

Draft SAB Report on EPA's
*Draft Technical Guidance for
Assessing EJ in Regulatory
Analysis*

EPA Presentation: Comments and Questions

July 22, 2014

Overview

- The agency appreciates the thorough SAB review and detailed comments.
- EPA recognizes that the report is currently in draft form and subject to change.
- EPA has several comments and clarification questions for the Panel to consider in finalizing the report.

Framework for Analyzing Human Health Risk

- The draft report acknowledges human health risk assessment (HHRA) is a dominant paradigm for analyzing human health risk in EPA's regulatory analyses, but also highlights a number of limitations of HHRA for considering EJ.
- Health Impact Assessment (HIA) or other holistic approach is suggested as an alternative. To the best of our understanding, HIA is a relatively new framework that has mainly been used for localized actions; rarely, if ever, been applied in a national decision-making context.
- In addition, the draft report encourages EPA to consider use of both quantitative and qualitative methods in analyzing EJ in a regulatory context.

Framework Questions

- HHRA will continue to be used at EPA for analyzing human health risks. Given the limitations of this tool identified in the report, what recommendations for best practices for conducting an HHRA can be included in the EJTG for considering EJ in a national rulemaking? Are there modifications or supplements to the standard HHRA that can be included to facilitate its use in an EJ analysis?
- EPA recognizes that there are other methods for considering EJ. Are there elements of HIA that can be included in a regulatory analysis for considering EJ, particularly in a national rulemaking context? Are there specific examples of HIA in a national context that can be referenced in the EJTG?
- Please provide recommendations, references or examples of qualitative assessments that can be applied to a national rulemaking context.

Cumulative Risk Assessment (CRA)

- The draft report states the EJTG lacks information on “how cumulative effects should be evaluated, quantified, or otherwise considered in the EJ analysis.” (page 13)
- EPA recognizes that this is an important component to EJ analysis. However, guidance for the EJTG is predicated on underlying Agency guidance for CRA. Currently, individual EPA programs have undertaken CRA for multiple chemicals with similar chemical structure and common mode(s) of toxicological action. Based on these and other CRA examples, EPA is in the process of developing comprehensive CRA Guidelines, but this is not expected to be completed for several years.
- Recognizing the scientific challenges and resource constraints facing EPA’s regulatory work, what recommendations can the Panel provide for work EPA could do in the interim to begin incorporating aspects of cumulative risk in national rules and help to build towards an Agency-wide guidance?
- Are there specific recommendations for incorporating cumulative considerations into EJ analyses in the more immediate short-term versus recommendations that would be more appropriate for longer-term research considerations (and inclusion in Section 6, for example)?

Section 3: Contributors and Drivers of EJ

- Section 3 is intended to provide basic, background information for analysts to highlight factors that can give rise to EJ. Many analysts will be unfamiliar with the context underlying EJ concerns and this section is intended to highlight relevant key issues to consider. It is not intended to be comprehensive or directly linked to analytic requirements.
- The draft report provides suggestions for improving this section. However, the draft response to Charge Question 7 is that this “section is a premature inclusion in the EJTG.” (page 32)
- Given the importance of this section as background information, what elements should be modified, refined, or removed?

Conducting an Analysis

- The draft EJTG is notably silent about which rules would receive an EJ analysis. However, EPA expects a meaningful discussion of EJ in all rules, recognizing that the type of analysis will vary along a continuum from simple to rigorous.
- The draft report suggests that an EJ analysis is conducted only when the standard “is not protective from an EJ perspective.” (page 14)
- Please clarify the Panel’s recommendations with regard to when an EJ analysis should be conducted, including any recommendations for criteria to determine how to make that determination. In addition, recommendations for criteria to determine the appropriate type of analysis are welcome.

Compilation of Examples

- The draft report provides many suggestions regarding the use of examples throughout the EJTG. Specifically, the Panel recommends adding examples, expanding the description of examples, and compiling examples in an Appendix.
- One of the challenges associated with adding examples is the limited number that are available for national regulations.
- Please comment on sources of examples and how those examples should be highlighted when they may often differ from the regulatory context. For example, the academic literature often includes studies that are of limited geographic scope, retrospective, or case study approaches. How would the Panel recommend highlighting studies from the literature when there may be limitations to applying them in a regulatory context? Specific citations are welcome.

Thank you!