Upcoming Activities in the IRIS Program

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Public Workshops and Meetings

IRIS Bimonthly Public Science Meetings allow the public the opportunity to provide input and participate in discussions about preliminary assessment materials and draft IRIS assessments.

December 2013	Preliminary materials (lit search/evidence tables) for RDX, ETBE and TBA; discussion of draft assessments for benzo[a]pyrene (B[a]P) and ethylene oxide (EtO).
February 2014	Canceled to allow time to prepare additional materials to promote more robust discussions at future public meetings based on public comments heard at the December bimonthly public meeting.
April 23, 2014	Preliminary materials (lit search/evidence tables/scoping information/study quality considerations) for hexabromocyclododecane (HBCD) and diethylphthalate (DEP).
June 25-27, 2014	Preliminary materials (lit search/evidence tables/scoping information/study quality considerations) for hexavalent chromium and inorganic arsenic; these materials also include some problem formulation information for chromium and a pilot risk-of-bias analysis for inorganic arsenic.
(August) September 3-4, 2014	TBD: Likely PF meeting for napthalene and ethylbenzene
October 29-30, 2014	TBD: Possibly DiNP and Part II of the preliminary package for chromium
December 15-16, 2014	TBD: Possibly preliminary packages for few other phthalates

Public Workshops and Meetings

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Most Recent IRIS Bimonthly
June 25-27, 2014 in Arlington, VA

- Preliminary materials related to the assessments of **hexavalent chromium** and **inorganic arsenic** were discussed.
- Most successful IRIS Bimonthly meeting yet!
- Adaptive changes made to format of meetings are now eliciting much more robust scientific discussion and input.
- Looking forward to more of same in Aug/Sept, October and December

Upcoming Public Workshops and Meetings

- May 2014 NRC report

- Commended EPA for:
    - substantive new approaches
    - continuing commitment to improving the IRIS process
    - successes to date

- They noted that the program has moved forward steadily in planning for and implementing changes in each element of the assessment process.

- They also provided several recommendations which they said should be seen as building on the progress that EPA has already made.

Upcoming Public Workshops and Meetings

- **EPA is planning a public workshop to get input from the public and scientific community on some of the specific recommendations from the May 2014 report on IRIS, related to further improving the scientific quality of IRIS assessments.**
    - October 15-16, 2014
    - Washington, DC area
    - Available by webinar
- Specific details, including the location, agenda, and how to register, will be available at a later date.

Upcoming chemicals and their evolution

New document structure

NRC 2011 Report on Formaldehyde

- Enhance the clarity of IRIS assessments.
- Reduce the volume of text.
- Address redundancies and inconsistencies.

IRIS Program fully embraced and implemented this recommendation

- Revised assessment template to reduce redundancy and the amount of text.
- Reduced the opportunity for inconsistencies from revision and transcription errors.

New IRIS assessment template has:

- Sections for the literature search and associated strategy.
- Section for study selection and evaluation.
- Better description of methods used to develop the assessment.

New document structure

IRIS documents are now more clear, concise, and systematic

Old structure

- Introduction (1/2 page)
- Literature search (1 page)
- Lengthy study summary narratives (all studies, many pages, detailed descriptions)
- Combined section with hazard identification and dose-response

New structure

- Executive summary
- Preamble (15 pages)
- Detailed literature search strategy
- Evidence tables of key studies for each adverse effect
- Identification of health hazards
- Dose response analysis
- Toxicity values for each health hazard

Standard assessment: 300 pages

Complex assessment: 1000 pages

Standard assessment: 1-200 pages

Complex assessment: 300 pages

The Pipeline

Step 0. Scoping and Problem Formulation materials under development	Step 1. Evidence tables under development	Step 1. Lit search, evidence tables released	Step 1. Writing draft assessment	Step 4a. Public comment	Step 4b. Peer review
Ethylbenzene Naphthalene	Several phthalates	Chromium VI Inorganic arsenic	ETBE t-Butanol n-Butanol RDX DEP HBCD	Ethylene oxide Benzo[a]pyrene	TMBs Ammonia

Upcoming chemicals and their evolution

TMBs and Ammonia

- First drafts with significant advancement in responding to the NRC 2011 recommendations
- New structure
- Format
- Preamble
- Supplementary materials
- Adopted the **principles** of systematic review
- New evidence tables/documented review of literature

- Inadequate information for a cancer evaluation
- No explicit problem formulation meeting/step*
- No explicit scoping document (although some scoping information is provided in the assessments)*

** Based on how advanced these chemicals were when the Enhancements were implemented*

Upcoming chemicals and their evolution

EtO and B[a]P

Ethylene Oxide (EtO) – SAB candidate list published

- Assessment well underway before the NRC reviews and enhancements.
- This assessment will be in the older-style IRIS format.
- Earlier version of the carcinogenicity assessment received public comment and underwent external peer review by an SAB panel in 2007.
- Revised external peer review draft is being developed in accordance with the original SAB panel recommendations and public comments .
- Revised draft will be released for additional review by the SAB CAAC (and also posted on the IRIS website) soon.
- This additional review is intended to solicit comments on how the Agency responded to the SAB panel recommendations, the exposure-response modeling of certain epidemiologic data, and the adequacy, transparency, and clarity of the revised draft.

Upcoming chemicals and their evolution

EtO and B[a]P

Benzo[a]pyrene (B[a]P) – SAB has solicited panel nominations

- This assessment builds on improvements incorporated into TMBs and Ammonia.
- It includes organ and system-specific reference values.
- It has a cancer analysis.
- Revisions are underway post public comment.
- External peer review draft will be released to the SAB for peer review (and also posted on the IRIS website) soon.

Upcoming chemicals and their evolution

RDX, TBA, ETBE

What was done:

- Preliminary packages released
- Discussed at IRIS public meeting in December 2013
- No formal scoping materials included at that time
- No formal problem formulation step

What we are doing:

- Developing draft assessment
- Scoping information will be included in upcoming drafts
- Not going back to problem formulation
- Will build upon what was done for B[a]P
- Further implement the 2011 NRC recommendations

Next Steps:

- Discuss draft assessment at IRIS bimonthly public science meeting
- Agency review
- Interagency review
- Public comment period
- Additional revision if needed
- Release for SAB CAAC Review

Upcoming chemicals and their evolution

HBCD and DEP

What was done:

- Preliminary packages released
- Discussed at IRIS public meeting in April 2014
- Formal scoping materials included
- Study quality considerations outlined
- No formal problem formulation step

What we are doing:

- Developing draft assessment
- Not going back to problem formulation
- Will build upon what was done for B[a]P
- Further implement the 2011 NRC recommendations

Next Steps:

- Discuss draft assessment at IRIS bimonthly public science meeting
- Agency review
- Interagency review
- Public comment period
- Additional revision if needed
- Release for SAB CAAC Review

*** Next chemicals to include problem formulation*

Upcoming chemicals and their evolution

Hexavalent Chromium (Part I) & Inorganic Arsenic

Chromium (Part I):

- Includes animal data only (no epi, no mechanistic info)
- Preliminary package released
- Scoping information included
- Study quality considerations outlined
- Includes problem formulation information (did not go backwards to include problem formulation step)
- To be discussed at IRIS public meeting June 25-27, 2014

Next Steps:

- Release of Chromium Part II (epi data and mechanistic data) for discussion at subsequent public meeting

Arsenic:

- Piloting a different approach in response to specific NRC review of arsenic
- Public meeting on problem formulation, planning and scoping for the development of the inorganic arsenic IRIS assessment (Jan 8-9, 2013)
- Preliminary package released
- Includes a pilot Risk of Bias analysis
- To be discussed at IRIS public meeting June 25-27, 2014

Next Step:

- Develop draft assessment

Providing Input to IRIS

Have general comments for the IRIS Program?

In response to public feedback, EPA has opened a "General Comments Docket" to receive feedback that has broad applicability to the IRIS Program.