

TESTIMONY OF
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Good morning, Chairman Miller and Members of the Committee. My name is Dr. George Gray, and I am the Assistant Administrator for Research and Development (ORD) at the U.S. Environmental Protection Agency (EPA). I also serve as the Agency's Science Advisor. Thank you for this opportunity to appear before the Subcommittee to discuss EPA's highly regarded Integrated Risk Information System (IRIS), which is managed by EPA's National Center for Environmental Assessment (NCEA) within ORD.

As you may know, IRIS is a repository of human health risk information on the potential adverse effects of long-term, or chronic, exposure to over 540 potential environmental contaminants. The risk information in IRIS can include quantitative risk estimates for both non-cancer and cancer effects, as well as a detailed narrative that accompanies the risk estimates. The narratives, or qualitative risk information, include a full discussion of the peer reviewed scientific literature used in the assessment, the EPA confidence in the IRIS risk estimates, and an explanation of the judgments (including application of default approaches and uncertainty factors) that the Agency must make in the face of inadequate data.

A significant part of EPA's efforts to fulfill its mission to protect public health and the environment is to regulate, when necessary, the release of contaminants into the Nation's air, water, and soil. As first outlined by the National Academy of Sciences (NAS) in its seminal 1983

report (“Risk Assessment in the Federal Government: Managing the Process,” National Academies Press, ISBN:0309033497, commonly called the “Red Book”), there are two distinct steps that should be used in the federal government to assess and manage risks. These steps are called risk assessment and risk management. Risk assessment, as defined by the NAS, is “the characterization of the potential adverse health effects of human exposures to environmental hazards” (p. 18). Risk assessments can entail either quantitative or qualitative expressions of risk, and should include characterization of the uncertainties inherent in the process of inferring risk. The risk assessment process has four components: hazard identification, dose-response evaluation, exposure assessment, and risk characterization. Risk management is defined by the NAS as “the process of evaluating alternative regulatory options and selecting among them” (p. 18). A risk assessment may serve as one of the bases of risk management.

IRIS assessments fall into the first step (risk assessment); however they only include information on hazard identification and dose-response evaluation. Combined with exposure information, government and private entities use IRIS to help characterize the public health risks of chemical substances and thereby support risk management decisions. Thus, it is important to note that an IRIS health assessment is not a complete risk assessment. It provides part of the foundation for EPA’s decision making and regulatory processes. In addition, risk managers consider other important factors in a risk management decision such as exposures, statutory and legal considerations, social considerations, public health considerations, economic factors, and political considerations.

It is important to recognize that although risk assessment is distinct from risk management, the risk assessment process consists of both “science” and “science policy” components. That is, although there are some instances at EPA where “pure science” is involved (e.g., conducting bench or lab research on animals in toxicity studies), much of the work done at EPA (including IRIS assessments) involves both science and science policy. For

example, due to the uncertainty in IRIS assessments, judgments and choices must be made about the most appropriate assumptions, data sets, health endpoints, models, etc. to use in deriving toxicity values. These are science policy choices because the science is not precise enough to provide definitive answers. For this reason, guidance documents such as EPA's "Guidelines for Carcinogen Risk Assessment" were developed and approved through the Agency's Science Policy Council to inform the many choices in the risk assessment process. This is an important distinction that is often overlooked or confused by the public, yet the NAS Red Book (1983) recognized and commented on this issue in the very first chapter and its section on "Scientific and Policy Judgments in Risk Assessment" (p. 28).

The IRIS program began in the mid-1980s. At that time, it was clear that the toxicity values that were being developed by EPA were not internally consistent across the Agency. For example, EPA's Program Offices were publishing toxicity values for a particular chemical in their rulemakings and in other policy documents that were based on the same set of available scientific data – but these values could be orders of magnitude different and based on different human health endpoints or default uncertainty factors. This example illustrates how important it is to acknowledge where the science stops and science policy begins, as credible scientists can (and often do) reach different conclusions based on their interpretation of the science or make different choices when confronted with several scientifically plausible options. IRIS was therefore formed in response to a critical need to have Agency-wide toxicity values in one place – including accompanying narratives detailing the supporting studies, key assumptions and choices, and text on confidence – that were developed through reviews by Agency health scientists.

IRIS was originally intended to be an internal system that provided EPA risk assessors and managers with an EPA consensus position on the potential human health hazard and dose-response information for environmental contaminants of interest to Agency programs and regions. Word spread quickly about the existence of IRIS and many asked to make it a publicly

available system. State and local public health and environmental agencies, as well as the regulated community, requested access to the IRIS information. Therefore, in the late 1980's, IRIS access was made available to the public. EPA was pleased to share this information resource with a large, external user community. IRIS first became available on a dial-up service and later through the National Library of Medicine's TOXNET family of information resources, and then on the Internet. The IRIS Web site is accessed over 20,000 times per day with inquiries coming from well over 100 other countries.

The IRIS process has evolved over time including in areas such as setting the annual IRIS agenda, level of independent external peer review, and opportunities for public and other federal agency review and comments. Because IRIS began as an internal EPA resource, the agenda for developing IRIS assessments focused on those chemical assessments of interest to EPA's program offices and regions. It was an informal process where only Agency needs were addressed. Now each year, EPA develops an annual agenda for the IRIS program and announces new assessments under review in the Federal Register. EPA uses five general criteria to determine which new chemicals to assess: (1) potential public health impact; (2) EPA statutory, regulatory, or program/regional-specific implementation needs; (3) availability of new scientific information or methodology that might significantly change the current IRIS information; (4) interest to other governmental agencies or the public; and (5) availability of other scientific assessment documents that could serve as a basis for an IRIS assessment.

In recent years, the IRIS Program has also sought nominations for IRIS chemical reviews from the public and other federal agencies. The list of new or updated assessments chosen for potential development is published in the Federal Register (FR) as part of the IRIS annual agenda. The Agency is also working to improve the prioritization process to more appropriately capture relative priorities of individual chemical assessments under development. For each of the assessments added to the IRIS agenda, an initial literature search is conducted. As literature searches are completed, the results are posted on the IRIS web site

www.epa.gov/iris) and the public and other agencies are invited to review the literature search results and submit additional information to EPA. Other recent changes to the IRIS process include creation of a chemical assessment tracking system (IRISTrack) on the IRIS Web site to inform the public and stakeholders of the status of the IRIS assessments that are underway, new opportunities for the public and other agencies to review and comment on the qualitative and draft IRIS assessments (including the ability to participate in “listening sessions” held during the public comment period), and enhanced independent external peer reviews of draft IRIS assessments. The IRIS program has also experienced an expansion of scientific staff and a significantly increased budget over the last few years. For example, based on the enacted FY 2003 resources, EPA has since nearly tripled the number of IRIS staff and have quadrupled the IRIS budget through the FY 2009 request to 37.0 FTE and \$9.4 million, respectively.

In 2005, a formal process for documenting all of the existing steps in the IRIS process, including formalizing recent changes to the process, was initiated, and on April 10, 2008, the revised IRIS process was announced by EPA. The public release of the revised IRIS process is especially noteworthy because the IRIS process has never before been transparently documented and made available to the public. Consequently, the IRIS process had often been viewed as a “black box” both within and outside of the Agency, as it was unclear what steps comprised the process, what the timing was for each step, or where opportunities existed for internal and external Agency involvement. The new IRIS process has been designed to provide greater transparency, objectivity, balance, rigor and predictability in IRIS assessments. Specifically, improvements to the IRIS process help define critical and appropriate roles for public and interagency comments and interactions, and promote greater communication and sharing of information between all interested parties and EPA. The outcome of these improvements are expected to result in a more predictable, streamlined, and transparent process for conducting IRIS assessments, which will ultimately lead to assessments that are of the highest quality and rigor.

Delays in the completion of IRIS assessments have been a long-standing problem at EPA. For example, prior IRIS assessments took an average of 5 years to complete, and EPA has been working on some assessments for a decade or longer. The revised process was designed to help address these delays, in part, by allowing for input from various stakeholders (e.g., EPA program and regional offices, other agencies, scientific organizations, NGOs, and the public) early in the process and providing clear descriptions and timeframes for each step. The early involvement of various stakeholders is consistent with recommendations from EPA's Science Advisory Board (SAB) as well as a prior report by the General Accounting Office (GAO). For example, in a September 26, 2000, letter from EPA's SAB to Administrator Carol Browner, it was noted that "critical data" were often missing from IRIS risk assessment discussions and it was suggested that one way to enhance the quality of toxicologic evaluations was to "make the IRIS process open to public stakeholder review in a more formal manner." A 2006 report by GAO (GAO-06-595) entitled "Human Health Risk Assessment: EPA Has Taken Steps to Strengthen Its Process but Improvements Needed in Planning, Data Development, and Training" also noted that "...several experts said that increased involvement with a broad range of stakeholders early in the planning process would help identify alternative methods and models and obtain stakeholder concurrence with the agency's approach." The new process therefore allows the EPA access to a wide range of scientific data, expertise, and knowledge that can be used to produce timely and high quality IRIS assessments. However, it should be noted that all draft IRIS assessments are peer reviewed by outside experts, and all final decisions on IRIS content remain with EPA.

It is important to recognize that many of the assessments today are more complex than ever before. For example, some chemicals have extensive toxicity testing data that must be reviewed and analyzed, new data are now available for assessing the mode of action of many chemicals, and more sophisticated statistical and modeling techniques (e.g., physiologically-based pharmacokinetic or PBPK models) are now available for evaluating intra-species and

inter-species differences. Recent peer reviews of IRIS assessments by the NAS and EPA's SAB have also recommended that EPA do a better job of incorporating quantitative uncertainty analyses into IRIS assessments. The timelines in the new IRIS process balance the need for careful consideration of science and science policy in assessments with the Agency's need for information.

An important aspect of the revised process includes "mission critical" chemicals that will be determined by a sponsoring agency together with EPA. A "mission critical" chemical is one that is an integral component to the successful and safe conduct of an agency's mission in any or all phases of its operations. Impacts on use of mission critical chemicals include cessation or degradation of the conduct of the mission and/or unacceptable resource constraints. Agencies must identify to ORD those chemicals on the IRIS Program Annual Agenda that they determine meet this definition, and generate a detailed report documenting what types of new research will address significant data gaps and whether such research can be conducted within the allotted time frame (but it is ultimately up to EPA to agree to allow new research to be conducted). Although we do not anticipate that many chemicals will receive this designation each year or that additional studies will be requested for all mission critical chemicals, any such new studies will help fill important data gaps to ensure assessments of the highest quality.

Independent external peer reviews are also a hallmark of EPA's commitment to ensuring we have high-quality science that has been vetted by a panel of outside experts. Consistent with past practices, the revised process specifies that all draft IRIS Toxicological Reviews will undergo independent external peer review. Most reviews will be conducted by external peer review panels at public meetings, although a small number of complex or high profile chemicals may undergo more in-depth SAB or NAS peer reviews. As part of the revised IRIS process, external peer reviewers will also for the first time have an opportunity to review the revised IRIS Toxicological Review and comment on ORD's responses to the peer reviewers and public

comments. This is an important step that is consistent with other peer review practices, such as publishing in the peer-reviewed literature, to ensure that peer reviewer comments are adequately addressed or sufficient rationale is provided for not addressing such comments.

It is noteworthy that the revised IRIS process meets many of the recommendations of the recently issued 2008 GAO report entitled “Toxic Chemicals: EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals” (GAO-08-743T). Specifically, the revised process (1) clearly defines and documents a streamlined IRIS assessment process; (2) sets time limits for all parties, including OMB and other federal agencies, to provide comments to EPA on draft IRIS assessments; (3) defines the appropriate role of external federal agencies in EPA’s IRIS assessment process; and (4) determines the types of IRIS assessments to conduct on the basis of the needs of EPA’s program offices and other users. The GAO (2008) report also lacks an appropriate characterization of several key issues. For example, the GAO report erroneously suggests that only pure science is involved in the risk assessment process. In reality, all risk assessments (including IRIS assessments) have always included a mix of science and science policy, as acknowledged in the NAS (1983) Red Book. The GAO report also mischaracterizes the interagency review process at EPA. Specifically, to ensure that scientists and policymakers are able to have full and frank discussions without being concerned about how these discussions may be viewed or misrepresented, all internal EPA comments and interagency comments and disposition documents on draft IRIS assessments are considered “deliberative” and do not become a part of the public record. This is not a new or unique process, as this protection is the same as that afforded any other policymaking setting at EPA (and other federal agencies follow similar processes). Additionally, once EPA comes to a conclusion and releases its external review draft, there is a transparent public comment and external peer review process. The GAO report also incorrectly suggests that EPA will not have the final say on the content of IRIS

assessments under the revised process. However, despite increased opportunities for public and other agency involvement, the revised process makes it clear that all final decisions on content will remain within EPA.

EPA now needs time to implement and evaluate the new process, recognizing that additional changes to the process may be needed in the future (i.e., it is intended to be a “living” document). Because the revised process attempts to streamline and set specific time frames for each step, it is expected to reduce the amount of time to complete future IRIS assessments.

Thank you, Chairman Miller and members of the Subcommittee for this opportunity to describe the scope, the purpose and the future of EPA’s IRIS program. I look forward to answering any questions you may have.