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Enhancements to EPA's Integrated Risk Information System (IRIS) Program

August 14, 2013

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Purpose of Briefing

To explain upcoming enhancements to EPA's Integrated Risk Information System (IRIS) Program.

IRIS: Issues and NRC Recommendations

- Issues:
  - Slow pace of assessment completion (e.g., difficulty in coming to closure on scientific issues, completion of review steps)
  - Delays to accommodate newly published studies or analyses
  - Conflict of interest problem with a contractor-managed peer review
  - Inadequate transparency (e.g., lack of clarity in documents, cumbersome structure, inadequate discussion of key elements in analysis)
  - On GAO list of "high-risk troubled federal programs"
- NRC Recommendations (Science and Decisions, 2009; Formaldehyde, 2011)
  - Engage stakeholders in problem scoping and formulation
  - Apply systematic review methodologies
  - Improve assessment documents by increasing transparency and clarity; streamline, standardize.

The IRIS Program moving forward

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A strong, scientifically rigorous IRIS Program is of critical importance, and EPA is making changes to:

1. improve the fundamental science of assessments;
2. improve the productivity of the Program; and
3. increase transparency so issues are identified and debated early in the process.

Some of these changes are based on our successes with developing Integrated Science Assessments

How Will These Changes Result in More Assessments per Year?

- Historically, it has taken longer than 23 months to complete assessments (from 3 ½ years to 13 years, depending on complexity)
- While estimated assessment development timelines are longer than 23 months, the changes will lead to more assessments per year because we:
  - Will identify controversial science issues early so assessments are not bogged down later on.
  - Are making significant changes to work and management processes.
  - Will implement stopping rules for new data and scientific issues.
  - Will focus on fewer chemicals in the pipeline in the near term, allowing us to put additional resources toward completing each assessment, thereby leading to more final assessments per year.

Enhancements

To address NRC recommendations, the IRIS Program will:

- Engage stakeholders/partners:
  - in planning, scoping, and problem formulation; and
  - to discuss literature search, study selection, and evidence tables.

- Convene workshop (August 2013) on and adopt:
  - systematic review methods and information management tools for study selection and analysis;
  - data integration or weight of evidence approaches to develop findings.

- Use a new document structure that is more clear, concise and systematic.

Enhancements (continued)

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Strengthen peer review and conflict of interest process.

- Science Advisory Board Chemical Assessment Advisory Committee dedicated to IRIS reviews

- EPA has also strengthened its practices for contractor-managed peer review to address any actual or potential conflicts of interest

Enhancements (continued)

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Modify IRIS practices to increase the number of assessments completed each year with a goal of completing 12-15 assessments per year by FY2015.

- Changes to workforce planning and support
- Fewer chemicals in pipeline to increase efficiency and output
- Develop tools to implement systematic review
- Develop stopping rules, with respect to including new or ongoing research and ending scientific debate

IRIS Process Steps with Enhancements

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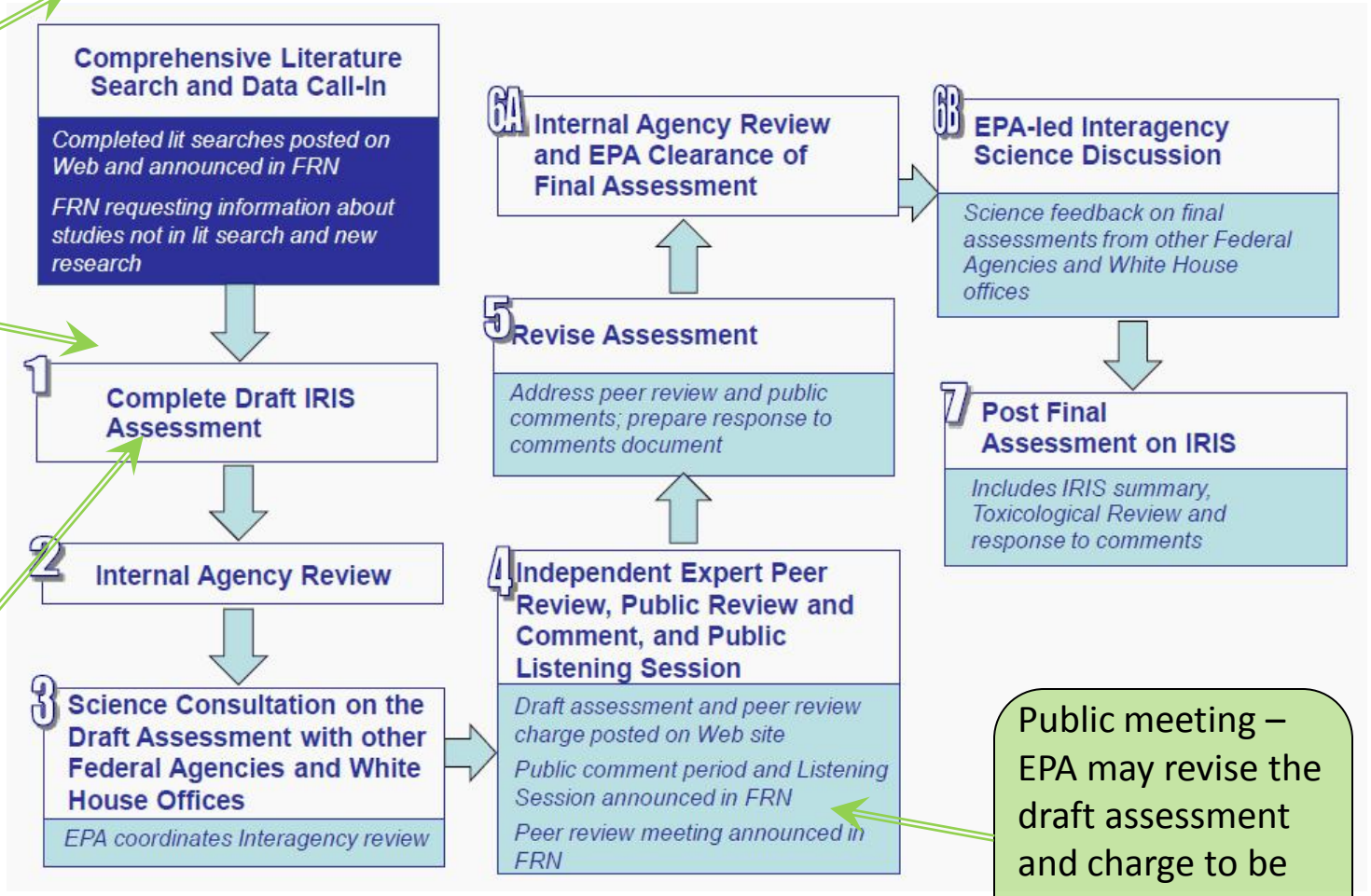
EPA scoping meeting

Public meeting on problem formulation

Public meeting on literature search, evidence tables, key issues



Public meeting – EPA may revise the draft assessment and charge to be responsive to public comments

Support for IRIS enhancements

- The IRIS Enhancements have been carefully vetted with:
  - EPA (multiple briefings with senior management and informational briefings for programs and regions)
  - Other Federal agencies
  - The Executive Office of the President
  - Congress (Senate Environment and Public Works; House Science, Space and Technology)
  - Other key external stakeholders (industry; NGOs)

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Summary

A strong, scientifically rigorous IRIS Program is of critical importance, and EPA is making changes to:

1. improve the fundamental science of assessments;
2. improve the productivity of the Program; and
3. increase transparency so issues are identified and debated early in the process.

These changes have been carefully vetted with multiple stakeholders; address NRC and GAO recommendations; and draw on our successes with Integrated Science Assessments

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Appendix Slides

Stopping Rules

Scientific issues: Alternative interpretations of the science and perspectives on bridging scientific uncertainty should be raised early in assessment development process. Opportunities include:

- Step 1 during public meeting to discuss literature search and evidence tables;
- Step 4 during public comment period and public meeting to discuss draft IRIS assessment and draft peer review charge;
- Step 4 during public external peer review process.

Scientific issues that are raised, but not resolved, will be highlighted for the peer review panel for their input.

Stopping Rules – New Data

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Step	Public Event	Studies Published or Accepted for Publication	Studies Submitted but Not Yet Accepted	Research in Progress
	Before public problem formulation meeting	Fully consider in assessment	Consider if published before Step 1 meeting	Review written research plan and discuss with researcher. Consider adjusting start of assessment if study promises to be critical.
1A	After problem formulation; before Step 1 meeting	Fully consider in assessment	Consider if accepted before release of Step 4 draft	Review written research plan. Determine if delay is warranted (the research must promise to be a highly critical addition to existing data).
At this point, the assessment should proceed without further delay. New studies accepted for publication may be considered in a manner that does not delay the review process.				

Stopping Rules – New Data

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Step	Public Event	Studies Published or Accepted for Publication	Research in Progress or Studies Submitted but Not Yet Accepted
1B, 2, 3	After Step 1 public meeting	Review for pertinence and quality. Discuss in Lit Search section. Do not repeat earlier steps.	No further consideration of studies that have not been accepted for publication. When accepted for publication, new studies may be considered as described at left.
4A	After release of public comment draft	Review for pertinence and quality. Discuss in Lit Search section. Do not repeat earlier steps.	
4B	After release of peer review draft	Review for pertinence, quality, and impact on conclusions. Discuss orally at peer review meeting. Add to assessment if recommended in writing by peer review panel.	
5,6,7	After peer review meeting	Review for pertinence, quality, and impact on credibility of assessment conclusions. Discuss with chair of peer review panel.	