United States House of Representatives Hearing: "Examining the Scientific and Operational Integrity of EPA's IRIS Program", September 6, 2017, 2318 Rayburn House Office Building, Washington, DC.

Committee on Science, Space, and Technology's Subcommittee on Environment and Subcommittee on Oversight.

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Good morning. I am Dr. James Bus, and I am a toxicologist with the consulting firm Exponent. I must preface my comments by noting that the increasingly financially and other resource-constrained realities confronting our nation demands nothing less than a cost-effective, transparent and science-based evaluation and regulation of environmental chemicals.

I will briefly highlight three major areas of concern with the IRIS program. First, IRIS has not effectively implemented the National Academy of Sciences recommendation that good risk assessment must start with good problem formulation. Second, IRIS use of chemical mode of action information to better inform its risk assessments is substantially flawed. And third, IRIS frequently does not effectively differentiate between highest quality science and that of substantially lower quality in its evaluations.

The National Academy has emphasized the importance the question "What problems are we trying to solve?" as an absolute necessity for focusing the priorities of the IRIS program. Although IRIS has recently implemented problem formulation dialog with the public, the IRIS program has not effectively integrated this key concept into its overall prioritization processes. For example, human exposures to many if not most chemicals have been substantially reduced or constrained over the last several decades as a direct result of regulatory and/or industry product stewardship interventions. Yet, IRIS often overlooks this important progress as screening mechanism to rule out the need for detailed evaluations. As is commonly said in the practice of toxicology, it is "the dose that makes the poison". Thus, more realistic consideration of the relationships of human exposures to doses producing toxicity at much higher doses used in experimental toxicity studies must become a key consideration to answering the practical question of: "Do real-world exposures indicate a reasonable need for a detailed risk assessment evaluation?"

Turning to the second point of concern, and speaking as a toxicologist, extensive taxpayer investments in toxicological sciences have yielded substantial advances in understanding how chemicals cause toxic effects in animals and humans. Such mode of action information is essential to establishing the human health relevance of toxicity observed in cell- or animal-based toxicity findings. In recognition of the value of mode of action science, the toxicology, risk assessment and regulatory scientific communities have developed detailed frameworks for credible and transparent translation of these data into chemical risk assessments. While mode of action framework processes have long been included within EPA guidance procedures, and are routinely and effectively used by the EPA Office of Pesticides, the IRIS program has yet to embrace their practice. Thus, IRIS assessments consistently default to risk decisions that do not reflect the substantial added value of mode of action science that has long been supported by taxpayer investments.

Finally, the IRIS program has not implemented consistent criteria, as have other EPA offices, for appropriately weighting study quality as key to meaningful data integration. Too often poorly

conducted and/or described studies carry equal weight to those of far higher quality in the final risk decisions. For example, the recent IRIS evaluation of trichloroethylene, a commercially important solvent, relied on published studies from a single university-based laboratory that were subsequently subject to three published error corrections that have still not clarified the experimental findings. In addition, not only were the original data from the problematic studies not available for review by EPA, the study findings also were not reproduced in two much higher quality studies. In the case of trichloroethylene the EPA decision to rely on the lower quality study to drive the risk assessment has created additional environmental remediation costs potentially in the hundred's of millions to even billions of dollars.

Thank you for the opportunity share my personal perspectives on some of the more serious concerns that continue to plague the IRIS program. Although the IRIS program has recently introduced new evaluation tools aimed at improving the quality of its evaluations, the IRIS program, given its past reluctance to embrace substantive change, will be challenged to efficiently and effectively evolve into a program that meets expectations of delivering timely, credible and science-based risk assessments of environmental chemicals.