

Oral Comments on Actions Related to Updating EPA Guidelines for Carcinogen and Noncancer Assessment

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by

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Conclusions

- EPA should develop a realistic plan and request a formal review of that plan by the SAB before proceeding (Step 1).
- It is realistic to plan for a 4-6 year process, at a minimum. Finishing by the end of 2020 is wholly unrealistic.
- Begin implementation by addressing the unresolved issues from the 2009 NRC *Science and Decisions* report before writing any guidelines.

Conclusions

- **Adequate agency resources and time need to be committed and sustained along with credible engagement of outside experts in both development and review roles.**
- **It would be wise to engage the NAS in the review of the *Science and Decisions*- related issue papers, the guidelines and the qualifications of the SAB review panel to confirm that the outputs reflect an objective view of the state of the science.**

Steps

1. **Development of Action Plans in consultation with the SAB and other key players**
2. **Drafting, with engaged external peer involvement**
3. **Discussions in public forums**
4. **Internal review and sign-off**
5. ***Executive Branch (EB) reviews (guidelines only?)***
6. ***Revision in response to EB reviews***
7. **Referral to NAS**
8. **Revision in response to NAS review**
9. **SAB peer review and public comment**
10. **Revision and response-to-comments**
11. **Internal review and sign-off**
12. **Publication of final issue papers and guidelines**

Timelines

- **Science and Decisions issue papers:**
An optimistic timeline might be 2 ½-3 years, but a more realistic estimate would be 3-3½ years.
- **Guidelines:** An optimistic timeline might be 3-3½ years, but a more realistic estimate would be 4-5 years.
- **Both tasks done in concert with no significant hurdles: 4-5 years.**
More realistic estimate, **because unanticipated hurdles always arise**: 5-6 years.