Welcome! . . . to the October 2014 IRIS Bimonthly Public Science Meeting
About IRIS

IRIS assessments critically review the publicly-available peer-reviewed studies to

- Identify adverse health outcomes
- Characterize exposure-response relationships

HAZARD IDENTIFICATION
Which health outcomes are credibly associated with the agent?

DOSE-RESPONSE ASSESSMENT
Characterize exposure-response relationships
Account for high-to-low-dose, animal-to-human, route-to-route, and other differences

EXPOSURE ASSESSMENT
How do people come in contact with this and other agents?
How much are they exposed to?

RISK CHARACTERIZATION
Integrate HAZARD, DOSE-RESPONSE, and EXPOSURE

RISK MANAGEMENT
Develop, analyze, compare options
Select appropriate response

LEGAL
POLITICAL
SOCIAL
ECONOMIC
TECHNICAL
IRIS Has Embraced and Is Acting To Implement Systematic Review

- Identify Pertinent Studies
- Evaluate Study Methods and Quality
- Integrate Evidence for Each Health Outcome
- Select Studies for Deriving Toxicity Values
- Derive Toxicity Values

1. Complete Draft IRIS Assessment
2. Internal Agency Review
3. Science Consultation on the Draft Assessment with other Federal Agencies and White House Offices
4. Independent Expert Peer Review, Public Review and Comment, and Public Listening Session
5. Revise Assessment
6. Internal Agency Review and EPA Clearance of Final Assessment
7. EPA-led Interagency Science Discussion
8. Post Final Assessment on IRIS

- Comprehensive Literature Search and Data Call-In
  - Completed lit searches posted on Web and announced in FRN
  - FRN requesting information about studies not in lit search and new research

- Science consultation on the Draft Assessment with other Federal Agencies and White House Offices
  - EPA coordinates interagency review
“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.” [NRC 2014, p 9]
IRIS Was Recently Reviewed by the National Research Council

“. . . 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 even as the program continues through the current transition phase . . .” [NRC 2014, p 135]

“Kenneth Olden . . . has made a far-reaching effort to engage the full array of stakeholders, including the general public, in providing input into the changes being made. The revisions embrace stakeholder engagement in all relevant phases of the process.” [p 135]
IRIS Provides Increased Opportunities for Public Engagement

1. Complete Draft IRIS Assessment
   - Comprehensive Literature Search and Data Call-In
   - Completed lit searches posted on Web and announced in FRN
   - FRN requesting information about studies not in lit search and new research

2. Internal Agency Review
   - EPA coordinates internal agency review

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

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

5. Revise Assessment
   - Address peer review and public comments; prepare response to comments document

6A. Internal Agency Review and EPA Clearance of Final Assessment

6B. EPA-led Interagency Science Discussion
   - Science feedback on final assessment from other Federal Agencies and White House offices

7. Post Final Assessment on IRIS
   - Includes IRIS summary, Toxicological Review and response to comments

Public Science Meeting on
Literature Search, Study Tables, Key Issues

Public Science Meeting on
Draft Assessment and Charge
(These may be revised in response to public comments)

Identify Pertinent Studies
Evaluate Study Methods and Quality
Integrate Evidence for Each Health Outcome
Select Studies for Deriving Toxicity Values
Derive Toxicity Values
Agenda for Today’s Public Science Meeting

For each assessment in step 1 . . .

- Introduction by the IRIS assessment managers
- Science questions – for each question:
  - Opening remarks by the registered discussants
  - Continued discussion involving all attendees
- Open Forum on the assessment

General Open Forum at the end of the meeting
Some Things to Keep in Mind

We are here to discuss key science questions

- We have not yet drawn conclusions
- We want to hear all scientific perspectives

The preliminary materials are intended to

- Facilitate subsequent assessment development
- Promote constructive public discussion
- Make efficient use of program resources
IRIS Strives for Broad Participation at These Meetings

All meetings by webinar – no travel needed

All meetings give the public advance notice

- Agenda and materials – 2 months in advance
- Timetable – 3-4 weeks in advance

IRIS reaches out to NGOs and academics

Telephone access for webinar participants

*IRIS will continue to improve the format to achieve meaningful scientific discussion that reflects all scientific perspectives*
New Contract with the NAS to Provide Scientific Experts for IRIS Meetings

How it will work

- 3 months prior: IRIS informs the NAS and the public of the assessments/topics to be discussed
- NAS identifies candidate experts
- NAS screens for availability, conflicts, biases
- NAS proposes a list of experts who represent a range of views for EPA concurrence
- NAS determines who will serve and makes travel arrangements

Other public participation will be as before
Upcoming Public Science Meetings

Dec 15-16
- Butyl benzyl phthalate: literature search/study tables/key issues
- Di-isobutyl phthalate: literature search/study tables/key issues

Feb 25-26, 2015
# The New, Enhanced IRIS

**Improved science**
- Systematic review
- Hazard statement and toxicity values for each credible health outcome
- Strengthened peer review

**Increased transparency**
- Clear, concise, systematic assessments
- Opportunities for public engagement

**Increased productivity**
*We must make the Enhanced IRIS work by completing more assessments in less time*

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