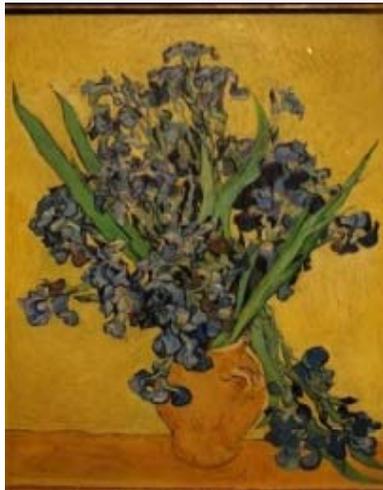




Building on the NRC's Recommendations

Realizing the Vision for IRIS



Vincent Cogliano

IRIS Program Director (interim)

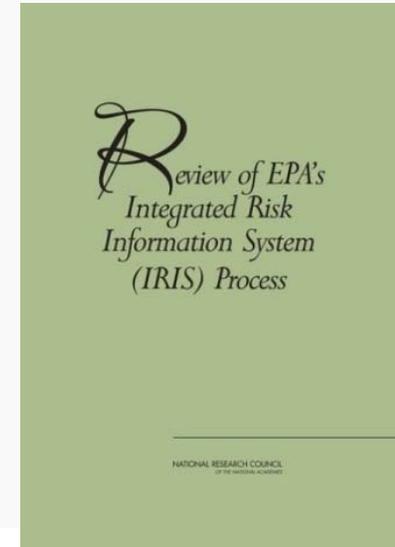
National Center for Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency

The views expressed here do not necessarily represent the views or policies of the U.S. Environmental Protection Agency



IRIS Thanks the NRC for Its Recommendations and Its Confidence

“Overall, the committee finds that substantial improvements in the IRIS process have been made, and it is clear that EPA has embraced and is acting on the recommendations in the NRC formaldehyde report. The NRC formaldehyde committee recognized that its suggested changes would take several years and an extensive effort by EPA staff to implement. Substantial progress, however, has been made in a short time, and the present committee’s recommendations should be seen as building on the progress that EPA has already made.” [p 9]



“ . . . the IRIS program has moved forward steadily in planning for and implementing changes in each element of the assessment process. The committee is confident that there is an institutional commitment to completing the revisions of the process . . .” [p 135]

NRC 2014, *Review of EPA's Integrated Risk Information System (IRIS) Process*



IRIS Is Building on the NRC's Recommendations

Chapter 2. General Process

IRIS is revising the Preamble and the *Handbook*, based on

- NRC recommendations
- SAB/CAAC advice
- comments
- experience with multiple assessments in progress

Each section will be released to the public and for peer review by the SAB/CAAC



IRIS Is Building on the NRC's Recommendations

Chapter 3. Problem Formulation and Protocol

IRIS has followed the NRC's guidance on problem formulation

Problem formulations for ethylbenzene and for naphthalene were released in July and were discussed on Sept 3 at the IRIS public science meeting

Protocol development will follow, to be coordinated with development of the *Handbook*



IRIS Is Building on the NRC's Recommendations

Chapter 4. Evidence Identification

Assessments in progress include search strategies, dates

Inclusion/exclusion criteria had been implicit in the PRISMA diagrams, but will also be captured in text

IRIS will evaluate its experience to optimize search procedures, evaluate the effectiveness of quality-control methods, and evaluate the need for multiple reviewers

The *Handbook* will more explicitly discuss these procedures



IRIS Is Building on the NRC's Recommendations

Chapter 5. Evidence Evaluation

The Oct 15-16 workshop seeks input on refining systematic review methodology

- Research identifying study features that can bias human or animal studies
- Research identifying factors beyond “risk of bias”
- Other aspects of internal and external validity
- What has been learned from research comparing different methods for evaluating sets of related studies



IRIS Is Building on the NRC's Recommendations

Chap 6. Evidence Integration for Hazard Identification

The Oct 15-16 workshop seeks input on systematic integration of evidence streams

- Merits of guided expert judgment vs structured processes
- Important determinants of strength-of-evidence and how to evaluate these in a replicable manner
- When to integrate study evaluation decisions: before or during evidence integration
- Lessons learned from experiences at national and international health agencies



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Chapter 7. Derivation of Toxicity Values

The Oct 15-16 workshop seeks input on two topics:

1. Combining multiple studies

- Replicable process for selecting studies
- Best ways to derive a bound from studies with biologically diverse results



IRIS Is Building on the NRC's Recommendations

Chapter 7. Derivation of Toxicity Values

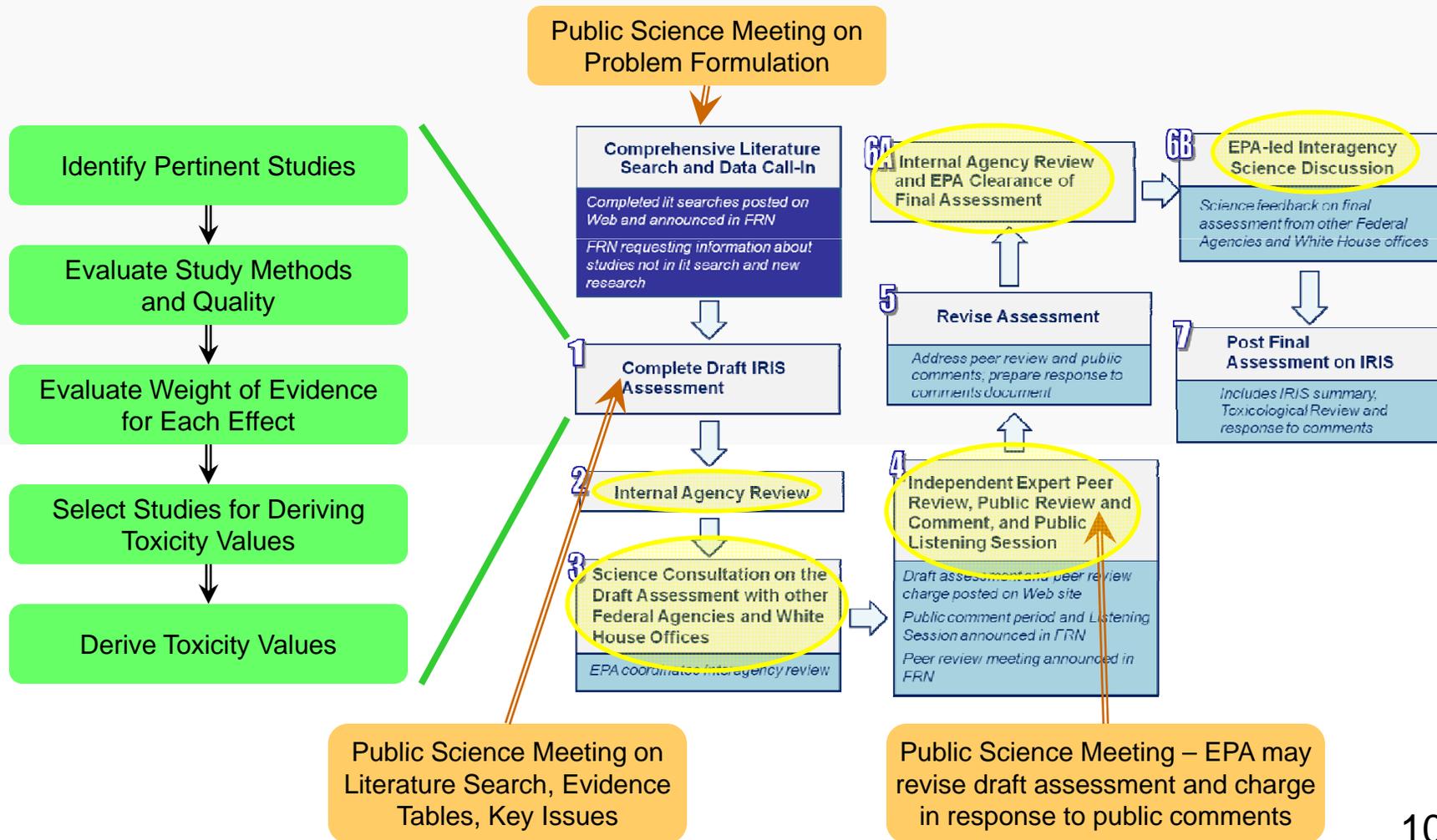
The Oct 15-16 workshop seeks input on two topics

2. Uncertainty analysis

- Users: How are uncertainty and variability estimates used “in the field”?
- Analysts: Practical approaches for characterizing uncertainty and variability
- How to derive bounds that reflect scientific uncertainty and population variability without being overly conservative



The Vision: An IRIS That Embodies Systematic Review, Public Engagement, and Productivity





Enhancing IRIS – Objectives

To improve the fundamental science

- by implementing principles of systematic review
- by strengthening peer review

To increase productivity to better meet stakeholder needs

To increase transparency so issues are identified and debated early



Other IRIS Initiatives

Multiyear plan for new assessments

New approaches to increasing and broadening scientific input

Evaluation of recent experience with an eye towards further improvement



Summary

IRIS has embraced and is acting on the NRC's recommendations

IRIS is convening a workshop on Oct 15-16 to address three key areas of NRC recommendations

- Evidence evaluation
- Evidence integration for hazard identification
- Derivation of toxicity values: (1) combining multiple studies and (2) uncertainty analysis

IRIS will continue to evolve as we receive public input and peer review advice . . . Thank you!