Advancing Scientific Integrity By Delivering Credible Hazard Assessments

Background

In 1985, the Environmental Protection Agency (EPA) created the Integrated Risk Information System (IRIS) Program in response to a growing demand for consistent information on chemical substances for use in risk assessments, policy-making and regulatory actions. The IRIS Program was intended to support EPA's mission by identifying and characterizing the human health effects that may result from exposure to chemicals in the environment.

Characterizing risk involves integrating information on hazard, dose-response and exposure and the IRIS Program does not assess actual human health risk. EPA must rely on the best available and most relevant science as the foundation for its decision-making. EPA's mission to protect public health and the environment is grounded in the public having confidence in the integrity of the assessments conducted by the Agency.

IRIS is not fulfilling that mission.

Lacks Transparency — The method by which substances are selected for IRIS hazard assessment remains unclear and there are no opportunities for stakeholders to provide input on IRIS assessment priorities. It continues to be a black box regarding how the chemicals under review by the IRIS Program will inform regulatory decision-making by the Agency. The IRIS Program has no specific number of hazard assessments that must be underway and the Program has consistently failed to meet its annual milestone progress score for completing IRIS hazard assessments. Additionally, there is no set timeline for completing an IRIS hazard assessment. While the Agency estimates a maximum of 3 years to complete an assessment, in reality, IRIS hazard assessments can take on average 5–10 years to complete.

Failure to Fully Address Peer Review and Stakeholder Recommendations — The IRIS Program has yet to fully demonstrate implementation of the series of recommendations by the National Academy of Sciences (NAS) which included developing a clear set of criteria for judging the relative merits of individual mechanistic, animal, and epidemiologic studies for estimating human dose-response relationships.

Out of Step with Best Available Science and Methods — The IRIS Program still fails to effectively or consistently utilize a weight-of-the-evidence process to identify, evaluate and integrate all available scientific evidence, including mode of action information and mechanistic data. This is necessary to derive scientifically defensible toxicity values that can be used by risk assessors to reach reliable conclusions regarding human health risk from chemical exposures. This is in contradiction to EPA's 2005 Carcinogenicity Assessment Guidelines that clearly recommends considering mode of action in the evaluation of carcinogenicity. IRIS assessments are known to generate overly conservative values that have not fully evaluated the best available science and have even proposed toxicity values that are below those levels naturally produced by the human body. Since IRIS assessments do not undergo a "reality check" to ensure the values make sense, they can lead to unnecessary public alarm and lead to inaccurate risk management decisions.

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7 Actions to Enhance the Scientific Integrity and Transparency of IRIS Assessments

1. Provide the criteria used for initiating a new IRIS assessment or updating an existing IRIS assessment, including how the assessment will be used to inform regulatory decision-making.

2. Document in every IRIS assessment how NAS recommendations have been addressed and incorporated into the assessment.

3. Integrate the available evidence using a mode of action framework. In 2011, NAS specifically asked EPA to select outcomes on the basis of available evidence and understanding of mode of action and to unify consideration of outcomes around common modes of action.

4. Present two dose-response estimates in the IRIS assessment. NAS recommended that EPA present a central estimate (such as a maximum likelihood estimate or a posterior mean) and a lower-bound estimate for a point of departure from which a toxicity value is derived.

5. Update the process, procedures and timelines for intra-agency review, interagency review and stakeholder review to ensure consistency in the review process for all assessments.

6. Ensure that peer reviewers do not have disqualifying conflicts of interests or inordinate bias and the composition of the peer review committees is balanced with members who possess a range of perspectives on the scientific methods and science policy issues being addressed.

7. Use an independent accountability procedure, wherein a science manager external to the IRIS Program verifies that revised IRIS assessments are accurate and fully responsive to scientific and peer review comments.