

Comments to the EPA Science Advisory Panel on the 2010 Dioxin Reassessment

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On behalf of the Research Foundation for Health
and Environmental Effects

EPA ignores its own risk assessment guidance and the NAS

- 2000 Risk Characterization Handbook
- 2002 Information Quality Guidelines
- 2003 Assessment Factors handbook
- 2004 Risk Assessment Principles and Practices documentation
- 2005 Guidelines for Carcinogen Risk Assessment
- 2006 NAS committee recommendations

No weight-of-evidence analysis

- Information Quality Guidelines: In the Agency's development of "influential" scientific risk assessments, we intend to use all relevant information [and] . . . reach a position based on careful consideration of all such information (i.e., a process typically referred to as the "weight-of-evidence" approach).
- Assessment Factors Handbook: The weight-of-evidence approach generally considers all relevant information in an integrative assessment . . . and explains how the various types of evidence fit together.
- Risk Assessment Principles & Practices: Risk assessment involves consideration of the weight of evidence provided by all available scientific data
- NAS review: . . . the committee notes that EPA does not use a rigorous approach for evaluating evidence from studies and the weight of their evidence in the Reassessment.

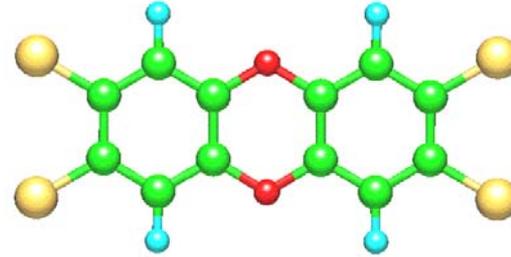
Instead, EPA . . .

- used study inclusion criteria that preclude a weight-of-evidence analysis because they select solely for studies that demonstrate a positive result & dose-response relationship:
 - studies that demonstrate “an association between TCDD and an adverse health effect”
 - studies for which the “magnitude of animal responses is outside the range of normal variability exhibited by control animals”
- specifically excluded studies that demonstrate no effect and thereby effectively preventing a balanced and transparent consideration of available evidence supporting or refuting the biological plausibility and likelihood of effects

No demonstrated clinical significance of noncancer effects chosen for RfD

- Risk Assessment Principles & Practices: As a general principle, our practice is not to base risk assessments on adaptive, non-adverse, or beneficial events.
- NAS: Attention should also be directed to addressing the potential biological significance of very small statistically significant physiological or biochemical changes that remain well within the normal range of variation and adaptation.
- NAS: The available studies have not yet shown clear associations among TCDD exposures and the risks of individual, clinically significant, non-cancer end points.

Conclusion



- EPA fails to evaluate the potential human cancer and noncancer effects of dioxin using a weight-of-evidence analysis, despite the direction to do so provided by its own risk assessment guidance documents and by the National Academy of Sciences committee that reviewed EPA's 2003 dioxin reanalysis
- Thank you for your attention