

MEMORANDUM

**SUBJECT: Science Advisory Board Chemical Assessment Advisory Committee (SAB-CAAC)
Briefing on the Integrated Risk Information System (IRIS) Evolution of Assessment
Practices**

**FROM: Kris Thayer, Director /s/
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**TO: Sue Shallal
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The EPA's National Center for Environmental Assessment (NCEA) is pleased to have the opportunity to present to the SAB Chemical Assessment Advisory Committee (CAAC) an update on the evolution of assessment practices in the IRIS Program. IRIS continues to implement and operationalize systematic review in its assessment practices, with the goal to increase transparency and efficiency in its processes and products. As part of the established scoping and problem formulation process for IRIS assessments, scientists from NCEA have prepared draft IRIS Assessment Plans (IAPs) for nitrate/nitrite, ethylbenzene, and chloroform. The draft IAPs represent recent efforts to more formally integrate systematic review into the existing IRIS scoping/problem formulation phase (Step 1 of the IRIS process). The IAPs will inform the subsequent development of chemical-specific systematic review protocols. While the IAP describes what the assessment will cover, protocols describe how the assessment will be conducted. These draft IAPs will be released for a 30-day public comment period.

Given the SAB-CAAC's role in the review of IRIS assessments, and the importance of the IAP in framing the assessment that will be developed, we wanted to make sure the SAB-CAAC had an opportunity to see and react to these documents during the 30-day public comment period. These draft IAPs are being provided to the SAB-CAAC as case studies to facilitate the committee's understanding, and to provide examples of the approaches that the IRIS Program is utilizing in the development of our chemical assessments. Any comments by the SAB-CAAC aimed at improving or clarifying the draft IAPs will be appreciated. Below are some suggested topics to facilitate the discussion:

- Are the objectives and specific aims articulated clearly?
- Is there sufficient background information and context to support the objectives described in these documents? Are there any other types of background information that may be helpful?
- Does the proposed PECO (Populations, Exposures, Comparators, Outcomes) framework identify the most pertinent evidence to address the stated needs of the Agency programs and regions? What could be improved?

Included with this memo is an overview document that provides more context on the role of the IAP in shaping an IRIS assessment. We request that you forward to the SAB-CAAC this memo and overview document. The draft IAPs are also being made available to the SAB-CAAC in the form of electronic files, and will be available on the IRIS website at <https://www.epa.gov/iris>.

We look forward to discussing the evolution of assessment practices and the draft IAPs with the SAB-CAAC at the upcoming meeting. Should you have any questions regarding these documents or the IRIS Program in general, please contact James Avery (703-347-8668; avery.james@epa.gov).

Attachments:

Attachment A: Overview of Integrated Risk Information System (IRIS) Assessment Plans (IAPs):
Development of a Portfolio Approach

ATTACHMENT A

Overview of Integrated Risk Information System (IRIS) Assessment Plans (IAPs): Development of a Portfolio Approach

EPA's National Center for Environmental Assessment (NCEA) supports the Agency's mission of protecting human health and the environment by identifying and characterizing the human health hazards of chemicals found in the environment. Health assessments developed by NCEA, such as the Integrated Risk Information System (IRIS) assessments, contain chemical-specific qualitative and quantitative health information in support of hazard identification and dose-response evaluation, two initial steps of the risk assessment process.

A Portfolio Approach

NCEA assessments support policy and regulatory decisions for EPA's programs and regions, and state and other federal agencies. To ensure this support is timely and responsive, NCEA is developing a portfolio of chemical evaluation products employing principles and state-of-the-art practices of systematic review. The portfolio approach will increase public health protection by:

- moving away from a 'one-size-fits-all' approach to chemical risk assessment towards a spectrum of assessment products to meet specific decision contexts;
- facilitating the incorporation of new science into risk assessment and decision-making;
- enabling assessments to be better tailored to meet needs of decision makers;
- increasing the number of chemicals that can be evaluated for their effects on human health by utilizing constrained resources in the most efficient manner.

This portfolio approach offers a nimble, flexible and efficient way to draw on new data streams, develop a continuum of risk assessment products, and better meet the needs of stakeholders and decision makers. It also increases the responsiveness to decision makers and timeliness of assessment products.

Operationalizing Systematic Review

A key to the success of this portfolio approach will be operationalizing systematic review. In general, the systematic review strategy is informed by criteria that are defined in scoping and problem formulation enabling assessments to be tailored to meet the needs of decision makers. As such, systematic review in assessments promotes transparency in the choice and application of the assessment type to a particular decision context.

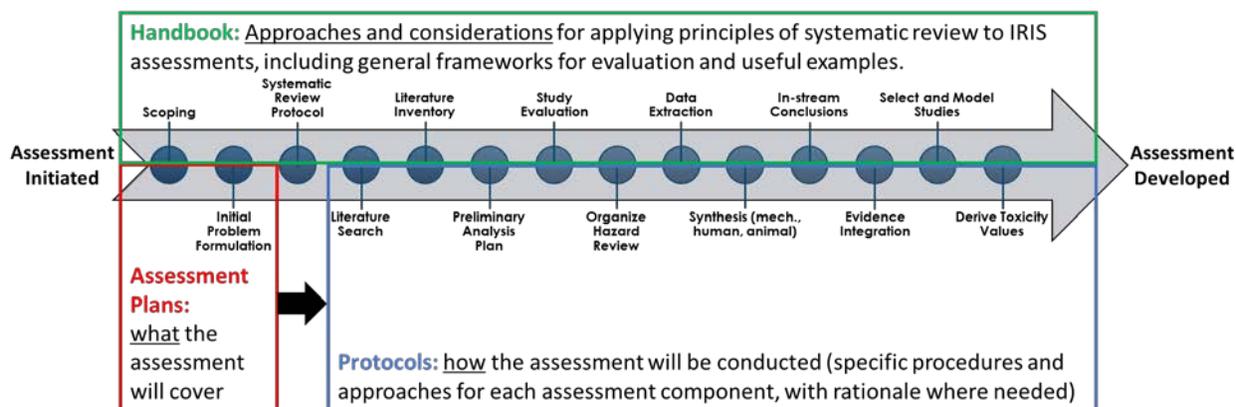
NCEA is collaborating with international organizations to accelerate the initial steps and reduce the burden of systematic reviews through use of automation and machine-learning tools. This will promote and facilitate incorporation of systematic review – pragmatically and effectively. As the portfolio approach unfolds, adhering to the methods and principles of systematic review allows the users and risk managers to apply the assessment products with improved understanding of the strengths and weaknesses of the underlying scientific evidence.

IRIS Assessment Plans

IRIS continues to implement systematic review in its assessment practices, with the goal to increase transparency and efficiency in its assessment processes and products. As part of scoping and initial problem formulation activities prior to the development of a draft assessment, the IRIS Program carries out a broad, preliminary literature survey to assist in identifying the extent of the evidence and health effects that have been studied in relation to the chemical or substance of interest. This information, in

conjunction with scoping needs identified by EPA program and regional offices, is used to inform the development of a draft IRIS Assessment Plan (IAP).

The draft IAP communicates the general plan for assessing the health effects literature for the chemical or substance, and includes summary information regarding the IRIS Program's scoping and initial problem formulation, objectives and specific aims for the assessment, and a PECO (Populations, Exposures, Comparators, and Outcomes) framework for the systematic review. The PECO framework is used to guide the process for developing literature search strategies and inclusion/exclusion criteria, particularly with respect to evidence streams (i.e., human, animal, mechanistic), exposure measures and outcome measures. The IAP serves to inform the subsequent development of chemical-specific systematic review protocols – as depicted in the figure below. While the IAP describes what the assessment plans to cover, protocols describe how the assessment will be conducted.



Public Consultation and Next Steps

For the September meeting of the EPA Science Advisory Board Chemical Assessment Advisory Committee (SAB-CAAC), draft IAPs prepared by NCEA scientists for the chemicals nitrate/nitrite, ethylbenzene, and chloroform are being provided as examples of the approaches being implemented. These draft IAPs represent recent efforts to formally integrate systematic review in the scoping/problem formulation step of IRIS. Each IAP is designed to fit the described needs of the EPA programs and regions. As such, each IAP was shaped in collaboration with these offices and is accordingly scaled to the scope of the decision context.

The IRIS Program is presenting these draft IAPs to the SAB-CAAC for their reference when discussing the clarity of the documents and the appropriateness of the approach. These draft IAPs are also being posted for public review and comment. Feedback from the public will be used to finalize the IAP before moving forward to develop the relevant, chemical-specific assessment protocols, which will also be shared publicly consistent with best practices in systematic review. We look forward to any comments from the SAB-CAAC to assist in strengthening the approach and enhancing these documents.