

**SAB Committee on Science Integration for Decision Making**  
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**“One EPA” Approach to Addressing NRC Recommendations and Incorporating the EPA Administrator’s Priorities**

**March 29, 2011**

- Good Morning. My name is Edward Ohanian. I am the Associate Director for Science at EPA’s Office of Water and Chairman of EPA Risk Assessment Forum (RAF). Today, I am wearing my RAF Chair’s hat.
- I would like to thank SAB for giving me this opportunity to provide you with the RAF’s feedback to your very timely draft report and recommendations which support our ongoing activities on developing an Agency action plan for advancing human health risk assessment using a **“one EPA”** approach to addressing NRC’s recent recommendations to EPA and incorporating the EPA Administrator Jackson’s priorities.
- The EPA RAF is composed of 30 expert scientists selected from EPA Program Offices, research laboratories, and Regions. Our mission is to promote Agency-wide consensus on difficult and controversial risk assessment issues and to ensure that this consensus is incorporated into appropriate Agency risk assessment and management guidance.
- The RAF reports to the Agency’s Science and Technology Policy Council (STPC), chaired by Dr. Paul Anastas, whom in turn reports to the EPA Administrator. Our products include:
  - RA guidelines,
  - science policy guidance,
  - special reports and issue papers, and
  - agency colloquia and external workshop reports
- A major effort of interest to this SAB Committee is the RAF’s Agency-wide 3-day Human Health Risk Assessment Colloquium held in Washington, DC on October 2010 and follow-up activities.
- The main goal of the Colloquium was to develop an Action Plan for Advancing Human Health RA addressing:
  - 1) several recommendations in recent NRC reports such as Science and Decisions, Phthalates and Cumulative Risk, and Toxicity in the 21<sup>st</sup> Century;
  - 2) the EPA Administrator Jackson’s cross-cutting priorities, particularly incorporating environmental justice and children’s health in decision making process; and
  - 3) Internal EPA identified risk assessment and management needs, including making risk assessments more useful for management decisions.
- Pre-Colloquium activities, aimed at preparing Agency scientists and managers for breakout group discussions, included three seminars, with concurrent Webinars, presented by the Chairs of the NRC 3 reports; Drs. Burke, Corey-Slecht, and Krewski. The breakout group topics were selected based on the NRC recommendations and a poll conducted by the Colloquium Planning Committee of over 100 Agency risk assessors and managers.
- A key feature of the Colloquium was the Senior Agency Managers’ panel discussion on key risk assessment needs for informed risk management control decisions to guide the Colloquium discussions.

In addition to developing an “actionable” priorities list, they stressed the importance of a risk manager-friendly framework for risk-based decision making.

- The Managers’ panel discussion was followed by breakout group discussions on:
  - 1) uncertainty and variability,
  - 2) dose-response assessment and use of default,
  - 3) cumulative risk assessment, and
  - 4) an EPA overarching human risk assessment framework and guideline for risk-based decision making.
- Because of today’s meeting theme to evaluate the extent to which EPA’s scientific assessments are integrated to support environmental decision making, I would like to elaborate further on our overarching Framework effort which has been underway since the October Colloquium.
- The purpose of this Framework is to illustrate the “implementation” of existing EPA guidance and to be responsive to the recommendations presented in the NRC’s *Science and Decisions*. It is also intended to recognize the important role of planning, scoping and problem formulation in designing the risk assessment to serve its intended purpose, as well as the important roles of scientific review and stakeholder involvement.
- This Framework will increase the transparency of the Human Health Risk Assessment process at the Agency consistent with the ideals of scientific integrity laid out by Administrator Jackson so as to ensure that the public will be able to trust the science and scientific process informing public policy decisions.
- It is also intended to represent an organizing process, not to replace any existing or developing guidance or guidelines. Rather, it will provide a series of steps and considerations important to formulating a risk assessment.
- A major objective of the Framework is to enhance consistency of risk assessments while enhancing harmonization of approaches across the Agency. It will promote early identification of risk management options and the use of risk assessment to discriminate among options. Also, it will maximize the use and utility of the risk assessment for informing risk management decisions by aligning the nature and scope of the risk assessment, including the needs of decision making under EPA’s regulatory mandates and efficient use of resources.
- This Framework will recognize the iterative nature of risk assessment. For example, as some scientific questions are answered, new ones may surface that require the development of additional data and/or analysis that better define the distribution of risk and address uncertainty. Iteration between each phase of the risk assessment process may lead to further refinement of the conceptual model and analysis plan.
- Finally, this Framework will accommodate areas of overarching Agency interest, such as the consideration of environmental justice and children’s health, and the concepts of sustainability and technology innovation in risk management decision making.
- To advance “new” science, RAF held a Computational Toxicology Tools for Risk Assessment Training in February 2011. In addition four webinars followed this successful training event to detail specific computational tools.
- Recently, RAF developed a Draft Action Plan with short, medium and long-term cross Agency projects and priorities related to the above four topics in addition to training and capacity building. The Action Plan, which will indeed bring risk assessment into the 21<sup>st</sup> Century, is currently being reviewed by the

STPC who will also be responsible for accepting and implementing the projects and guidance stemming from the Action Plan.

- As you can see, the RAF has started adopting some of the practices that promote successful science integration discussed in your draft report and moving forward to further integrate the science of risk assessment into decision making at EPA.
- In closing, the RAF welcomes your draft recommendations and is looking forward to engaging SAB as we start embarking on this challenging journey.
- Thank you.