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Hearing on Status of Reforms to EPA's Integrated Risk Information System (IRIS) Process
before the
U.S. House of Representatives
Committee on Science, Space, and Technology
Subcommittees on Oversight and the Environment
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Good morning, Chairman Broun, Ranking member Maffei, Chairman Schweikert, Ranking member Bonamici and other distinguished members of the two Subcommittees. My name is Kenneth Olden, and I am the director of the National Center for Environmental Assessment in the Office of Research and Development at the U.S. Environmental Protection Agency (EPA). I appreciate the opportunity to talk with you today about EPA's Integrated Risk Information System Program – commonly called IRIS. Specifically, I am pleased to report on the progress we have made in IRIS over the past two years and the actions that are part of our ongoing efforts to enhance this critical program. A number of areas have been enhanced that further strengthen the scientific integrity of assessments, further increase transparency, and further improve productivity.

These changes were reviewed recently by a panel of the National Academies' National Research Council (NRC), who commended our progress and successes and recognized that we have made a tremendous amount of progress in a short period of time. Recommendations from the National Academies help make EPA's science stronger and we value their guidance in gauging our progress. We appreciate the rigorous scientific review of the IRIS program's assessment development process which,

in the end, will help the Agency better protect human health and the environment.

Background and Description of the IRIS Program

EPA's IRIS program plays a critical role in disseminating timely, high-quality and accessible human health risk information on environmental contaminants that may endanger the health of the American public. The IRIS Program provides health effects information on chemicals to which the public may be exposed from releases to air, water, and land and through the use and disposal of products.

IRIS assessments provide a solid scientific foundation for EPA decisions to protect public health under an array of environmental laws. It is important to state that IRIS assessments are not regulations and they are not environmental decisions. Rather, the assessments are a resource that EPA draws on for its decision making process and can also be a resource for other risk assessors and environmental and health professionals in state and local governments and other countries. Given the potential impact that regulatory decisions have on human health and the economy, it is critically important that the IRIS assessment development process be efficient, transparent and, above all, scientifically rigorous.

2011 National Research Council Recommendations for IRIS and Summary of Progress

In April 2011, the National Academies' National Research Council (NRC) provided EPA with recommendations for improving the development of IRIS assessments.[1] The NRC was clear that their intent was not to delay assessments and that fully addressing their recommendations should be a multi-year, continuous improvement process. Consistent with this advice, EPA has been implementing the recommendations using a phased approach.

[1] National Research Council, 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde.

EPA has since released several draft assessments that represent major advancements in implementing the NRC's 2011 recommendations. EPA immediately adopted NRC's short-term recommendations including increasing transparency and clarity, using more tables and figures to present information and data in IRIS assessments, and editing and streamlining documents to enhance communication. Next EPA implemented the more substantive NRC recommendations which were focused on improving approaches for identifying and selecting the most pertinent studies to inform the assessments; evaluating and describing the strengths and weaknesses of the critical studies in a uniform, clear manner; strengthening the integration of quantitative evidence for hazard identification; establishing clearer criteria for study selection for dose-response analysis, including toxicity values for multiple effects associated with the chemical; routinely considering the use of multiple data sets of combined multiple responses in deriving toxicity values; and increasing overall transparency in dose-response analysis. To address these, EPA's IRIS assessments now include:

- An Executive Summary at the beginning of the assessment that concisely summarizes the major conclusions of the assessment related to hazard characterization and dose response analyses.
- A Preamble that describes how we applied methods, criteria, and existing EPA guidance to develop the assessments. These methods and evaluation criteria are being applied consistently across IRIS assessments.
- A detailed description of the literature search strategy and study evaluation process used to develop the assessment.
- Two distinct sections, Hazard Identification and Dose-Response Analysis, to reduce the volume of text and redundancies and to increase transparency into the process that led to the assessment's conclusions.

- An appendix documenting the implementation of the NRC recommendations to the assessment process as it relates to the individual chemical assessment.
- An appendix summarizing the peer review of the assessment, public comments, and EPA's responses.
- Improved public access to the science basis for the IRIS assessments via the Health and Environmental Research Online (HERO) system.

We have also further strengthened quality control in the IRIS Program through organizational changes that capitalize on EPA's effort to modernize its human and informational resources. Previously, we used individual assessment teams to develop IRIS assessments. We now have discipline-specific workgroups that coordinate across assessments to ensure consistency, deep expertise, advanced scientific understanding, and the ability to solve cross cutting issues common among groups of assessments. The discipline-specific workgroups cover topics related to: reproductive/developmental toxicity, neurotoxicity, respiratory/inhalation toxicity, systemic and general toxicity, immunotoxicity, cancer, epidemiology, toxicity pathways/genetic toxicity, statistics and dose-response analysis, and physiologically-based pharmacokinetic modeling.

The expertise needed for each chemical undergoing assessment by the IRIS Program varies by chemical. The areas of expertise needed are identified in the early stages of planning and document development and the appropriate scientific personnel and discipline-specific workgroups are assigned to lead or assist in the development of the assessment.

We have also formed a group of senior science managers, who report to me, to oversee the work of the chemical assessment teams during the assessment development process. This group ensures

consistency across chemical groups and helps to identify and resolve any implementation challenges or inefficiencies early in the process to ensure the assessments are of the very highest scientific quality.

Finally, we have expanded IRIS quality control measures by developing a draft handbook of procedures for IRIS assessment development. This handbook details the internal processes and evaluation steps to develop assessments and the information management tools to identify and address scientific or data issues that may occur during assessment development.

2013 Enhancements to the IRIS Program

We have also taken more recent steps to further improve IRIS. In July 2013, EPA announced a series of enhancements to the IRIS Program with the goal of improving the scientific integrity of assessments, increasing the productivity of the IRIS Program, and increasing transparency so issues are identified and discussed earlier in the assessment development process.[2] These enhancements incorporate additional opportunities for stakeholder and public engagement at various stages of the IRIS process, and since announcing them, we have been convening bimonthly IRIS public science meetings to discuss scientific issues related to preliminary assessment materials and draft IRIS assessments. The IRIS enhancements will help ensure transparency throughout the IRIS assessment development process, and they will help ensure that major science decisions are rigorously vetted.

Additionally, the Agency has established a new Chemical Assessment Advisory Committee, under the auspices of the Science Advisory Board, to review draft IRIS assessments. EPA will also consult with the committee on questions regarding the IRIS Program. The committee is comprised of 26

[2] http://www.epa.gov/iris/pdfs/irisprocessfactsheet2013.pdf

highly qualified scientists with a broad range of expertise relevant to human health assessments. This committee will help ensure that IRIS assessment receive rigorous scientific peer review.

Ultimately, these changes will help EPA meet the goal of using the best available science to produce high quality scientific IRIS assessments in a timely and transparent manner. The 2013 IRIS enhancements are in line with the NRC's recommendations related to improving the development of IRIS assessments and advancing risk assessment in general, including the importance of up front planning and scoping in the risk assessment process.[3]

National Research Council May 2014 Review of the IRIS Process

Two years ago, we asked the NRC to conduct a comprehensive review of the IRIS assessment development process. As part of this review, EPA sent written materials to the NRC which provide information about the changes that have been made or are being made in the IRIS Program along with chemical-specific examples of how the Program is implementing the NRC recommendations.[4] The NRC considered these materials as they reviewed the IRIS assessment development process.

In May 2014, the NRC released their report reviewing the IRIS assessment development process. In this report, the NRC commends EPA's movement forward in each element of the assessment process and cites substantial improvement in a short period of time. Specifically, the report notes, "overall, the committee finds that substantial improvements in the IRIS process have been made, and it is clear that EPA has embraced and is acting on the recommendations in the NRC formaldehyde report."[5]

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[3] National Research Council, 2009. Science and Decisions: Advancing Risk Assessment

[4] http://www.epa.gov/iris/iris-nrc.htm

[5] National Research Council, 2014. Review of EPA's Integrated Risk Information System (IRIS) Process.

Especially appreciated by EPA, the Committee expressed confidence in the current leadership of the IRIS Program and the Agency's commitment to completing the revisions underway. To quote the committee:

> "Overall, the changes that EPA has proposed and implemented to various degrees constitute substantial improvements in the IRIS process. If current trajectories are maintained, inconsistencies identified in the present report are addressed, and objectives still to be implemented are successfully completed, the IRIS process will become much more effective and efficient in achieving the program's basic goal of developing assessments that provide an evidence-based foundation for ensuring that chemical hazards are assessed and managed optimally."[6]

The 2014 NRC report provides recommendations that the committee states should be seen as further building on the progress that EPA has already made.

EPA is grateful to the NRC for their thorough and thoughtful review. The NRC reviewed materials that we submitted in the first half of 2013. Since that time, we have continued to evolve, and we have made further changes that are in line with the recommendations in this report. We embrace and will implement the recommendations in the NRC report. We plan to convene a public workshop in October 2014 to address some specific recommendations from this report.

As the director of EPA's National Center for Environmental Assessment – home of the IRIS Program – I can assure you that I fully intend to maintain this critical national Program to the highest standards possible. I have high confidence that the ORD senior management team also provides their unwavering support.

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[6] National Research Council, 2014. Review of EPA's Integrated Risk Information System (IRIS) Process.

In conclusion, EPA is committed to transparency and scientific excellence and we appreciate the scientific community's work – through the National Academy – in helping us meet that commitment. We are committed to a strong, vital, and scientifically sound IRIS Program. We have worked hard to further strengthen the scientific basis underlying the IRIS Program, improve transparency and accessibility, and to streamline processes to be more efficient. As the IRIS Program continues to evolve, we are committed to evaluating how well our approaches promote constructive public discussion with our stakeholders, as well as reviewing how our approaches can more effectively facilitate subsequent assessment development.

I look forward to keeping this Committee updated on our progress, and thank you for the opportunity to appear before you today. I am happy to take any questions you may have at this time.