

EPA's Integrated Risk Information System Program

Public Stakeholder Meeting

Kenneth Olden, Ph.D., Sc.D., L.H.D.
Director, National Center for Environmental Assessment



Overview

- Since IRIS was created in 1985, hazard assessment has become more complex, more time consuming, and more controversial.
- It will likely become more complex and scientifically challenging as we attempt to integrate new science into our evaluations.
- Many challenges with hazard assessment cannot be fixed, but we can manage them more effectively by making the IRIS assessment development process more transparent and collaborative.
- We are not here to discuss whether or not IRIS is broken; we are here to discuss whether we can make the IRIS process more efficient and less adversarial.
- We want your input on several issues that may possibly enhance the Administrator's seven step IRIS process announced in May 2009.

Issue #1: Systematic Review

We would like to hear your views on the use of systematic review methodology and information management tools to review and synthesize the relevant literature.

- Systematic review is a process (supported by automation) used to identify, evaluate, and integrate data from scientific studies that are relevant to specific questions.
- Will explicit, pre-specified methods to identify, select, summarize, and assess various studies make the assessment development process more objective, efficient, standardized and transparent?
- Will systematic review help address concerns that IRIS “cherry-picks” the literature?

Issue #2: Public Engagement

We would like to hear your views on engaging the public in dialogue early in the process to assess the “state-of-the-science” during the scoping and problem formulation phase of the assessment.

- Early public engagement will help ensure that EPA is evaluating all relevant data and that data gaps are identified up front.
- If data gaps are identified at least two years before the assessment is initiated, needed research could be conducted.
- The time honored way to resolve complex scientific issues is to engage the scientific community in vigorous give and take dialogue.

Issue #2: Public Engagement Assessment Output

We would like to hear your views about strategies to increase IRIS assessment output.

- Will systematic review and early public engagement help increase IRIS output?
- Should we focus our efforts on fewer chemicals as a way to increase IRIS output?
- Can we make better use of our human resources, and ultimately increase IRIS output, by reducing the workload associated with submission of redundant comments?

Issue #4: Stopping Rules

We would like to hear your views about developing rational stopping rules.

- Stopping rules identify the point at which the scientific record will be closed and emerging scientific debate will be set aside for a later time so decisions can be made.
- For example, one stopping rule might be: If new science emerges after a draft IRIS assessment has been peer reviewed, it will not be considered unless it has substantial implications for the assessment.
- Stopping rules allow closure; they will help EPA produce assessments in a timely manner. Stopping rules exist for Integrated Science Assessments and are supported by EPA's Clean Air Scientific Advisory Committee.

Issue #5: Wider accessibility for public interactions

We would like to hear your views about how the IRIS Program can make our public interactions more accessible to a wider audience of stakeholders.

- We recognize not all stakeholders have the resources to come meet with us in person.
- Is a webinar an efficient way to engage stakeholders who cannot be physically “at the table”?
- Are there other ways the IRIS Program can achieve this?

Issue #1: Systematic Review

Issue #2: Public Engagement

**Issue #3: Strategies to Increase IRIS
Assessment Output**

Issue #4: Stopping Rules

**Issue #5: Wider accessibility for public
interactions**