Testimony of

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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.

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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.

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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.

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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.

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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

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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

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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.

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