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VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

September 19, 2016

Dr. Thomas Burke
Deputy Assistant Administrator, ORD
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Washington, DC 20460

Dr. Robert Kavlock
Deputy Assistant Administrator for Science, ORD
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William Jefferson Clinton Building
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Washington, DC 20460

Sent via email to: Kavlock.robert@epa.gov and Burke.thomas@epa.gov

**RE: IRIS Program Lack of Responsiveness to Public Comments**

Dear Drs. Burke and Kavlock:

In 2013, the EPA Integrated Risk Information System (IRIS) Program revised the IRIS process to incorporate an explicit response-to-comments step. Unfortunately, the IRIS final toxicological review of trimethylbenzenes (TMB), released 10 days ago, does not incorporate that step. On behalf of the American Chemistry Council (ACC), I urge you to require the program to respond to public comments on the TMB review, and to adhere to the IRIS process steps in all future releases.

The 2013 revision to the IRIS process clearly notes that Step 7 (final assessments) includes a response to comments. This response stems from Step 5, when EPA revises the assessment and "evaluates external peer review panel recommendations and public comments" and "develops a disposition of peer review and public comments and provides these as an appendix to the IRIS assessment" (see page 5 of Attachment A, emphasis added). We have attached the 2013 document as it is difficult to find on the revised EPA webpage.[1]

[1] We also note that EPA's webpage now only summarizes the full 2013 document and mischaracterizes step 5. The webpage should also be clarified to clearly depict the 2013 process.



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EPA followed this process when making the Libby Amphibole Asbestos (LAA) Assessment final in December 2014. That assessment incorporated an appendix entitled "EPA Response to Major External Peer-Review and Public Comments," that responded to both public and peer review comments the agency received.

Without explanation, EPA's September 9, 2016, release of the final toxicological review of TMBs contains no response to public comments, and in fact only addresses peer review comments. Responses to public comments do not appear to be publicly available.
As the Chemical Assessment Advisory Committee (CAAC) has no responsibility to address or respond to public comments, it is critically important that the IRIS program provide the necessary transparency by responding to public comments. This was clearly reflected in the 2013 IRIS process documentation – a process for which EPA has announced no changes. Thus, the public expects that EPA will respond to public comments in its releases.

ACC recommends that EPA provide responses to public comments in a new addendum to the Toxicological Review of Trimethylbenzenes, and also ensure that EPA follows the 2013 IRIS process in all future releases. A change in the IRIS process would signal a retreat from EPA's commitment to stakeholder engagement.

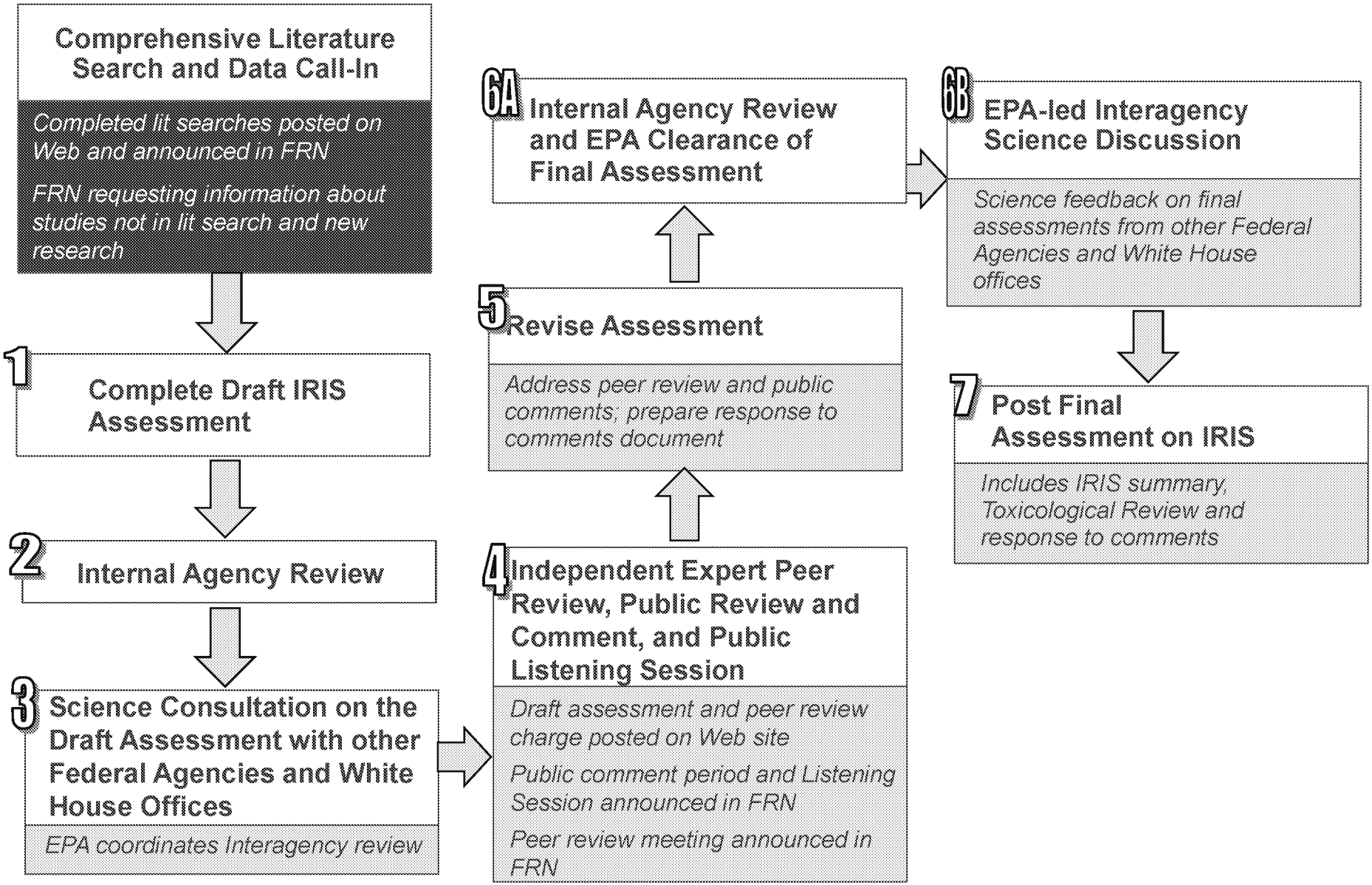
I would welcome the opportunity to speak with you further about our important concerns. If I can provide any additional information, please contact me or Dr. Nancy Beck of ACC's Regulatory and Technical Affairs staff.

Sincerely,

Michael P. Walls
Vice-President
Regulatory & Technical Affairs

Attachment

cc:
Lek Kadeli, EPA
Mike Slimak, EPA
Vince Cogliano, EPA
Christopher Zarba, EPA
Dominic Mancini, OMB



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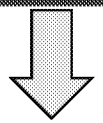
**Comprehensive Literature Search and Data Call-In**

*Completed lit searches posted on Web and announced in FRN*

*FRN requesting information about studies not in lit search and new research*



1 **Complete Draft IRIS Assessment**

## 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**

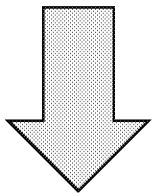
*Address peer review and public comments; prepare response to comments document*

## Additional Details about Step 5

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

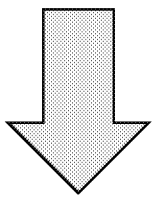
- Evaluates external peer review panel recommendations and all public comments;
- Revises draft assessment, as appropriate;
- Develops a disposition of peer review and public comments and provides these as an appendix to the IRIS assessment.

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



**6B** EPA-led Interagency Science Discussion

*Science feedback on final assessments from other Federal Agencies and White House offices*



**7** Post Final Assessment on IRIS

*Includes IRIS summary, Toxicological Review and response to comments*

## 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.



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# 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<br>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