

# Welcome! . . . to the Apríl 2014 IRIS Bimonthly Public Science Díscussion



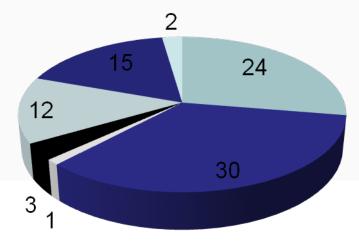




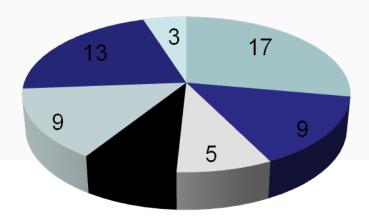


### **Today's Attendance Is More Diverse Than Before**

#### Affiliations of attendees, December 2013



#### Affiliations of attendees, April 2014



- Industry/Trade assoc NGOs
- Fed/Int'l govt
- Media

- Consultants
- Academic
- State/Local/Tribal gov't

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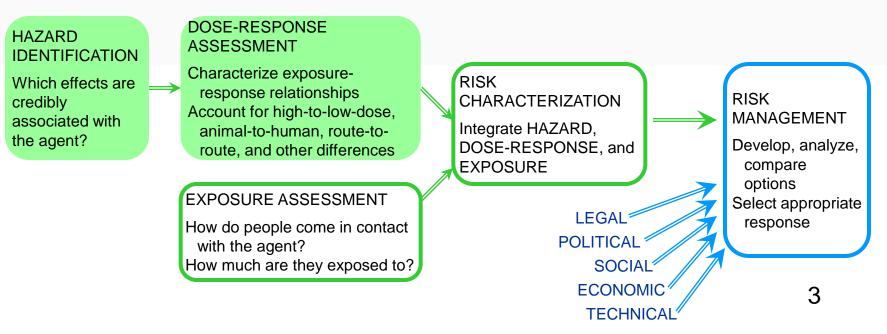
- Consultants
- Academic
- State/Local/Tribal gov't



### **About IRIS**

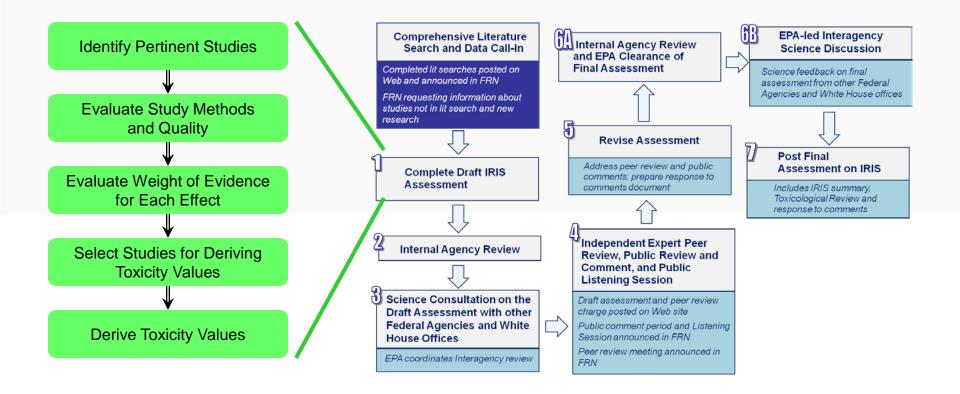
IRIS assessments critically review the publicly available scientific studies on chemicals found in the environment to

- Identify adverse health effects
- Characterize exposure-response relationships



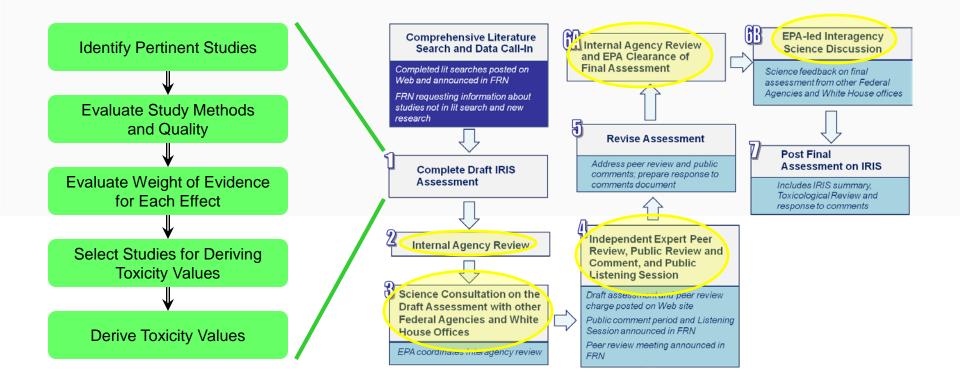


#### **IRIS Means Systematic Review**



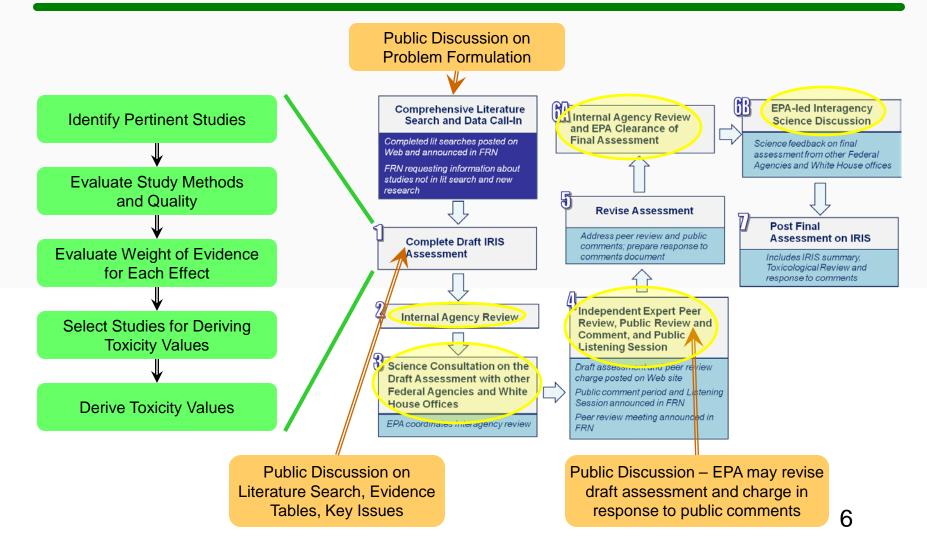


#### **IRIS Means Multi-level Comment and Peer Review**





#### **IRIS Means Public Engagement**





## There Are Now Multiple Ways to Engage with IRIS

- General comments docket (*NEW!*)
- Assessment-specific dockets
- Public science discussions during steps 1 and 4
- Public science workshops on specific topics

Broadly attended meetings are useful for discussing science issues where there are multiple points of view

• Ad-hoc meetings with external stakeholders



#### **Public Science Discussion**

### Purpose: to discuss key science issues

What are key science issues? ... They may pertain to

- > study methods or quality
- > approaches to reconciling positive and negative results
- mode-of-action hypotheses
- > alternative interpretations of the evidence
- scientific considerations to address in the upcoming draft assessment



### Agenda for Today's Public Science Discussion

For each assessment . . .

- > Introduction by EPA assessment managers
- For each science issue . . .
  - Opening remarks by registered discussants
  - Continued discussion by all meeting attendees
- > Open Forum on the assessment

General Open Forum at the end of the meeting



### Scoping and Problem Formulation: Advice from the NRC

#### **Scoping**

- Direct hazards and stressors
- Sources
- Environmental exposure pathways
- Individual intake pathways
- At-risk populations
- Direct adverse health outcomes

Source: NRC 2009, Science and Decisions, boxes 3-1, 3-2

#### Problem formulation

- Hazard-identification methods
- Stressor-characterization methods
- Computational methods
- Uncertainty-characterization methods
- Intake and internal-dose models
- Dose-response models and methods
- Health-outcome measurements
  methods



- Advice from the NRC
- 1. Literature search to identify pertinent studies
- 2. Evidence tables to summarize study methods and results
- 3. Evaluate study methods and quality

#### Studies in humans

- Study population selection, potential for selection bias
- Study population characteristics, generalizability
- Exposure assessment, potential for information bias
- Outcome identification, potential for bias
- Appropriateness of analytic methods
- Potential for confounding
- Precision of effect estimates
- Availability of exposure metrics

#### Source: NRC 2011, Formaldehyde, pp 158-159

#### Studies in laboratory animals

- Species and sex
- Dose, duration, route of exposure
- Health effects considered
- Relevance to human health
  effects of concern



### Identifying and Selecting Studies: Current Thinking in IRIS

- 1. Literature search summarized by PRISMA diagram
- 2. Evidence tables summarize study methods and results
- 3. Evaluation of study methods and quality
  - Start with all pertinent, publicly available studies
  - Exclude studies based on problem formulation (beginning with Cr6, just released)
  - Exclude studies with fundamental flaws
  - Focus on studies with most robust methods (approaches can be discussed today)



### **Future Public Science Discussions**

#### April releases

- Literature search, evidence tables for Hexavalent Chromium (animal studies)
- Literature search, evidence tables for Inorganic Arsenic
- These will be discussed at the June 25-27 meeting

June releases

- Additional literature-search/evidence-table materials
- Problem formulation materials
- These will be discussed at the Sept 3-4 meeting



#### The Enhanced IRIS

- Systematic review

Improved

science

- Toxicity values for all credible health hazards
- Strengthened peer review

Increased - Clear, concise, systematic assessmentstransparency - Opportunities for public engagement

IncreasedWe must make the Enhanced IRIS work byproductivitycompleting more assessments in less time

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