Draft March 1, 2006

"A Framework for Assessing Health Risks of Environmental Exposures to Children"
External Peer Review Panel Meeting Charge Questions

Purpose of the Document:
The purpose of the draft document entitled "A Framework for Assessing Health Risks of Environmental Exposures to Children" is to provide an overarching approach for the assessment of health risks to children, taking into account potential exposures during all developmental stages and focusing on the major health outcomes that may occur as a result of such exposures. This draft document provides a roadmap for assessing risk of environmental exposures to children, describing the process of children's health risk assessment using a series of questions for each component that lead the reader through the analysis and evaluation. A series of flowcharts are used to illustrate this process. In addition, other resources that provide more detailed information are referenced, and are in a linked database that can be easily accessed by the reader.

Purpose of Expert Peer Panel Meeting and Review:
The purpose of the Expert Peer Panel Meeting is to carry out an independent external peer review of the draft document entitled, "A Framework for Assessing Health Risks of Environmental Exposure to Children." Independent external panel reviewers with expertise in multiple disciplines relating to children's health risk assessment will be invited to address the posed charge questions (see below). We also invite comments on the value added of this approach to the Agency's current practice on children's health risk assessment.

Questions:
1. Is the purpose of this draft framework document clearly articulated? Are the graphic presentations of various concepts and methods (e.g., flowchart approach) and the questions to prompt review considerations clear and useful? If not, do you have suggestions for improving clarity?

2. This report is intended to highlight specific concerns of children's risk assessment. However, there are some general aspects of risk assessment that need to be described. To what extent is this document inconsistent with how you have interpreted existing risk assessment guidance? Are there major gaps in what has been presented, for either children's risk assessment or for risk assessment more generally? Considering the various types of Agency chemical assessments that you are familiar with or anticipate performing, are there gaps in the process outlined?

3. Risk assessment is a multi-step process and done at many different scales depending upon the problem. Do you think the document provides enough flexibility for users to understand how it applies to them? If not, for what audience(s) would you suggest clarification is needed and what kind of clarification?

4. Is the list of potential involved parties (e.g., risk assessors, risk managers, others) discussed in the problem formulation inclusive enough?

5. The approach described uses a life stage perspective; that is, it focuses on assessing exposures for developmental life stages (embryo, fetus, child, and adolescent) and resulting health outcomes for all life stages (embryo, fetus, child, adolescent, reproductive adult, and aging adult The EPA is soliciting your input regarding whether this approach is a more comprehensive approach than the focus on organ systems (e.g., neurotoxicity, cancer, reproductive toxicity, and developmental toxicity) used in previous risk assessment guidelines. Please comment on the advantages and disadvantages of this approach within the context of our current understanding of the influence of exposure in different life stages and the available data.

6. The report addresses the integration of hazard data with exposure information from a life stage perspective. This discussion brings together information from the toxicological evaluation, life stage of susceptibility, exposure factors for children, and age binning for exposures. Have we clearly articulated the approach? Are their sufficient data and understanding available to inform such an approach? Do you have additional suggestions that improve or clarify the approach?

7. Has EPA's interest in moving toward a harmonized approach for risk assessment, moving away from the dichotomous consideration of cancer versus noncancer been clearly articulated within this document?

8. Is the iterative approach between the different analytical phases (hazard characterization, dose response analysis and exposure assessment) clearly articulated in the framework? If not, how can this be improved? How does this iterative approach compare with your practical (or real-life) experience?

9. With the kind of data typically available currently for chemicals, do you think an assessor would understand how to use this framework with existing data? If not, what would you suggest we clarify?

10. Does the risk characterization section for children risk adequately address data gaps and how they are incorporated into the risk assessment uncertainties?

11. EPA is planning to develop case studies to demonstrate the applicability of the life stage approach for children’s health risk assessment and a training module for risk assessors. Do you have other suggestions that could aid in the implementation of this framework?