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IRIS Public Stakeholder Meeting

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Introduction

- The NAS, GAO and Congress have expressed strong concerns regarding longstanding problems with IRIS.

- Fixing IRIS will improve the accuracy and usefulness of assessments as the basis for future regulation and timely decisions to protect human health and the environment.

- ACC has been actively and constructively engaged in scores of IRIS assessments, and continues to advocate for significant fundamental improvements.

- EPA has begun to acknowledge problems and make modest changes to IRIS.

- ACC believes that enhancements to IRIS, if properly implemented, will improve:
  - the scientific quality,
  - transparency and
  - the pace of IRIS assessments.

- IRIS improvements may be applicable to other programs, including the RoC.
Success Indicators in Reforming IRIS

1. Transparency and Reproducibility
2. Meaningful stakeholder input
3. Robust peer review
4. Improved responsiveness to stakeholder and peer review comments
1. Transparency and Reproducibility

- The new Preamble is a step in the right direction, but does not delineate the criteria relied upon by EPA in either selecting studies or assessing their quality.

- Use of weight of evidence framework to weigh the best available science, including mode of action (MOA)
  - During its review of formaldehyde, the NAS concluded that EPA had not applied a WOE framework in assessing LHP cancer causality.
  - More recent assessments do not indicate how EPA assigns weight to studies or how much weight is assigned.
2. Meaningful Stakeholder Input

- EPA has made important strides in converting the listening sessions into active dialogue sessions.
- The scoping and problem formulation step, however, has yet to be fleshed out and applied to an IRIS assessment.
3. Robust Peer Review

- ACC applauds EPA’s commitment to providing stakeholders with an opportunity to contribute to peer review charge questions.
- Stakeholders should be afforded sufficient time to present comments to and dialogue with peer reviewers.
- EPA has also proposed revising draft assessments to reflect public input before the assessment is peer reviewed.
  - EPA should ensure that it builds into the process sufficient time to fully consider public comment and amend the draft assessment before peer review.
- ACC does not support concurrent public and interagency review.
- HR 6564 - the SAB Reform Act - would strengthen SAB review.
4. Improving Responsiveness to Public and Peer Review Comments

- Assessing the adequacy of EPA’s response to public and peer review comments could be the role of:
  - SAB staff and subset of peer review panel?
  - Independent ombudsman?
  - Other options?
Additional Short-term Recommendations to Improve IRIS

- EPA should use regulations.gov to post all IRIS assessment documents, comments, peer review drafts, etc.

- For all IRIS assessments underway, EPA should either apply systematic approaches to data evaluation and weight of evidence or explain the rationale for not doing so.