EPA's Integrated Risk Information System (IRIS)

IRIS Process, Opportunities for Stakeholder Engagement, and Timing of Assessments

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Overview

- Integrated Risk Information System (IRIS)
- IRIS process
- Opportunities for stakeholder engagement in the process
- Timing involved in developing new or updating previous assessments

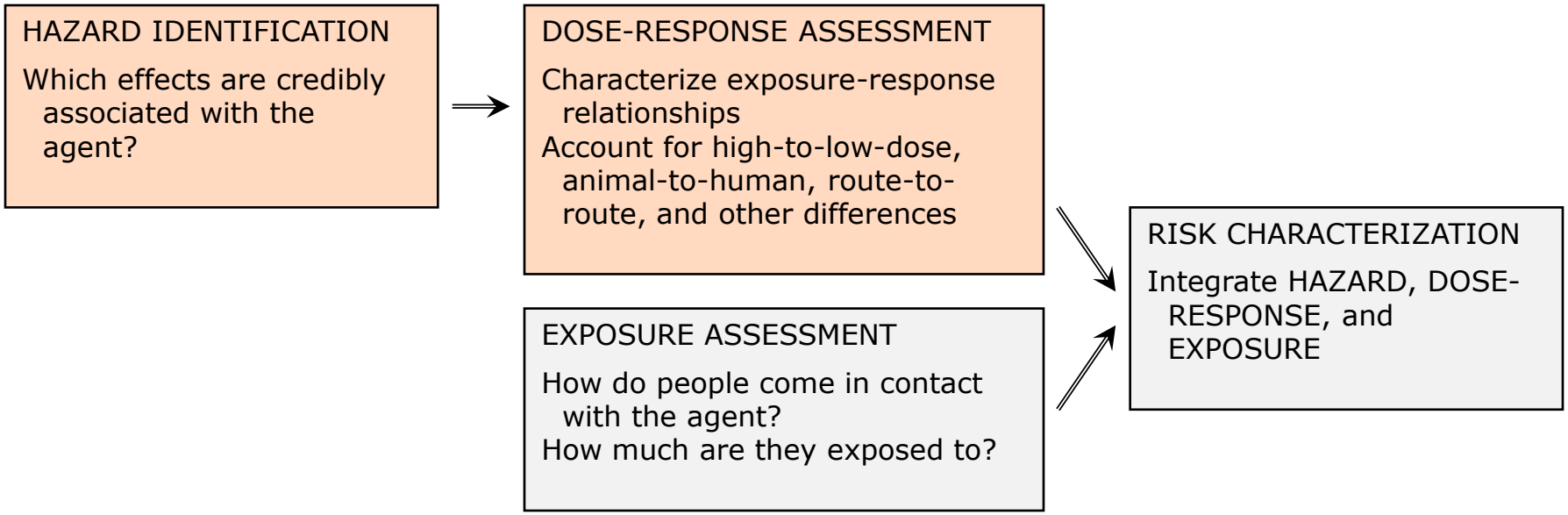
IRIS: Human Health Hazard Assessments

- Multidisciplinary scientists critically review publicly available epidemiologic and experimental studies.
- Create scientific reports known as IRIS assessments that:
  - Identify adverse health effects of chemicals in the environment (e.g., reproductive effects, cancer, immune effects, etc).
  - Estimate the amount of a chemical that people can be exposed to daily without facing an appreciable risk of harmful health effects other than cancer.
  - Characterize the potential for a chemical to cause cancer in people (e.g., carcinogenic to humans, likely carcinogenic to humans, etc).
  - Estimate the excess risk of cancer that people face from exposure to a chemical over the course of a lifetime (oral and/or inhalation).
- These assessments are available to the public on the IRIS database.

www.epa.gov/iris

IRIS Assessments

- IRIS assessments are hazard identification and dose-response assessments that are combined with other information (extent of exposure to people, cost of cleanup, available technology, etc) to inform risk assessments and regulatory actions and decisions.



Chemicals Nominated for IRIS Assessment

- The IRIS program submits queries to EPA Program Offices and Regions and the public for nominations.

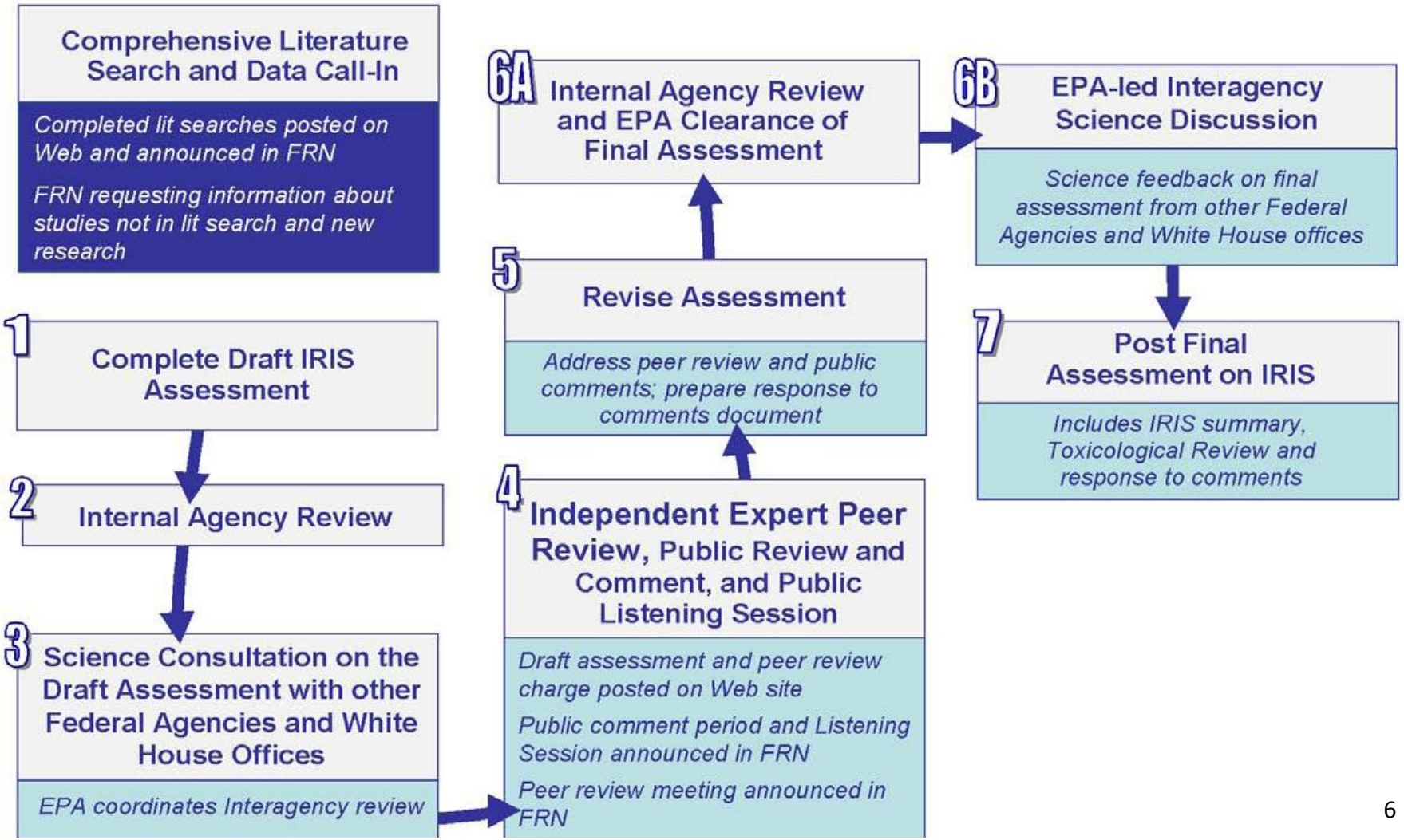
- Substances selected based on one or more of the following factors:

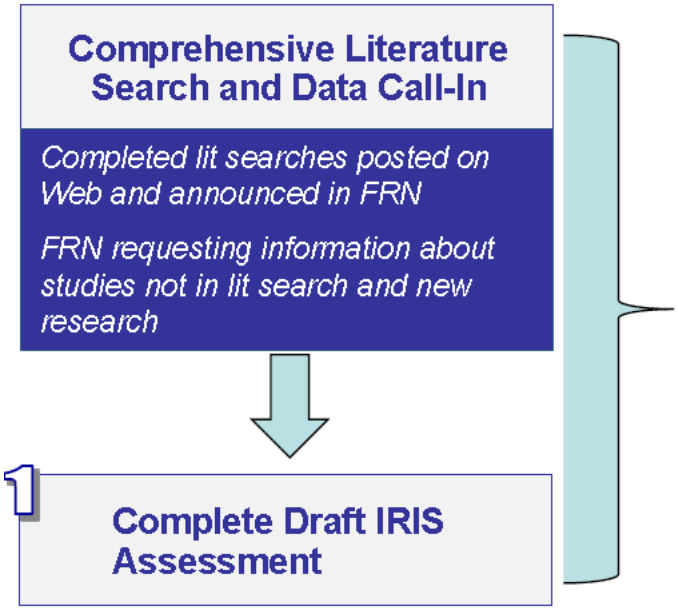
  - (1) potential public health impact;
  - (2) EPA statutory, regulatory, or program-specific implementation needs;
  - (3) availability of new scientific information or methodology that might significantly change the current IRIS information;
  - (4) interest to other governmental agencies or the public; and
  - (5) availability of other scientific assessment documents that could serve as a basis for an IRIS assessment.

- The decision to assess depends on available Agency resources. Availability of risk assessment guidance, guidelines, and science policy decisions may also have an impact on the timing of EPA's decision to assess a chemical substance.

- The list of new or updated assessments is published in the Federal Register (FR) as part of the IRIS agenda.

IRIS Assessment Process





Additional Details about Step 1

Before beginning draft development, the IRIS Program:

- Conducts internal planning and scoping meeting to identify EPA needs for the assessment; and
- Conducts public meeting on technical problem formulation (planning and scoping summary will be publicly released).

As part of developing the draft assessment, the IRIS Program:

- Conducts literature search and critical study selection;
- Develops evidence tables that succinctly summarize the critical studies to be considered in developing the assessment;
- Publicly releases literature search, literature search strategy, critical study selection criteria, evidence tables for critical studies, and exposure-response figures (which graphically depict responses at different exposure levels for studies in evidence tables);
- Convenes public meeting to discuss literature search, evidence tables, exposure-response figures, and key issues;
- Implements recommendations from the National Research Council related to developing IRIS assessments, including systematic review of scientific information and enhanced evidence integration;
- Identifies hazards;
- Selects studies for dose-response assessment;
- Derives toxicity values;
- Prepares draft assessment and draft external peer review charge.

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2 Internal Agency Review

Additional Details about Step 2

During Internal Agency Review, the IRIS Program:

- Shares draft assessment with EPA's program and regional offices;
- Convenes a meeting to discuss draft assessment;
- Identifies any scientific issues; and
- Determines needed disciplines of peer review panel members and the scope of the external peer review.

3 Science Consultation on the Draft Assessment with other Federal Agencies and White House Offices

EPA coordinates Interagency review

Additional Details about Step 3

During Science Consultation, the IRIS Program:

- Shares draft assessment and draft external peer review charge with other Federal Agencies and the Executive Office of the President (EOP) for a science consultation (which is managed and coordinated by EPA);
- Provides a specific date for receiving written comments (written comments will become part of the public record);
- Convenes a meeting of the other Federal Agencies and EOP to discuss issues raised in the written comments;
- If appropriate, may include science questions raised during this step in the draft external peer review charge; and
- Revises the draft assessment, as appropriate.

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4 Independent Expert Peer Review, Public Review and Comment, and Public Listening Session

Draft assessment and peer review charge posted on Web site

Public comment period and Listening Session announced in FRN

Peer review meeting announced in FRN

Additional Details about Step 4

As part of public review, comment and discussion and independent expert peer review, the IRIS Program:

- Publicly releases draft assessment on IRIS website;
- ➢ Publicly releases draft peer review charge on IRIS website (concurrent with the public release of the draft assessment);
- Convenes public meeting on draft assessment;
- ➢ Discusses draft peer review charge at public meeting;
- ➢ May revise the draft assessment or peer review charge prior to peer review to be responsive to public comments;
- Submits draft IRIS assessment and peer review charge questions to external peer review panel (organized by a contractor or by EPA's Science Advisory Board); and
- Participates in public peer review meeting.

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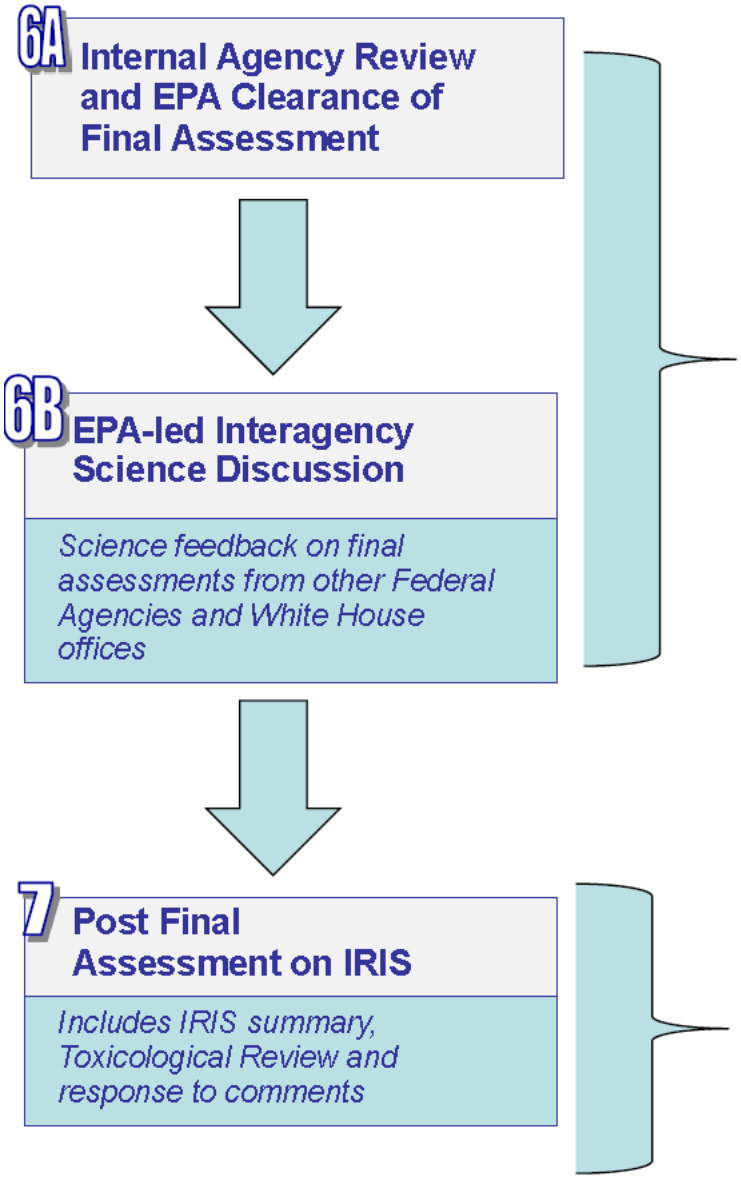
5 Revise Assessment

Address peer review and public comments; prepare response to comments document

Additional Details about Step 5

As part of revising the draft assessment, the IRIS Program:

- Evaluates external peer review panel recommendations and all public comments;
- Revises draft assessment, as appropriate;
- Develops a disposition of peer review and public comments and provides these as an appendix to the IRIS assessment.



Additional Details about Steps 6A and 6B

As part of step 6A, internal Agency review and EPA clearance of final assessment, the IRIS Program:

- Sends final draft assessment for final internal review by EPA's program and regional offices.

As part of step 6B, EPA-led interagency science discussion, the IRIS Program:

- Provides other Federal Agencies and EOP with final draft assessment and related materials (e.g., IRIS Summary; appendices);
- Provides a specific date for receiving written comments with a focus on the disposition of peer review and public comments (written comments will become part of the public record); and
- Convenes a meeting with other Federal Agencies and EOP to discuss final comments.

NOTE: Steps 6A and 6B occur simultaneously.

Additional Details about Step 7

As part of posting the final IRIS assessment, the IRIS Program:

- Completes the IRIS assessment (including the Toxicological Review, IRIS Summary, and any appendices);
- Posts final IRIS assessment and related materials to IRIS website.

Opportunities for Stakeholder Engagement

- Nominations of chemicals for assessment
- Selection of chemicals for IRIS assessment development

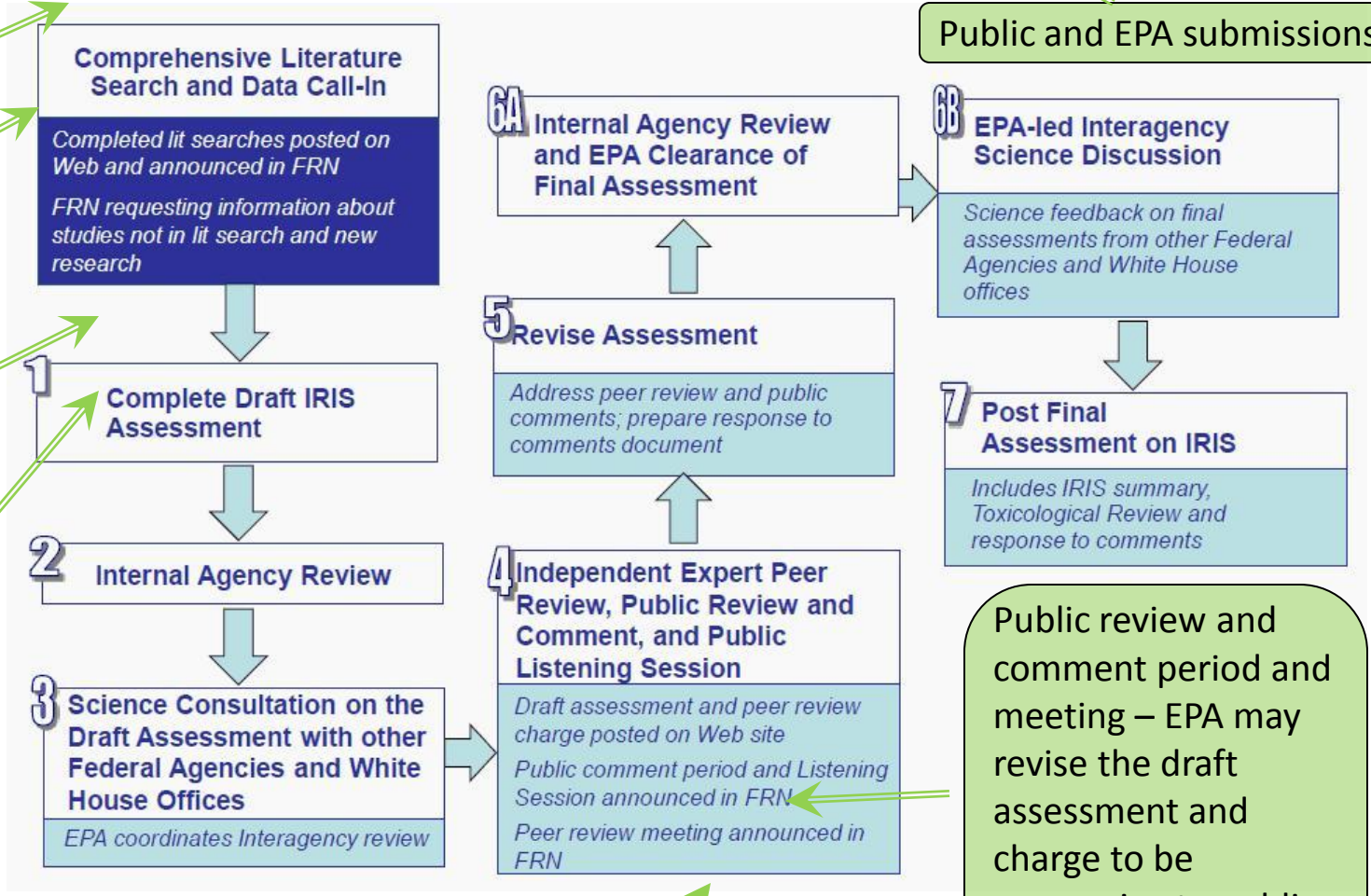
Public and EPA submissions

EPA scoping meeting

Public submissions

Public meeting on problem formulation

Public meeting on literature search, evidence tables, key issues



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

Public peer review meeting – the public can address the peer reviewers

Stakeholder Notification and Participation

Notification

- Human Health Risk Assessment research program monthly bulletin which includes updates about activities in the IRIS Program.
- IRIS email bulletin to regularly update stakeholders about opportunities to engage the IRIS Program; the availability of newly released draft and final assessments; and general updates about the IRIS Program.
- The IRIS website (www.epa.gov/iris).
- The Federal Register.

Participation

- Submit comments and materials to the docket at http://www.regulations.gov.
- Attend and participate in public meetings and scientific workshops.
- Provide comments on potential topics and speakers for workshops.

Scientific Workshops and Public Meetings

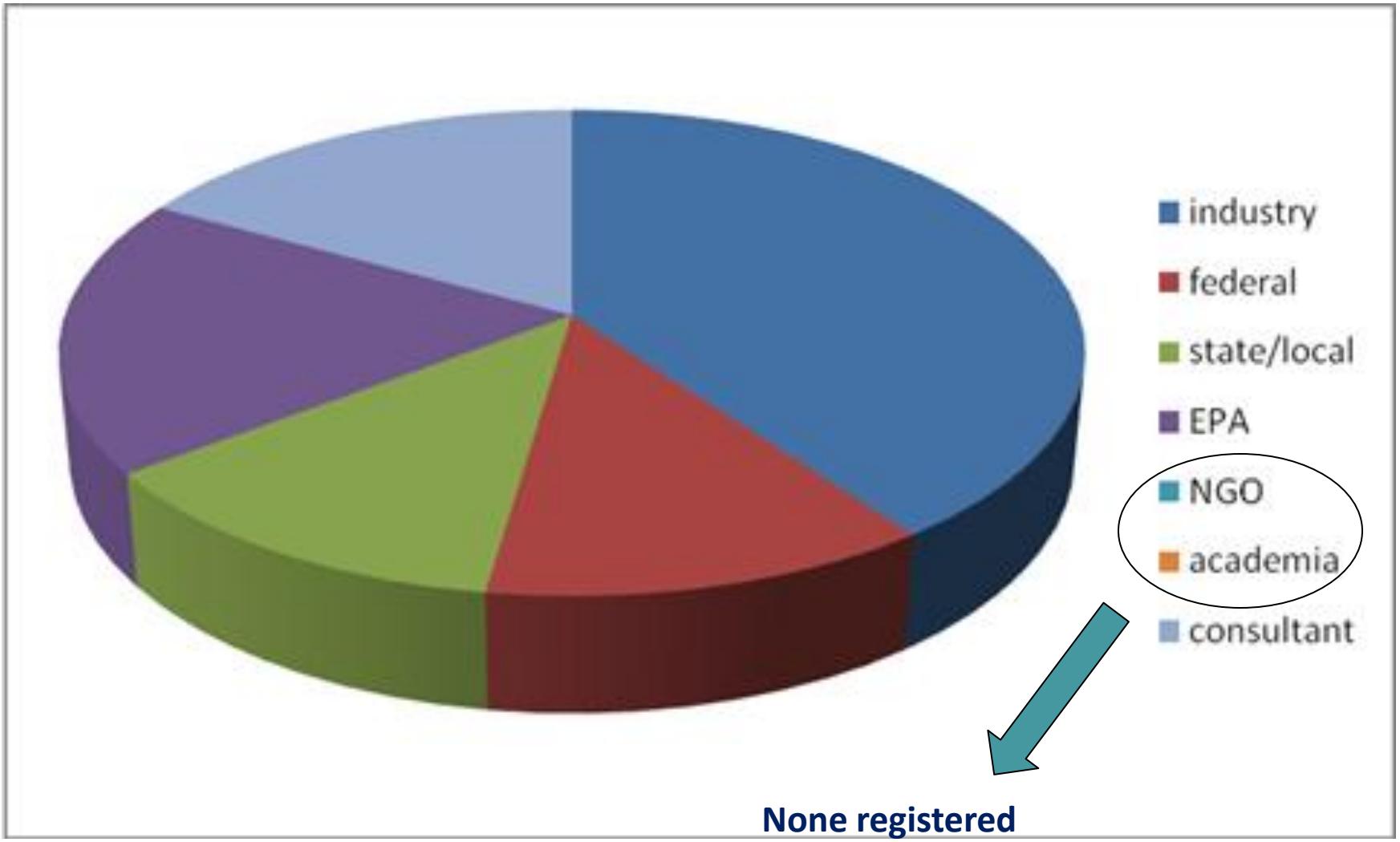
Workshops

- Systematic Review
  - August, 2013
- Hexavalent Chromium
  - September, 2013
- Mouse Lung Tumor
  - January, 2014
- Formaldehyde
  - March/April, 2014

Bimonthly Public Meetings

- December 12-13, 2013
- February 26-27, 2014
- April 23-24, 2014
- June 25-26, 2014
- September 3-4, 2014
- October 29-30, 2014
- December 15-16, 2014

Registered Participants at December IRIS Public Meeting



As of 11-21-13

Assessment Development Timelines

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Step	Time Frame: Standard Assessments	Time Frame: Complex Assessments
1 IRIS draft assessment completed	10.5 months	15 months
2 Internal Agency Review	3 months	3 months
3 Interagency science consultation	2 months	3 months
4 Public comment and External peer review	5 months	9.5 months
5 Draft assessment revised	2 months	4 months
6a Internal Agency Review 6b Interagency science discussion	2 months	3 months
7 Final IRIS assessment	1.5 months	1.5 months
TOTAL	**26 months**	**39 months**

The time frames are anticipated to represent an average, with some assessments potentially taking longer depending on the nature of the analytical tasks and the range of issues raised during peer review

Summary

- IRIS human health assessments are important for informing actions to protect public health – by EPA and other health agencies.
- The process for developing IRIS assessments incorporates multiple opportunities for stakeholder engagement
- IRIS is developing a more open process to encourage greater public participation to help identify controversial science issues early, and ensure transparency and the use of the best available science in IRIS assessments.
- EPA's IRIS Program is committed to engaging stakeholders in a meaningful way, and the Program welcomes comments and input from all stakeholders.

THANK YOU!!

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Additional Slides

Developed Stopping Rules for New and Ongoing Research

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.				

Developed Stopping Rules for New and Ongoing Research

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.	