Testimony at the Subcommittee on Investigations & Oversight and Subcommittee on Environment Hearing – EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead

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Thank you for the opportunity to speak today. I am Dr. Julie Goodman, an epidemiologist and board-certified toxicologist at Gradient, an environmental sciences consulting firm. We assist public and private organizations in evaluating the risks of chemicals and other substances on human health and the environment. I have been developing and applying weight-of-evidence and systematic review methodology in a variety of settings for over 10 years. I taught a graduate-level class on this topic at Harvard University, and much of my work has been published in the peer-reviewed literature. I am presenting testimony today as an independent scientist. While my travel costs have been paid by my company, I am here today on my own time, and I am not being compensated for the time I spent preparing this testimony.

In 2011, a National Academy of Sciences (NAS) National Research Council (NRC) committee provided recommendations for the US Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Program in the context of a review of the formaldehyde assessment (NRC, 2011). In response, EPA released a Draft Handbook for IRIS Assessments in 2013 (US EPA, 2013). In 2014 and 2018, NAS reviewed and evaluated the IRIS assessment process more generally, including progress made since 2011 (NRC, 2014; NAS, 2018).

Both the 2011 and 2014 NAS reviews stated that the IRIS program lacked a clear conceptual framework and clear and transparent methods. Further, NAS concluded that EPA did not fully assess the weight of evidence or justify the selection of studies for the derivation of toxicity values. The 2014 NAS review also specifically called for the finalization of the draft IRIS Handbook. Since this time, EPA has made substantial improvements to the IRIS process, including the development and application of systematic review methods for evidence identification, evaluation, and integration, but not all of the identified issues have been resolved (NAS, 2018).

To date, EPA has shown progress on a chemical-by-chemical basis, using the IRIS Assessment Plans (IAPs) for uranium and ammonia (US EPA, 2018a,b) and Systematic Review Protocols for the IRIS chloroform and chromium assessments (US EPA, 2018c, 2019) as examples of its new portfolio approach. EPA announced it will move forward with a revised IRIS Handbook, which will be put through peer review and public comment processes this year. This is undoubtedly needed and a critically important step forward, and EPA is to be commended for these actions.

I note that while it is true that a "one-size-fits-all" protocol for all chemicals is not feasible, and details of the individual chemical assessments will vary based on the specific research questions identified and on the available data, all IRIS assessments will benefit from a clearly written framework that serves as a standard operating procedure (SOP) for agency systematic reviews. This SOP can be expanded to include chemical-specific tailoring, as needed, to each phase of specific chemical reviews. An iterative approach can be used to incorporate new issues and knowledge into the SOP as it becomes available.

To follow through on its intention to use systematic review and weight-of-evidence methodology for hazard identification, EPA needs to complete an individual assessment using the new process. My experience with developing these types of approaches has shown that it is important to apply a framework in a chemical-specific setting to determine where its strengths lie and where it falls short and should be revised.

IRIS assessments both identify hazards associated with chemicals and characterize these hazards by generating toxicity values. With regard to the latter, EPA is always limited to studies with sufficient data for dose-response analysis, so the Handbook should describe what will be done if these studies are not reflective of the science as a whole. In addition to studies that identify toxic effects, part of the hazard identification process is to consider studies that inform the mechanism of toxicity. EPA should indicate how it will consider this mechanistic evidence when deriving toxicity values. For example, if mechanistic studies clearly show a threshold effect, then it should be incorporated into the dose-response analysis, and linear low-dose extrapolation should not be applied.

There is no doubt that conducting systematic reviews takes more time and resources than non-systematic reviews. However, a completed Handbook (that can and should be revised to reflect the best available science) will go a long way towards expediting assessments and increasing transparency and consistency across assessments. More importantly, with an established standard procedure in place, EPA staff will have better guidance to conduct IRIS assessments in a systematic and unbiased manner. This will allow stakeholders and members of the public to better understand the process and provide input and, ultimately, will increase their confidence in EPA's assessments.

In conclusion, to address the NAS recommendations for the IRIS Program dating back to 2011, EPA needs to complete a general guidance framework for IRIS assessments in a revised Handbook. EPA also needs to complete assessments that both apply this guidance and demonstrate that dose-response analyses and toxicity value derivations will be informed by the overall weight of evidence and biological mechanisms.

References

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