

Comments on Draft NTP Systematic
Review Approach,
Robert J. Fensterheim, MPH

Board of Scientific Counselors
December 11, 2012

Background

- Robert J. Fensterheim, MPH (Environmental Sciences)
- President, RegNet Environmental Services
- Actively engaged in chemical issues for over 30 years, including risk assessment and associated research initiatives

Draft SR Approach

- NTP's promotion of Systematic Review for chemical evaluations is strongly endorsed. There is a clear need for greater transparency, documentation and the step-wise approach being advanced.
- At the same time, there is a large body of experience in conducting chemical evaluations and it is unclear to what extent NTP has considered these efforts in developing its draft SR Approach.
 - The draft should recognize the extensive approaches that are currently being used to evaluate studies (e.g., Klimisch score) nor the various systems that are currently being used to summarize information (EPA-HPVIS, IUCLID, etc.)
- **Recommendation:** Adopt as a goal, describing the Systematic Review approach in a sufficiently clear and detailed manner so that Stakeholders and other Risk Assessors can replicate NTP's SR Approach recognizing that the outcome might differ due to scientific judgment.

Draft SR Approach

- The draft document is succinctly written and provides a nice “Overview” of the anticipated SR approach; this was possible because all of the difficult issues were deferred and are to be address in the “Protocol.”
- Unfortunately, the document does not adequately convey the complexities and difficulties that will assuredly be encountered in preparing and utilizing the Protocol.

Draft SR Approach: Protocol

Examples of issues to be addressed in the Protocol:

- Establishes criteria for including or excluding references based on applicable outcomes, relevant exposures, and types of studies.
- Outline specific plans for: reviewing studies for inclusion, resolving conflicts between reviewers, and documenting the reasons that studies were excluded. (Page 2)
- Detail project-specific factors of study design and performance that result in specific risk of bias ratings for each question being addressed. (Page 2)
- The project-specific explanation of the strategy used to combine confidence ratings across multiple outcomes is documented in the protocol. (Page 5)

Draft SR Approach

- There is no indication that the draft SR approach described has been used for a chemical evaluation. If it has, these examples should be made available.
- Recommendation: Before the BSC seriously considers “blessing” the overview, NTP is encouraged to work thru a few examples/pilots addressing a range of issues.
- Recommend organizing a workshop to discuss.

Public/Stakeholder Input

- Agree with the comments of others on the need for adequate notice and opportunity for public comment on the SR Approach
- Additionally, the approach should be revised to clarify that public input would be sought throughout the process and not just Step 1 and 7.

THANK YOU