EPA Guidelines for Human Health Hazard and Dose Response
A Recommendation for Risk Assessment Forum (RAF) Action

This recommendation was developed in response to a request the Science Advisor has conveyed from the Administrator. The request was for the RAF to develop guidance on the most important elements of hazard identification and dose-response that can be harmonized across the agency.

Recommendation

An STPC leadership group (or their designees) will consider a set of hazard and dose-response issues and decide on which issues the RAF should develop harmonized approaches across the agency such as linear vs. threshold dose response extrapolation, non-cancer hazard identifiers, and updating reference dose and reference concentration processes[1]. The leadership group will prioritize from the issue list one or more priorities for the RAF to develop guidance in the near term. The STPC members will support this effort by assuring necessary staff are available to enable timely success of the effort at each stage (project selection, execution, review and resolution). Narrowly-defined charges will aid in expediting the drafts of technical work products and limit the amount of staff resources needed. This approach will likely yield one or more products within the desired timeframe. The RAF Human Health Oversight Committee (HHOC) will also be able to use this input to inform a longer-term action plan.

The objectives that will guide this activity include, but are not limited to:

- Providing EPA-wide guidance where risk-assessment practices diverge across EPA offices that conduct hazard and dose-response evaluations.
- Considering existing and new science and/or methods that could influence EPA-wide guidance.
- EPA-wide guidance should be based on validated scientific findings or best practices, distinct from risk management decision-making.

Process

Upon STPC agreement for the action, the RAF will develop a charge for STPC review and approval. Draft guidance will be developed by the RAF through one or more technical panels, approved through the STPC, and submitted for independent external peer review pursuant to the RAF and STPC charters. Consultation with the EPA Scientific Advisory Board may be desirable. The timeframe is to have review drafts by late Fall of 2019, and a completed guidance by December 2020, but sooner if possible. This process may be used to assist the HHOC develop it 5-yr action plan.

Next Steps

- STPC discussion, approval of recommendation, and identification of participants for the leadership group (March 27 – April 5).
- STPC leadership group prioritizes the list of candidate issues for harmonization. (April)
- RAF drafts a charge(s) and timeline for STPC approval. (May)
- RAF develops the scope of work, technical panel(s), and resource requirements.

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[1] EPA 2002, A Review of the Reference Dose and Reference Concentration Processes, Risk Assessment Forum. EPA/630/P-02/002F