

Framework for Cumulative Risk Assessment Planning and Scoping

Background. During the June 2003 meeting the Environmental Justice Advisory Board (EJAB) discussed cumulative impacts. At this time, EJAB considered the definition of cumulative impacts, why we are conducting cumulative impacts and the circumstances to conduct a cumulative impact analyses. As a result of this discussion EJAB decided to consider the EJAB Cumulative Impact Subcommittee definition of cumulative impacts and include Opt-in Permits under the circumstances to conduct a cumulative impact analyses. In an effort to further develop EJAB issues and concerns related to addressing cumulative impacts (i.e. scoping) PADEP will present a series of discussions.

The discussion today (planning and scoping) is the first in a series of summary discussions about the Environmental Protection Agency's (EPA) Framework for Cumulative Risk Assessment issued on May 2003. Although the purpose of the framework is to offer a simple flexible structure for conducting and evaluating cumulative risk assessment within the EPA, it provides insight useful to our deliberations. Remember, this framework is intended to provide a foundation for developing future detailed guidelines and it is neither a procedural guide nor a regulatory requirement within EPA.

Overview of the framework. The framework describes three main phases to cumulative risk assessment¹:

- (1) Planning, scoping, and problem formulation. In this first phase, a team of risk managers, risk assessors, and other stakeholders establishes the goals, breadth, depth, and focus of the assessment. The end products of this phase are a conceptual model and an analysis plan. The conceptual model establishes the stressors to be evaluated, the health or environmental effects to be evaluated, and the relationships among various stressor exposures and potential effects.
- (2) Analysis. The analysis plan lays out the data needed, the approach to be taken, and the types of results expected during the analysis phase. The analysis phase includes developing profiles of exposure, considering interactions (if any) among stressors, and predicting risks to the population or populations assessed. It is in this phase that difficult technical issues such as the toxicity of mixtures, the vulnerability of populations, or the interactions among stressors that may be chemical or nonchemical are addressed and, hopefully resolved. The end product of this phase is an analysis of the risks associated with the multiple stressors to which the study population or populations are exposed.

¹ In this report, "cumulative risk" and "cumulative risk assessment" are defined as follows:
Cumulative risk: The combined risks from aggregate exposures to multiple agents or stressors.
Cumulative risk assessment: An analysis, characterization, and possible quantification of the combined risks to health or the environment from multiple agents or stressors. Note, these definitions require that the risks from multiple agents or stressors be combined. This does not necessarily mean that they be "added," but rather that some analysis should be conducted on if and how the effects or risks from the various agents or stressors interact. See Framework for Cumulative Risk Assessment at pages 6 and 7.

Risk characterization. The third phase, risk characterization (interpretation), puts the risk estimates into perspective in terms of their significance, the reliability of the estimates, and the overall confidence in the assessment. It is also in this phase that an evaluation is made of whether the assessment met the objectives and goals set forth in phase one.

Planning and Scoping, and Problem Formulation Phase.

Planning and Scoping. The framework emphasizes that planning and scoping begins with a dialogue among interested groups or individuals that may include decision makers, risk experts (such as ecologists, toxicologists, chemists, and other technical experts such as economists and engineers), public officials, community leaders including those, if any, who are legally mandated to be part of the process. The other important planning and scoping concepts include the following:

- (1) Risk Assessment Planning team (RAPT). The above interested groups or individuals or a subset of the groups or individuals may be used to develop a RAPT. The purpose of the RAPT is to seek agreement through extensive dialogue and discussion on what analytical and deliberative steps need to be taken and by whom, when, and why. The RAPT should also focus on documentation and peer review consideration.
- (2) Agency Balancing. While including stakeholders in the risk assessment process, a regulatory agency should balance stakeholder participation with the Agency's need to retain the ability to carry out its responsibility to protect health and the environment. (i.e. developing timeliness boundaries.) The most successful cumulative risk assessments will likely be those where cooperation among organizations (Federal, State, private, environmental, academic, etc.) leads to use of the best data and tools for the various parts of the assessment.
- (3) Defining the Purpose of the Assessment. After the RAPT is assembled the dialogue between the decision maker and risk experts begins with a discussion of risk management objectives and information needed to manage risks in the particular situation. The manager and assessment planning team should discuss any regulatory or legal basis for the risk assessment and what kind of information is needed to satisfy such requirements. If interested and affected parties are part of the risk assessment planning team, it is especially important that the entire team agree on the purpose of the assessment because a differing sense of purpose among the team will lead to problems later on. (For example, note the lessons learned from the Environmental Justice Work Group related to the purpose of the workgroup expressed near the end of a two year deliberative process.)
- (4) Defining the Scope of analysis and products needed. Scoping a cumulative risk assessment includes determining the elements that will or will not be included in the risk assessment. These include the stressors, sources,

pathways, routes, populations, and effects or assessment endpoints to be evaluated. An adequate assessment scope should make it clear what is included in and what is excluded from the assessment. Care should be taken to reconcile the limitations of the scope with the list of questions to be answered in the statement of purpose. If, for example, data limitations preclude addressing certain questions outlined in the purpose, the list of questions should be modified and the RAPT should agree to the narrower scope of the assessment. Defining the scope of an assessment is a process that can include both analytical and deliberative aspects.

- (5) Other issues to address upfront in the Scoping process. As with any group forming to achieve an objective, the RAPT should agree on the participants, the roles and the responsibilities to ensure task achievement and group efficiency. Also, there should be agreement on the depth of the assessment and the analytical approach as well as the schedule and resources available. Finally, the RAPT should review lessons learned from those who have already been through this process or similar processes.

Problem Formulation, Conceptual Model, and Analysis Plan. This phase includes the following:

- (1) Problem Formulation. Problem formulation is a systematic planning step that identifies the major factors to be considered in a particular assessment. It is linked to the regulatory and policy context of the assessment. Problem formulation is an iterative process within which the risk assessor develops preliminary hypotheses about why adverse effects might occur or have occurred. It provides the foundation for the technical approach of the assessment. An important objective of the problem formulation phase is a conceptual model that identifies relevant stressors, sources, pathways, exposure routes, receptors, and effects and the relationships among them.
- (2) Conceptual Model. The conceptual model serves as a basis for the analysis plan, which is used to focus the analysis phase of the assessment. The conceptual model should include both a written description and a visual representation of actual or predicted relationships between humans (or populations or population segments) or ecological entities and the chemicals or other stressors to which they may be exposed. Also, the conceptual model should identify the stressors, the population exposed, and the assessment endpoints that will be addressed in the risk assessment and it should describe the relationships among them. (Note, one of the major differences between a cumulative risk assessment and a more traditional, single-chemical assessment is that in a cumulative assessment special attention should be given to identification of stressors and endpoints and the relationship between them.)
- (3) Analysis Plan. The analysis plan is the final stage of the planning and scoping process. It describes the analytical process. For example, it may describe

how hypotheses about the relationships among the sources, stressors, exposure conditions, populations, and adverse effects/endpoints presented in the conceptual model and narrative will be considered during the risk analysis phase of the assessment.

- (4) Uncertainty and other considerations. Also, while preparing the conceptual model and analysis plan, there should be some early discussion about uncertainty. This may range from so-called epistemological uncertainty (not yet knowing what questions to ask) to “acceptable uncertainty” (that is, how much uncertainty is the planning team willing to accept in the results of the study). Also, today there is a movement for cumulative risk assessments to include both human health and ecological aspects during the planning phases.
- (5) The Final Step Before, the Analysis Phase: Discussion of Possible Outcomes. Before the analytical efforts of the cumulative risk assessment are started, the RAPT should discuss the possible results, their implications and whether the members of the RAPT can accept the possibility of a range of results (including possibilities adverse to their interest). If members of the RAPT will not accept the possibility of a range of results, then it is important to reopen the entire planning and scoping discussion before anything is done in the analysis phase, because the planning and scoping phase has not been satisfactorily completed. (Note, although it is not necessary to have unanimity among stakeholders before proceeding with the plan, knowing where some of the potential disagreements may occur after the analysis and risk characterization phases are started allows the stakeholders as a group to plan beforehand for how such disagreements will be addressed, should they occur. Also note, although it is possible to ensure that all stakeholders have been heard and their opinions given due consideration and weight, that does not necessarily mean that all of them will get what they want.)