

## **EDF Comments NRC IRIS Meeting – 2.2.18**

Good afternoon, my name is Jennifer McPartland and I am a senior scientist in the health program at Environmental Defense Fund.

As we've heard from others already, the IRIS program serves a critical public health function that not only includes the development of toxicological reviews, but also technical support to offices across EPA, other federal agencies, regions, states, and tribes.

The purpose of the current National Academies review is to evaluate enhancements, made or planned, to the IRIS program in consideration of earlier Academy reviews. The most recent review, from 2014, pointed to substantial and expeditious improvements to IRIS including the implementation of recommendations from its 2011 review of the draft formaldehyde assessment. Further, the committee indicated that these improvements had been achieved in significant part through the adoption of systematic review—an approach the committee emphasized IRIS should continue to use. EDF likewise applauds the significant effort and improvements made by IRIS over the past several years, and supports the approach IRIS has taken to adapt systematic review for chemical assessment.

Born out of the clinical sciences, systematic review employs structured approaches to evidence identification, evaluation, and synthesis in a manner that promotes scientific rigor, consistency, transparency, objectivity, and reduction of bias. Indeed, systematic review transformed the field of medicine—serving today as the method for evaluating the effectiveness of interventions and diagnostic tools.

Prominent systematic review methods in medicine, particularly Cochrane and GRADE, have been shaped and refined over several decades based on empirical evidence and experience in application. Appropriately, leading systematic review approaches that have emerged in environmental health, including the UCSF Navigation Guide and the National Toxicology Program's literature-based reviews, have modeled themselves from these methods. As evidenced in the presentations and discussions over the past day-and-a-half, the IRIS program is similarly adopting best practices in systematic review. Notably, this transformation is occurring under the leadership of Dr. Kristina Thayer, who for the past several years has been spearheading the uptake of systematic review for chemical assessment in the federal government. Dr. Thayer has led this work in consultation and collaboration with prominent systematic review experts across the globe, and has established herself as one of the foremost experts in the application of systematic review for chemical assessment.

As interest and enthusiasm for systematic review grows, it is critical that its core principles and strictures remain intact. The worst, most dangerous, and unfortunate scenario would be for EPA, or other federal agencies, to advance chemical assessment approaches under the guise of systematic review that are simply just reincarnations of outdated approaches to chemical assessment, such as those oriented around the presumed superiority of guideline studies like Klimisch. Such methodologies are significantly limiting in their consideration of scientific evidence, and undermine use of best available science.

IRIS is a forward looking program. It is taking a leadership role in the field of chemical assessment—bravely, boldly, and deliberately tackling challenging issues such as how best to evaluate and integrate mechanistic information in a systematic review paradigm. Catherine Gibbons (EPA) demonstrated clear examples of that yesterday. I have no doubt IRIS will be at the forefront of developing approaches and tools to further the consideration of mechanistic information in chemical assessment in a manner that is protective of public health, including susceptible subpopulations, and not in a manner that is overly simplistic and constraining like forcing assessments around a mode of action framework.

Two final points. On occasion, concerns have been raised about the length of time and resource requirements associated with systematic reviews. While opinions may differ here, it is clear that the IRIS program is making significant investments in specialized software tools to facilitate and make more efficient the application of systematic review. Such tools are also enormously helpful when updating chemical assessments, allowing reviewers to easily add new studies and determine what, if any, effect such information has on the body of evidence and conclusions drawn.

Finally, it is absolutely critical that IRIS be adequately resourced and afforded opportunities to educate others within and outside the agency on the systematic review methods it is developing. IRIS can only accomplish its core responsibilities, support stakeholder needs, and provide training, as an independent, scientific program within EPA's Office of Research and Development.

It has been a pleasure to learn more about how the IRIS program has been working to advance the science of chemical assessment. And I thank the committee for the opportunity to comment.