

WRITTEN TESTIMONY

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Good morning Chairman Shimkus, Ranking Member Greene and other members of the Committee. My name is Paul Anastas. I am the Assistant Administrator for Research and Development (ORD) at the Environmental Protection Agency and the Agency's Science Advisor. It is a pleasure to be here with you this morning to discuss EPA's Integrated Risk Information System (IRIS).

Background and Description of IRIS Program

EPA recognizes the critical role we play in providing timely, high-quality and accessible human health risk information on environmental contaminants that may endanger the health of the American public. Central to this aspect of EPA's mission is the Integrated Risk Information System, commonly called the IRIS program. This 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 scientific foundation for EPA decisions to protect public health across EPA's programs and regions under an array of environmental laws. These documents provide federal, state, local and other policy makers with the latest scientific information to make decisions about cleanup and other actions to protect

people's health. While they are not complete risk assessments, they provide important information that helps to inform regulations. IRIS assessments provide information on a chemical's potential for causing adverse health effects along with information about the relationship between the dose of the substance and the biological response. When this information is combined with information about exposure, government and private entities frequently use IRIS values to characterize the public health risks of chemical substances. When EPA and others make decisions about chemicals, the scientific information in an IRIS assessment is combined with relevant considerations such as statutory and legal requirements, economic and social factors, risk management options, and public health and cost/benefit information. Therefore, IRIS assessments provide the science to support risk management decisions to protect public health. For instance, the EPA recently released IRIS toxicity values for trichloroethylene (TCE) will be considered in:

- Establishing cleanup methods at the 761 Superfund sites where TCE has been identified as a contaminant
- Understanding the risk from vapor intrusion as TCE vapors move from contaminated groundwater and soil into the indoor air of overlying buildings
- Revising EPA's Maximum Contaminant Level for TCE as part of the carcinogenic volatile organic compounds group in drinking water, as described in the agency's drinking water strategy
- Developing appropriate regulatory standards limiting the atmospheric emissions of TCE – a hazardous air pollutant under the Clean Air Act

2009 Improvements

After becoming Administrator in early 2009, Administrator Jackson reviewed the IRIS program and asked the Office of Research and Development (ORD) to implement a new IRIS process that would revitalize the program and make it more responsive to the needs of the Agency. The aim of the new process was to ensure the highest level of scientific quality, integrity, transparency, and timeliness.

EPA undertook several actions to implement the new IRIS process in 2009. EPA regularly solicits public comments on the IRIS agenda, and ORD works directly with program

and regional offices to ensure that IRIS assessments meet their needs. To ensure that IRIS assessments are focused on the highest priority needs, EPA expanded the role of the program and regional offices in nominating and prioritizing chemicals for assessment. EPA also has increased efforts to work with other agencies to share data and avoid duplication of effort. These efforts help to increase efficiency and assessment output.

There have been many improvements to the IRIS program as a result of the changes made in 2009. Assessment development time was shortened to 23 months for most assessments, which will speed the availability of IRIS assessments for use by the risk assessment community and public. The IRIS program is now entirely managed by EPA. All of the assessments undergo rigorous, open and independent external peer review that offer multiple opportunities for public review and comment. Additionally, changes in IRIS assessments that occur during the interagency and public process are documented and explained, ensuring a transparent final product.

EPA has created an IRIS logistics team to help streamline the assessment development process. We have developed the Health and Environmental Research Online Database – or HERO – which makes the scientific studies selected and used by the Agency to develop assessments available to the public.

Response to the NAS Report

In April 2011, the National Academy of Sciences (NAS) made suggestions to improve the development of draft IRIS assessments. EPA welcomed those suggestions and is addressing all of them. The Academy recognized that implementing these changes would require a phased-in approach. Although the public will not see the changes for some time, EPA is already implementing many of the NAS recommendations and EPA has a plan for implementing them all.

In their report, the Academy suggested steps that EPA could take “to improve IRIS assessment through the implementation of methods that would better reflect current practices.” The Academy report also stated that: “The committee recognizes that the changes suggested

would involve a multiyear process and extensive effort by the staff of the National Center for Environmental Assessment and input and review by the EPA.” (see NRC report at page 135)

EPA is working closely with the agency’s Science Advisory Board on how to bring to bear its expertise on an ongoing basis to focus on the quality, transparency and scientific rigor of IRIS assessments and guide EPA’s response to the NAS recommendations.

A summary of the NAS overall recommendations and EPA’s responses to them are described below.¹

1. NAS recommended that EPA rigorously edit documents to reduce the text volume and address redundancies and inconsistencies.

To respond to this recommendation, EPA is rigorously editing our assessment documents to substantially reduce the volume of text and address redundancies and inconsistencies; building on the existing IRIS guidelines and process to enhance the clarity and transparency of data evaluation and the presentation of findings and conclusions; consolidating related discussions to eliminate redundancies; increasing the use of tables and figures to improve communication of information; and providing reference information on the IRIS website for all studies considered.

¹ Full text from p. 152 of the final published NAS report.

- To enhance the clarity of the document, the draft IRIS assessment needs rigorous editing to reduce the volume of text substantially and address redundancy and inconsistency. Long descriptions of particular studies, for example, should be replaced with informative evidence tables. When study details are appropriate, they could be provided in appendixes.
- Chapter 1 needs to be expanded to describe more fully the methods of the assessment, including a description of search strategies used to identify studies with the exclusion and inclusion criteria clearly articulated and a better description of the outcomes of the searches (a model for displaying the results of literature searches is provided later in this chapter) and clear descriptions of the weight-of evidence approaches used for the various non-cancer outcomes. The committee emphasizes that it is not recommending the addition of long descriptions of EPA guidelines to the introduction, but rather clear concise statements of criteria used to exclude, include, and advance studies for derivation of the RfCs and unit risk estimates.
- Standardized evidence tables for all health outcomes need to be developed. If there were appropriate tables, long text descriptions of studies could be moved to an appendix or deleted.
- All critical studies need to be thoroughly evaluated with standardized approaches that are clearly formulated and based on the type of research, for example, observational epidemiologic or animal bioassays. The findings of the reviews might be presented in tables to ensure transparency. The present chapter provides general guidance on approaches to reviewing the critical types of evidence.
- The rationales for the selection of the studies that are advanced for consideration in calculating the RfCs and unit risks need to be expanded. All candidate RfCs should be evaluated together with the aid of graphic displays that incorporate selected information on attributes relevant to the database.
- Strengthened, more integrative, and more transparent discussions of weight of evidence are needed. The discussions would benefit from more rigorous and systematic coverage of the various determinants of weight of evidence, such as consistency.

- 2. NAS recommended that EPA include a fuller discussion of methods and develop concise statements of the criteria used to exclude, include and advance studies for hazard evaluation and derivation of toxicity values.**

In response to this recommendation, EPA is providing a fuller discussion of the methods used in our assessments, along with concise statements of the criteria used to exclude, include, and focus on the highest quality studies for hazard assessment and for derivation of toxicity values.

- 3. NAS recommended standardized evidence tables for all health outcomes.**

EPA is working towards replacing text descriptions of the studies with standardized evidence tables that provide the methods and results of each study for all health outcomes; and including text that will accompany evidence tables to present the criteria used to include or exclude studies.

- 4. NAS recommended that EPA provide a clearer articulation of the rationale and criteria for screening studies.**

To accomplish this, EPA is enhancing our sequential approach for progressively focusing on the most pertinent information, including: searching the literature, identifying the pertinent studies, and evaluating study characteristics; evaluating the overall weight of evidence for each health outcome; identifying plausible approaches for developing toxicity values; selecting the most pertinent data and developing toxicity values for each health hazard; and portraying toxicity information graphically.

- 5. NAS recommended that EPA use uniform approaches to thoroughly evaluate the strengths and weaknesses of critical studies, summarize findings in tables, and clearly articulate the rationale for the studies used to calculate toxicity values.**

To respond to these two suggestions EPA is streamlining IRIS assessment documents and more fully documenting our approach for assembling and evaluating the range of scientific data. As the NAS report indicated, we have already made similar changes to how we present the scientific evidence on the criteria air pollutants in our Integrated

Science Assessments, and we are confident we can make comparable improvements in how we present our analysis of health study findings for chemicals evaluated in the IRIS program. EPA is also implementing a more uniform approach to our evaluation of the strengths and weaknesses of critical studies to increase the clarity of the rationale for selecting the studies used to calculate toxicity values. Lastly, we are increasing the use of evidence tables that summarize the factual details of pertinent studies for each health hazard and developing standardized language to describe study strengths and limitations.

6. NAS recommended that EPA provide descriptions to indicate various determinants of weight of evidence to promote understanding of what elements were emphasized in synthesizing the evidence.

In response, EPA is augmenting its current analysis of data to indicate which criteria were most influential in evaluating the weight of evidence.

Timeline for Responding to NAS Recommendations

EPA's overarching goal is to continually improve our IRIS assessments, recognizing that these improvements will have a greater impact on our new assessments as opposed to those already in the pipeline. It is important to note that the NAS report viewed the implementation of their recommendations as a multi-year process. For example, the NAS stated "it is not recommending that EPA delay the revision of the formaldehyde assessment to implement a new approach." To that end, EPA is doing the following:

- ***Assessments that have already been peer-reviewed or released for peer review:*** EPA is revising these assessments to address peer review comments, especially those that call for increased transparency of study selection and evidence evaluation. In addition, we are editing the text of these assessments to reduce volume where possible, either by removing redundant text or by moving study descriptions into appendices to enhance readability.
- ***Assessments currently under development but not yet released for peer review:*** EPA is revising these assessments to ensure that the rationale for study selection and evidence evaluation is clear. These assessments will also be streamlined and edited to reduce redundancy.

- *New assessments that have not yet been started*: EPA will comprehensively implement the NAS recommendations, including developing a tighter document structure, using evidence tables to summarize details from pertinent studies, increasing transparency in study selection and evaluation criteria, and placing a greater emphasis on clear analysis and synthesis of available data and clear evaluation of the weight of the evidence for potential health effects.

IRIS assessments are held to the highest Agency standards, including the rigorous independent external peer review for every draft IRIS assessment, as well as internal review by EPA scientists, public review and comment, and opportunities for review by other federal agencies. These standards are among the best in the federal government and the scientific community. In 2008 EPA's Board of Scientific Counselors² noted in their reviews of the program that "IRIS assessments are considered to be of the highest quality and reliability" and among "the most heavily peer-reviewed documents produced by scientists anywhere."

Thank you for the invitation to share my thoughts on this important topic. I will gladly answer any questions you have.

² Board of Scientific Counselors. 2008. Human Health Risk Assessment Subcommittee Program Review Report.

<http://www.epa.gov/osp/bosc/pdf/hhra0804rpt.pdf>