revise the CASAC process. What the changes in IRIS and in CASAC have in common is the longstanding strong support of major industry groups to counter science-based decisions, irrespective of whether this causes the wholesale disruption of EPA's interface with science. The only reasonable question is whether Mr Weaver recognizes the difference between disemboweling and streamlining. Based upon the evidence to date, I think he does. I think that his goal is to change the consensus processes of science to the confrontational processes central to law and to politics. Madame Chair, with the help of this Committee perhaps this destruction of EPA's science can be prevented.

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Biomarkers Prev 2010;19:80–8.

**BERNARD D. GOLDSTEIN, M.D.**

Dr. Goldstein is Emeritus Professor of Environmental and Occupational Health and Emeritus Dean of the University of Pittsburgh Graduate School of Public Health. He is a physician, board certified in Internal Medicine, Hematology and in Toxicology. He was the founding director of the Rutgers University Environmental and Occupational Health Sciences Institute. He is an elected member of the National Academy of Medicine and of the American Society for Clinical Investigation and has published over 200 papers in scientific journals. His experience includes serving as Assistant Administrator for Research and Development of the U.S. Environmental Protection Agency, 1983-1985. He has chaired more than a dozen National Research Council (NRC) and NAM/IOM committees and has chaired or served on numerous committees for local, national and international organizations, including chairperson of the NIH Toxicology Study Section and EPA's Clean Air Scientific Advisory Committee. He was the initial chair of the National Board of Public Health Examiners, president of the Society for Risk Analysis, and vice-president and editor-in-chief of the Scientific Committee on Problems of the Environment (SCOPE).

Chairwoman SHERRILL. Thank you very much.
Dr. Ivan Rusyn, you are now recognized for 5 minutes.

**TESTIMONY OF DR. IVAN RUSYN,**
**PROFESSOR, DEPARTMENT OF VETERINARY INTEGRATIVE BIOSCIENCES; CHAIR, INTERDISCIPLINARY FACULTY OF TOXICOLOGY; AND DIRECTOR, SUPERFUND RESEARCH CENTER, TEXAS A&M UNIVERSITY**

Dr. RUSYN. Thank you. Chairwoman Sherrill, Chairwoman Fletcher, distinguished Members of the Subcommittees, I'm honored to appear before you today for this hearing.

As a matter of disclosure pertaining to the topic of today's hearing, I'm currently chairing a workshop committee of the National Academies to support development of EPA's IRIS toxicological review. However, I appear before you today representing my own perspectives, not those of the Academies or the Texas A&M University.

I would like to offer insights from my role as a researcher in the field of toxicology and a person with understanding of the process of developing human health assessment in general and those of the IRIS Program in particular. I have more than a decade of service as peer reviewer of various IRIS assessments, including 2011 *Review of the EPA's Draft IRIS Assessment of Formaldehyde*. I also served as a faculty fellow to the IRIS Program for 2 years where I interacted with IRIS staff in a variety of scientific methodological issues directly relevant to implementation of the advice from the National Academies. My laboratory is funded by the NIH (National Institutes of Health), the EPA, the National Academies, California EPA, and the European Petroleum Refineries Association.

With respect to the Committee's interest in the role that IRIS plays in the field of chemical toxicity assessment, I note that it is difficult to overstate the importance of the IRIS Program to the protection of public health in the United States and abroad. Both the National Academies and the EPA themselves acknowledged the key role that IRIS-produced assessments play in many risk management decisions and superfund site cleanup.

IRIS values are relevant for protecting the health and well-being of everyone, not only those who may be exposed in the workplace and not only by a narrow choice of the routes of exposure. As such, IRIS values are held to the highest standard in terms of the quality of their assessments, undergo exhaustive intra-government and external reviews, and the process generates very important and widely used toxicity values and classifications.

With respect to the Committee's interest in the progress IRIS has made addressing recommendations from the National Academies, I note that a 2011 NRC (National Research Council) report: *Review of the EPA's Draft IRIS Assessment of Formaldehyde* offered a roadmap for the overall changes of the process, as well as some specific guidance. And the report did recognize that this process may take time and that EPA is fully capable of implementing suggested improvements, hence no delay in releasing other assessments was recommended.

Two subsequent committees of the National Academies weighed in on the process and progress and have commended the IRIS Program for the work that they're doing. I fully agree with the conclusions of those reports.

Overall, it is my opinion that substantial improvements in the IRIS process have been made in a relatively short period of time, and it is clear that the IRIS Program welcomed the advice it had been receiving from the National Academies and other stakeholders. The IRIS Program fully embraced the concept of systematic review. Systematic review is neither easy, nor it is straightforward, and the IRIS Program is to be commended for their leadership in this area.

Also, a number of strategic decisions were made by IRIS to develop specific guidance documents and further standardize the process. A number of software solutions have been implemented, and investments in staff training and improvements to the interactions with outside stakeholders were made.

It is disconcerting to me, however, that it appears that the IRIS Program lacks the support from the leadership of the EPA in terms of providing it with sufficient financial resources and adequate staffing. It has been stated in the 2019 GAO report discussed this morning that a number of recent events may have grave consequences to the ability of the IRIS Program to continue implementation of the advice from the National Academies to complete their draft assessments and to set further priorities commensurate with the needs of other offices at the EPA and of their other stakeholders. These developments are troubling, and I encourage the Subcommittees to look into the GAO report's facts and conclusions and to determine whether EPA may need to support and strengthen the IRIS Program, as suggested by the National Academies.

In conclusion, it is my opinion that the IRIS Program has implemented the recommendations of the National Academies. The IRIS Program should be supported with adequate financial resources and staff. I also support strengthening the oversight by Congress of the implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Thank you for the opportunity to appear in this hearing, and I'd be happy to answer any questions the Members might have.

[The prepared statement of Dr. Rusyn follows:]

**EPA'S IRIS PROGRAM: REVIEWING ITS PROGRESS AND ROADBLOCKS AHEAD**

Statement of

Ivan Rusyn, MD, PhD

Professor, Department of Veterinary Integrative Biosciences
Chair, Interdisciplinary Faculty of Toxicology
Director, Superfund Research Center
Texas A&M University

before the

Subcommittee on Investigations and Oversight, and Subcommittee on Environment
Committee on Science, Space, and Technology
U.S. House of Representatives

March 27, 2019

Chairwoman Sherrill, Chairwoman Fletcher, distinguished members of the Subcommittees, I am honored to appear before you today for this hearing entitled, "EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead." My name is Ivan Rusyn. I am Professor in the Department of Veterinary Integrative Biosciences, Chair of the Interdisciplinary Faculty of Toxicology and Director of a Superfund Research Center at Texas A&M University.

As a matter of full disclosure pertaining to the topic of today's hearings, I am currently chairing a Workshop Committee of the National Academies of Sciences, Engineering & Medicine to Support Development of EPA's IRIS Toxicological Reviews. However, I appear before you today representing my own perspectives, and not those of the National Academies, or Texas A&M University. I will offer insights from my role as a researcher in the field of toxicology and a person with understanding of the process of developing human health assessments in general, and the IRIS program in particular. I have more than a decade of service as peer reviewer of various IRIS assessments, including *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*, which was released in 2011. I also served as a faculty fellow to the IRIS Program for 2 years where I interacted with IRIS staff on a variety of scientific and methodological issues directly relevant to implementation of the advice from the National Academies. In addition, I reviewed a number of listings in the Report on Carcinogens by the National Toxicology Program, served on the working groups conducting human cancer hazard evaluations at the International Agency for Research on Cancer, and advise several state environmental protection agencies. My laboratory is funded by the National Institutes of Health, the Environmental Protection Agency, the National Academies, California EPA, and the European Petroleum Refiners Association. Of nearly 230 scientific publications that I have co-authored, many include colleagues in academia, government and industry. Therefore, I believe I have a good

understanding of the importance of IRIS, the challenges that this program has, and the progress that it has made in the past decade.

As requested by the Subcommittees, I am here to offer my thoughts on the progress IRIS has made addressing recommendations made by the National Academies, and the role IRIS plays in the field of chemical toxicity assessment. I also would like to use a case example of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde to highlight the challenges that IRIS is facing with timely delivery of its products and the apparent controversies with the division of responsibilities in developing chemical toxicity assessments between the offices within EPA.

**The role IRIS plays in the field of chemical toxicity assessment**

I begin with stating my personal opinions on the role IRIS plays in the field of chemical toxicity assessment. The history of the IRIS program and its goals have been already widely addressed and I will not re-state the well known facts. I do wish to point out the importance of the placement of this program within the Office of Research and Development, independent of the program and regional offices of the EPA. IRIS is responsible for developing toxicologic assessments of environmental chemical contaminants, these assessments contain hazard identifications and dose-response assessments and cover cancer and noncancer outcomes. It is difficult to overstate the importance of the IRIS program to the protection of public health in the United States and abroad.

It was noted by the National Research Council in 2014 that "*although [IRIS] was created to increase consistency among toxicologic assessments within [EPA], other federal agencies, various state and international agencies, and other organizations have come to rely on IRIS assessments*

*for setting regulatory standards, establishing exposure guidelines, and estimating risks to exposed populations.*"[1] The EPA itself acknowledges the key role that IRIS-produced assessments play in many risk management decisions and Superfund site cleanup. EPA OSWER Directive 9285.7-53 states that "*IRIS remains in the first tier of the recommended hierarchy as the generally preferred source of human health toxicity values. IRIS generally contains [toxicity] values that have gone through a peer review and EPA consensus review process. IRIS normally represents the official Agency scientific position regarding the toxicity of the chemicals based on the data available at the time of the review.*"[2]

The process of conducting toxicologic assessments of environmental contaminants by IRIS involves many steps, requires comprehensive and systematic review of all available evidence followed by integration and synthesis of the voluminous information. Draft assessments are subject to public comment and undergo extensive intra-governmental and external peer review. These are among the most scrutinized assessments of the potential hazardous effects of chemicals. The products are toxicity values for health effects resulting from chronic exposure to chemicals and, if the chemical was evaluated for its potential carcinogenicity in humans, a classification with respect to the chemical's potential to pose human cancer hazard. The focus of IRIS is on protecting the human population (including sensitive subgroups) under conditions of continuous inhalation or oral exposure to chemicals; therefore, IRIS values are relevant for protecting the health and wellbeing of everyone, not only those who may be exposed in the workplace, and not

[1] Review of EPA's Integrated Risk Information System (IRIS) Process. Report of the National Research Council. 2014.
[2] OSWER Directive 9285.7-53: Human Health Toxicity Values in Superfund Risk Assessments. December 05, 2003. https://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/EPA-Tox-Criteria-Hierarchy-OSWER-Directive-9285-7-53.pdf

only by a narrow choice of the routes of exposure or conditions of use. As such, IRIS values are broadly applicable in a variety of risk management decisions.

**The progress IRIS has made addressing recommendations from the National Academies**

As of March 22, 2019, the IRIS program lists a total of 482 substances with assessments that derived reference dose (RfD), reference concentration (RfC), drinking water unit risk values, or inhalation unit risk values.[3] The first assessments were completed in 1987 and the most recent assessment was added in 2018. The IRIS database contains a total of 354 substances with an oral non-cancer toxicity value, 159 with an inhalation non-cancer toxicity value, and 265 with at least one of the cancer slope values. There are 22 assessments currently listed by IRIS as "*in development for which draft materials have been released to the public.*"[4] The number of chemicals with an IRIS toxicity value is woefully small as compared to the estimated number of chemicals in the environment; therefore, other parts of the EPA and Federal government, as well as many States, derive similar values for chemicals of concern.

The number of chemicals with new or updated assessments by IRIS has been on a steady decline since the program released a large number of assessments in the late 1980s (Figure 1, data from[3]). It is especially obvious that the number of completed or updated assessments is particularly low since 2011, only 14 assessments have been released in 2012-2019 time period. A slow-down in the rate of assessment completion by IRIS can be due to a number of reasons, one of them is likely a 2011 National Research Council's report *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*. The 15-member committee that produced this report focused

[3] IRIS Advanced Search: https://cfpub.epa.gov/ncea/iris/search/index.cfm
[4] https://cfpub.epa.gov/ncea/iris_drafts/atoz.cfm?list_type=erd

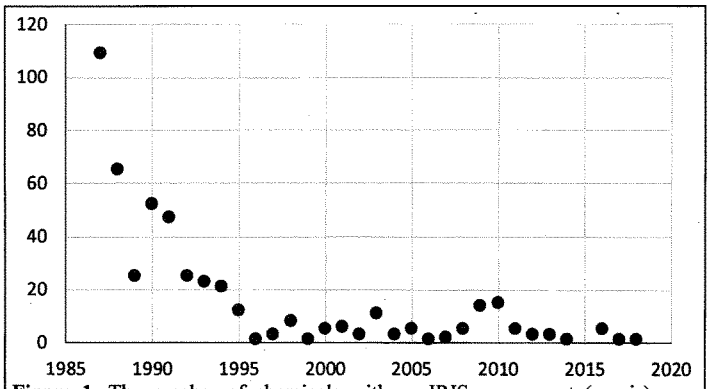


**Figure 1.** The number of chemicals with an IRIS assessment (y-axis) as a function of the year (x-axis) when an assessment was finalized or last revised. Data are from the online IRIS database[3] as of March 22, 2019.

on addressing specific questions related to the derivation of the RfCs for noncancer effects and of unit risk estimates for cancer from exposures to formaldehyde. In addition, the committee assessed the processes underlying the development of the IRIS assessments and made a number of suggestions on how the process can be improved and expedited. The committee identified a number of recurring methodologic problems with how IRIS assessments were developed and presented. Most of the committee's comments were on the general methodology of the assessment and the processes used by EPA to develop IRIS assessments, but not on the IRIS program itself. The committee was concerned with the persistence of the problems, particularly in light of the continued evolution of risk assessment methods and the increasing societal and legislative pressure to evaluate a greater number of chemicals in an expedient manner. The committee offered a roadmap for changes in the overall process and some more specific guidance on the steps of evidence identification, evidence review and evaluation, weight-of-evidence evaluation, selection of studies, and calculation of toxicity values. The committee recognized that

this process may take some time and that the EPA is fully capable of implementing suggested improvements, hence no delay in releasing other assessments was recommended.

Two subsequent committees of the National Academies have weighed in on the progress made by the IRIS program in implementing recommendations and improving the process. As an external peer-reviewer of the 2014 National Research Council's report *Review of EPA's Integrated Risk Information System (IRIS) Process*,[1] I fully agree with the committee's conclusion that "*the changes that EPA has proposed and implemented to various degrees constitute substantial improvements in the IRIS process.*" In 2018, the National Academies issued another report *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation,*[5] which concluded that "*The committee is encouraged by the steps that EPA has taken, which have accelerated during the last year under new leadership. It is clear that EPA has been responsive and has made substantial progress in implementing National Academies recommendations.*" I have read this report and its appendices and fully agree with this conclusion.

Another important reason for why the productivity of IRIS is suffering, in my personal opinion, is the lack of support to this program from the EPA leadership. It is disconcerting to me that it appears that IRIS lacks sufficient financial resources and adequate staffing. As has been stated in the 2019 GAO report[6], there have been a number of recent events that may have grave long-term consequences to the ability of IRIS to continue implementation of the advice from the National Academies, to complete draft assessments, and to set priorities commensurate with the needs of

[5] Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Report of the National Academies of Sciences, Engineering, and Medicine. 2018.
[6] CHEMICAL ASSESSMENTS: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act. GAO-19-270. United States Government Accountability Office. 2019.

the other offices at the EPA and of other stakeholders. These developments are troubling and I encourage the Subcommittees to look into the GAO report's facts and conclusions to determine whether the EPA may need to support and strengthen IRIS, as suggested by the National Academies.

Overall, it is my opinion that substantial improvements in the IRIS process have been made in a relatively short period of time, and it is clear that IRIS welcomed the advice it has been receiving from the National Academies and other stakeholders. IRIS fully embraced the concept of systematic review and has become a leader in creating a process for implementation of the best practices from the systematic review in clinical medicine to environmental health. This process is neither easy, nor it is straightforward and IRIS is to be commended for their leadership. Also, a number of strategic decisions were made by the leadership of NCEA and IRIS to develop specific guidance and further standardize the process of developing the assessments. A number of software solutions have been implemented to streamline the process and facilitate teamwork. Investments in staff training and interactions with outside stakeholders were made, which further increases my personal confidence that the program is on the right track.

**Formaldehyde assessment: A case study of the challenges facing IRIS**

The 2011 National Research Council's report *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde* has hastened the evolution of IRIS, a process that has been implemented with full embrace of the recommendations from several subsequent committees of the National Academies. However, it is worth reminding everyone that the 2011 report did not recommend that EPA delay the revisions and release of the formaldehyde assessment while amendments to the overall approach and process are undertaken. In fact, the

2011 committee provided specific guidance as to the steps needed to revise and finalize the draft that was presented to the Academies in 2010. Not only has the draft assessment been in development for many years before 2010, but also, very regrettably, it remains in draft form still. The formaldehyde IRIS assessment has not yet been released for public comment and moved to completion; to the contrary, some in the EPA appear to be inclined to stop this assessment by IRIS and instead conduct evaluation of formaldehyde under the Toxic Substances Control Act.[7]

Before 2016, the EPA had no mandate to review or assess the safety of chemicals already in commerce as part of TSCA. The Frank R. Lautenberg Chemical Safety for the 21st Century Act does provide that under TSCA, Office of Pollution Prevention and Toxics evaluates and regulates, as appropriate, the full life cycle, i.e., manufacture (import), distribution in commerce, use and disposal, of industrial chemicals, which includes both existing and new industrial chemicals. Therefore, formaldehyde and other existing industrial chemicals can be evaluated under TSCA; however, this evaluation should not duplicate or negate high-quality comprehensive assessments that are ready for completion under the IRIS process. In my personal opinion, the potential transfer of the formaldehyde assessment from IRIS to TSCA is a very troubling development that, at the least, will further delay the release of the assessment and establishment of public health-protective guideline toxicity values for formaldehyde exposure to the general population, including sensitive individuals. Formaldehyde is a known human carcinogen as listed in the Congress-mandated

[7] Initiation of Prioritization Under the Toxic Substances Control Act (TSCA). A Notice by the Environmental Protection Agency on 03/21/2019. 84 FR 10491. https://www.federalregister.gov/documents/2019/03/21/2019-05404/initiation-of-prioritization-under-the-toxic-substances-control-act-tsca

Report on Carcinogens[8] and as concluded by the committee of the National Research Council[9] (for full disclosure I have served as a member of the committee that produced the 2014 report[9]). Therefore, delays in completing the evaluation of this chemical are unacceptable and detrimental to the protection of public health.

**Recommendations**

- The IRIS program has implemented the recommendations of the National Academies, in fact, it is a leader in the evolution of risk assessment practices. Therefore, IRIS should be supported with adequate financial resources and staff.
- While important improvements are being made to the IRIS process, it is important to complete IRIS assessments that are in draft, including formaldehyde assessment, and to increase the number of evaluations that IRIS generates. These changes will need an increase in resources as compared to the current budget. IRIS is vital to public health protection in the United States and abroad.
- Congress shall strengthen oversight of the implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Thank you for the opportunity to appear before the hearing of the United States House of Representatives Committee on Science, Space and Technology Subcommittee on Investigations and Oversight and Subcommittee on Environment. I would be happy to answer any questions the members might have.

[8] NTP (National Toxicology Program). Formaldehyde. Pp. 195-205 in Report on Carcinogens, 12th Ed. U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program, Research Triangle Park, NC. 2011.
[9] Review of the Formaldehyde Assessment in the National Toxicology Program 12th Report on Carcinogens. Report of the National Research Council. 2014.

***Ivan Rusyn*** is Professor in the Department of Veterinary Integrative Biosciences in the College of Veterinary Medicine & Biomedical Sciences, Chair of the Interdisciplinary Faculty of Toxicology, Director of an NIEHS T32 training program in "Regulatory Science in Environmental Health and Toxicology," and Director of the Superfund Research Center at Texas A&M University in College Station. Prior to joining Texas A&M University in 2014, he was Professor of Environmental Sciences and Engineering at the University of North Carolina in Chapel Hill. His laboratory has an active research portfolio with a focus on the mechanisms of chemical toxicity, genetic determinants of susceptibility to toxicant-induced disease and the use of new approach methods in decision-making. His studies on health effects of chemical agents resulted in over 225 peer-reviewed publications which were cited over 16,000 times (*h*-index=65). He has served on many US National Academies committees, World Health Organization/International Agency for Research on Cancer monograph working groups (as an overall chair, or a chair of "Mechanistic and Other Relevant Evidence" sub-group) and on the Expert Taskforce for the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). His other notable service commitments include serving on the Board of the Scientific Councilors of the United States National Institute of Environmental Health Sciences, the advisory board for Texas Department of Public Health, and membership on the Research Committee of the Health Effects Institute. Dr. Rusyn received a doctor of medicine degree from Ukrainian State Medical University in Kyiv and a Ph.D. in toxicology from the University of North Carolina at Chapel Hill. He conducted postdoctoral research at the Massachusetts Institute of Technology and Heinrich-Heine University in Dusseldorf. Dr. Rusyn's laboratory has been funded by grants and cooperative research agreements from the National Institutes of Health and US Environmental Protection Agency, institutional funding from Texas A&M University, the industry, and other sources.

Chairwoman SHERRILL. Thank you very much.
Dr. Goodman, you're now recognized for 5 minutes.

## TESTIMONY OF DR. JULIE E. GOODMAN, PRINCIPAL, GRADIENT

Dr. GOODMAN. Thank you very much for the opportunity to speak today. I am Dr. Julie Goodman, an epidemiologist and board-certified toxicologist at Gradient, an environmental sciences consulting firm. We assist public and private organizations in evaluating the risks of chemicals and other substances to human health and the environment.

I have been developing and applying weight-of-evidence and systematic review methodology for over 10 years in a variety of settings, and I taught a graduate-level class on this topic at Harvard University. Much of my work has been published in the peer-reviewed literature. I'm presenting testimony today as an independent scientist. While my travel costs have been paid by my company, I'm here today on my own time and I am not being compensated for the time I spent preparing this testimony.

As you heard earlier, in 2011, a National Academy of Sciences or NAS committee provided recommendations for the IRIS Program in the context of a review of formaldehyde. In response, EPA released a draft handbook for IRIS assessments in 2013, and then in 2014 and 2018, NAS reviewed and evaluated the IRIS assessment process more generally, including progress made since 2011.

Both the 2011 and 2014 NAS reviews stated that the IRIS Program lacked a clear conceptual framework and clear and transparent methods. Further, NAS concluded that EPA did not fully assess the weight of evidence or justify the selection of studies for the derivation of toxicity values. The 2014 NAS review also specifically called for the finalization of the draft IRIS handbook.

Since that time, EPA has made substantial improvements to the IRIS process, including the development and application of systematic review methods for evidence identification, evaluation, and integration, but not all of the identified issues have been resolved.

To date, EPA has shown progress on a chemical-by-chemical basis using the IRIS Assessment Plans for uranium and ammonia and systematic review protocols for chloroform and chromium assessments as examples of its new portfolio approach. EPA announced it will move forward with a revised handbook, which will be put through peer review and public comment processes this year. This is undoubtedly needed and a critically important step forward, and EPA is to be commended for these actions.

I note that while it is true that a one-size-fits-all protocol for all chemicals is not feasible, and details of the individual chemical assessments will vary based on the specific research questions identified and on the available data, all IRIS assessments will benefit from a clearly written framework that serves as a standard operating procedure, or SOP, for agency systematic reviews. The SOP can be expanded to include chemical-specific tailoring as needed to each phase of specific chemical reviews. An iterative approach can be used to incorporate new issues and knowledge into the SOP as it becomes available.

To follow through on its intention to use systematic review and weight-of-evidence methodology for hazard identification, EPA needs to complete an individual assessment using the new process. My experience with developing these types of approaches has shown that it is important to apply a framework in a chemical-specific setting to determine where its strengths lie and where it falls short and should be revised.

IRIS assessments both identify hazards associated with chemicals and characterize these hazards by generating toxicity values. With regard to the latter, EPA is always limited to studies with sufficient data for dose-response analysis, so the handbook should describe what will be done if these studies are not reflective of the science as a whole.

In addition to studies that identify toxic effects, part of the hazard identification process is to consider studies that inform the mechanism of toxicity. EPA should indicate how it will consider this mechanistic evidence when deriving toxicity values. For example, if mechanistic studies clearly show a threshold effect, then it should be incorporated into the dose-response analysis, and linear low-dose extrapolations should not be applied.

Now, there's no doubt that conducting systematic reviews takes more time and resources than nonsystematic reviews. However, a completed handbook that can and should be revised to reflect the best-available science will go a long way toward expediting assessments and increasing transparency and consistency across assessments. More importantly, with an established standard procedure in place, EPA staff will have better guidance to conduct IRIS assessments in a systematic and unbiased manner. This will allow stakeholders and members of the public to better understand the process and provide input and ultimately will increase their confidence in EPA's assessments.

In conclusion, to address the NAS recommendations for the IRIS Program dating back to 2011, EPA needs to complete a general guidance framework for IRIS assessments and a revised handbook. EPA also needs to complete assessments that both apply this guidance and demonstrate that dose-response analyses and toxicity value derivations will be informed by the overall weight of evidence and biological mechanisms. Thank you very much.

[The prepared statement of Dr. Goodman follows:]

**Testimony at the Subcommittee on Investigations & Oversight and Subcommittee on Environment Hearing – EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead**

**Julie E. Goodman, Ph.D., DABT, FACE, ATS**
**March 27, 2019**

Thank you for the opportunity to speak today. I am Dr. Julie Goodman, an epidemiologist and board-certified toxicologist at Gradient, an environmental sciences consulting firm. We assist public and private organizations in evaluating the risks of chemicals and other substances on human health and the environment. I have been developing and applying weight-of-evidence and systematic review methodology in a variety of settings for over 10 years. I taught a graduate-level class on this topic at Harvard University, and much of my work has been published in the peer-reviewed literature. I am presenting testimony today as an independent scientist. While my travel costs have been paid by my company, I am here today on my own time, and I am not being compensated for the time I spent preparing this testimony.

In 2011, a National Academy of Sciences (NAS) National Research Council (NRC) committee provided recommendations for the US Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Program in the context of a review of the formaldehyde assessment (NRC, 2011). In response, EPA released a Draft Handbook for IRIS Assessments in 2013 (US EPA, 2013). In 2014 and 2018, NAS reviewed and evaluated the IRIS assessment process more generally, including progress made since 2011 (NRC, 2014; NAS, 2018).

Both the 2011 and 2014 NAS reviews stated that the IRIS program lacked a clear conceptual framework and clear and transparent methods. Further, NAS concluded that EPA did not fully assess the weight of evidence or justify the selection of studies for the derivation of toxicity values. The 2014 NAS review also specifically called for the finalization of the draft IRIS Handbook. Since this time, EPA has made substantial improvements to the IRIS process, including the development and application of systematic review methods for evidence identification, evaluation, and integration, but not all of the identified issues have been resolved (NAS, 2018).

To date, EPA has shown progress on a chemical-by-chemical basis, using the IRIS Assessment Plans (IAPs) for uranium and ammonia (US EPA, 2018a,b) and Systematic Review Protocols for the IRIS chloroform and chromium assessments (US EPA, 2018c, 2019) as examples of its new portfolio approach. EPA announced it will move forward with a revised IRIS Handbook, which will be put through peer review and public comment processes this year. This is undoubtedly needed and a critically important step forward, and EPA is to be commended for these actions.

I note that while it is true that a "one-size-fits-all" protocol for all chemicals is not feasible, and details of the individual chemical assessments will vary based on the specific research questions identified and on the available data, all IRIS assessments will benefit from a clearly written framework that serves as a standard operating procedure (SOP) for agency systematic reviews. This SOP can be expanded to include chemical-specific tailoring, as needed, to each phase of specific chemical reviews. An iterative approach can be used to incorporate new issues and knowledge into the SOP as it becomes available.

To follow through on its intention to use systematic review and weight-of-evidence methodology for hazard identification, EPA needs to complete an individual assessment using the new process. My experience with developing these types of approaches has shown that it is important to apply a framework in a chemical-specific setting to determine where its strengths lie and where it falls short and should be revised.

IRIS assessments both identify hazards associated with chemicals and characterize these hazards by generating toxicity values. With regard to the latter, EPA is always limited to studies with sufficient data for dose-response analysis, so the Handbook should describe what will be done if these studies are not reflective of the science as a whole. In addition to studies that identify toxic effects, part of the hazard identification process is to consider studies that inform the mechanism of toxicity. EPA should indicate how it will consider this mechanistic evidence when deriving toxicity values. For example, if mechanistic studies clearly show a threshold effect, then it should be incorporated into the dose-response analysis, and linear low-dose extrapolation should not be applied.

There is no doubt that conducting systematic reviews takes more time and resources than non-systematic reviews. However, a completed Handbook (that can and should be revised to reflect the best available science) will go a long way towards expediting assessments and increasing transparency and consistency across assessments. More importantly, with an established standard procedure in place, EPA staff will have better guidance to conduct IRIS assessments in a systematic and unbiased manner. This will allow stakeholders and members of the public to better understand the process and provide input and, ultimately, will increase their confidence in EPA's assessments.

In conclusion, to address the NAS recommendations for the IRIS Program dating back to 2011, EPA needs to complete a general guidance framework for IRIS assessments in a revised Handbook. EPA also needs to complete assessments that both apply this guidance and demonstrate that dose-response analyses and toxicity value derivations will be informed by the overall weight of evidence and biological mechanisms.

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# Julie E. Goodman, Ph.D., DABT, FACE, ATS

**Principal**

jgoodman@gradientcorp.com


Dr. Goodman is an expert in toxicology and epidemiology, and their application to human health risk assessments. She focuses on substances in consumer products, pharmaceuticals, and medical devices, as well as chemicals in the workplace and the environment. Dr. Goodman is board certified in toxicology, and a fellow of both the American College of Epidemiology and the Academy of Toxicological Sciences. She was also an adjunct faculty member in the Department of Epidemiology at the Harvard T. H. Chan School of Public Health, where she taught a class on meta-analysis for several years. Before joining Gradient, she was a Cancer Prevention Fellow at the National Cancer Institute. Dr. Goodman has authored numerous original peer-reviewed research articles, review articles (including systematic reviews, meta-analyses, and weight-of-evidence evaluations), and book chapters on a wide variety of chemicals and health outcomes. She has presented scientific findings and analyses at scientific and professional conferences, to community groups and regulatory and legislative bodies, and in litigation settings.

## Representative Projects

**Cancer Cluster Analysis:** Investigated whether there was a cancer cluster in residents living near a municipal landfill. Communicated findings to city officials and residents at public meetings.

**Epidemiology Analysis:** Using hospital discharge and air monitoring data, conducted statistical analyses to determine the associations between air pollutants and pediatric asthma hospital admissions.

**Regulatory Comment:** Provided written and oral comments to several agencies and organizations (*e.g.* US EPA, National Toxicology Program) on clinical, epidemiology, toxicity, and mode-of-action studies and their bearing on regulations for pesticides, air pollutants, and other chemicals.

**Post-market Safety Assessment:** Evaluated whether on-label use of a pharmaceutical increased cardiovascular disease risk based on a systematic review of randomized controlled trials and observational epidemiology studies.

**Product Safety Analysis:** Designed and oversaw laboratory studies to determine possible exposures and subsequent toxicity of a chemical in a toy, considering several routes of exposure.

**Systematic Review and Meta-analysis:** Conducted a systematic review and meta-analyses of the herbicide, 2,4-dichlorophenoxyacetic acid (2,4-D), and non-Hodgkin's lymphoma (NHL), gastric cancer, and prostate cancer.

**Medical Device Safety Assessment:** Evaluated the potential health risks of saline-filled breast implants based on a review of the peer-reviewed literature and pre- and post-market studies of silicone- and saline-filled breast implants.

## Areas of Expertise

- Epidemiology
- Toxicology
- Exposure
- Risk Assessment
- Systematic Review
- Product Safety

## Education

Ph.D., Toxicology, Johns Hopkins University

Sc.M., Epidemiology, Johns Hopkins University

S.B., Environmental Engineering, Massachusetts Institute of Technology

Diplomate of the American Board of Toxicology

Fellow of the American College of Epidemiology (FACE)

Fellow of the Academy of Toxicological Sciences (ATS)

## Selected Publications


**Goodman, JE**; Lynch, HN. 2017. "Improving the International Agency for Research on Cancer's consideration of mechanistic evidence." *Toxicol. Appl. Pharmacol.* 319:39-46.

Zu, K; Shi, L; Prueitt, RL; Liu, X; **Goodman, JE**. 2018. "Critical review of long-term ozone exposure and asthma development." *Inhal. Toxicol.* 30(3):99-113.

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Chairwoman SHERRILL. Thank you. Ms. Subra, I now recognize you for 5 minutes.

**TESTIMONY OF WILMA SUBRA,**
**PRESIDENT, SUBRA COMPANY;**
**AND TECHNICAL ADVISOR,**
**LOUISIANA ENVIRONMENTAL ACTION NETWORK**

Ms. SUBRA. Thank you, Madams Chairwomen and distinguished Members of the Subcommittees for the opportunity to testify here today. I have provided technical assistance to community groups throughout the United States and in some foreign countries dealing with environmental and human health issues for more than 52 years.

From the beginning of the publication available through IRIS assessment program, the information provided by IRIS has been extremely valuable in identifying health hazards of chemicals and evaluating exposure situations in the impacted communities. The toxicological information provides a complete evaluation of each chronic pathway of exposure and resulting risk. This information is critical in providing community members accurate and focused exposure and risk information per chemical.

No matter what the situation, impacted community members are never exposed to just a single chemical. Focused on only one chemical or contaminant results in the underestimation of exposure, risk, and associated health. Community members' risk has to be included in all chemicals, all pathways of exposure, and all concentrations in all media in order to adequately identify the risk and develop pathways moving forward.

When we look at the impacts of formaldehyde, formaldehyde is a precursor to many other chemical compounds produced by industrial facilities. In Louisiana, we have 31 major industrial facilities with more than 13 million pounds of formaldehyde being released into the environment each year. In Texas, we have 77 major industrial facilities releasing more than 819,000 pounds of formaldehyde into the environment each year. In the United States, we have 727 major industrial facilities releasing 19 million pounds into the environment.

So an example of some of the communities that have been impacted by formaldehyde, the work I've done, in Natchitoches, Louisiana, there's a plywood mill. The citizens around the facility were very ill. We did air samples to determine that formaldehyde was the major toxic component. We went in and met with the company that was making the plywood and determined that they were using a formaldehyde-based glue or resin. Working with the community and the industry, they changed the kind of resin or glue that they were using, and therefore, the health impacts of the community were much improved.

Then we have a Georgia-Pacific facility in Crossett, Arkansas. It has a pulp mill, it has a paper mill, and it has a chemical mill. The chemical mill actually makes the formaldehyde for use at all three facilities. The citizens complained of two things: Air emissions, odors of hydrogen sulfide, and formaldehyde. Hydrogen sulfide is the most disruptive to their health, but formaldehyde is the most toxic.

Based on all the work with the citizens, we convinced EPA and they brought in the National Enforcement Investigation Center, which identified that the emissions of formaldehyde were being missed by the facility because they were using the wrong kind of detector to do their leak detection and repair. So, as a result of that, they issued them all sorts of violations and then in December of last year there came the penalty notice where they required them to pay $300,000 for each agency, that State agency and the Federal agency. They required them to do $1.2 million in restitution and $1 million over 3 years for supplemental environmental projects. These were all reduced emissions of the toxic chemicals, primarily formaldehyde.

Then we have a self-help group that does housing for disadvantaged people. They were looking at changing to a contractor that build the houses and would put it on their lots. As it turned out, they were using a resin that had formaldehyde in it. We had conversations with them. They declined to change the kind of resin they were using. Therefore, the self-help group no longer even considered having those houses because they didn't want their environmental justice community members exposed.

And then finally, we had the hurricanes of 2005, Katrina and Rita, a huge impact to Louisiana, Mississippi, Alabama, and Texas. And, as a result, we found out by doing sampling with Sierra Club that a large number of people were living in the FEMA (Federal Emergency Management Agency) trailers that were provided that had huge emissions of formaldehyde. We did 32 tests in one set. Thirty exceeded EPA's criteria for formaldehyde, 44 tests and 40 exceeded. As a result of that, 120,000 families were estimated as living in FEMA trailers with formaldehyde over the acceptable level. And in a FEMA trailer, it's an enclosed environment. Emissions into the air, everyone in the families are impacted. And so that was a situation where you did good for the community members but resulted in health impacts to those community members. And a large number of them were children and pregnant females.

[The prepared statement of Ms. Subra follows:]

Testimony of Wilma Subra

President of Subra Company

Technical Advisor, Louisiana Environmental Action Network

Before the House Committee on Science, Space and Technology

Subcommittee on Investigations & Oversight

Subcommittee on Environment

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

March 27, 2019

Thank you Madams Chairwomen and distinguished Members of the Subcommittees for the opportunity to testify today. My name is Wilma Subra. I am President of Subra Company (formed in 1981) and Technical Advisor to Louisiana Environmental Action Network , a non-profit formed in 1986. I have provided technical assistance to community groups throughout the United States and in some foreign countries, dealing with environmental and human health issues, for more than 52 years.

I have served on a number of EPA advisory panels representing the communities perspectives. I served for seven years as Vice-Chair of the Environmental Protection Agency National Advisory Council for Environmental Policy and Technology (NACEPT), five years on the National Advisory Committee of the U. S. Representative to the Commission for Environmental Cooperation and six years on the EPA National Environmental Justice Advisory Council (NEJAC) where I served as co-chair of the Cumulative Risk and Impacts Working Group of the NEJAC Council, and chaired the NEJAC Gulf Coast Hurricanes Work Group. In 2011, I chaired the Environmental Protection Agency Technical Workshop for the Hydraulic Fracturing Study on Chemical and Analytical Methods. I participated in the EPA Shale Technical Roundtables on Water Acquisition, Chemical Mixing, and Well Injection in November 2012. I co-chaired the EPA Shale Analytical Chemical Methods Workshop in February 2013.

The Goal of Louisiana Environmental Action Network is to foster cooperation and communication between individual citizens and corporate and government organizations in an effort to assess and mend the environmental problems in Louisiana. I educate and empower community members to be able to respond to, address and reduce their health hazards, reduce their exposure risk and improve their quality of life.

In the early days of my career of working with impacted communities, there was a lack of technical information available on which to evaluate and base risk, impacts to human health, exposure to toxic chemicals and better information that was mostly not publicly available, nor easily accessible.

From the beginning of the publicly available IRIS assessment program, the information provided by IRIS has been extremely valuable in identifying health hazards of chemicals and evaluating exposure situations in impacted communities.

The toxicology information provided a complete evaluation of each chronic pathway of exposure and resulting risks. This information is critical in providing community members accurate and focused exposure and risk information per chemical.

**Cumulative Risk**

The IRIS assessment information is also available on multiple chemicals and provides necessary exposure pathways and risk on which to evaluate cumulative impacts and risk. No matter what the situation, impacted community members are never exposed to just a single chemical. The community may be impacted by multiple major toxic chemical components and usually a whole host of other chemical contaminants. Focusing on only one contaminant, results in the under estimation of exposure, risk and associated health impacts. This information is critical to identifying methods and procedures to reduce community member exposure and

improve the health of the communities. The IRIS assessments are key to providing all available information and data to inform methods of reducing community members exposure and educate community members with the data they need to have a positive path forward to improve their health and quality of life.

The IRIS assessments provide the information that I need to work with the negatively impacted communities to identify exposure risk and develop methods to reduce their exposure and address and improve their health outcomes.

Toxicology was in its infancy and animal cancer studies were being performed on only a few chemicals when I began working with negatively impacted communities. The progress over the years has provided better more complete data and methods of addressing exposure, risk and reducing risk. IRIS assessments are a very important contribution to that process.

NATA Assessments, based on IRIS assessments, were released on December 2015 for Chloroprene and August 2018 for Ethylene Oxide. The community members living in the zones negatively impacted by industrial facilities releasing these two chemicals into the air are also being exposed to as many as 45 additional chemicals from the same industrial source and/or facilities adjacent to and in the immediate area as the sources of Chloroprene and Ethylene Oxide.

The pathways and quantities of exposure, risk and health impacts based on a single chemical and/or from a single source are severely lacking. Community members risk has to include all chemical, all pathways of exposure, and all concentrations in all media in order to adequately identify the risk and develop pathways forward.

I consistently receive desperate request from communities who are "sick and tired of being sick and are desperately seeking answers to why they are sick and what is causing them to be sick." Various data bases,

environmental, conservation and health agency files provide who and what may be responsible for causing emissions, releases and contaminants to the environment. Once the data is accumulate, the IRIS Assessment data bases are the next critical source to identify pathways of exposure, risk and toxicity. Thus the IRIS data base system is critical to being able to help community members deal with and address their chemical exposure, risk and health issues.

**Denka/DuPont - Chloroprene**

The NATA 2011 Assessment of Chloroprene – released in December 2015, focused on Chloroprene at the DuPont Pontchartrain Works facility, purchased by Denka in November 2015. Chloroprene is and has been released into the air since 1969 (50 years of air emissions of Chloroprene). Based on the IRIS Assessment, a value of 0.2 ug/m3 was recommended. EPA air monitoring at 6 locations around the Denka facility has provided ambient air concentrations since May 2016.

Modeling by Denka has established the extent of air concentrations in excess of 0.2 ug/m3 out from the Denka facility. The area covers the entire parish (County) of St. John the Baptist and beyond.

Census tract data from the 2011 NATA data base included cancer risk for each census tract in St. John the Baptist parish. The highest cancer risk census tracts are the two census tracts on which the Denka facility is located.

Urine samples collected from adults and children in St. John the Baptist Parish identified Chloroprene metabolites in each individual tested.

Based on ambient air concentrations of Chloroprene in the community and the Chloroprene metabolites in the community members urine, a completed pathway of exposure has been demonstrated.

The state of Louisiana Department of Environmental Quality signed an Administrative Order on Consent in January 2017 with Denka for Denka to

install four air emissions control technologies in 2017. Since that time, the ambient air concentrations of Chloroprene have trended downward somewhat, but are still in excess of 0.2 ug/m3 by up to hundreds of times.

Without the IRIS Assessment, the community would have been unaware of their risk, the associated chronic health impacts (cancer of the liver, lungs, kidneys, colon and leukemia) and their continued exposure based on the EPA ambient air monitoring program. Thus the IRIS Assessment provided critical information to the community members in St. John the Baptist Louisiana.

The amount of information constantly being generated has made it necessary for me to conduct community workshops once every two weeks to keep the community members up to date on the ongoing developments.

**Ethylene Oxide**

The NATA 2014 assessment was released in August 2018. Information on the IRIS assessment has been included in the St. John the Baptist workshop community meetings and workshops have been provided to impacted community members in other areas of Louisiana where 11of 13 industrial facilities releasing Ethylene Oxide are located. EPA considers a cancer risk due to Ethylene Oxide over 100 per million individuals a concern. All of the census tracts in St. John the Baptist Parish exceed 100 per 1 million individuals risk.

Once again the IRIS Assessment is critical to providing information to the negatively impacted, primarily Environmental Justice, communities and providing information to community members in other states where Ethylene Oxide is being released into the air.

**Impacts of Formaldehyde Released into the Environment**

Walk into a biology laboratory in high school or a biology building in college and you will immediately be greeted with a very strong distinct pungent odor of Formaldehyde. The gas Formaldehyde is dissolved in water to form formalin and formalin is used to preserve tissue.

Formaldehyde is a precursor to many other chemical compounds produced by industrial facilities. In Louisiana 31 major industrial facilities release more than 13 million pounds of Formaldehyde into the environment each year, and more than 340,000 pounds into the air each year. These industrial facilities consist of petrochemical plants, fertilizer production facilities, pulp and paper mills and plywood mills. The facility in Louisiana releasing the largest quantity of Formaldehyde into the environment is the Monsanto facility in Luling. The facility manufactures pesticides and other agricultural chemicals. It manufactures all the components of Roundup utilized in the United States. The Monsanto facility releases 900pounds of Formaldeyde into the air from fugitive sources and 14,000 pounds of Formaldehyde from stacks sources on a yearly basis. 3,400 pounds of Formaldehyde are discharged into the Mississippi River on an annual basis.

In Texas 77 major industrial facilities release more than 819,000 pounds of Formaldehyde into the environment each year. Of that quantity, more than 416,000 pounds are released into the air. The industrial facilities releasing Formaldehyde consist of petrochemical plants, petroleum refineries, resin manufacturers, waste treatment facilities and medical production facilities.

In the United States, 727 major industrial facilities release more than 19 million pounds of Formaldehyde per year. Of that quantity, more than 4.8 million pounds are released into the air each year. Overall, Louisiana is the largest released of Formaldehyde into the environment in the United States.

The releases of Formaldehyde into the environment from these major industrial facilities and other smaller types of facilities result in community members living on the fence line, in close proximity to and in the vulnerable zone surrounding each of these facilities and being exposed to Formaldehyde as it is continually being released into the environment in which they live.

**Impacts of Formaldehyde Exposure to Impacted Communities**

The following are a few examples of community impacts as a result of Formaldehyde Exposure.

**Natchitoches Plywood Mill**

A plywood mill in Natchitoches, Louisiana was causing the adjacent Environmental Justice community members to have negative health impacts as a result of the operation of the mill. Community members were experiencing eye, nose, throat and skin irritation and severe respiratory impacts. Suspecting potential air emissions from the adjacent plywood mill, air samples were collected and analyzed for Volatile Organic Compounds. One of the major chemicals detected in the air samples were Formaldehyde. Meeting with the plywood mill management, it was determined that the resins used in the plywood process contained Formaldehyde. As part of the manufacturing process, the plywood was heated to cure the resins. The major source of Formaldehyde air emissions was determined to be from that process. The company volunteered to replace the resins with non-Formaldehyde based resins.

As a result of the change in resins, the negative health impacts being experienced by community members was drastically reduced.

**Georgia-Pacific Crossett Arkansas**

Georgia-Pacific had three mills in Crossett, Arkansas. The facilities consisted of a paper mill, chemical plan and plywood plant. The plywood plant has been shut down. The chemical plant manufactured Formaldehyde. The plywood plant, paper mill and chemical plant released Formaldehyde into the air, which caused very negative health impacts to the community members (primarily Environmental Justice members). The community of Crossett (primarily Environmental Justice) is located completely around the Georgia-Pacific facilities on the fence line.

The paper mill also released large quantities of Hydrogen Sulfide into the air and into the waste water treatment system which was located in the Environmental Justice community of West Crossett and added to the communities negative health burdens.

Based on working with members of the Crossett community over many years, their odor complaints always centered around rotten egg/Hydrogen Sulfide and Formaldehyde air emissions and their health symptom corresponded to the acute health impacts associated with Formaldehyde and Hydrogen Sulfide. Air sampling documented the presence of excessive concentrations of Formaldehyde and Hydrogen Sulfide in the air in association with the community odor complaints.

Over the last 20 years, data indicates that the Georgia-Pacific operations in Crossett released more than 876,000 pounds of Formaldehyde into the air. The annual quantities of Formaldehyde ranged from 20,052 pounds per year to 101,330 pounds per year. Over the last three years, the air emissions of Formaldehyde were in the range of 20 to 24.6 thousand pounds per year. The facility no longer manufactures Formaldehyde but continues to receive, store and utilize Formaldehyde in their processes.

Based on the air emissions released from the Georgia-Pacific facilities and the very negative health impacts experienced by the community members, EPA Region 6 requested the National Enforcement Investigations Center (NEIC) to perform a Multimedia Compliance Investigation of the Georgia-Pacific Crossett Paper Operations and Chemicals facility in Crossett, Arkansas.

Both Multimedia Compliance Investigations were performed from **February 3, 2015 through February 12, 2015**, at the respective facilities.

The report of the findings and observations for the Georgia-Pacific Chemicals facility was dated **July 15, 2015** and for the Georgia-Pacific Crossett Paper Operations, **August 14, 2015**.

On **November 9, 2015**, the reports were released to the public.

I compiled a summary of the results for each facility based on:

-**Areas of Concern** – potential problems or activities that could impact the environment or result in future or current noncompliance

-**Areas of Noncompliance**

The regulatory authorities included in the investigations included:

-**Clean Air Act** – Air Emissions

-**Clean Water Act** –Wastewater Discharges

-**Resource Conservation and Recovery Act** – Hazardous materials and Waste. Georgia-Pacific Chemicals and Georgia-Pacific Crossett Paper Operations are both large quantity generator of hazardous waste.

The **Georgia-Pacific Crossett Paper Operations** in Crossett, Arkansas consist of:

-Kraft Pulp Mill

-Bleach Plant

-Processes for hard wood and softwood (pine)

-8 Paper machines

-2 Paper extruding machines

The **Georgia-Pacific Chemicals, LLC** facility in Crossett, Arkansas manufacturing processes consist of:

-Crude tall oil fractionation with resin reaction kettles – no longer in operation

-Liquid resin manufacturing - spray dry resin manufacturing (amine-phenolic resin process)

-Urea formaldehyde process unit – unit idled in September 2012. Formaldehyde is shipped from off site, stored in formaldehyde tanks on site that are vented to regenerative thermal oxidizer (RTO)

**Air Emissions from Georgia-Pacific Crossett Paper Operations**

Georgia-Pacific states there are no gases from any affected portion of the Kraft pulp mill in excess of 5 ppm total reduced sulfur being discharged into the atmosphere. However, the inspectors observed visible defects where gases were released to the atmosphere from the capper valves on five batch digesters and from brown stock washers.

Brown stock washers from the pine and hardwood pulping lines are not vented to a control device.

The Betsy tank which collects filtrate from the brown stock washer in the pine pulping line is vented to the atmosphere.

Georgia-Pacific stated their existing emission calculations and factors concerning Hazardous Air Pollutant concentrations in the pulping process, condensate collection and destruction systems need to be updated.

Gases containing Total Reducing Sulfur were released to the atmosphere from the batch digesters. On a walk through of the digester system, NEIC inspectors observed vapors emanating from the top of capper valves on five batch digesters. Inspectors also observed vapors emanating from the flange on the side of the #3 digester capper valve. GP asserted that because the digesters are located within a building and the gases are being emitted into the building, the standards are being met. However, it appears that the building is equivalent to the atmosphere in this situation.

The total Hazardous Air Pollutants from GP's batch digesters are not enclosed and vented into a closed-vent system, and are not routed to a control device.

The total Hazardous Air Pollutants from the GP-2 and GP-3 washers are not enclosed, not vented into a closed-vent system, and not routed to a control device.

The total Hazardous Air Pollutants from the Betsy tank, a filtrate tank, are not controlled and are vented to the atmosphere.

The total Hazardous Air Pollutants from the pine liquor fill storage tank and filter feed tank and filtrate tanks, are not controlled and are vented to the atmosphere.

GP did not promptly address findings from the 2010 compliance audit because the same findings were found in the 2013 compliance audit.

**Air Emissions from the Georgia-Pacific Chemicals Facility**

GP Chemicals' leak detection and repair (LDAR) contractor, Team Industrial Services, is not using the appropriate detector to monitor for formaldehyde in the process area. Team has been GP Chemicals'

contractor since the inception of the facility's LDAR program. GP personnel called Team and confirmed that TEAM has always used a flame ionization detector (FID) to conduct all monitoring. Formaldehyde is not detected by an FID at a response factor less than 10. Therefore, no leaks are detected even if components in the LDAR program were leaking.

NEIC received a copy of GP Chemicals' current LDAR list of all equipment containing formaldehyde. As of February12, 2015, there were 78 pieces of equipment that contain formaldehyde. Each piece is identified as being in gas vapor service.

**Georgia-Pacific in Crossett, Arkansas Settles EPA Claims of Violations of the Clean Air Act for:**

**$600,000 Civil Penalty**
**$2.9 million in Mitigation Project**
**$2 million in Supplemental Environmental Projects**

By Wilma Subra Subracom@aol.com

On December 14, 2018, the US Environmental Protection Agency (EPA) announced a settlement with Georgia-Pacific Chemicals (Chemical Manufacturing Facility) and Georgia- Pacific Consumers Products (Pulp/Paper Manufacturing Facility) in Crossett, Arkansas for violations of the Clean Air Act that were documented in an EPA National Enforcement Investigation Center (NEIC) Inspection that occurred in 2015 at the Georgia-Pacific paper and chemical products facilities in Crossett.

EPA Region 6 had requested the National Enforcement Investigations Center (NEIC) to perform a Multimedia Compliance Investigation of the Georgia-Pacific Crossett Paper Operations and Chemicals Facility in Crossett, Arkansas.

Both Multimedia Compliance Investigations were performed by the NEIC from **February 3, 2015 through February 12, 2015**, at the respective facilities.

The NEIC report of the findings and observations for the Georgia-Pacific Chemicals facility was dated **July 15, 2015** and for the Georgia-Pacific Crossett Paper Operations, **August 14, 2015**.

On **November 9, 2015**, the reports were released to the public. On December 2, 2015, Wilma Subra of Louisiana Environmental Action Network (LEAN) presented the information and results from the two NEIC reports of the Georgia-Pacific facilities to the Crossett Concerned Citizens for Environmental Justice at the Living Word Church of God in Christ in Crossett, Arkansas.

**Settlement Requirements**

The December 14, 2018 settlement required Georgia-Pacific to pay:

$600,000 in Civil Penalties - $300,000 to the United States and $300,000 to Arkansas Department of Environmental Quality (ADEQ).

$2.9 million in a Mitigation Project to reduce Hydrogen Sulfide emissions and odors from the wastewater discharge.

$2 million in three Supplemental Environmental Projects to reduce the potential for Hydrogen Sulfide air emissions from the Georgia-Pacific Wastewater Process (2 projects) and an air monitoring project for Hydrogen Sulfide along the fence line of the facilities, for at least three years.

The 2015 EPA National Enforcement Investigation Center (NEIC) inspections of the two Georgia-Pacific Crossett facilities on adjoining properties, identified the following:

-A lack of air pollution controls, required under the Clean Air Act's New Source Performance Standards (NSPS) and the National Emissions Standards for Hazardous Air Pollutants (NESHAP) at the Chemical facility and at the Pulp/Paper facility, of the two wood pulp washers at the facilities.

Georgia-Pacific is required by the terms of the settlement to:

-Install the appropriate pollution controls on the washers.

-Update leak-control and compliance monitoring procedures.

-Conduct emissions and performance testing on other control systems.

The required measurements under the terms of the settlement are designed to achieve reductions of **hazardous air pollutants** released from the two facilities.

The settlement will further efforts by EPA and ADEQ to address residents' health and odor complaints stemming from **Hydrogen Sulfide** emissions from the two Georgia-Pacific facilities.

The measurers required by the settlement are designed to achieve reductions in hazardous air pollutants released from the two Georgia-Pacific Crossett facilities and the installation of $2.9 million in a Mitigation Project to reduce Hydrogen Sulfide emissions and odors from the wastewater discharges.

Wilma Subra of LEAN has provided expert technical assistance, hydrogen sulfide air monitoring, wastewater sampling projects, as well as evaluation of data and presentations to community members, local, state and federal environmental and health agencies, for many years to and on behalf of the Crossett Concerned Citizens for Environmental Justice (CCCEJ) .

LEAN's Board President, Cheryl Slavant, the Ouachita Riverkeeper, has interacted with the Crossett Concerned Citizens for Environmental Justice(CCCEJ) for many year and has focused on projects on the Crossett facility wastewater discharge plume as it is discharged into Coffee Creek and eventually into the Ouachita River.

Tulane Environmental Law Clinic has filed a Title VI complain with the EPA Administrator and EPA Office of Civil Rights against continuing the NPDES wastewater discharge permit for Georgia-Pacific.

The wastewater issues involved in the EPA settlement include the treatment of wastewater from both the Georgia-Pacific Pulp/Paper Operations and the Georgia-Pacific Chemical Plant in Crossett. The City of Crossett wastewater is handled in the Georgia-Pacific wastewater treatment system.

As a result of working with the community of Crossett, the Arkansas Department of Environmental Quality and the Environmental Protection Agency and having the technical information on Formaldehyde available from IRIS, the negative health impacts experienced by the Crossett community will be decreasing and their quality of life should be improving.

**Prevented Communities from Being Exposed to Formaldehyde**

A non-profit self help organization that was instrumental in helping poor, disadvantaged community members to become first time home owners, was looking into housing units produced by a local fabrication company. On reviewing all of the data and specifications it became apparent that the fabrication company was using plywood, particle board and fiberboard that was manufactured with Formaldehyde based resins. Structures constructed with this type of material were known to off gas Formaldehyde vapors at unacceptable levels within the structures and could result in negative health impacts to residents, known to be associated with Formaldehyde.

The information was providing to the non-profit and then a meeting was set up with the fabrication company. After lengthy interaction, the fabrication company indicated they would have to consider whether they could change to plywood, particle board and fiber board that were not constructed with Formaldehyde resins. The fabrication company declined to change to utilizing products made from non-Formaldehyde resins. Thus, the non-profit continues to construct homes without Formaldehyde based resins in any of their plywood, particle board and fiber board materials. As a result the first time home owners were not exposed to Formaldehyde.

**Hurricanes Katrina and Rita and FEMA Trailers**

Hurricane Katrina struck the northern coast of the Gulf of Mexico in the states of Louisiana, Mississippi and Alabama on August 29, 2005. Severe damage and destruction occurred all along the coastal areas. Less than a month later, on September 24, 2005, Hurricane Rita struck the coastal areas of Texas, Louisiana and Mississippi. As a result of these two hurricanes a large population of community members, particularly in the greater New Orleans area, were relocated to other parts of the United States. A large part of the remaining population, that had totally lost their homes, were eventually provided FEMA trailers, in which to live.

The FEMA trailers were constructed in response to the needs for temporary housing as a result of the hurricanes. A large number of individuals , as soon as they moved into their FEMA trailers, began complaining of headaches, runny noses and nose bleeds. The symptoms then increased to include burning eyes and throats, nausea and respiratory distress and chronic respiratory problems. When they complained they were told to air out the trailer when first going inside.

Working with the Sierra Club in Mississippi, formaldehyde testing badges were provided to FEMA trailer occupants along the coastal area of Mississippi. In May 2006, 32 FEMA trailers were tested. Thirty of 32 trailers had Formaldehyde levels over the EPA acceptable level. In July 2006, a total of 44 trailers were tested for Formaldehyde. All but four FEMA trailers tested higher than 0.1 ppm for Formaldehyde. EPA considered 0.1 ppm to be an "elevated level of Formaldehyde." The highest concentration of Formaldehyde detected was 0.34 ppm. FEMA established a threshold of 0.016 ppm.

Based on further investigation, a Phenol Formaldehyde adhesive was used to construct composite wood and plywood panels used to construct the FEMA trailers. The off gassing of the Formaldehyde resulted in severe health impacts to individuals living in the FEMA trailers that were known to be associated with exposure to Formaldehyde. It was estimated that 120,000 families lived in FEMA trailers as a result of hurricanes Katrina and Rita.

**Conclusion**

The information in IRIS Assessments is critical to evaluating situations of community exposure, concentrations, pathways of exposure, health impacts and risk. The IRIS information is an important base of data to convey to community members their risk, sources of chemical emissions. cumulative impacts of chemicals the community members are being exposed to, associated health impacts and establishing strategies to reduce exposure and improve health outcomes.

The IRIS program is extremely important to provide information to exposed community members about their level of risk and the associated health conditions.

WILMA SUBRA
President, Subra Company
Technical Advisor, Louisiana Environmental Action Network

Wilma Subra is president of Subra Company and provided technical assistance to citizens, across the United States and some foreign countries, concerned with their environment and human health by combining technical research and evaluations. She has a BS and MS in Microbiology and Chemistry from the University of Southwestern Louisiana (University of Louisiana at Lafayette). She has over 52 years of experience in sampling and chemical and microbiologic analysis of ground water, surface water resources, air and waste, monitoring the environmental impacts of oil, gas and shale drilling and production activities, waste treatment and disposal practices, impacts of industrial facilities and associated human health impacts.

She has completed a seven year term as Vice-Chair of the Environmental Protection Agency National Advisory Council for Environmental Policy and Technology (NACEPT), a five year term on the National Advisory Committee of the U. S. Representative to the Commission for Environmental Cooperation and a six year term on the EPA National Environmental Justice Advisory Council (NEJAC) where she served as a member of the Cumulative Risk and Impacts Working Group of the NEJAC Council, and chaired the NEJAC Gulf Coast Hurricanes Work Group. In 2011, she chaired the Environmental Protection Agency Technical Workshop for the Hydraulic Fracturing Study on Chemical and Analytical Methods. She participated in the EPA Shale Technical Roundtables on Water Acquisition, Chemical Mixing, and Well Injection in November 2012. She co-chaired the EPA Shale Analytical Chemical Methods Workshop in February 2013. She currently serves as chair of the STRONGER Air Guidelines Work Group.

She received the MacArthur Fellowship "Genius" Award from the MacArthur Foundation in 1999 for helping ordinary citizens understand, cope with and combat environmental issues in their communities. She also received the 2011 Domestic Human Rights Award from the Global Exchange for her dedication to human rights issues.

Chairwoman SHERRILL. Thank you. Thank you. Well, thank you to all of our witnesses. At this point we'll begin our first round of questions. The Chair recognizes herself for 5 minutes.

So, Dr. Goldstein, in your testimony you spoke about the state of EPA chemical assessments prior to the establishment of IRIS. Can you please elaborate on the impetus to establish the IRIS Program and what needs it was filling that program offices were unable to address?

Dr. GOLDSTEIN. Yes, the—IRIS to me was always a—sort of a smooth just continuation of the description of what I gave under Administrators Ruckelshaus and Thomas. How to name it was lots of debate. I remember one of the original ideas was the Coordinated Risk Assessment Program, but the acronym served to be of no value.

The issue of how to move forward for EPA always came down to the natural tension between the program offices and a central administrative type of structure as the Office of Research and Development. And through the years that has just progressed. So it was just a building onto the issue of we need a centralized approach, the Administrator has to understand what the relative—what risk means to priorities and prioritize among the various problems that the Administrator was facing in responding to Congress. Congress needed to know which were the riskier problems that EPA was dealing with. And it should come from a central organizational structure with lots of external reviews.

Chairwoman SHERRILL. Thank you very much. And from our previous panel we learned that EPA's Office of Children Health Protection, or OCHP, believes formaldehyde is one of the top three or four IRIS priority chemicals for its office. That means formaldehyde is one of the major chemical dangers facing children today. Unfortunately, OCHP did not submit its priorities until it was too late in the process for them to be included. But, Dr. Rusyn, can you describe some of the documented health impacts of formaldehyde particularly for children and why our children are especially vulnerable to formaldehyde exposure?

Dr. RUSYN. Thank you. I speak on my recollection from the information contained in the draft IRIS formaldehyde assessment that the committee that I served on reviewed in 2010 and 2011. I do not work on formaldehyde, so I'm not expert by any stretch of imagination. But the draft assessment included evaluation of the literature and derivation of toxicity values for inhalation exposure, which was of greatest concern. And the concerns that already were pointed out today especially from the particleboard in FEMA trailers and others, are something that is definitely bringing this type of a route of exposure to concern and especially because children are also exposed and are also considered a vulnerable population. This is something that the agency needed to account for in how they derived toxicity values from some of the studies in adults. So respiratory irritation and exacerbation of asthma and other types of respiratory illnesses were some of the health effects that were pointed out in the draft assessment.

Chairwoman SHERRILL. Thank you very much. And, Dr. Rusyn, since your participation in the 2011 National Academies' review of the draft formaldehyde assessment, what progress have you ob-

served in IRIS' ability to implement the recommendations made and to increase its productivity and transparency?

Dr. RUSYN. So, as I mentioned in my oral and written testimony, the process of IRIS evaluations is under a microscope and has been from all sides, from GAO, from Congress, from the National Academies, and from other stakeholders. The progress has been primarily focused on the process because the criticism that the 2011 report has provided was largely on the process and the transparency of the documents. So the systematic review process, the frequent releases of information that are now part of the IRIS Program's standard operating procedures increased transparency, increased the stakeholder engagement, and actually move the field forward. But it's important to note that risk assessment is not something that is stagnant. There's a lot of new data. There's a lot of methodological work, and I think IRIS is the leader in this pushing the methodology forward.

Chairwoman SHERRILL. And we have a few more seconds. How are they the leader would you say?

Dr. RUSYN. The systematic review is something that is more established in the medical community where systematic reviews are undertaken to create centralized guidelines for certain conditions and for their treatments, so to standardize across different physicians and make sure that they're treating their patients based on best science. How to apply this process to environmental health was really unclear, so this is something that has only begun about 5 or 6 years. So IRIS Program has taken the leadership position in actually creating case studies and guidelines for this, so they're really pushing the field forward.

Chairwoman SHERRILL. Thank you. Thank you, everyone. And now the Chair will recognize Mr. Norman for 5 minutes.

Mr. NORMAN. Thank you, Chairwoman Sherrill.

Dr. Goodman, there's been a lot of talk about systematic review and higher standards to improve the IRIS Program. Can you explain the systematic review in layman's terms and describe why its implementation is critical to improving IRIS?

Dr. GOODMAN. Yes, so the idea behind a systematic review is that there is a clearly formulated question and, based on that question, a protocol is developed for every aspect of the review, including the literature search strategy, what studies you're going to include and exclude, what information you're going to take from that—those studies, importantly, how you evaluate the quality of those studies, their strengths and limitations, and then how you integrate evidence from all these studies, especially when there's contradicting evidence, what you're going to do.

And the reason why it's so critical is so that you truly get a sense of the whole state of the science. When a review is conducted that's not systematic, what ends up happening is critical information is ignored and then your conclusions aren't really based on a good solid scientific foundation.

Mr. NORMAN. Thank you. And, again, Dr. Goodman, over the years, there's been a lot of uncertainty surrounding formaldehyde, specific criticisms of the IRIS Program's handling of the formaldehyde assessment. Last week, EPA announced that it will review formaldehyde in the TSCA program, which is an actual regulatory

program that can set useful guidelines for the formaldehyde use. I think this is a tremendously positive step toward making meaningful determinations as to the risk associated with formaldehyde, and I applaud the Administration for taking this step. Can you—Dr. Goodman, again, can you please explain the potential downside of relying on an IRIS assessment of formaldehyde to dictate how we regulate that substance at the Federal level?

Dr. GOODMAN. Well, I think, as it stands, the IRIS handbook hasn't been completed yet, so there's no standard operating procedure for conducting IRIS assessments. And so even though the assessments are moving in the direction of using systematic review, it hasn't—systematic review hasn't been fully implemented in any review to date, including what's been done on formaldehyde to date. So in that sense I think what's most important is that formaldehyde is reviewed in a systematic fashion.

And I think the other aspect, as was talked about with the first panel, IRIS provides toxicity values and that—and these toxicity values take into account the hazard information, but they don't take the next step in saying what are uses, how are people using it, and what are the risks for those particular uses? And that is done under TSCA.

Mr. NORMAN. OK. I'd like to thank each one of the witnesses for taking your time again. There's been a lot of controversy over IRIS, and we just want results. And thank you for taking the time. Chairwoman, I have no further questions.

Chairwoman SHERRILL. Thank you, Mr. Norman. I now recognize Ms. Bonamici for 5 minutes.

Ms. BONAMICI. Thank you so much to the Chairs and Ranking Members. Thank you to all of our witnesses for being here.

I said during the first panel I've been on this Committee for more than 7 years, and I have sat through many hearings about IRIS and know that there—without question, there was a need to improve. But the direction that I'm seeing I do not consider improvement.

Dr. Goldstein, in your testimony you discuss a development of the IRIS Program. I read your—back in the Ruckelshaus days and the importance of a centralized ORD-led approach to risk assessments and the value of independence of IRIS from other program offices. In a September 2017 letter, the EPA's Science Advisory Board reaffirmed that no other Federal entity performs IRIS functions and that IRIS helps ensure consistency in chemical assessment within the agency. I disagree with my colleagues who continue to call for the elimination of IRIS.

And, Dr. Goldstein, based on your years of experience at the EPA, what are the consequences of diminishing the independence of IRIS? And how would consolidating the functions of IRIS into various program offices affect the quality of assessments?

Dr. GOLDSTEIN. I think the quality of assessments would rapidly decline. It would be under the leadership of someone appointed as a political appointee to make sure that air is taken care of, water is taken care of, individual groups that have individual laws and they will respond by looking at ways that the risk be most supportive of what they think their policy approaches ought to be. We need an independent group that says what the science is and then

everyone can use it but cannot play with it as much as would occur if you got rid of IRIS.

Ms. BONAMICI. Thank you. And, Dr. Goldstein, in your testimony you state that Administrator Wheeler's abrupt dismantling of extensive science-based independent review processes is unforgivable, and the current actions of EPA's leadership to be incredibly shortsighted at best. I'm very concerned about the lack of transparency, what appears to be a significant limitation on the number of chemicals that are being considered.

I also appreciated the candid statement in your testimony that you would have resigned as Assistant Administrator of ORD if EPA leadership had tried to make the changes now being insisted on by Administrator Wheeler. I don't think we can brush this aside or ignore it. It's—I'm deeply concerned about the efforts to undermine scientific integrity and dismiss agency scientists and the EPA's work and the consequences that may endanger the EPA's ability to fulfill its mission. And we know that mission is protecting public health and the environment. What are the long-term consequences of the continued disrespect and dismissal of science at the EPA?

Dr. GOLDSTEIN. Well, EPA will soon cease to function effectively. It will continue to have debate after debate after debate. The formaldehyde to me is a poster child of what happens when we let politics get in the way of making scientific—looking at the scientific basis for the decisionmaking. One can take the science and make a decision based upon what the laws are, what the policy issues are, but one should not discard the science and basically decide in advance I know what the science ought to be and then try to make policy on that. That policy will eventually fail.

Ms. BONAMICI. And thank you. And I have a question about the career staff. I know that there are still many career staff at the agency. How can we defend the work of the career staff when the EPA leadership is limiting the release of information to the public? What are your suggestions there?

Dr. GOLDSTEIN. I think you've asked the most important question. My suggestion is as much oversight as you can give would be very, very welcome in this way. You know, hearings like this are just so important. And the career staff recognizes that.

Ms. BONAMICI. Thank you. And I want to reiterate what I mentioned in the hearing on the first panel that IRIS is an important program, yes. Based on the information we'd heard in the past and the recent GAO report, yes, there is room for improvement, and we can work together to bring about that improvement, but we absolutely must maintain the separation and respect the work of the career folks who are there trying to make sure that there is, science and transparency regarding IRIS and overall with the EPA.

So thank you for your leadership, Chairwoman Fletcher and Chairwoman Sherrill and Ranking Members, and I yield back.

Chairwoman SHERRILL. Thank you very much.

Now, the Chair recognizes Dr. Babin for 5 minutes.

Mr. BABIN. Thank you, Madam Chair. I appreciate it. And thank you, all you expert witnesses for being here as well.

Dr. Goodman, do IRIS assessments integrate all lines of evidence, including potential adverse health effects to humans?

Dr. GOODMAN. I think the goal of IRIS assessments is certainly to do that, and they do attempt to consider epidemiology, toxicology, mode of action, mechanistic evidence, but in practice sometimes relevant evidence is missed or in other times the evidence is all there but it's not evaluated in a systematic manner, meaning that, you know, not all studies are created equal. Some are more robust, they have more strengths. Others have more limitations. Just as an example, sometimes in epidemiology it's very difficult to estimate exposure, and some studies do a better job than others at coming up with good exposure measurements. So I think that can sometimes be an issue with IRIS assessments.

Mr. BABIN. OK. And then do IRIS assessments include any consideration of actual human exposures or make any determination of the actual human risk?

Dr. GOODMAN. I believe that IRIS—the goal of the IRIS assessment is really to conduct a hazard assessment, and then once that assessment is done, it can then be used to evaluate risk——

Mr. BABIN. Oh.

Dr. GOODMAN [continuing]. Based on human uses of chemicals and exposures.

Mr. BABIN. OK. Does the TSCA program consider human exposure?

Dr. GOODMAN. Yes, it does.

Mr. BABIN. OK. And also is it true that other chemical assessment agencies like the World Health Organization recognize a safe threshold for formaldehyde exposure when they establish values for long-term exposure to formaldehyde?

Dr. GOODMAN. Yes, I believe the World Health Organization has acknowledged that the key mechanism for formaldehyde in causing cancer is through cytotoxicity and cell proliferation, and that specific mechanism has a threshold. And what that means is there's an exposure level below which the body can actually handle exposures to formaldehyde, and this won't happen.

Mr. BABIN. OK. Well, then would you elaborate on—just a little bit on the importance of setting these safe threshold values?

Dr. GOODMAN. Well, I think the idea is—the goal of all of these programs is to determine what safe levels are or what levels below which we can be confident that there isn't an increased risk for adverse effects on human health. And so we need that based on the best available science, and if the science suggests that a mechanism of cancer or any other health effect has a threshold, has a level below which there is no increased risk, that needs to be incorporated in an assessment.

Mr. BABIN. I see. And, Ms. Subra, you had mentioned—are you from Louisiana by the way? Are you from Louisiana? Did I hear you say you had some studies in Natchitoches and——

Ms. SUBRA. Right.

Mr. BABIN [continuing]. Other areas? OK. Did you hear my last question? Would you like to elaborate on it as well?

Ms. SUBRA. Could you repeat your question?

Mr. BABIN. Yes, OK. The importance of setting safe threshold values for anything——

Ms. SUBRA. Right.

Mr. BABIN [continuing]. But we're talking about formaldehyde here, if you would elaborate on that as well because I know that you've had a lot of experience with this.

Ms. SUBRA. Right. So based on the citizens' complaints we did air sampling and found that formaldehyde was the chemical present in the largest quantity in the ambient air around the facility where these people live, and then being able to coordinate that back to the resins that were used by the facility, that was the source of those emissions. And then we worked with the facility to get those resins replaced, and as a result, the formaldehyde in the air was non-detect once they changed the resin they were using. So the health impacts to the community improved tremendously based on removing that source of pollution.

Mr. BABIN. OK. Thank you. And I yield back, Madam Chair. Thank you very much.

Chairwoman SHERRILL. Well, thank you. And now the Chair recognizes Chairwoman Fletcher for 5 minutes.

Mrs. FLETCHER. Thank you, Madam Chair.

The EPA program—program and regional offices routinely utilize IRIS assessments to meet the agency's mission. Similarly, as I mentioned earlier, State regulatory agencies are also highly dependent on IRIS values. I have with me a letter from the Colorado Department of Public Health and Environment (CDPHE), and I would like to add it to the record. So I'll ask that the letter be added to the record.

Chairwoman SHERRILL. Without objection.

Mrs. FLETCHER. And this letter from the CDPHE unequivocally states that they utilize IRIS toxicity values daily to protect Coloradans' health. Additionally, nongovernmental stakeholders utilize IRIS assessments to better educate and protect impacted communities.

Ms. Subra, and your testimony describe how you utilize IRIS assessments in your work. How regularly do you reference the IRIS assessment values? Yes.

Ms. SUBRA. Depending on what facility and community I'm working with and what all the chemicals are that are being released by that facility, if there are some that I want additional information on, I'll quickly check the IRIS database and see if it's available. So it may be once a week, it may be once a month, it may be once every 2 months, depending on what new issues I'm working on. But on issues I'm working on a regular basis I check it to see if anything new has been added to that website to enable the citizens to better understand what's going on.

Mrs. FLETCHER. And what is it specifically about the IRIS assessments that makes them a valuable resource to you as compared to other toxicity values?

Ms. SUBRA. So early in the—my career you'd have to have access to TOXNET and things like that, and only medical schools had access and they didn't share that access, whereas when you look at IRIS, they have all the literature available, and you can then, if you are interested in any particular one, get access to it. So it pulls together all of the available information and journal articles in one place. I don't have to go to three, four, five, or six places. And they've done the compiling for me so I can quickly have access to

that, and it saves time as I'm trying to work and educate and empower the communities.

Mrs. FLETCHER. And on a related note in connection with your work, what impacts to your work do you anticipate if the IRIS Program is stifled in its ability to be able to produce timely and comprehensive assessments?

Ms. SUBRA. So I only respond to communities that request assistance, and then I look to see what those chemicals are. One of the things we found is when IRIS does the assessment and does come out with it, then it takes a long time to get it implemented and get the results of their assessment to reduce the exposure going on in the communities by working with the industrial facilities that are sources of that emission.

Mrs. FLETCHER. And how will impacted communities be affected by a delayed IRIS process?

Ms. SUBRA. They are affected because of primarily the air emissions. In a lot of other cases it's water, groundwater, and solid waste. But when they're affected by the air, then we need a handle to be able to say this is what's going on in the ambient air in the community around this facility or these facilities, and then, because of the IRIS information, then we can determine whether or not it's harmful to the community and what impacts it has on their health and then work with both the industry, the local, the State, and the national, environmental, and health agencies to get those emissions in the ambient air reduced and thus reduce their exposure.

Mrs. FLETCHER. Thank you. And I just have a limited amount of time left, so I'll put this question out to everyone on the panel, all the witnesses. Do you believe or why do you believe the value of IRIS assessments for external stakeholders has improved and increased over time? If anybody wants to take that question.

Dr. GOLDSTEIN. Lots of hard work and lots of oversight and insistence that that information be available.

Dr. RUSYN. And I think as well the level of scrutiny that this program has and the level of scrutiny that each draft assessment undergoes really provides the best available science for that particular protective value in the cancer hazard classification.

Mrs. FLETCHER. Thank you. And I see I've gone over my time, so, Chairwoman Sherrill, I will yield back.

Chairwoman SHERRILL. Thank you. The Chair now recognizes Ranking Member Marshall.

Mr. MARSHALL. Thank you so much, Chairwoman. I'll start with Dr. Goodman.

I'm trying to understand linear assessments. When, as a physician, we give a patient medicine, we start off with the lowest dose possible, and then usually you'll hit a certain dose to finally get the response you're wanting. And I never see a linear progression to the side effects. It looks like we just steadily go up and then suddenly, there's a number that causes side effects. And I would think, you know, trying to apply toxicology might be the same in reverse. So do you typically use some type of linear analysis or is there typically drop-off points?

Dr. GOODMAN. So right now, cancer is evaluated differently than noncancer effects, so for noncancer health effects, it's exactly as you

say. When assessments are done, it's assumed that a minimum exposure is necessary to see any type of toxic effects, and below that exposure, those effects won't occur.

Now, it's actually—it's based on a regulatory context, not based on biology, this idea that if there's something that can cause cancer, one molecule of that something can cause cancer. And so they do this process called linear low-dose extrapolation meaning obviously you can't do a scientific study of one molecule, so you take the higher doses and basically plot out on a curve what the association is between the dose of the chemical or exposure of the chemical and cancer risk, and then you extrapolate from that lowest dose down to zero, essentially assuming that there's risk down to zero. But if—biologically that's not necessarily the case, particularly for certain carcinogens that have certain mechanisms. And in that case you should do exactly as you said. You should find the exposure level—the minimum exposure level where you can increase cancer risks, and then below that there's no evidence for an increased cancer risk.

Mr. MARSHALL. How do you take the IRIS assessment cancer classifications and then apply them to actual human health risk? How do companies do that? The IRIS assessment cancer classifications and then I'm trying to relate that from taking that data to human risk.

Dr. GOODMAN. Well, I think the idea—I mean, if you're talking about cancer, so a cancer slope factor, a number is calculated, that's an estimate of what—you know, what cancer risk is associated with specific exposures. But, as I said, there's this extrapolation down to low exposure levels because that can't be studied and so, by design, it is overestimating cancer risk.

Mr. MARSHALL. Do private companies feel like IRIS has been transparent?

Dr. GOODMAN. I don't know that I can speak for private companies, so I don't know that I should answer that. I think in some cases I would say I've heard——

Mr. MARSHALL. Does industry feel like IRIS has been transparent?

Dr. GOODMAN. Again, I don't know that I should speak for the industry, but I think there are some cases where the scientific judgments have not been clear in IRIS assessments.

Mr. MARSHALL. OK. If you were in charge of IRIS, what solutions would make it better? What are your thoughts to improve IRIS?

Dr. GOODMAN. First priority is complete that handbook because then we have a standard operating procedure so that all assessments are done in the same manner. Also make sure that all protocols and then actually the executed assessments are completely transparent so it's absolutely clear when decisions were made and the basis for those decisions.

Mr. MARSHALL. Why has it taken so long to do it? Any idea? I'm kind of new to the game here. What have they told you why they haven't gotten it done before?

Dr. GOODMAN. I don't think I'm the right person to answer that.

Mr. MARSHALL. OK. All right. Think here for a second. Mr. Goldstein, what do you think—I mean, certainly, there's been a handbook that they'd used for decades I would assume. They have to

have one. You could not supervise a lab without a handbook. What's taken so long to get this to Congress and to all of us?

Dr. GOLDSTEIN. Sir, may I first answer the question you asked before? I'm a physician, and you used the issue of toxicity.

Mr. MARSHALL. I guess I'd really—I got 38 seconds left, so I'd rather you answer this question.

Dr. GOLDSTEIN. OK. I'll be—may I send that to you?

Mr. MARSHALL. Sure.

Dr. GOLDSTEIN. The answer to this question is simple, I just don't know. I'm not active at EPA right now. I do know that doing something like a handbook, unless Congress requires me to do it, in which case it becomes highest priority, is really not that easy on a moving subject like this. And as new science is brought in, as you heard about systems approaches, boy, by the time you get this finished——

Mr. MARSHALL. I would say the first 20 steps are the same, though. The first 20 steps should be the same no matter which substance we're looking at, and I just can't believe it's been 8 or 10 years.

Thank you, and I yield back.

Chairwoman SHERRILL. Thank you.

The Chair now recognizes Mr. Tonko for 5 minutes.

Mr. TONKO. Thank you, Chairwoman Sherrill. And welcome to the panel. I firmly believe that we must ensure that inappropriate political interference in the scientific process does not get in the way of protecting our national security and public health. And, Dr. Goldstein, I know that you had an earlier exchange with my colleague, Representative Bonamici, and I wanted to delve a little further. But before I do that, why don't you express what you wanted to express if you could do that in a matter of seconds.

Dr. GOLDSTEIN. OK. It's a very good question asked by Dr. Marshall. It had to do with toxicity. You see the toxicity very quickly, though, so if you're going to change the dose of a drug and see toxicity, that's an immediate response. Cancer is 20, 30 years later. You won't see it as a physician. So it's not really pertinent to the way they do risk assessment, although it's a very good question.

Mr. TONKO. OK. Thank you. And now back to political influence. In your testimony you touch upon how the current political manipulations in the IRIS Program reflect the general dysfunction at the EPA over the past 2 years, particularly with the CASAC (Clean Air Scientific Advisory Committee) particulate matter review. You go so far as to state that, and I quote, "There is no question that today we are at the lowest point ever since the formation of the EPA," close quote. This is alarming to hear from someone who has been a close observer of the agency for decades, particularly since you came to work at the EPA following the infamously dysfunctional and frequently hostile tenure of former Administrator Anne Gorsuch. How does this Administration follow the pattern of behavior exhibited by that Gorsuch EPA, and what makes this the lowest point in the agency's history?

Dr. GOLDSTEIN. That's an easy question to answer. You mentioned the Clean Air Scientific Advisory Committee. Before becoming Assistant Administrator, I chaired that under Anne Gorsuch.

Anne Gorsuch did not interfere with the actions of the Clean Air Scientific Advisory Committee. Administrator Wheeler is.

Mr. TONKO. Well, what do you believe is the goal of these attempts to undermine science at the EPA wherever possible?

Dr. GOLDSTEIN. Policymakers like to get the science they want rather than the science that exists. I mean, it's built into the tension of how we develop our regulations and how we protect the public.

Mr. TONKO. So sheer manipulation. Dr. Goldstein, in your testimony you mentioned that when you found evidence that benzene is leukemogenic using funding from the American Petroleum Institute, your funding was cutoff. While you say you maintain respect for the scientific aptitude of industry, I must say this is troubling to hear. When you were working for industry, was there an understanding that your funding was dependent upon a particular outcome?

Dr. GOLDSTEIN. They never said that they cut it off because of the outcome. They were short of money that year was the reason they gave. I think we all understood what the answer really was. But, no, the issue of working with industry I think it's really important. I think good scientists in academia should work with industry, but it must be done in a way that's very careful and must be understood exactly what industry wants.

On the formaldehyde issue, I was asked to consult with industry right after the IARC (International Agency for Research on Cancer) meeting in 2010 said that it was a known leukemogen, and I told them they had to repeat the key study. They have yet to repeat it. Instead, they fund consultants to nitpick the study.

Mr. TONKO. OK. Thank you. And given your experience, what is your impression of the insistence by the American Chemistry Council that the studies it funds exonerating formaldehyde are sufficient to upend or at least call into serious question the current weight of evidence regarding formaldehyde carcinogenicity—whatever—carcinogens——

Dr. GOLDSTEIN. Cancer causation, sir.

Mr. TONKO. Yes.

Dr. GOLDSTEIN. These studies just indicate why this transparency idea is simply a ruse to be able to get raw data, not to be able to repeat the study but to be able to nitpick the study. Consultants get paid for nitpicking studies, changing blemishes into scars so that we will think there's a real problem. One of the studies is one that I responded to in print showing that their own data if anything proved the—proved is too strong, but certainly strengthened the initial study, not discredited it.

Mr. TONKO. Thank you very much. I just want to make a statement that scientific integrity is about, in my opinion, ensuring a process and atmosphere in which the science leads us to the results. Public science informs national policy on everything from pesticides to power grids. Our Nation's cities and States need credible information to prepare for climate change, and our families deserve to know if unsafe chemicals are being sprayed on their food, dumped into their water supplies, or added into the products they buy.

The efforts to silence science, distort, and bury or delay the release of valuable science at EPA—and they serve as a reminder of the urgency of passing the *Scientific Integrity Act*, which I've introduced, to codify the requirement that all agencies have strong scientific integrity policies that ensure that science leads the way no matter the Administration. Anything short of that is simply unacceptable.

And with that, Madam Chair, I will yield back.

Chairwoman SHERRILL. Thank you so much.

I'd now like to recognize Mr. Cohen for 5 minutes.

Mr. COHEN. Thank you, Madam Chair, and Merritt's mother.

Dr. Goldstein, I am obviously not a toxicologist, not obviously but I'm not. But Mr. Marshall asked some questions earlier about ethylene oxide. He expressed concern that IRIS risk values for inhalation of ethylene oxide are 19,000 times lower than what the human body naturally produces. Do I have to go further? I see your kind of—you're ready to respond. Isn't it true that the human body produces and expels a lot of substances that it would be dangerous to consume or inhale? And is the presence of a chemical in some concentration—in the digestive system, for example—going to mean the same level of risk as if that chemical is found in your lungs? So can you tell us about comparing these different levels and various—also the chemicals if they're in the soil versus the air versus the water we drink, et cetera, et cetera?

Dr. GOLDSTEIN. Thank you for the question. The—what's fascinating to me is that industry has welcomed some recent research, which I think is pretty good research, that shows that about one-third of the—in my estimation, about one-third of all cancer is due to bad luck. Well, what—yes, I mean, it's going to happen whether we were exposed to anything or changed our environment. That's not true for all cancers, certainly lung cancer, others. But if you start with that as something that industry believes, well, that means it's something internal to our body. Well, if our body makes formaldehyde and ethylene oxide, those are likely causes of this if you live long enough you're going to get mutations to yourself that will cause cancer, which is what bad luck really is about.

If you believe that, then clearly ethylene oxide can cause cancer and basically would be responsible for some bad luck. And if you think of it from the point of view of numbers, about 25 percent of us will get cancer. If one-third is due to bad luck, that's about 8 percent of us. If we're talking about Congress telling us we have to regulate it, say, 1 in 100,000 risk, well, 1 in 100,000, 8 percent of that is, what, 8,000 in 100,000 is due to this bad luck. If you're telling us to regulate 1 in 1,000, a little bit more of ethylene oxide from the outside, a little bit more formaldehyde from the outside could easily produce that 1 in 8,000 that I just talked about, and that's the level that IRIS is supposed to be informing people about.

So it—to me it doesn't—I just don't understand why ethylene oxide being an internal causation should make any difference to the IRIS approach.

Mr. COHEN. Now you've got me totally confused.

Dr. GOLDSTEIN. Sorry.

Mr. COHEN. I took an aspirin religiously, taking it from right to left of course, for years, and then I read recently that for people

that are—have the ability to remember Bill Mazeroski that this was a bad thing to do, that it was going to be hazardous to my health. Now you're telling me that cancer is caused by water. So is it—what——

Dr. GOLDSTEIN. I didn't say that.

Mr. COHEN. Well, I'm just thinking, is it kidney stones or is it cancer? Do I have to make a choice?

Dr. GOLDSTEIN. No, please don't make that choice. But there is—I mean, none of us lives forever, and, as I said, there is reasonably good evidence that mutations occur spontaneously in the body for causes we don't understand but could well be ethylene oxide or formaldehyde or other carcinogens we make within our body, and that these represent—as I say, it's only one-third of cancer, so two-thirds are out there ready to be prevented. But if it's one-third, that's still, in relationship to the 1 in 100,000 risk, which isn't IRIS' choice. That's, if you will, your choice. That's the level of protection that the country wants. It's a very big number.

Mr. COHEN. Let me ask you this. You worked at the EPA when President Reagan was in office, is that correct?

Dr. GOLDSTEIN. Correct.

Mr. COHEN. And Reagan was kind of known as a conservative and a guy that was pro-business. How would you compare Ruckelshaus and other EPA Administrators to Scott Pruitt?

Dr. GOLDSTEIN. There's no comparison. I mean, it's—you're talking about a completely different approach. The respect for getting the science right from Bill Ruckelshaus, Lee Thomas, the two Administrators I worked under, was very strong. And, as I say, Anne Gorsuch did not interfere with the Clean Air Scientific Advisory Committee. I chaired it.

Mr. COHEN. And then the Reagan Administration didn't try to interfere with EPA from giving information to the public to protect them as this Administration is?

Dr. GOLDSTEIN. That's not—that wasn't my level of approach, so I can't really comment on that, but I do—on the other things, I certainly do feel there's a difference.

Mr. COHEN. Thank you. And I yield back.

Chairwoman SHERRILL. Thank you very much.

I now yield 5 minutes to Ms. Wexton.

Ms. WEXTON. Thank you, Madam Chair, and thank you to the witnesses for coming to testify before us this morning.

Dr. Goodman, what kinds of organizations fund Gradient's research? Is it nonprofit organizations, trade organizations, corporations? What kind of groups fund your research?

Dr. GOODMAN. We—it really runs the gamut from private to public and government and nonprofit and for-profit and trade groups.

Ms. WEXTON. OK. And some of the groups that you've done work for include the National Marine Manufacturers Association? Do remember doing some work for them?

Dr. GOODMAN. I believe so, yes.

Ms. WEXTON. The Styrene Information and Resource Center?

Dr. GOODMAN. Yes.

Ms. WEXTON. The Formaldehyde Council?

Dr. GOODMAN. It—I don't remember, but it's possible.

Ms. WEXTON. OK. BPA Global Group?

Dr. GOODMAN. Yes.
Ms. WEXTON. The American Petroleum Institute?
Dr. GOODMAN. Yes.
Ms. WEXTON. ExxonMobil?
Dr. GOODMAN. Yes.
Ms. WEXTON. The American Chemistry Council?
Dr. GOODMAN. Yes.
Ms. WEXTON. OK. So are you—have you heard of this—the analysis by the Center for Public Integrity of 149 Gradient-produced scientific articles and letters that found that 98 percent of the time the research that was conducted by scientists at your company concludes that the chemical in question is harmless at levels to which people are typically exposed? Are you aware of that study?

Dr. GOODMAN. I'm familiar with that article. I haven't looked at that statistic in a while, but if I remember correctly, it was quite misleading, and I'm happy to go back and look at it and provide you with something more——

Ms. WEXTON. So you don't agree that it was 98 percent?
Dr. GOODMAN. No, I do not.
Ms. WEXTON. OK. So can you then give me an example of a time during your research at Gradient that you came to conclude that the exposure for—the exposure threshold for a particular chemical should actually be lower than an existing standard would suggest?

Dr. GOODMAN. I don't know—I can't think of—not everything I do has to do with standards and whether the standard should be lower or higher, but I'm certainly—you know, the first thing that comes to mind was when I was doing an evaluation of a chemical in a toy and basically coming to the conclusion that there was a possible toxic effect for children playing with the toy, so that's just the one off the top of my head.

Ms. WEXTON. So was that a specific level that you came to conclude was—should be lower than what it was at the time?

Dr. GOODMAN. Well, basically that the chemical shouldn't be in the toy at all because there was a not at risk.

Ms. WEXTON. OK. And in your research at Gradient, can you give me an example of a time that you came to a conclusion that a chemical you were hired to study is carcinogenic at typical exposure levels?

Dr. GOODMAN. Again, I don't know—I—the types of things we do range from hazard assessment to risk assessment, so it's not always about, you know, common uses and what people are typically exposed to, but I'm actually—you know, this isn't cancer, but I—I'm thinking now I actually have in the published literature and actually some of this work was funded by the American Petroleum Institute, as you mentioned, and some by actually the Texas Commission on Environmental Quality, which is a government agency, where we looked at air pollutants and risks of asthma and some other respiratory effects, and we did find that there was an increased risk for certain effects. So—and again, I'm happy to give you a list of that if you——

Ms. WEXTON. And was that research that you specifically participated in at Gradient or just peer-reviewed articles and scholarly journals that you have read?

Dr. GOODMAN. It was research we—I'm not exactly sure what the question is. It was some—we've done some original research where we actually look at air pollution data and health outcomes, and then we done systematic reviews like we're talking about here today where we looked at all the published studies and said what it came to together. And all of that work has been published in the peer-reviewed literature.

Ms. WEXTON. And have you ever worked on a study for Gradient where the client proposed their own conclusion, that is, what they were hoping that the data would show?

Dr. GOODMAN. I—not that I can think of, but in the end, it doesn't matter. I mean, that's—we get hired to do independent scientific analyses and conduct them with rigor and transparency and adhere to the highest scientific principles.

Ms. WEXTON. And, Dr. Goldstein, in your testimony you indicated that you have some extensive knowledge or experience working with industry. And based on your knowledge of industry-supported science, how frequently are results found that contradict the business interests of the company or trade group that's funding the research?

Chairwoman SHERRILL. And if you could answer quickly. The gentlewoman's time——

Dr. GOLDSTEIN. I will say not that unusually internally. I mean, that's the role of internal scientists and industry is to keep them out of trouble by having them not do the wrong thing, so that's not uncommon. How much gets public is——

Ms. WEXTON. Is another story, right. Thank you very much. I yield back.

Chairwoman SHERRILL. Thank you. And now, I believe the Ranking Member, Mr. Norman, has a question he would like to add, so I yield 1 minute to him.

Mr. NORMAN. Thank you, Chairwoman Sherrill.

Just to kind of follow up with this conversation we've been having, I mean, Dr. Goodman, you're independent, and I think Dr. Goldstein was mentioning as independent contractors if you will you may cherry-pick different things to have a desired outcome. Of all the companies you've had, have you had anybody put pressure on you to come up with an outcome that may or may not be what they wanted?

Dr. GOODMAN. The answer to that is no. Again, I get hired to do independent analyses. But I think this whole idea of systematic review and transparency, that's kind of the whole point. That is the work I do. I use a protocol, we do it systematically, and everything is transparent, so the idea is anyone can see the methods we use, the judgments that were made.

Mr. NORMAN. And I'm in the private arena, and we hire a lot of consultants. For liability reasons alone, it would not make sense for us to put any pressure on any business. We want to be protected—as I think Dr. Goldstein mentioned, we want to be protected, and the easiest way to have—invite a lawsuit is to try to have a desired outcome, which is not the end result. The media portrays that, but it's—in real life, in the real world that's not how it works.

Thank you so much. I yield back.

Chairwoman SHERRILL. Thank you to the Ranking Member.

Before we bring this hearing to a close, I want to thank our witnesses for testifying before the Committee today. The record will remain open for 2 weeks for additional statements from the Members and for any additional questions the Committee may ask of the witnesses.

The witnesses are excused, and the hearing is now adjourned. Thank you.

[Whereupon, at 12:55 p.m., the Subcommittees were adjourned.]

# Appendix I

## Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

*Responses by Dr. Jennifer Orme-Zavaleta*

**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 Mikie Sherrill (D-NJ)**

1. In the 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?

**A: In her role as Principal Deputy Assistant Administrator of the Office of Research and Development (ORD), Dr. Jennifer Orme-Zavaleta was not involved in the second round of prioritization; ORD received the final lists of program office priority assessments. As such, Principal Deputy Assistant Administrator Orme-Zavaleta cannot speak to ORD Deputy Assistant Administrator David Dunlap's involvement in the second round of prioritization or decisions relating to formaldehyde.**

**Principal Deputy Assistant Administrator 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 priorities. This process included a requirement that all IRIS 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.**

**Through this new process, EPA programs and regions can formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. As detailed in the December 4, 2018 memorandum from Principal Deputy Assistant Administrator Orme-Zavaleta, ORD consolidated the program and region input on high priority assessment needs and presented this to the Agency's Assistant Administrators and Deputies. The April 2019 Program Outlook was posted by IRIS program staff and reflected the priority assessments identified in December 2018.**

2. 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?

**A: "Discontinued" assessments are those for which the IRIS program is not planning to develop new or updated assessments at this time. This means that we do not anticipate these to become Agency IRIS priorities in the near future. These include hexabromocyclododecane (HBCD), acrylonitrile, n-butyl alcohol, and phthalates (butyl benzyl phthalate, dibutyl phthalate, diethyl phthalate, di-isobutyl phthalate, and di-isononyl phthalate).**

**"Suspended" assessments are those that have been placed on hold and may be restarted as Agency priorities change. This means that we are prepared for future Agency needs. The assessments suspended in the April 2019 Program Outlook include ammonia, chloroform, ethylbenzene, formaldehyde, manganese, naphthalene, nitrite/nitrate, PAH mixtures, and uranium.**

**Draft assessment materials previously released on the IRIS program website will remain accessible for reference on individual chemical pages. Additionally, existing toxicity values found on IRIS will remain available for use. More information about these chemicals can be found on the IRIS program website.**

3. 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 received 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?

**A: Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, Principal Deputy Assistant Administrator 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 priorities. This process included a requirement that all IRIS 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.**

**Through this new process, EPA programs and regions can formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. As detailed in the December 4, 2018 memorandum from Principal Deputy Assistant Administrator Orme-Zavaleta, ORD consolidated the program and region input on high priority assessment needs and presented this to the Agency's Assistant Administrators and Deputies. Based on that input, this prioritization process identified eleven priority chemicals: hexavalent chromium, inorganic arsenic, mercury salts, methylmercury, polychlorinated biphenyl (PCBs), five per- and polyfluoroalkyl substances (PFAS), and vanadium. The IRIS program will conduct this same formal request and prioritization process annually, but programs and regions are still able to identify and nominate additional chemicals at any time.**

4. In September 2018, the Director of OCHP was places 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.

**A: Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, Principal Deputy Assistant Administrator 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 priorities. This process included a requirement that all IRIS 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.**

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5. 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?

**A: Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, Principal Deputy Assistant Administrator 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 priorities. This process included a requirement that all IRIS 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.**

**Through this new process, EPA programs and regions can formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. As detailed in the December 4, 2018 memorandum from Principal Deputy Assistant Administrator Orme-Zavaleta, ORD consolidated the program and region input on high priority assessment needs and presented this to the Agency's Assistant Administrators and Deputies. Based on that input, this prioritization process identified eleven priority chemicals: hexavalent chromium, inorganic arsenic, mercury salts, methylmercury, polychlorinated biphenyl (PCBs), five per- and polyfluoroalkyl substances (PFAS), and vanadium. The IRIS program will conduct this same formal request and prioritization process annually, but programs and regions are still able to identify and nominate additional chemicals at any time.**

6. 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?

**A: OCHP submitted priorities after the list of priority IRIS assessments had been finalized. This final list informed the April 2019 Program Outlook.**

**The EPA will conduct its annual IRIS priority survey later this year. At that time, EPA program offices will have the opportunity to formally nominate their priority chemicals, but program offices may nominate a chemical for IRIS at any time.**

7. 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?

**A: Through ORD, the Agency will conduct its IRIS priority survey annually and plans to begin this process in summer 2019. The EPA plans to conduct this process similar to that which occurred in August 2018, with a memo from ORD leadership to the EPA program offices. The memo will include the standardized prioritization template for nominating IRIS assessments, and the memo will clearly state the purpose, type of assessment needed, and deadlines. This will ensure every program office has the opportunity to submit its priorities.**

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

**A: Formaldehyde, because of the complexity and volume of data, is primarily an FTE investment. In addition to the FTE investment, EPA costs associated with IRIS assessments include workshops, contractor support, and NAS peer review, among other expenses.**

**Submitted by Representative Don Beyer (D-VA)**

9. 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?

**A: IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources. Because of the IRIS program's importance, IRIS program staff initiated a review of IRIS priorities at the staff level in May 2018. Then-Acting Administrator Wheeler requested a more formal, structured survey of IRIS priorities in July to be signed at the Assistant Administrator level. This formalized prioritization process was completed in December 2018, and it is bringing further stability and accountability. Through this new process, EPA programs formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. Not only does this improve the scope of IRIS assessments and help the IRIS program prioritize its activities, it also reinforces accountability between the requesting program and the IRIS program.**

**Through ORD leadership, the Agency initiated the first survey of IRIS program priorities in August 2018. ORD was not involved in the EPA program offices' further prioritization efforts.**

**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 and 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.

10. What were the reasons for a 15-ear delay in this type of situation?

**A: The IRIS ethylene oxide assessment, which was initiated in 2002, took about 15 years to complete because of the complexity of the data that needed to be evaluated, as well as the peer review process to which this assessment was subjected. The current assessment reflects the IRIS program's evaluation of the best available science published through 2015 on the health hazards associated with ethylene oxide exposure.**

**Ethylene oxide is a chemical with a large and robust literature of human epidemiology data. These data are often more complex and time-consuming to analyze compared with data from animal studies. Moreover, the EPA needed to gain access to the original data from one of the key epidemiology studies to conduct specific analyses recommended by external peer reviewers. During the first peer review conducted by the EPA's Science Advisory Board (SAB) in 2006, the reviewers specifically recommended that the EPA conduct original dose-response modeling of the individual epidemiology data using approaches that EPA had not previously used. This recommendation resulted in a significant amount of new work in revising the assessment. Then, given the significant additional modeling of the epidemiologic data, the revised assessment underwent a second peer review in 2012, because the EPA was aware of the critical importance of ethylene oxide, both in terms of its potential human health risk and its importance as a sterilization agent and a feedstock chemical. It is important to note that the ethylene oxide assessment is somewhat unique and that since 2016, the EPA has significantly streamlined its assessment development processes and timelines.**

11. 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?

**A: Ethylene oxide is a chemical with a large and robust literature of human epidemiology data. These data are often more complex and time-consuming to analyze compared with data from animal studies. Moreover, the EPA needed to gain access to the original data from one of the key epidemiology studies to conduct**

**specific analyses recommended by external peer reviewers. During the first peer review conducted by the EPA's Science Advisory Board (SAB) in 2006, the reviewers specifically recommended that the EPA conduct original dose-response modeling of the individual epidemiology data using approaches that the EPA had not previously used. This recommendation resulted in a significant amount of new work in revising the assessment. Then, given the significant additional modeling of the epidemiologic data, the revised assessment underwent a second peer review in 2012, because the EPA was aware of the critical importance of ethylene oxide, both in terms of its potential human health risk and its importance as a sterilization agent and a feedstock chemical. It is important to note that the ethylene oxide assessment is somewhat unique and that since 2016, the EPA has significantly streamlined its assessment development processes and timelines.**

12. What is the best estimate of the number of people that will eventually get cancer, nationwide, because of that delay?

**A: An IRIS assessment addresses only the first two (of four) steps of the risk assessment process; the reference values derived in an IRIS assessment describe the quantitative relationship between dose or concentration and the effect. An IRIS assessment alone cannot be used to predict health risk (or number of cases of cancer) in a population.**

*Responses by Mr. Alfredo Gomez*

House Committee on Science, Space, and Technology
Subcommittee on Investigations and Oversight

"EPA's IRIS Program: Reviewing Its Progress and Roadblocks Ahead."

Questions for the Record to:
J. Alfredo Gómez
Director, Natural Resources and Environment
U.S. Government Accountability Office
**Submitted by Subcommittee Chairwoman Mikie Sherrill (D-NJ)**

- How was GAO's work impacted by the 2018-2019 government shutdown?

With respect to our report on chemical assessments, we provided a draft report to EPA for its review and comment on December 11 and EPA subsequently provided comments on February 5, 2019, about 7 business days after the government shutdown ended on January 25, 2019. Prior to the shutdown, we had requested comments back from the agency on December 31, 2018; thus, our work was delayed by about 5 weeks.

Questions for the Record to:
J. Alfredo Gómez
Director, Natural Resources and Environment
U.S. Government Accountability Office
**Submitted by Representative Bill Foster (D-IL)**

- Does the EPA or any 3rd party maintain estimates of:
  - The cumulative number of lives saved by EPA regulations and actions?
  - The cumulative costs of those regulations (both direct and indirect, to industry, government, and people)?
  - The number of lives saved per dollar of cost.
  - In cases where regulations or actions were delayed due to lack of resources or manpower, the number of lives lost due to those delays?

EPA has guidelines for preparing economic analyses and numerous studies but we are unaware of whether the estimates listed are available. In addition, OMB publishes an annual report that includes estimates of the total annual costs and benefits of Federal regulations; the most recent report is *2017 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act*.

- If the answers to (4) above are not available, could you estimate the scope and resource requirements for a Congressional mandate to make this information available annually?

We do not have any specific information on what the scope and resource requirements would be for a Congressional mandate to make this information available annually. We suggest contacting entities such as the Environmental Protection Agency, the Office of Management and Budget, the National Institutes of Health, and academic institutions who may provide useful input.

# Appendix II

## Additional Material for the Record

LETTER SUBMITTED BY REPRESENTATIVE RALPH NORMAN


April 9, 2019

The Honorable Ralph Norman
Ranking Member
Science, Space, and Technology Committee
Subcommittee on Investigations and Oversight
United States House of Representatives
2321 Rayburn HOB
Washington, DC 20515

Dear Ranking Member Norman:

On March 27, 2019, the House Science, Space, and Technology Subcommittee on Investigations and Oversight and the Subcommittee on Environment held a hearing on "EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead." The hearing focused on issues with the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Program. During the hearing, the status and science regarding EPA's IRIS review of formaldehyde was raised.

The scientific community has regularly commented on the lack of transparency by the IRIS program, its failure to utilize the best available science, and its reluctance to employ modern scientific approaches (i.e., apply threshold approaches when the scientific data supports them) to draw conclusions regarding human health risk. To help inform the hearing record, summarized below and included as references or as attachments to this letter, we provide information regarding: (1) international agencies that have recognized safe formaldehyde exposure thresholds when setting air guidelines and toxicity values; (2) peer-reviewed published articles which demonstrate formaldehyde safe exposure thresholds; and (3) peer-reviewed publications that highlight the importance of data transparency, replication and consistency associated with formaldehyde evaluations. This information is meant to provide a snapshot of publicly available information and should not be considered all inclusive.

1. **<u>International Agencies Recognizing Safe Formaldehyde Exposure Thresholds</u>**

   - The French Agency for Food, Environmental and Occupational Health & Safety (ANSES)[1] – Based on its 2018 review of the current science, ANSES used a threshold approach to recommend an indoor air quality guideline of 80 parts per billion (ppb) to protect the general population from acute and chronic effects of

[1] The French Agency for Food, Environmental and Occupational Health & Safety. 2018. Opinion on the revision of ANSES's reference values for formaldehyde: occupational exposure limits (OELs), derived no-effect levels (DNELs) for professionals, toxicity reference values (TRVs) and indoor air quality guidelines (IAQGs)

formaldehyde exposure and recommended a chronic inhalation toxicity reference value of 100 ppb. Notably, ANSES also assessed sensitive subpopulations (e.g., children and other populations) and found that "*Regarding the existence of susceptible populations, no particular susceptibility to formaldehyde has been found.*"

- The World Health Organization (WHO)[2] – In 2010, the WHO evaluated potential non-cancer and cancer effects to establish air quality guidelines for formaldehyde. Using a threshold based approach, WHO derived indoor air quality guidelines for short- and long-term exposures to formaldehyde of 80 ppb.

- Health Canada[3]– In 2006, Health Canada established indoor air quality guidelines for long-term and short-term formaldehyde exposures of 40 ppb and 100 ppb respectively. Health Canada noted that "*The risk of cancer associated with formaldehyde levels sufficiently low to prevent irritation and inflammatory responses appears therefore to be negligible.*"

**2. <u>Peer-Reviewed Publications Recognizing Safe Formaldehyde Exposure Thresholds</u>**

- Leng et al. 2019[4] evaluated the potential impacts between inhaled formaldehyde and formaldehyde found naturally in the human body. The study indicated that low doses of formaldehyde were not likely to increase risk of cancer in humans.

- Sheehan et al. 2017[5] evaluated formaldehyde concentrations in approximately 18,000 residences that contained a specific composite wood flooring. Using the most recent data available and threshold cancer risk assessment models, formaldehyde emissions were found to pose virtually no cancer risk in the homes assessed.

- Nielsen et al. 2016[6] conducted a re-evaluation of the 2010 WHO formaldehyde indoor air quality guideline values to consider new science and determined that the guideline values were still scientifically valid and health protective.

[2] World Health Organization (WHO). 2010. Formaldehyde. In: Selected pollutants. WHO Guidelines for Indoor Air Quality. WHO, Regional Office for Europe, Copenhagen, Denmark, pp. 103-156.
[3] Health Canada. April 15, 2006. Residential Indoor Air Quality Guideline.
[4] Leng, J., Liu, C.W., Hartwell, H.J., Yu, R., Lai, Y., Bodnar, W.M., Lu, K. and Swenberg, J.A., 2019. Evaluation of inhaled low-dose formaldehyde-induced DNA adducts and DNA–protein cross-links by liquid chromatography–tandem mass spectrometry. Archives of toxicology, pp.1-11.
[5] Sheehan, P., Singhal, A., Bogen, K.T., MacIntosh, D., Kalmes, R.M. and McCarthy, J. 2017. Potential Exposure and Cancer Risk from Formaldehyde Emissions from Installed Chinese Manufactured Laminate Flooring. Risk Analysis, 38(6): 1128-1142
[6] Nielsen, G.D., Larsen, S.T. and P. Wolkoff. 2016. Re-evaluation of the WHO (2010) formaldehyde indoor air quality guideline for cancer risk assessment. Archives of Toxicology, 91(1): 35-61.

- Starr et al. 2016[7] and 2013[8] employed models to demonstrate that risks for developing cancers decrease to negligible levels at formaldehyde exposures below 2 parts per million (ppm).

- Golden 2011[9] concluded that a formaldehyde indoor air limit of 100 ppb would be protective from both irritation effects and any potential cancer hazard.

- Conolly et al. 2004[10] indicated that cancer risks associated with inhaled formaldehyde are negligible at relevant human exposure levels.

3. **Peer-Reviewed Publications Highlighting Importance of Replication, Transparency and Consistency in Chemical Evaluations of Formaldehyde**

   - Mundt et al. 2018[11] highlights why consistent methods to evaluate formaldehyde are critically important. The article evaluated completed reviews of formaldehyde carcinogenicity by several federal and international chemical assessment agencies and discusses differences in their conclusions, due in part to the methods used to evaluate and integrate the strength and quality of the science.

   - Mundt et al. 2017 [12] conducted analysis on the underlying data from a study relied upon by EPA in its 2010 IRIS assessment of formaldehyde. The completed analysis found conclusions that were different than those of the original study authors.

   - Van Landingham et al. 2016 [13] conducted an analysis of the dose-response models used by the IRIS program in its 2010 IRIS assessment of formaldehyde, relying upon the documentation provided in the IRIS assessment. The authors noted that the documentation of the methods applied by EPA lacked sufficient detail for duplication of the risk estimates.

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[7]Starr, T.B. and Swenberg, J.A. 2016. The bottom-up approach to bounding potential low-dose cancer risks from formaldehyde: An update. Regulatory Toxicology and Pharmacology, 77: 167-174.

[8] Starr, T.B. and Swenberg, J.A., 2013. A novel bottom-up approach to bounding low-dose human cancer risks from chemical exposures. Regulatory Toxicology and Pharmacology, 65(3): 311-315.

[9] Golden, R. 2011. Identifying an indoor air exposure limit for formaldehyde considering both irritation and cancer hazards. Critical Reviews in Toxicology, 41(8): 672-721.

[10] Conolly, R.B., Kimbell, J.S., Janszen, D., Schlosser, P.M., Kalisak, D., Preston, J., Miller, F.J. 2004. Human Respiratory Tract Cancer Risks of Inhaled Formaldehyde: Dose-Response Predictions Derived from Biologically-Motivated Computational Modeling of a Combined Rodent and Human Dataset. Toxicological Sciences, 82: 279-296.

[11] Mundt, K., Gentry, P.R., Dell, L., Rodricks, J., and Boffetta, P. 2018. Six years after the NRC review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity. Regulatory Toxicology and Pharmacology, 92: 472-490.

[12] Mundt, K., Gallagher, A., Dell, L., Natelson, E., Boffetta, P., and Gentry, R. 2017. Does occupational exposure to formaldehyde cause hematotoxicity and leukemia-specific chromosome changes in cultured myeloid progenitor cells? Critical Reviews in Toxicology, 47(7): 592-602.

[13] Van Landingham, C., Mundt, K.A., Allen, B.C., and Gentry, P.R. 2016. The need for transparency and reproducibility in documenting values for regulatory decision making and evaluating causality: The example of formaldehyde. Regulatory Toxicology and Pharmacology, 81: 512-521

- Checkoway et al. 2015 [14] sought to replicate the findings reported in a study relied upon by EPA's IRIS program to draw conclusion regarding potential formaldehyde leukemia risk. The findings from the analysis did not support the original study hypothesis.

- Rhomberg 2015[15] highlighted how the methods used by two federal agencies to conduct the chemical assessment led to differing views of the available evidence. Rhomberg noted key differences in the approaches, scientific methods and criteria used.

We appreciate this opportunity to provide relevant information to the hearing record.

Sincerely,

Kimberly Wise White, Ph. D.
American Chemistry Council (ACC)
Senior Director, Chemical Products and Technology Division
On Behalf of the ACC Formaldehyde Panel

Attachments

1. The French Agency for Food, Environmental and Occupational Health & Safety. 2018. Opinion on the revision of ANSES's reference values for formaldehyde: occupational exposure limits (OELs), derived no-effect levels (DNELs) for professionals, toxicity reference values (TRVs) and indoor air quality guidelines (IAQGs)
2. World Health Organization (WHO). 2010. Formaldehyde. In: Selected pollutants. WHO Guidelines for Indoor Air Quality. WHO, Regional Office for Europe, Copenhagen, Denmark, pp. 103-156.
3. Health Canada. April 15, 2006. Residential Indoor Air Quality Guideline.
4. Sheehan, P., Singhal, A., Bogen, K.T., MacIntosh, D., Kalmes, R.M. and McCarthy, J. 2017. Potential Exposure and Cancer Risk from Formaldehyde Emissions from Installed Chinese Manufactured Laminate Flooring. Risk Analysis, 38(6): 1128-1142
5. Nielsen, G.D., Larsen, S.T. and P. Wolkoff. 2016. Re-evaluation of the WHO (2010) formaldehyde indoor air quality guideline for cancer risk assessment. Archives of Toxicology, 91(1): 35-61.
6. Starr, T.B. and Swenberg, J.A. 2016. The bottom-up approach to bounding potential low-dose cancer risks from formaldehyde: An update. Regulatory Toxicology and Pharmacology, 77: 167-174.

[14] Checkoway, H., Dell, L.D., Boffetta, P., Gallagher, A.E., Crawford, L., Lees, P.S., and Mundt, K.A. 2015. Formaldehyde exposure and mortality risks from acute myeloid leukemia and other Lymphohematopoietic Malignancies in the US National Cancer Institute cohort study of workers in Formaldehyde Industries. Journal of Occupational and Environmental Medicine, 57(7): 785-794.
[15] Rhomberg, L.R. 2015. Contrasting directions and directives on hazard identification for formaldehyde carcinogenicity. Regulatory Toxicology and Pharmacology, 73(3): 829-833.

7. Starr, T.B. and Swenberg, J.A., 2013. A novel bottom-up approach to bounding low-dose human cancer risks from chemical exposures. Regulatory Toxicology and Pharmacology, 65(3): 311-315.
8. Golden, R. 2011. Identifying an indoor air exposure limit for formaldehyde considering both irritation and cancer hazards. Critical Reviews in Toxicology, 41(8): 672-721.
9. Conolly, R.B., Kimbell, J.S., Janszen, D., Schlosser, P.M., Kalisak, D., Preston, J., Miller, F.J. 2004. Human Respiratory Tract Cancer Risks of Inhaled Formaldehyde: Dose-Response Predictions Derived from Biologically-Motivated Computational Modeling of a Combined Rodent and Human Dataset. Toxicological Sciences, 82: 279-296.
10. Mundt, K., Gentry, P.R., Dell, L., Rodricks, J., and Boffetta, P. 2018. Six years after the NRC review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity. Regulatory Toxicology and Pharmacology, 92: 472-490.
11. Mundt, K., Gallagher, A., Dell, L., Natelson, E., Boffetta, P., and Gentry, R. 2017. Does occupational exposure to formaldehyde cause hematotoxicity and leukemia-specific chromosome changes in cultured myeloid progenitor cells? Critical Reviews in Toxicology, 47(7): 592-602.
12. Van Landingham, C., Mundt, K.A., Allen, B.C., and Gentry, P.R. 2016. The need for transparency and reproducibility in documenting values for regulatory decision making and evaluating causality: The example of formaldehyde. Regulatory Toxicology and Pharmacology, 81: 512-521
13. Checkoway, H., Dell, L.D., Boffetta, P., Gallagher, A.E., Crawford, L., Lees, P.S., and Mundt, K.A. 2015. Formaldehyde exposure and mortality risks from acute myeloid leukemia and other Lymphohematopoietic Malignancies in the US National Cancer Institute cohort study of workers in Formaldehyde Industries. Journal of Occupational and Environmental Medicine, 57(7): 785-794.

LETTER SUBMITTED BY REPRESENTATIVE LIZZIE FLETCHER

COLORADO
Department of Public
Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

Committee on Science, Space, and Technology
U.S. House of Representatives
2321 Rayburn HOB
Washington, D.C. 20515

The Honorable Mikie Sherrill
Chairwoman
Subcommittee on Investigations and Oversight
1208 Longworth HOB
Washington, DC 20515

The Honorable Ralph Norman
Ranking Member
Subcommittee on Investigations and Oversight
319 Cannon HOB
Washington, DC 20515

The Honorable Lizzie Fletcher
Chairwoman
Subcommittee on Environment
1429 Longworth HOB
Washington, DC 20515

The Honorable Roger Marshall
Ranking Member
Subcommittee on Environment
312 Cannon HOB
Washington, DC 20515

March 22, 2019

The Honorable Mikie Sherrill, The Honorable Lizzie Fletcher, The Honorable Ralph Norman and The Honorable Roger Marshall,

I am writing to express the importance of the EPA's Integrated Risk Information System (IRIS) Program to the State of Colorado. The program's toxicity values serve as the underpinning for numerous environmental standards, guidelines, and remedial goals.

The IRIS program develops profiles that provide toxicity values for substances in our environment. The program evaluates both cancer and non-cancer risks from ingesting or inhaling substances. For health effects other than cancer, IRIS provides a reference dose or concentration that is unlikely to cause adverse effects over a lifetime of exposure. For cancer, which, in theory, could be caused by one molecule of a substance, IRIS provides an oral slope factor or inhalation unit risk that allows us to associate an exposure concentration with a lifetime cancer risk. The toxicity values from IRIS is a key tool we use to understand the potential risk from exposure to substances and make sound decisions on environmental regulations to protect public health.

4300 Cherry Creek Drive S, Denver, CO 80246-1530 P 303-692-2000 www.colorado.gov/cdphe
Jared Polis, Governor | Jill Hunsaker Ryan, MPH, Executive Director

Toxicity values from IRIS undergo rigorous review by the National Academy of Sciences and a panel of internal and external scientific experts, as well as public comment. Therefore, developing new or revised values can take several years. However, it is this very process that makes these scientific, consensus-based values critical to our work. Colorado, as well as several EPA programs, such as the Comprehensive Environmental Response, Compensation, and Liability Act, rank these toxicity values as the top tier when deriving environmental levels as remedial goals and health-based guidance and/or standards.

While information from other states and from federal programs such as the Agency for Toxic Substances and Disease Registry (ATSDR) also provide toxicological information about substances, these lower-tier toxicity values present some challenges. ATSDR does not address cancer risk, which is often of concern at levels much lower than non-cancer risk. The use of toxicity values derived at the state level may necessitate the critical comparison of different values from different states. For example, there is currently a lack of IRIS toxicity values for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), two per- and polyfluoroalkyl substances (PFAS). States have interpreted toxicity information on PFOA and PFOS to arrive at protective water levels that span two orders of magnitude. Both ATSDR and EPA's Office of Water have also published toxicity values, but they do not align. Colorado and other states struggling with PFAS contamination must continually evaluate information from the various agencies in order to justify to our citizens why our guidance relies on the Office of Water's health advisory. In the face of credible yet differing scientific interpretation, and without a top tier toxicity value from the IRIS program, Colorado's resources may be overburdened.

Colorado relies on IRIS toxicity values to provide guidance on safe consumption of fish, develop recommended water quality criteria to protect the domestic water supply, derive health guideline values for oil and gas activities, conduct human health risk assessments that feed into remedial determinations, and offer guidance to the public and local public health agencies on all matters of environmental exposures. I cannot emphasize enough the importance of the IRIS Program. We use it daily to help us protect Coloradans' health.

Sincerely,

Jill Hunsaker Ryan

Jill Hunsaker-Ryan
Executive Director

cc: Office of Congressman Ed Perlmutter

4300 Cherry Creek Drive S, Denver, CO 80246-1530 P 303-692-2000 www.colorado.gov/cdphe
Jared Polis, Governor | Jill Hunsaker Ryan, MPH, Executive Director

DOCUMENT SUBMITTED BY REPRESENTATIVE BILL FOSTER

EPA/635/R-16/350Fc
www.epa.gov/iris

# Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide

## EXECUTIVE SUMMARY

(CASRN 75-21-8)

**In Support of Summary Information on the Integrated Risk Information System (IRIS)**

*December 2016*

National Center for Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC

## 1. EXECUTIVE SUMMARY

Ethylene oxide (EtO) is a gas at room temperature. It is manufactured from ethylene and used primarily as a chemical intermediate in the manufacture of ethylene glycol. It is also used as a sterilizing agent for medical equipment and a fumigating agent for spices.

### CHARACTERIZATION OF THE CARCINOGENIC HAZARD

The DNA-damaging properties of EtO have been studied since the 1940s. EtO is known to be mutagenic in a large number of living organisms, ranging from bacteriophage to mammals, and to induce chromosome damage. It is carcinogenic in mice and rats, inducing tumors of the lymphohematopoietic system, brain, lung, connective tissue, uterus, and mammary gland. In humans employed in EtO-manufacturing facilities and in sterilizing facilities, there is strong evidence of an increased risk of cancer of the lymphohematopoietic system and of breast cancer in females. Increases in the risk of lymphohematopoietic cancer have been seen in most (but not all) of the epidemiological studies of EtO-exposed workers, manifested as an increase either in leukemia or in cancer of the lymphoid tissue. Of note, one large epidemiologic study conducted by the National Institute for Occupational Safety and Health (NIOSH) of sterilizer workers that had a well-defined exposure assessment for individuals reported positive exposure-response trends for lymphohematopoietic cancer mortality, primarily in males and in particular for lymphoid cancer (i.e., non-Hodgkin lymphoma [NHL], myeloma, and lymphocytic leukemia), and for breast cancer mortality in females (Steenland et al., 2004). The positive exposure-response trend for female breast cancer was confirmed in an incidence study based on the same worker cohort (Steenland et al., 2003). There is supporting evidence for an association between EtO and breast cancer from other studies, but the database is more limited than that for lymphohematopoietic cancers, in part because there are not as many studies that include sufficient numbers of females.

Although the evidence of carcinogenicity from human studies was deemed short of conclusive on its own, EtO is characterized as "carcinogenic to humans" by the inhalation route of exposure based on the total weight of evidence, in accordance with the U.S. Environmental Protection Agency's (EPA's) 2005 *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a). The lines of evidence supporting this characterization include: (1) strong, but less than conclusive on its own, epidemiological evidence of lymphohematopoietic cancers and breast cancer in EtO-exposed workers, (2) extensive evidence of carcinogenicity in laboratory animals, including lymphohematopoietic cancers in rats and mice and mammary carcinomas in mice following inhalation exposure, (3) clear evidence that EtO is genotoxic and sufficient weight of evidence to support a mutagenic mode of action for EtO carcinogenicity, and (4) strong evidence

that the key precursor events are anticipated to occur in humans and progress to tumors, including evidence of chromosome damage in humans exposed to EtO. Overall, confidence in the hazard characterization of EtO as "carcinogenic to humans" is high.

**DERIVATION OF THE INHALATION UNIT RISK ESTIMATE**

Inhalation unit risk estimates were developed for evaluating the potential cancer risks posed by inhalation exposure to EtO. The unit risk estimates for cancer mortality and incidence were based on the human data from the NIOSH study (Steenland et al., 2004; Steenland et al., 2003). This study was selected for the derivation of risk estimates because it is a high-quality study,[1] it is the largest of the available studies, and it has exposure estimates for the individual workers from a high-quality exposure assessment. Multiple modeling approaches were evaluated for the exposure-response data, including modeling the cancer response as a function of either categorical exposures or continuous individual exposure levels. Model selection for each cancer data set was primarily based on a preference for models of the individual-level continuous exposure data, prioritization of models that are more tuned to local behavior in the low-exposure data, and a weighing of statistical and biological considerations.

Unit risk estimates based on the human data were first derived under the common assumption that relative risk is independent of age. This assumption is later superseded by an assumption of increased early-life susceptibility, and it is the unit risk estimates derived under this latter assumption that are the ultimate estimates proposed in this assessment (presented further below).

Under the assumption that relative risk is independent of age, an $LEC_{01}$ (lower 95% confidence limit on the $EC_{01}$, the estimated effective concentration associated with 1% extra risk) for excess lymphoid cancer mortality (Steenland et al., 2004) was calculated using a life-table analysis and the lower spline segment from a two-piece linear spline model. Linear low-dose extrapolation below the range of observations is supported by the conclusion that a mutagenic mode of action is operative in EtO carcinogenicity. Linear low-dose extrapolation from the $LEC_{01}$ for lymphoid cancer mortality yielded a lifetime extra cancer unit risk estimate of $1.1 \times 10^{-3}$ per $\mu g/m^3$ ($2.0 \times 10^{-3}$ per ppb)[2] of continuous EtO exposure. Applying the same lower-spline regression coefficient and life-table analysis to background lymphoid cancer

[1]The NIOSH study (Steenland et al., 2004; Steenland et al., 2003) was judged to be a "high-quality" study based on the attributes discussed in Section 3.1 and in Section A.2.8 of Appendix A, including availability of individual worker exposure estimates from a high-quality exposure assessment, cohort study design, large size, inclusion of males and females, adequate follow-up, absence of any known confounding exposures, and use of internal comparisons. The breast cancer incidence study using the subcohort of female workers with interviews had the additional attribute of investigating and controlling for a number of breast cancer risk factors (Steenland et al., 2003).

[2]Conversion equation: 1 ppm = 1,830 $\mu g/m^3$.

*incidence* rates and applying linear low-dose extrapolation resulted in a preferred lifetime extra lymphoid cancer unit risk estimate of $2.9 \times 10^{-3}$ per $\mu g/m^3$ ($5.3 \times 10^{-3}$ per ppb), as cancer incidence estimates are generally preferred over mortality estimates.

Breast cancer incidence risk estimates were calculated directly from the data from a breast cancer incidence study of the same occupational cohort (Steenland et al., 2003). Using the same life-table approach, the lower spline segment from a two-piece linear spline model, and linear low-dose extrapolation, a unit risk estimate of $8.1 \times 10^{-4}$ per $\mu g/m^3$ ($1.5 \times 10^{-3}$ per ppb) was obtained for breast cancer incidence. A unit risk estimate for breast cancer mortality was also calculated from the cohort mortality data; however, the incidence estimate is preferred over the mortality estimate.

Combining the incidence risk estimates for the two cancer types resulted in a total cancer unit risk estimate of $3.3 \times 10^{-3}$ per $\mu g/m^3$ ($6.1 \times 10^{-3}$ per ppb).[3]

Unit risk estimates (for total cancer) were also derived from the three chronic rodent bioassays for EtO reported in the literature. These estimates, ranging from $2.2 \times 10^{-5}$ per $\mu g/m^3$ to $4.6 \times 10^{-5}$ per $\mu g/m^3$, are about two orders of magnitude lower than the estimate based on human data. The Agency takes the position that human data, if adequate data are available, provide a more appropriate basis than rodent data for estimating population risks (U.S. EPA, 2005a), primarily because uncertainties in extrapolating quantitative risks from rodents to humans are avoided. Although there is a sizeable difference between the rodent-based and the human-based estimates, the human data are from a large, high-quality study, with EtO exposure estimates for the individual workers and little reported exposure to chemicals other than EtO. Therefore, the estimates based on the human data are the preferred estimates for this assessment.

Because the weight of evidence supports a mutagenic mode of action for EtO carcinogenicity, and as there are no chemical-specific data from which to assess early-life susceptibility, increased early-life susceptibility should be assumed, according to the EPA's *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*—hereinafter referred to as the "EPA's *Supplemental Guidance*" (U.S. EPA, 2005b). This mode-of-action-based assumption of increased early-life susceptibility supersedes the assumption of age independence under which the human data-based estimates presented above were derived. Thus, using the same approach and exposure-response models as for the estimates discussed above but initiating exposure in the life-table analysis at age 16 instead of at birth, adult-exposure-only unit risk estimates were calculated for lymphoid cancer incidence and breast cancer incidence under an alternate assumption that relative risk is independent of age for adults, which represent the life stage pertaining to the occupational cohort data which were used

[3]The method used to derive the total cancer unit risk estimate involves estimating an upper bound on the sum of the maximum likelihood estimates of risk; see Section 4.1.3.

for the exposure-response modeling. These adult-exposure-only unit risk estimates were then rescaled to a 70-year basis for use in the standard age-dependent adjustment factors (ADAFs) calculations and risk estimate calculations involving less-than-lifetime exposure scenarios. The resulting adult-based unit risk estimates were $2.6 \times 10^{-3}$ per $\mu g/m^3$ ($4.8 \times 10^{-3}$ per ppb) for lymphoid cancer incidence, $7.0 \times 10^{-4}$ per $\mu g/m^3$ ($1.3 \times 10^{-3}$ per ppb) for breast cancer incidence in females, and $3.0 \times 10^{-3}$ per $\mu g/m^3$ ($5.5 \times 10^{-3}$ per ppb) for both cancer types combined. The adult-based unit risk estimates, which were derived under an assumption of increased early-life susceptibility, supersede those presented earlier that were derived under the assumption that relative risk is independent of age. When using the adult-based unit risk estimates to estimate extra cancer risks for a given exposure scenario, the standard ADAFs should be applied, in accordance with the EPA's *Supplemental Guidance* (U.S. EPA, 2005b). Applying the ADAFs to obtain a full lifetime total cancer unit risk estimate yields $5.0 \times 10^{-3}$ per $\mu g/m^3$ ($9.1 \times 10^{-3}$ per ppb), and the commensurate lifetime chronic (lower-bound) exposure level of EtO corresponding to an increased cancer risk of $10^{-6}$ is $2 \times 10^{-4}$ $\mu g/m^3$ ($1 \times 10^{-4}$ ppb).

The unit risk estimate is intended to provide a reasonable upper bound on cancer risk from inhalation exposure. The estimate was developed for environmental exposure levels (it is considered valid for exposures up to about 40 $\mu g/m^3$ [20 ppb]) and is not applicable to higher level exposures, such as those that may occur occupationally, which appear to have a different exposure-response relationship (see below for a summary of risk estimates for occupational exposure scenarios).

**CONFIDENCE IN THE UNIT RISK ESTIMATE**

The primary sources of uncertainty in the unit risk estimates derived from the human data include the retrospective exposure assessment conducted for the epidemiology study, the exposure-response modeling of the epidemiological data, and the low-dose extrapolation.[4] Despite uncertainties in the unit risk estimate, confidence in the estimate is relatively high. First, confidence in the hazard characterization of EtO as "carcinogenic to humans," which is based on strong epidemiological evidence supplemented by other lines of evidence, is high. Second, the unit risk estimate is based on human data from a large, high-quality epidemiology study with individual worker exposure estimates. Retrospective exposure estimation is an inevitable source of uncertainty in this type of epidemiology study; however, the NIOSH investigators put extensive effort into addressing this issue by developing a state-of-the-art regression model to estimate unknown historical exposure levels using variables, such as sterilizer size, for which historical data were available. In addition, the two-piece spline models used in this assessment

[4]See Section 4.1.4 for additional discussion of these and other sources of uncertainty in the unit risk estimates.

to model the supralinear exposure-response relationships are considered to provide a reasonable basis for the derivation of unit risk estimates. Finally, the use of linear low-exposure extrapolation is strongly supported by the conclusion that EtO carcinogenicity has a mutagenic mode of action.

Confidence in the unit risk estimate is particularly high for the breast cancer component, which is based on over 200 incident cases for which the investigators also had information on other potential breast cancer risk factors. The selected model for the breast cancer incidence data provided a good global fit as well as a good local fit in the lower exposure range of greatest relevance for the derivation of a unit risk estimate. The actual unit risk might be higher or lower; however, considering the continuous-exposure linear model as a lower bound for the supralinear exposure-response relationship suggests that while a unit risk estimate for breast cancer incidence that is up to fourfold lower is plausible, unit risk estimates lower than that are considered unlikely from the available data. Sensitivity analyses for lag time, inclusion of covariates, knot, upper-bound estimation approach, use of the full incidence cohort, and inclusion of only invasive cancers for the breast cancer background rates in the life table indicate that the unit risk estimate is not highly influenced by these factors, with comparison unit risk estimates differing by at most 40%.

There is somewhat less, although still relatively high in general, confidence in the lymphoid cancer component of the unit risk estimate because it is based on fewer events (53 lymphoid cancer deaths); incidence risk was estimated from mortality data; and the exposure-response relationship is exceedingly supralinear, complicating the exposure-response modeling and model selection to a greater extent than for breast cancer incidence. The actual unit risk might be higher or lower than that from the selected model, and there were no clear upper or lower bounds for the apparent exposure-response relationship provided by other models. Sensitivity analyses for lag time, knot, and upper-bound estimation approach, indicate that the unit risk estimate for lymphoid cancer is more influenced by these factors than was the estimate for breast cancer incidence. Comparison unit risk estimates from the sensitivity analyses ranged from about 50% of the preferred unit risk estimate to about three times that estimate. While there is less confidence in the lymphoid cancer unit risk estimate than in the breast cancer unit risk estimate, the lymphoid cancer estimate is considered a reasonable estimate from the available data, and overall, there is relatively high confidence in the total cancer unit risk estimate.

## RISK ESTIMATES FOR OCCUPATIONAL EXPOSURE SCENARIOS

As noted above, the inhalation unit risk estimate was developed for environmental exposure levels (up to about 40 $\mu g/m^3$ [20 ppb]) and is not applicable to higher exposure levels,

such as those that may occur occupationally, which appear to have a different exposure-response relationship. However, occupational exposure levels of EtO are of concern to the EPA when EtO is used as a pesticide (e.g., sterilizing agent or fumigant). Therefore, this document also presents estimates of extra risk for the two cancer types for a range of occupational inhalation exposure scenarios (see Section 4.7). Maximum likelihood estimates of the extra (incidence) risk of lymphoid cancer and breast cancer combined for the range of occupational exposure scenarios considered (i.e., 0.1 to 1 ppm 8-hour time-weighted average [TWA] for 35 years) ranged from 0.037 to 0.11; upper-bound estimates ranged from 0.081 to 0.22. The uncertainty associated with the extra risk estimates for occupational exposure scenarios is less than that associated with the unit risk estimates for environmental exposures, and the overall confidence in the extra risk estimates for occupational exposure is high. The extra risk estimates are derived for occupational exposure scenarios that yield cumulative exposures well within the range of the exposures in the NIOSH study. Moreover, the NIOSH study is a study of sterilizer workers who used EtO for the sterilization of medical supplies or spices (Steenland et al., 1991); thus, the results are directly applicable to workers in these occupations, and these are among the occupations of primary concern to the EPA.

**SUMMARY OF ASSESSMENT FINDINGS**

Table 1-1 provides a summary of the major findings in this assessment.

**Table 1–1. Summary of major findings**

| **Hazard conclusions** | |
|---|---|
| **Hazard characterization** | The weight of evidence from epidemiological studies and supporting information is sufficient to conclude that ethylene oxide is carcinogenic to humans. |
| **Mode of action** | The weight of evidence is sufficient to conclude that ethylene oxide carcinogenicity has a mutagenic mode of action. |
| **Inhalation unit risk estimates (for environmental exposures)[a]** | |
| **Basis** | **Inhalation unit risk estimate[a] (per μg/m³)[b]** |
| **Full lifetime unit risk estimate (includes ADAFs)[c]** | |
| Total cancer risk based on human data[d]—lymphoid cancer incidence and breast cancer incidence in females | **$5.0 \times 10^{-3}$** |
| **Adult-based unit risk estimates (for use with ADAFs)[e]** | |
| Total cancer risk based on human data[d]—lymphoid cancer incidence and breast cancer incidence in females | **$3.0 \times 10^{-3}$** |
| Lymphoid cancer incidence in both sexes based on human data | $2.6 \times 10^{-3}$ |
| Breast cancer incidence in females based on human data | $7.0 \times 10^{-4}$ |
| Total cancer incidence risk estimate from rodent data (female mouse) | $4.6 \times 10^{-5}$ |
| **Extra risk estimates for occupational inhalation exposure scenarios (see Section 4.7)** | |
| Maximum likelihood estimates of the extra risk of lymphoid cancer and breast cancer combined for the range of occupational exposure scenarios considered (i.e., 0.1 to 1 ppm 8-hr TWA for 35 yr)[f] | 0.037–0.11 |
| Upper-bound estimates of the extra risk of lymphoid cancer and breast cancer combined for the range of occupational exposure scenarios considered (i.e., 0.1 to 1 ppm 8-hr TWA for 35 yr)[f] | **0.081–0.22** |

[a]These unit risk estimates are not intended for use with continuous lifetime exposure levels above about 40 μg/m³. See Section 4.7 for risk estimates based on occupational exposure scenarios. Preferred estimates are in bold.
[b]To convert unit risk estimates to $(ppm)^{-1}$, multiply the $(\mu g/m^3)^{-1}$ estimates by 1,830 (μg/m³)/ppm. Also, 1 ppb = 1.83 μg/m³.
[c]Because the weight of evidence supports a mutagenic mode of action for EtO carcinogenicity, and because of the lack of chemical-specific data, the EPA assumes increased early-life susceptibility and recommends the application of ADAFs, in accordance with the EPA's *Supplemental Guidance* (U.S. EPA, 2005b), for exposure scenarios that include early-life exposures. For the full lifetime (upper-bound) unit risk estimate presented here, ADAFs have been applied, as described in Section 4.4.
[d]To be precise, this unit risk estimate reflects the total (upper-bound) cancer risk to females and not to the general population because the breast cancer risk estimate only applies to females. As a practical matter for regulatory purposes, however, females comprise roughly half the general population and this unit risk estimate enables risk managers to evaluate the individual risk for this substantial population group. For the purposes of estimating numbers of cancer cases attributable to specific exposure levels (e.g., for benefits analyses), it would be more appropriate to use the cancer-specific unit risk estimates (or central tendency estimates), taking sex into account.
[e]These (upper-bound) unit risk estimates are intended for use in ADAF calculations and less-than-lifetime adult exposure scenarios (U.S. EPA, 2005b). Note that these are not the same as the unit risk estimates derived directly from the human data in Section 4.1 under the assumption that RRs are independent of age. See Section 4.4 for the derivation of the adult-based unit risk estimates.
[f]Technically, these sums would reflect the total cancer risk to females and not a mixed-sex workforce because the breast cancer risk estimate only applies to females. As a practical matter for regulatory purposes, however, females typically comprise a substantial proportion of the sterilizer workforce and summing these extra risk estimates enables risk managers to evaluate the individual risk for this substantial workforce group. In a situation in which the workforce of concern is comprised predominantly of males, it might be appropriate to use a sex-weighted sum of the extra risks from the two cancer types (see Section 4.7 for the cancer-specific extra risk estimates).
hr = hour; yr = year.

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