U.S. Environmental Protection Agency
Risk Assessment Forum

Human Health Risk Assessment Colloquium

Summary Report

April 25, 2012

Hilton Crystal City at Washington Reagan National Airport
2399 Jefferson Davis Highway, Arlington, VA

October 26 – 28, 2010

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List of Acronyms

CHPAC	Children's Health Protection Advisory Committee
CRA	Cumulative Risk Assessment
EPA	U.S. Environmental Protection Agency
FACA	Federal Advisory Committee Act
HHRA	Human Health Risk Assessment
MOA	Mode of Action
NCEA	EPA National Center for Environmental Assessment
NRC	National Research Council
OAR	EPA Office of Air and Radiation
OCHP	EPA Office of Children's Health Protection
OCSPP	EPA Office of Chemical Safety and Pollution Prevention
OEJ	EPA Office of Environmental Justice
OPEI	EPA Office of Policy, Economics and Innovation
OPP	EPA Office of Pesticide Programs
ORD	EPA Office of Research and Development
OSWER	EPA Office of Solid Waste and Emergency Response
OW	EPA Office of Water
RAF	Risk Assessment Forum
RfC	Reference Concentration
RfD	Reference Dose
STPC	Science and Technology Policy Council

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Executive Summary

The U.S. Environmental Protection Agency held a Human Health Risk Assessment Colloquium on October 26 to 28, 2010, in Arlington, Virginia. Approximately 120 risk assessors and risk managers from across the agency convened to develop a plan to advance human health risk assessment at the EPA, focusing on the recommendations presented in three National Research Council (NRC) reports: *Science and Decisions: Advancing Risk Assessment*; *Phthalates and Cumulative Risk Assessment: The Tasks Ahead*; and *Toxicity Testing in the 21st Century: A Vision and A Strategy*. Implications of the recommendations were also considered in the context of the Administrator's priorities relative to children's health protection and environmental justice. The participants evaluated the recommendations and developed proposed agency actions in breakout group discussions. The recommendations were divided into the following categories for breakout group discussions: uncertainty and variability, unified dose-response assessment and defaults, cumulative risk assessment, and overarching framework for human health risk assessment. Such discussions at the colloquium and subsequently are contributing to the agency's development of an action plan to advance human health risk assessment at the EPA.

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1.0 Introduction

This Colloquium Report provides a summary of the U.S. Environmental Protection Agency Risk Assessment Forum Human Health Risk Assessment Colloquium held October 26 to 28, 2010, in Arlington, Virginia. The agenda for the three day-Colloquium is included in Appendix I. Approximately 120 risk assessors and risk managers from across the agency convened to develop a plan for advancing risk assessment, focusing on the recommendations presented in three National Research Council (NRC) documents: *Science and Decisions: Advancing Risk Assessment*, *Phthalates and Cumulative Risk Assessment: The Tasks Ahead*, and *Toxicity Testing in the 21st Century: A Vision and A Strategy* (NRC 2007, 2008, and 2009). Implications of the recommendations were also considered in the context of the Administrator's Priorities. The wide range of issues associated with human health risk assessment practices at the agency was addressed in detail by the participants at the Colloquium in four breakout discussions:

- Uncertainty and Variability
- Unified Dose-Response Assessment and Defaults
- Cumulative Risk Assessment
- Overarching Framework for Human Health Risk Assessment

1.1 Pre-Colloquium Activities

The Colloquium, sponsored by the EPA RAF, was organized by a planning committee of 20 scientists from across the agency. Prior to the Colloquium, the RAF convened several work groups or technical panels of subject matter experts to review the NRC recommendations, identify related existing agency guidance and practices, and develop background materials for the Colloquium. The products from these groups formed the basis of the four breakout group discussions at the Colloquium and subsequently contributed to development of the action plan to advance human health risk assessment. The work groups and technical panels and their foci are listed below.

- The Uncertainty and Variability work group focused on Chapter 4 of *Science and Decisions*.
- The Unified Dose-Response Assessment and Defaults Technical Panel focused on Chapters 5 and 6 of *Science and Decisions*, and considered relevant sections of the other NRC reports.
- The Cumulative Risk Assessment Technical Panel focused on Chapter 7 in *Science and Decisions* and general CRA recommendations in Chapter 5 in *Phthalates and Cumulative Risk Assessment.*
- The Framework work group developed a draft outline for an Overarching Framework for Human Health Risk Assessment considering recommendations in Chapters 3 and 8 of *Science and Decisions.*

The Planning Committee conducted a poll of agency staff relative to human health risk assessment needs and NRC recommendations. A goal of this input was to ensure that the Planning Committee included all major agency issues in the planning of the Colloquium. Telephone interviews were conducted with 116 agency risk assessors and risk managers. Participants were questioned about: their knowledge and views of the NRC reports; their program's risk assessment activities; their needs for new and/or updated guidance; and their vision for risk assessment and the steps that the agency can take to achieve that vision.

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Prior to the Colloquium, three seminars (open by web to all agency staff) were presented by the chairs of each of the NRC reports. Thomas Burke, Johns Hopkins Bloomberg School of Public Health presented details of *Science and Decisions: Advancing Risk Assessment*. Deborah Cory-Slechta, University of Rochester School of Medicine and Dentistry, presented details of *Phthalates and Cumulative Risk Assessment: The Tasks Ahead.* Daniel Krewski, University of Ottawa, presented details of *Toxicity Testing in the 21st Century: A Vision and A Strategy.* The purpose of the seminars was to be sure all the participants understood the recommendations presented in the reports and had the opportunity to ask the chairs clarifying questions. These seminars were conducted in the month prior to the Colloquium to give the participants time to evaluate the recommendations relative to their program or regional office needs.

2.0 Plenary Sessions

Welcoming Remarks

Kathryn Gallagher, RAF Executive Director, and Edward Ohanian, RAF Chair, provided welcoming remarks. They encouraged the participants to seize the opportunity to meet the overall goal of the Colloquium to develop an action plan for advancing human health risk assessment to guide the future direction of human health risk assessment at the agency.

Keynote Presentation

Paul T. Anastas, Science Advisor and Assistant Administrator of the Office of Research and Development, noted that the Colloquium would be a significant step in advancing risk assessment and that the Colloquium participants could make serious changes happen. Dr. Anastas emphasized the overarching theme of sustainability, indicating his view that all of the agency's efforts to solve problems, chemical by chemical, are building blocks for sustainability. Dr. Anastas further suggested that the agency would need to assemble the building blocks to protect the environment in a more holistic, less fragmented way and that the types of tools discussed at this Colloquium and developed as part of the action plan should seek to implement an integrated systems perspective.

Senior Managers Panel

Senior agency managers participated in a panel discussion on human health risk assessment needs: Rob Brenner, Office of Air and Radiation (OAR); Peter Grevatt, Office of Children's Health Protection (OCHP); Jim Jones, Office of Chemical Safety and Pollution Prevention (OCSPP); Al McGartland, Office of Policy, Economics and Innovation (OPEI); Barnes Johnson, Office of Solid Waste and Emergency Response (OSWER); Edward Ohanian, Office of Water (OW); and Ira Leighton, Region 1. The panel asked the participants to consider different ways in which risk assessments are conducted throughout the agency. Key points presented by the senior managers included: focusing on what can be done in the short and medium term to improve risk assessments; transferring approaches that are already in use in the agency; considering a broader perspective to solve environmental problems and protect human health; and showing the importance of accomplishments from this Colloquium in the near future so that the agency can build momentum for additional projects.

Administrator's Priorities: Children's Health Protection and Environmental Justice

Peter Grevatt, Director of the Office of Children's Health Protection, urged the Colloquium participants to take a near-term focus, thinking how to leverage what is already happening in agency programs. He also challenged the participants to consider the confluence of risk assessment and public health with an eye to the big picture when working in their breakout groups. Dr. Grevatt highlighted recommendations from the Children's Health Protection Advisory Committee (CHPAC), a Federal Advisory Committee Act (FACA) committee reporting to the Administrator, that staff at the colloquium focus on how the agency's risk assessment practices can improve consideration of the prenatal period and

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consider how best to take into account exposures to carcinogens during this period. Onyemaechi Nweke, Office of Environmental Justice, presented key scientific concepts in environmental justice including exposure to multiple risk factors, cumulative risk, background exposures, and vulnerability. She urged participants in all breakout groups to consider how to integrate these factors into risk assessment.

3.0 Breakout Groups

To address the main themes identified in the NAS reports, four breakout groups were identified with representatives from various program offices and regions. The breakout groups are described below, and the participants are listed in Appendix II. Prior to the breakout group discussions, a plenary presentation provided an overview of the NRC recommendations, background preparations for the Colloquium, and approaches for the participants to consider in addressing the issues. The breakout group discussions were guided by a breakout group charge and focused on formulating a path forward. In the final plenary session, each breakout group reported on their discussions, providing input into the action plan for advancing human health risk assessment.

3.1 Uncertainty and Variability

Bob Hetes, ORD, the technical lead of the uncertainty and variability breakout group, presented the overview in the plenary session. He noted that the issues of uncertainty and variability cut across all breakout groups, and that the agency is continually faced with decision-making under uncertainty. Risk managers must understand how best to make decisions and how to characterize and communicate the uncertainty and variability associated with the decision making process. This breakout group considered NRC recommendations to improve uncertainty and variability characterization in agency risk assessments (NRC, 2009, p. 121-122), including those in the following areas:

- A process to address and communicate the uncertainty and variability that are parts of any risk assessment that would encourage risk assessors to characterize and communicate uncertainty and variability in all key computational steps of risk assessment—emissions, fate-and-transport modeling, exposure assessment, dose assessment, dose-response assessment, and risk characterization.
- Guidance to help analysts determine the appropriate level of detail needed in uncertainty and variability analyses to support decision-making, with use of a "tiered" approach for selecting the level of detail used in uncertainty and variability assessment.
- Key terms of reference used in the presentation of uncertainty and variability and Agency capacity to address and implement the principles of uncertainty and variability analysis.

The uncertainty and variability breakout group's near term suggestion was to summarize current practices by listing available guidance, including those used internationally and by other federal agencies. It was recommended that this effort be followed by the development of a detailed document that will document decisions and assessments with a description of how they are used in the agency regulatory decisions across programs and regions. The uncertainty and variability breakout group proposed a Roadmap of uncertainty and variability that would detail the appropriate level of analysis and transparency based on the expected type of risk management decision. The Roadmap would include the context of the decision and list categories of risk assessment where uncertainty and variability are used. Case examples would be included, outlining the development of the risk assessment, the context of the

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decision, why uncertainty and variability were used, and how uncertainty and variability were used. The matrix should be simple and flexible to meet the needs of different environmental mandates.

The breakout group also recommended the identification of existing tiered approaches as a starting point but did not specify a tiering method. To evaluate a tiered approach, the workgroup indicated that criteria should include: type of analysis, sensitivity analysis, data availability and quality of data, transparency, generic criteria to assist risk management decisions (matching uncertainty analysis to the decision), simplicity, and flexibility. Selection of a tiered approach must consider the drivers (e.g., the "value of information" analysis [data quality, availability, cost], societal value, economic tiering, the importance of the decision, science issues), the level of intensity of analysis, and the category of analysis (e.g., deterministic, sensitivity analysis, semi-probabilistic, full probabilistic, and expert elicitation). There is often confusion across programs on definitions of key risk terms. The group recommended development of a central online location where the definitions of key risk terms can be found.

The breakout group proposed that the agency should consider capacity building, succession planning and the current expertise of the workforce. The group indicated that the agency should train not only risk assessors, but also risk managers at all levels, on issues and analyses of uncertainty and variability. A clearinghouse of resources online would be one way of bringing together the agency's understanding of tools, methods, and techniques. It could serve as a central place where risk assessors and managers can find out about uncertainty and variability.

3.2 Unified Approach to Dose-Response and Defaults

Anna Lowit, OCSPP, and Weihsueh Chiu, ORD, the technical leads for the unified approach to dose-response and defaults breakout group, presented key issues of the NRC recommendations in dose-response assessment and the selection and use of defaults. They also reviewed the materials developed by the Technical Panel for the Colloquium. The NRC recommendations for dose-response assessment and defaults were organized into scientific themes for consideration by the Colloquium Participants.

Endogenous and Exogenous Additivity

Endogenous Additivity (Susceptibility): The NRC reports recommend gathering data and information on human susceptibility and vulnerability from a variety of data sources (clinical, biochemical, epidemiologic, biomedical, genomic, and systems biology) and for a variety of potential uses (developing biomarkers of effect and susceptibility/vulnerability, monitoring/surveillance, informing test designs, quantifying susceptibility/vulnerability for dose-response).

Exogenous Additivity (Cumulative): All three NRC reports address the need to consider multiple chemicals in a single evaluation, but they differ as to how the "grouping" is described; for example, "common adverse outcome" (*Phthalates and Cumulative Risk Assessment*); "common toxicity pathway" (*Toxicity Testing in the 21st Century*); and "common toxicological process" (*Science and Decisions*).

Dose-Response Analysis and Extrapolation: Science and Decisions recommends a unified approach to dose-response: redefining the Reference Dose and Reference Concentration to take into account probability of harm; evaluating mode of action (MOA), background exposure, disease processes and vulnerable populations; and using linear extrapolation at the population level as a default. *Toxicity Testing in the 21st Century* describes the concept of toxicity pathways, and it presents a vision for toxicity-pathway-based risk assessment involving: extrapolation modeling to estimate exposure/intakes that would lead to concentrations associated with toxicity pathway perturbations *in vitro* and would account for host

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factors; comparisons with human exposure biomonitoring to ensure an adequate margin of safety; and recognizing continued reliance on default approaches for low-dose extrapolation.

Probabilistic Approaches vs. Uncertainty Factors

Science and Decisions recommends incorporating probabilistic and distributional methods for non-linear dose-responses and encourages the agency to develop default distributions for key uncertainties typical in dose-response assessment.

Improving Defaults

Science and Decisions recommends continuing and expanding the use of the current science to support and revise defaults, including making explicit currently "implicit or missing" defaults. *Science and Decisions*, consistent with the recommendations presented in *Toxicity Testing in the 21st Century,* recommends developing a system to support risk estimation for chemicals lacking chemical-specific information, taking advantage of high-throughput assays and structure-activity relationships. *Science and Decisions* also recommends developing criteria for the level of evidence needed to use defaults and/or alternative approaches and characterizing the impact of default versus alternative approaches.

This breakout group's contribution to the action plan was presented as a list of prioritized activities to be conducted in evaluating the NRC recommendations. The breakout group considered endogenous and exogenous additivity, additivity to background, and probability distributions and uncertainty factors. Two high-priority recommendations were presented. As an initial step, the group recommended that the agency develop a multi-dimensional matrix to characterize dose response activities across the agency. The recommended matrix would include areas where simple analysis is needed and progressing to more comprehensive analysis. The agency could then develop a plan focused on where additional methods are needed, considering all programs and regions. This matrix would also assist in identifying and reviewing existing explicit and implicit defaults. In addition, the Group recommended scoping and developing "state-of-the-science" reviews on "Endogenous and Exogenous Additivity." In particular, the Group recommended convening a Technical Panel to identify priority topics and to generate white papers with case studies for evaluation by agency scientists to define and clarify the state-of-the-science, so that agency scientists can make better-informed decisions about dose-response assessment.

3.3 Cumulative Risk Assessment

Louis (Gino) Scarano, OCSPP, and Chuck Maurice, ORD/Region 5, were the Technical leads of the Cumulative Risk Assessment breakout group. NRC recommendations considered by the breakout group included those presented in *Science and Decisions* and *Phthalates and Cumulative Risk Assessment*. Prior to the Colloquium, the CRA Technical Panel evaluated the report recommendations and developed background materials as the basis for the discussion at the Colloquium.

The RAF publication, *Framework for Cumulative Risk Assessment* (U.S. EPA 2003), defines cumulative risk assessment as "an analysis, characterization, and possible quantification of the combined risks to health or the environment from multiple agents or stressors." NRC's *Science and Decisions* defines it as "...evaluating an array of stressors (chemical and nonchemical) to characterize –

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quantitatively to the extent possible – human health or ecologic effects, taking into account of such factors as vulnerability and background exposures."

Science and Decisions recommended that the agency maintain the core definitional components of cumulative risk assessment from the *Framework for Cumulative Risk Assessment* (U.S. EPA 2003), including planning, scoping, and problem formulation, and encouraged the agency to be more explicit about the consideration of vulnerability and background exposures. NRC stressed the use of screening tools and other methods (specifically mentioning drawing from social epidemiology and ecological risk assessment arenas) to ensure that the appropriate level of analytic complexity is used to support the decision. NRC also recommended that the agency draw on approaches incorporating interactions between chemical and non-chemical stressors, increase the role of biomonitoring, use epidemiology and surveillance data in cumulative risk assessments, and develop guidelines and methods for simpler analytical tools to support cumulative risk assessment.

Phthalates and Cumulative Risk Assessment strongly recommended that the agency take a broader view of chemical toxicity by identifying a common health outcome as the reference point to group chemicals for cumulative effects rather than focusing on structural similarity, mechanism or mode of action.

The Cumulative Risk Assessment breakout group recommended consideration of the following activities and information sources:

- A workshop for agency staff to consider "common adverse outcomes" and other approaches to grouping stressors for assessing cumulative risk;
- Training for agency risk assessors and others on perspectives needed for effective Cumulative Risk Assessment;
- Training for managers in the use of cumulative risk assessment in decision making;
- A white paper to clarify the agency use of dose addition as currently written in the *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA 2000);
- Databases to support cumulative risk assessment;
- Cumulative Risk Assessment Guidelines;
- Program and regional office efforts and examples of use of baseline population exposures in risk;
- Information on baseline data for stressors (e.g., census population tracts) and make them available across the agency; and
- Use of hotlinks, data.gov, or other Internet approaches to distribute information.

3.4 Framework for Overarching Human Health Risk Assessment Guidance

Rita Schoeny, Office of Water, served as the technical lead for the framework breakout group. One of the key recommendations provided to the agency by the NRC in *Science and Decisions* was to adopt a framework for risk-based decision-making that maximizes the utility of risk assessment. The suggested Human Health Risk Assessment Framework presented in *Science and Decisions* includes these components: formalization of initial problem formulation and scoping; upfront identification of risk management options; and the use of risk assessment to discriminate among options. The RAF Colloquium Planning Committee assembled a work group to consider these recommendations and present a draft framework for discussion at the Colloquium. The work group presented a framework diagram and an extended outline for a companion document that builds upon existing agency guidance. Concepts and definitions from the *Framework for Ecological Risk Assessment* (U.S. EPA 1992 and 1998) were included in the draft framework presented at the Colloquium. The draft HHRA framework included

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planning and scoping of the risk assessment, emphasis on its utility, and stakeholder involvement at several points of the process.

The draft HHRA framework was intended to represent an organizing process, not to develop or replace any existing guidance or Guidelines. Rather, the draft framework presented a series of questions or issues to consider in formulating a risk assessment. A major objective of the framework was to enhance consistency and transparency of risk assessments while enhancing harmonization of approaches across the agency. Key points the Group considered in developing the draft HHRA framework included:

- Risk assessment is not a linear process – rather it is iterative and one goes back and forth among the steps.
- One size does not fit all; risk assessments should be designed to fit a purpose or purposes.
- Understanding of available risk management options informs risk assessment planning.
- Stakeholder involvement will vary with assessment purpose, complexity, and resources.
- Peer review may be needed at several steps.

The breakout group was in agreement that adopting an HHRA framework would increase the agency's ability to maximize the utility of risk assessment by emphasizing the need to focus the design of risk assessments on the decision-making process. The group suggested that the Framework should tie existing frameworks and guidance together and have the ability to accommodate changes in the science of risk assessment. Implementation of the Framework was noted to require capacity building including agencywide outreach and training for risk assessors and risk managers. The group viewed management support as critical for implementation of an HHRA framework.

4.0 Cross Cutting Reports: Environmental Justice and Children's Health Protection

Onyemaechi Nweke, OEJ and Brenda Foos, OCHP, reported on cross-cutting issues of environmental justice and children's health protection addressed by the four breakout groups. All of the breakout groups noted issues related to definitions, particularly for the terms susceptibility, vulnerability, and sensitivity. These terms may be used differently across the agency and are important when comparing population groups.

The framework breakout group recognized the importance of children's health protection and environmental justice in their draft framework diagram. Attention to existing agency policy is key in assessing risks to highly exposed and susceptible lifestages. The group agreed to consider environmental justice in all phases of the Framework.

The cumulative risk assessment breakout group recommended replacing the terminology "chemical and non-chemical stressors" with "stressors," a change that Dr. Nweke and Ms. Foos applauded. The break out group proposal to incorporate baseline population exposures into cumulative risk assessment incorporated environmental justice concerns. The cumulative risk assessment guidelines should be flexible enough to encompass susceptible groups and lifestages.

The uncertainty and variability breakout group presented many linkages with children's health protection and environmental justice, noting that sensitive populations and lifestages should be considered in all tiered assessments of uncertainty and variability. A thorough analysis of uncertainty and variability will by definition consider lifestages and disproportionately impacted populations.

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The unified dose response and defaults breakout group recognized that environmental justice and children's health protection issues must be considered in each thematic area. The group recognized the need for transparency in all areas with respect to defaults.

5.0 Senior Managers Panel

A second senior managers panel respond to the breakout group reports. The panel included these participants: Rob Brenner, Office of Air and Radiation (OAR); Keesha Reed, Office of Children's Health Protection (OCHP); Jim Jones, Office of Chemical Safety and Pollution Prevention (OCSPP); Al McGartland, Office of Policy, Economics and Innovation (OPEI); Barnes Johnson, Office of Solid Waste and Emergency Response (OSWER); Edward Ohanian, Office of Water (OW); Lisa Garcia, Office of the Administrator; and Ron Hammerschmidt, Region 7. The managers responded to the breakout group reports and made recommendations to be considered in the development of the action plan.

The Senior Managers Panel supported the importance of defining key risk terms and the need to clearly explain to the public how risk assessment works. The recommendation regarding common definitions of key terms fits in well with the goal of transparency; having different offices use terms in different ways is confusing.

The managers recommended more efficient ways of accomplishing cross agency consensus development to include bringing staff together for dedicated periods of time while being temporarily relieved from normal work. The discussions on children's health protection and environmental justice were encouraging as the participants considered how EPA can fill gaps and use sound science to make decisions.

The panel noted that Colloquia such as this one encourage agency staff to think in terms of "One EPA." It is very important for all programs to come together to formulate consistent ideas and approaches within regulatory requirements. Attendees were encouraged to consider focusing on near-term advances in three critical areas: addressing risks from chemicals currently without toxicity values; expanding the range of endpoints for which dose-response assessments could be used to calculate economic benefits; and moving beyond single chemical/stressor-based assessments.

The panel agreed that the agency needs to be committed to capacity building. It is especially important to make sure that mid-level managers understand risk assessment and the application of appropriate tools. In moving forward with training will also be necessary to build upon the training that exists across the agency and to avoid duplication. It was recommended that a training curriculum be developed, and kept up to date, for risk assessors and those who use risk assessment.

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Appendix I Colloquium Agenda

October 25, 2010	***Pre-Colloquium Remarks***		
5:00 – 7:00	Remarks by EPA Science Advisor and Chairs of the NRC Reports	Paul Anastas, EPA Science Advisor Thomas Burke, *Science & Decisions* Deborah Cory-Slechta, *Phthalates & CRA* Daniel Krewski, *Tox Testing 21st Century*	Remarks approximately 15 minutes each
October 26, 2010	***Plenary Day***		
8:30 – 8:40	Welcome	Kathryn Gallagher, RAF Executive Director	
8:40 – 8:50	Colloquium Overview & Speaker Introduction	Edward Ohanian, RAF Chair	
8:50 – 9:20	Opening Speaker	Paul Anastas, EPA Science Advisor	
9:20 – 10:20	Panel: *Senior Agency Managers – Risk Assessment Needs for Informed Decision Making*	Rob Brenner, OAR Peter Grevatt, OCHP Jim Jones, OCSPP Al McGartland, OPEI Barnes Johnson, OSWER Edward Ohanian, OW Ira Leighton, Region 1	5 minute statements from panelists on risk assessment needs and challenges to the Colloquium participants, followed by 30 minutes of discussion between panelists and questions from participants on advancing risk assessment.
10:20 – 10:35	AM Break		
10:35 – 10:45	Colloquium Planning Process	Julie Fitzpatrick, RAF Staff	
10:45 – 11:15	Agency Poll Summary	Colette Hodes, OSWER, Planning Committee Co-chair	
11:15 – 12:15	Administrator's Priorities: *Cross Cutting Issue – Children's Health*	Peter Grevatt, OCHP	30 minute presentation 30 minute discussion
12:15 – 1:30	Lunch		
1:30 – 2:30	Administrator's Priorities: *Cross Cutting Issue – Environmental Justice*	Onyemaechi Nweke, OEJ	30 minute presentation 30 minute discussion
2:30 – 3:20	Session I: *Uncertainty and Variability*	Bob Hetes, ORD	20 minute presentation 30 minute discussion
3:20 – 3:35	PM Break		
3:35 – 4:25	Session II: *Unified Approach to Dose-Response and Defaults*	Anna Lowit, OCSPP Weihsueh Chiu, ORD	20 minute presentation 30 minute discussion
4:15 – 5:15	Session III: *Cumulative Risk Assessment*	Louis (Gino) Scarano, OCSPP Chuck Maurice, ORD/Region 5	20 minute presentation 30 minute discussion
5:15 – 5:30	Wrap up	Edward Ohanian, RAF Chair	

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October 27, 2010	***Framework & Breakout Group Day***		
8:30 – 9:00	Day 1 Summary	Edward Ohanian, RAF Chair	
9:00 – 10:00	Session IV: *Framework for Overarching Human Health Risk Assessment Guidance*	Rita Schoeny, OW, Planning Committee Co-chair	20 minute presentation 40 minute discussion
10:00 - 10:15	Charge to Breakout Groups	Kathryn Gallagher, RAF Executive Director	
10:15 - 10:30	AM Break		
10:30 - 12:00	Breakout Groups (Associated with Sessions I, II, III, IV)		
12:00 - 1:15	Lunch		
1:15 - 3:00	Breakout Groups (Associated with Sessions I, II, III, IV)		
3:00 - 3:15	PM Break		
3:15 - 5:30	Breakout Groups Develop and Prepare Report		
October 28, 2010	***Challenge Forward Day***		
8:30 - 9:00	Breakout Group Leadership Meeting		Finalize Report Materials
9:00 - 9:10	The Challenge Forward	Edward Ohanian, RAF Chair	
9:10 - 9:30	Report from Group I	Marian Olsen, Region 2	
9:30 - 9:50	Report from Group II	Kathleen Raffaele, ORD/NCEA	
9:50 - 10:10	Report from Group III	Bob Benson, Region 8	
10:10 - 10:25	AM Break		
10:25 - 10:45	Report from Group IV	Margaret McDonough, Region 1	
10:45 - 11:15	Cross Cutting Report: *Children's Health and EJ*	OCHP and OEJ Representatives	
11:15 - 12:15	Panel: *Senior Agency Manager Report Out Discussion*	Rob Brenner, OAR Khesha Reed, OCHP Jim Jones, OCSPP Al McGartland, OPEI Barnes Johnson, OSWER Edward Ohanian, OW Ron Hammerschmidt, Region 7 Lisa Garcia, OA	5 minute remarks from panelist on response to breakout group reports followed by 30 minutes of discussion between panelists and questions from participants on advancing risk assessment.
12:15 - 1:30	Lunch		
1:30 - 3:30	Formulation of an Action Plan : *Response to NRC Reports and Addressing Administrator Cross-Cutting Priorities*	Edward Ohanian, RAF Chair Kathryn Gallagher, RAF Executive Director Julie Fitzpatrick, RAF Staff	60 minute discussion 60 minute Action Plan Development
3:30 - 4:00	Colloquium Wrap up	Edward Ohanian, RAF Chair	
October 29, 2010	***Chairs Planning Day***		
9:00 - 12:00	Chairs Planning Meeting at EPA		Potomac Yards Conference Center

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Appendix II Colloquium Participants

Uncertainty and Variability Breakout Group

Name	Role	Office
Bob Hetes	Technical lead	Office of Research and Development
Stiven Foster *	Facilitator	Office of Solid Waste and Emergency Response
Marian Olsen *	Rapporteur	Region 2
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Jeff Dawson		Office of Chemical Safety and Pollution Prevention/Office of Pesticide Programs
Helen Dawson		Office of Superfund Remediation and Technology Innovation
Vicki Dellarco		Office of Chemical Safety and Pollution Prevention/Office of Pesticide Programs
Tim Frederick		Region 4
Keith Fusinski		Region 5
Joseph Greenblott		Office of Chief Financial Officer/Office of Planning, Analysis, and Accountability
Charles Griffiths		Office of the Administrator/Office of Policy, Economics, and Innovation/National Center for Environmental Economics
Karen Hamernik		Office of Science Coordination and Policy/Office of Chemical Safety and Pollution Prevention
Samantha Jones		Office of Research and Development/National Center for Environmental Assessment
Egide Louis		Region 4
Mario Mangino		Region 5
Elizabeth Margosches		Office of Chemical Safety and Pollution Prevention/Office of Pollution Prevention and Toxics
Gabriel Olchin		Office of the Science Advisor/Council on Regulatory Environmental Modeling
Zachary Pekar		Office of Air Quality Planning and Standards
Linda Phillips		Office of Research and Development/National Center for Environmental Assessment
Elisa Reaves		Office of Chemical Safety and Pollution Prevention/Office of Pesticide Programs
Daniel Schulson		Office of General Counsel
Marc Stifelman		Region 10, Environmental Assessment

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Unified Dose Response Assessment and Defaults Breakout Group

Name	Role	Office
Weihsueh Chiu	Technical lead	Office of Research and Development/National Center for Environmental Assessment
Anna Lowit	Technical lead	Office of Chemical Safety and Pollution Prevention/Office of Pesticide Programs
Neil Stiber	Facilitator	Office of Research and Development/Office of the Science Advisor
Kathleen Raffaele	Rapporteur	Office of Research and Development/National Center for Environmental Assessment
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Daniel Axelrad *		Office of Policy, Economics, and Innovation
Stan Barone		Office of Research and Development
Marye Clark		Office of Air and Radiation/Office of Radiation and Indoor Air
Rory Conolly *		Office of Research and Development/National Health and Environmental Effects Research Laboratory
Jeneva Craig		Office of Air and Radiation
Lynn Flowers		Office of Research and Development/National Center for Environmental Assessment
Brenda Foos		Office of Children's Health Protection
Jeff Gift		Office of Research and Development/National Center for Environmental Assessment
Brenda Groskinsky		Region 7
Lee Hofmann		Office of Solid Waste and Emergency Response
Amal Mahfouz *		Office of Water/Office of Science and Technology/Health and Ecological Criteria Division
Matt Martin		Office of Research and Development/National Center for Computational Toxicology
Deborah McKean		Region 8
Tim McMahon		Office of Chemical Safety and Pollution Prevention
Wendy O'Brien		Region 8
Ines Pagan *		Office of Air and Radiation
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Santhini Ramasamy		Office of Science and Technology/Health and Ecological Criteria Division
Bruce Rodan		Office of Research and Development/Office of Science Policy
Jeffrey Ross		Office of Research and Development
Jennifer Seed		Office of Chemical Safety and Pollution Prevention/Office of Pollution Prevention and Toxics
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Cumulative Risk Assessment Breakout Group

Name	Role	Office
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Robert Benson	Rapporteur	Region 8
Roseanne Lorenzana	Chart Writer	Region 10
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Marcia Bailey		Region 10
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Thomas Baugh		Region 4
George Bollweg		Region 5/Air and Radiation Division
Michele Burgess		Office of Solid Waste and Emergency Response
Laureen Burton		Office of Air and Radiation/Office of Radiation and Indoor Air/Indoor Environments Division
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Elaine Francis		Office of Research and Development
Noha Gaber		Office of the Science Advisor/Council on Regulatory Environmental Modeling
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Sasha Koo-Oshima		Office of International and Tribal Affairs
Jason Lambert		Office of Research and Development/National Center for Environmental Assessment, Cincinnati
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Gregory Miller *		Office of Children's Health Protection
Mark Miller *		Office of Environmental Information
Michael Morton		Region 6
Onyemaechi Nweke *		Office of Environmental Justice
Devon Payne-Sturges		Office of Research and Development
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Timothy Taylor		Office of Solid Waste and Emergency Response/Office of Research Conservation and Recovery
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Framework for Overarching Human Health Risk Assessment Breakout Group

Name	Role	Office
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Michael Beringer		Region 7
Michael Brody		Office of Chief Financial Officer
Iris Camacho *		Office of Chemical Safety and Pollution Prevention/Office of Pollution Prevention and Toxics
David Dix		Office of Research and Development
Chris Dockins		Office of Policy/National Center for Environmental Economics
Michael Firestone		Office of Children's Health Protection/Office of the Administrator
Julie Fitzpatrick *		Office of the Science Advisor, Risk Assessment Forum
Jack Fowle *		Office of Chemical Safety and Pollution Prevention/Office of Pesticide Programs
Kim Hoang *		Region 9
Ofia Hodoh		Region 4
Richard Kapuscinski		Office of Solid Waste and Emergency Response/Office of Superfund Remediation and Technology Innovation/Science Policy Branch
William Lovely		Region 1
Anthony Maciorowski		Science Advisory Board
Mark Maddaloni		Region 2
Carl Mazza		Office of Air and Radiation
Jennifer McLain		Office of Chemical Safety and Pollution Prevention/Office of Pesticide Programs
Jayne Michaud		Office of the Science Advisor
Anna Milburn		Region 6
Deirdre Murphy		Office of Air Quality Planning and Standards
Solomon Pollard		Region 4
Jon Rauscher		Region 6
Stig Regli		Office of Water/Office of Ground Water and Drinking Water
Keith Sappington		Office of Chemical Safety and Pollution Prevention/Office of Pesticide Programs
Sue Shallal		Office of the Administrator/Science Advisory Board
Patti Tyler		Region 8

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