



# ***Risk Assessment Forum: Projects and Priorities***

**Briefing for the EPA Science Advisory Board (SAB)  
Exposure and Human Health Committee (EHHC)**

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Washington, DC  
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## ***Objectives of Presentation***

- Provide SAB/EHHC with an overview of past and present RAF activities
- Obtain SAB/EHHC feedback on RAF Priorities



## ***Overview of Presentation***

- Overview of OSA and RAF
- Status of Current RAF Projects
- RAF Priorities
  - Future Directions: Input considered
    - Administrator's Priorities
    - Science Advisor's Guidance
    - RAF and SPC input
    - Advisory bodies' (SAB and NAS) recommendations
- SAB/EHHC feedback on RAF Strategic Priorities



## ***The Office of the Science Advisor (OSA) Mission and Functions***

- Provides leadership for cross-Agency science and science policy development and integration to promote the best use of science by the Agency
  - **The Science Advisor**, Dr. Paul Anastas, provides leadership on cross-Agency science issues to ensure that the highest quality science is better integrated into the Agency's policies and decisions
  - **The Chief Scientist**, Dr. Pai-Yei Whung, provides program management and technical support to the EPA Science Advisor both independently and by leading the OSA staff



# ***The Office of the Science Advisor (OSA) Mission and Functions***

- OSA promotes science integration through coordinating several cross-Agency bodies:
  - Science Policy Council (SPC)
  - **Risk Assessment Forum (RAF)**
  - Program in Human Research Ethics (PHRE)
  - Global Earth Observations (EPA GEO, US GEO, GEO)
  - Council for Regulatory Environmental Modeling (CREM)
  - Forum on Environmental Measurements (FEM)
  - Environmental Technology Council (ETC)
- OSA builds on its core competencies and through an Agency system of connections (committees of more than 200 members) to support EPA's mission



## ***RAF Overview***

- **Mission:** 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 guidance
- **Members:** RAF composed of 30 EPA expert scientists drawn from Program Offices, research laboratories, and Regions. Selected from nominations from Senior Managers across the Agency. Forum work is in addition to their Office or Regional work



## ***RAF Organization***

- **RAF Chair:** Appointed by Deputy Administrator in consultation with EPA Science Advisor
- **RAF Executive Director:** Selected by Science Advisor or delegatee through Agency hiring process. OSA staff
- **RAF Oversight Groups (3):** Human Health Risk Assessment, Exposure Assessment, and Ecological Risk Assessment
- **RAF Executive Steering Committee:** Composed of Forum Chair, Executive Director, and Oversight Group Chairs
- **RAF Staff:** Selected through the Agency hiring process. Currently 3 staffers assigned generally to work with the Oversight Groups, as expertise and workload appropriate. OSA staff



## ***RAF Organization (Cont'd)***

- **RAF Membership**
  - Call for members issued from Science Policy Council to Assistant Administrators and Regional Administrators
    - Nominated by respective organizations
  - Selection based on experience and expertise in risk assessment and underlying disciplines
  - Although Forum membership is not based on office affiliation, its overall composition reflects a balance of scientific disciplines and Agency experience
  - 3-year terms that are renewable

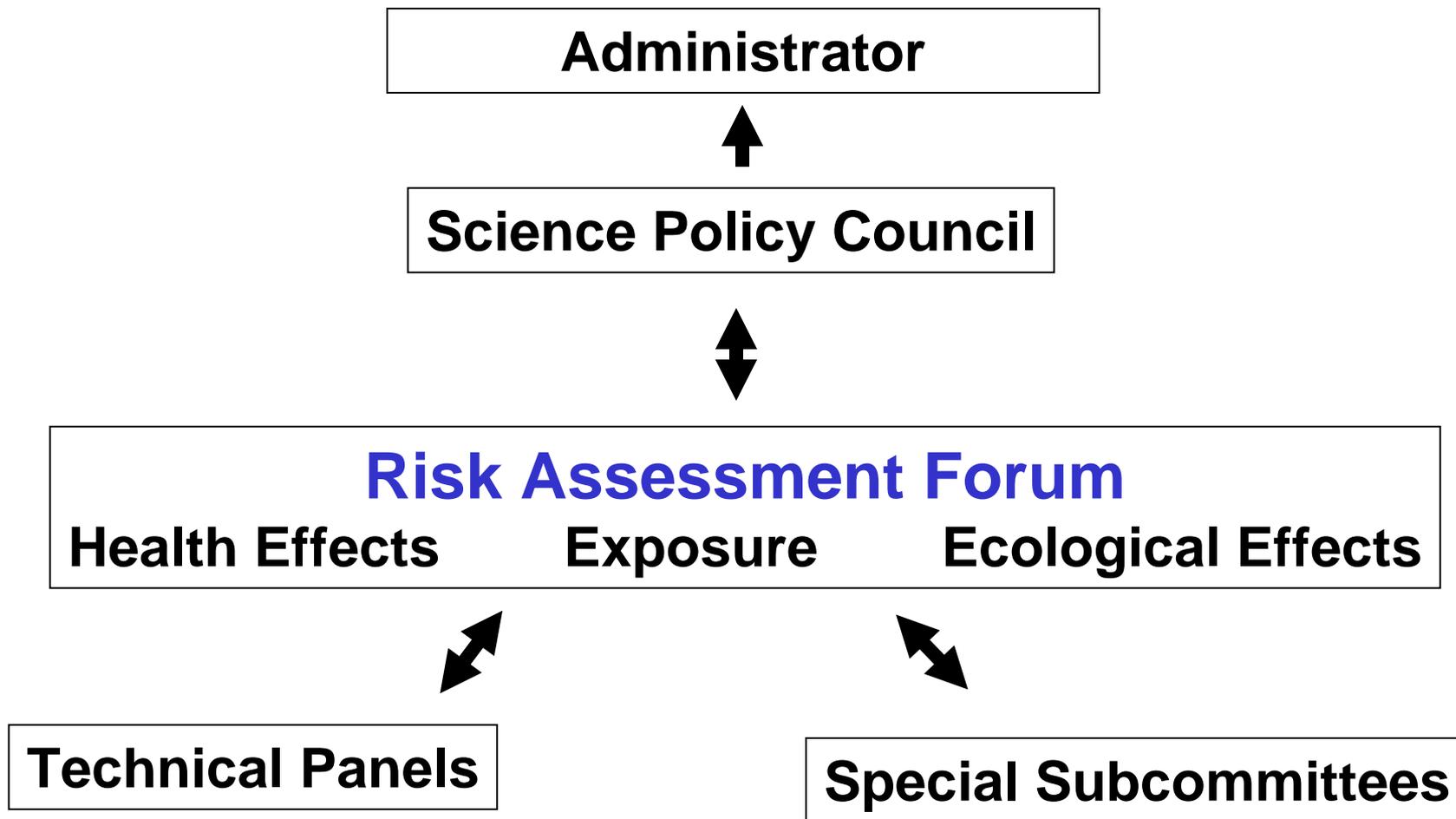


## ***RAF Technical Panels***

- Technical panels conduct RAF's substantive work
  - Composed of RAF members and other scientists with appropriate technical expertise
  - Nominated by SPC members from interested and affected offices and Regions or RAF Executive Steering Committee
  - Serve for the life of the project
  - Volunteers who take on RAF work in addition to their normal duties
- Following their nominations, panel members are chosen to assure that necessary technical expertise is represented
- External experts, particularly scientists from other governmental agencies, may be invited to participate as consultants or, as appropriate, panel members
- Each technical panel is assigned to one of the Oversight Groups that provides technical oversight and review
- Technical panel is responsible for final content of document



# ***Risk Assessment Forum***





# *Genesis of RAF Projects*

- Top Down:
  - Directed by the Science Policy Council
    - Examples: cumulative risk, metals assessment framework
- Bottom Up:
  - Proposed by Forum members, programs, or regions
    - Examples: guidance on the use of Monte Carlo analysis, age groupings for childhood exposure, immunotoxicity guidance, microbiological risk assessment
  - Proposals submitted are reviewed and approved by RAF Executive Steering Committee
  - Project approval criteria: precedent setting, importance across Agency, critical mass of staff to work on the project (management support)
  - Communicate project specifics to the SPC for approval



## ***RAF Products***

- Controversial or precedent-setting scientific or science policy topics addressed for the benefit of EPA
- Intended to guide the Agency as a whole, rather than any specific program
- Developed by scientists and staff in the Forum with SPC interaction
- Undergo extensive internal and external peer review and public comment



## ***RAF Products (Cont'd)***

- Risk Assessment Guidelines
- Science Policy Guidance
- Special Reports and Issue Papers
- Agency Colloquia and External Workshop Reports
- RAF website: [www.epa.gov/raf](http://www.epa.gov/raf)



# ***Internal Peer Review of RAF Products***

- Draft RAF products are:
  - Approved by the Technical Panel
  - Internally peer reviewed by
    - Oversight Group(s)
    - Full RAF membership
    - SPC Steering Committee prior to release for public comment and external peer review
- Final RAF products are reviewed and approved by
  - Technical Panel and Oversight Group(s)
  - Full RAF membership
  - SPC Steering Committee
  - SPC
- Products are generally shared with appropriate federal agencies for interagency comment/review prior to publication
- Completed RAF products are transmitted to RAF members, SPC, Programs and Regions, and are made available to the public



## ***External Peer Review and Public Participation***

- RAF may seek public input on risk assessment issues at specific times in the development of products
- Opportunities for input include RAF sponsored colloquia and workshops convened to obtain the opinion of the scientific community on particular risk assessment issues
- Major draft Forum products are externally peer reviewed and the public has an opportunity to comment on draft documents
- In finalizing its products, RAF takes under advisement the comments and recommendations received through the peer review and public involvement process



# ***Human Health Oversight Group***

<b>Vicki Dellarco (Chair)</b>	Office of Chemical Safety and Pollution Prevention/ Office of Pesticide Programs (OCSPP/OPP)
<b>Stan Barone</b>	Office of Research and Development/ National Center for Environmental Assessment (ORD/NCEA)
<b>Robert Benson</b>	Region 8
<b>Weihshueh Chiu</b>	ORD/NCEA
<b>Kevin Crofton</b>	ORD/National Health and Environmental Effects Laboratory (ORD/NHEERL)
<b>Elizabeth Doyle</b>	Office of Water
<b>Roseanne Lorenzana</b>	Region 10
<b>Deirdre Murphy</b>	Office of Air and Radiation/ Office of Air Quality Planning and Standards (OAR/OAQPS)
<b>Jeffrey Ross</b>	ORD/NHEERL
<b>Stephen Schaub</b>	Office of Water
<b>Jennifer Seed</b>	OCSPP/Office of Pollution Prevention and Toxics (OCSPP/OPPT)
<b>Julie Fitzpatrick</b>	OSA, RAF Staff



# ***Exposure Oversight Group***

<b>Marian Olsen (Chair)</b>	Region 2
<b>Jeff Dawson</b>	OSCPP/OPP
<b>Mike Firestone</b>	Office of Children's Health Protection and Environmental Education
<b>Stiven Foster</b>	Office of Solid Waste and Emergency Response
<b>Henry Kahn</b>	ORD/NCEA
<b>Chris Saint</b>	ORD/National Center for Environmental Research (ORD/NCER)
<b>Linda Sheldon</b>	ORD/National Exposure Research Laboratory (ORD/NERL)
<b>Cynthia Stahl</b>	Region 3
<b>D. Payne-Sturges</b>	ORD/NCER
<b>Zachary Pekar</b>	OAR/OAQPS
<b><i>Michael Broder</i></b>	<i>OSA, RAF Staff</i>



# ***Ecological Assessment Oversight Group***

<b>Glenn Suter (Chair)</b>	ORD/NCEA
<b>Mace Barron</b>	ORD/NHEERL
<b>Kathryn Gallagher</b>	OSA
<b>Tala Henry</b>	OSCPP/OPPT
<b>Chuck Maurice</b>	Region 5
<b>Wayne Munns</b>	ORD/NHEERL
<b>Matt Nicholson</b>	Region 3
<b>Ed Odenkirchen</b>	OSCPP/OPP
<b>Mary Reiley</b>	Office of Water
<b><i>Lawrence Martin</i></b>	<i>OSA, RAF Staff, detail</i>



## ***Selected Past RAF Products***

### **Guidelines:**

- Guidelines for Carcinogen Risk Assessment (2005)
- Guidelines for Ecological Risk Assessment (1998)

### **Guidance:**

- Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans and Biphenyls in Ecological Risk Assessment (2008)
- Framework for Metals Risk Assessment (2007)
- Guidance for Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants (2006)
- Supplemental Guidance for Assessing Susceptibility from Early Life Exposure to Carcinogens (2005)
- Generic Ecological Assessment Endpoints for Ecological Risk Assessment (2004)
- Framework for Cumulative Risk Assessment (2003)
- A Review of the Reference Dose and Reference Concentration Processes (2002)



# Selected Past RAF Products

United States Environmental Protection Agency | Office of Research and Development | Washington DC 20460 | EPA/633/R-00/002 | August 2000

**Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures**

EPA | United States Environmental Protection Agency

**Framework for Cumulative Risk Assessment**

EPA | United States Environmental Protection Agency | EPA 100/R-08/004 | June 2008 | www.epa.gov/osa

**Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans, and Biphenyls in Ecological Risk Assessment**

EPA | United States Environmental Protection Agency

**Guidance on Selecting Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants**

RISK ASSESSMENT FORUM

EPA | United States Environmental Protection Agency | EPA 120/R-07/001 | www.epa.gov/osa

**Framework for Metals Risk Assessment**

EPA | United States Environmental Protection Agency | EPA/100/R-09/036 | October 2009 | www.epa.gov/osa

**Summary Report: Risk Assessment Forum Technical Workshop on Population-level Ecological Risk Assessment**

RISK ASSESSMENT FORUM

Office of the Science Advisor | Risk Assessment Forum

Office of the Science Advisor | Risk Assessment Forum



## ***Current and New RAF Projects***

- 17 projects under development at RAF
- Various stages of completion
  - 3 in final revision/review
  - 2 in external peer review
  - 7 in development
  - 5 new projects as of Spring 2010



## ***RAF Documents In Final Revision/Review***

- **Benchmark Dose Technical Guidance: Final Draft**
  - Undergoing final revision/review
- **Recommended Toxicity Equivalence Factors (TEFs) for Human Health Risk Assessments of 2,3,7,8-tetrachlorodibenzo-p-dioxin and Dioxin-Like Compounds: Final Draft**
  - Undergoing final review/revision
- **Harmonization in Interspecies Extrapolation: Use of Body Weight  $^{3/4}$  as a Default Method in Derivation of the Oral Reference Dose (RfD) (Body Weight  $^{3/4}$ ): Final Draft**
  - Undergoing final review/revision



# ***Benchmark Dose (BMD)***

## ***Technical Guidance***

- BMD is a statistical method applied to experimental data to examine relationship between the chemical dose administered and the effect observed
- Document provides guidance for the Agency and outside risk assessment/management community on BMD methodology and its application
- Targets statistical issues: computation of benchmark doses/concentrations and their lower confidence limits, data requirements, model selection, and reporting/documenting results



## ***Human Health Toxicity Equivalence Factors***

- Describes EPA's updated approach for evaluating human health risks from exposures to environmental media containing mixtures of 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) and dioxin-like compounds (DLCs)
- Explains the Toxicity Equivalence Factors (TEF) methods and history of its use to evaluate human health risks
- Recommends the use of the 2005 consensus TEF and DLCs values from the World Health Organization



## ***Body Weight 3/4***

- Provides background on methods used to extrapolate from experimental animal exposures or doses to human equivalent exposure estimates, discusses basis for use of Body Weight (BW)<sup>3/4</sup> scaling as a default procedure for interspecies scaling, and provides examples
- Supports a hierarchy of approaches, including PBTK modeling, depending on data availability.
- In the absence of data to support a more chemical-specific approach, the default procedure results in calculation of a human equivalent dose for use in deriving the oral reference dose (RfD) that is consistent with the other Agency default dosimetric approaches, including oral cancer assessments based on experimental animal data.



## ***RAF Documents In External Peer Review***

- **Utilizing Probabilistic Analyses in Decision Making: White Papers**
  - External peer review completed on May 6, 2010
    - Peer review discussion: review was favorable overall
  - Final peer review report due in July, 2010
  - Panel will revise document after final report received
- **Data-Derived Extrapolation Factors: External Review Draft**
  - Completing response to internal comments and preparing for external peer review and public comment



## ***White Papers on Using Probabilistic Risk Assessment (PRA) Methods***

- **Purpose: Enhance the recognition and application of PRA methods across the Agency**
- **Scope: Identify the role of PRA to support EPA decisions**
  - Describe particular needs of the risk managers with respect to use of probabilistic methods
  - Outline benefits and limitations of PRA methods
  - Identify barriers, issues of concern, and what is needed to support the acceptance of these methods
  - Provide background on EPA's experiences with PRA
- **Descriptions of methods (including sensitivity and uncertainty analysis), ranging from:**
  - simple to complex
  - rapid to more time consuming
  - least to most resource intensive
- One paper targeted to risk assessors, one to managers



## ***Data-Derived Extrapolation Factors***

- **Purpose**
  - Evaluate available data to produce quantitative, non-default values for inter- and intraspecies dose extrapolation.
  - Increase reliance on data rather than employing default assumptions,
    - Reduce uncertainty in risk assessments
- **Scope**
  - Inter- and intraspecies extrapolations for non-carcinogens
- External peer review expected in Fall 2010



## ***RAF Projects Under Development***

- Updating Exposure Assessment Guidelines: Draft
  - Technical panel reviewing
- Cumulative Risk Assessment: Drafts
  - Compendium of Case Studies, Workshop Report, and Research needs documents under revision
- Interagency Microbial Risk Assessment Guidance: Draft
  - Technical Panel reviewing
- Mutagenic Mode of Action: Draft
  - Oversight Group reviewing
- Peroxisome Proliferator-Activated Receptor alpha (PPAR) White Paper: Draft
  - Under revision
- Immunosuppression White Paper
  - Under revision
- Integrating Climate Change Information into Risk Assessment Practices
  - Under initial development



## ***Guidelines for Exposure Assessment (Current Version)***

- Published in 1992
- Established a broad framework for Agency exposure assessments
  - General concepts and definitions
  - Planning and conducting an exposure assessment
  - Presenting results
  - Characterizing uncertainty
- Guide Agency scientists in the conduct of Agency risk assessments
- Guide exposure assessors outside the Agency
- Inform Agency decision-makers and the public



## ***Why Update the 1992 Exposure Guidelines?***

- Incorporate most current scientific approaches in exposure assessment
- Incorporate current Agency guidance documents, policies, and procedures
- Align ORD research with Program office and Region practices
- Create a resource tool for exposure assessors
- Incorporate recommendations from the SAB and NAS



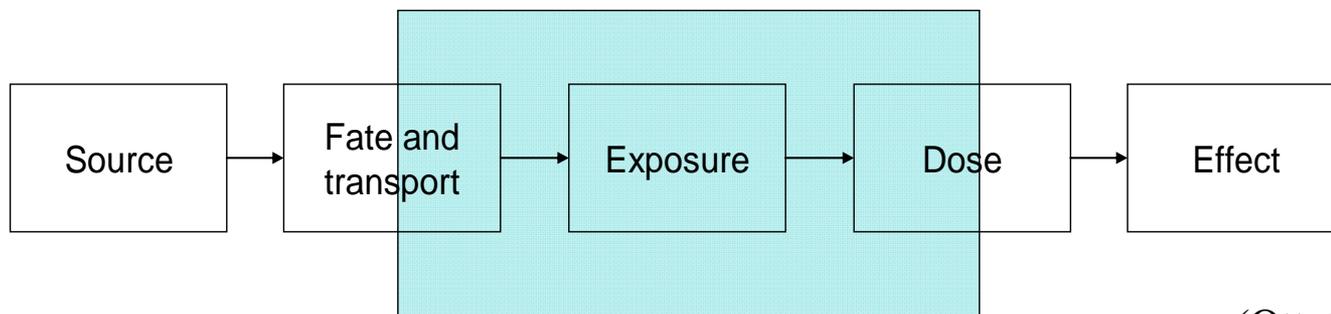
## ***Engaging Internal and External Stakeholders***

- Process began in 2005
  - Formation of Technical Panel
  - Held an Agency Colloquium
  - Risk assessment teleconference for Superfund presentation
  - Identification of internal and external participants
- Sought participation of Agency Regional scientists, state scientists, the scientific community
  - ISEA 2005 symposium
  - SRA 2006 presentation
  - EPA Regional Risk Assessors meeting
- SAB consultation on September 7, 2006



# Overall Goals

- Provide an overview of the science of exposure assessment
- Represent an Agency approach for exposure assessment guidance and policies
- Provide a resource for risk assessors and risk managers using exposure information in decision-making



(Ott, 1985)



# *Key Features*

- Emphasis on exposure science
- Includes the entire process from planning and scoping to reporting results
  - Iterative nature of an exposure assessment
  - Communication
  - Stakeholder involvement
- Emphasizes Agency priority issues
  - Lifestage approach
  - Vulnerable groups
- Text boxes
- References
- Hyperlinks
- Figures and Tables
- Glossary
  - Corrects many terminology challenges



## ***Next Steps on Exposure Guidelines and Monitoring Update***

- Exposure Assessment and Monitoring Guidelines Technical Panel review
- Exposure Assessment Oversight Group/full RAF, SPC-SC, interagency review
- Science Advisory Board (SAB)
  - Federal Register notice
  - 60 day public comment period
  - Anticipated in Spring 2011
- Address comments from the public and SAB
- Final document review by RAF, SPC SC, SPC, federal partners
- Release of final document



# ***Interagency Microbial Risk Assessment Guidance***

- Interagency working group
  - Main participants: EPA, USDA, NASA, CDC, NIOSH, DoD
- Interagency Draft Review
  - Currently under review by Technical Panels at individual agency level
  - For EPA next steps include RAF and SPC SC Review
- Following interagency clearance, anticipate SAB review in late 2010/early 2011



## ***Objectives of the MRA Guidance***

- Introduce consistency in language, approaches and in methods across the federal government
- Foster interagency cooperation
  - Leverage expertise and resources
  - Inform planning and prioritize research initiatives
- Improve transparency with government partners, stakeholders and interested parties



## ***RAF Planning***

- Focused on meeting the Agency's risk assessment guidance needs in a timely manner
  - Completing previously initiated projects as soon as feasible
  - Considering external advisory input (SAB, NAS, SAP, etc.)
  - Preparing Agency risk assessors to address emerging trends and needs
- Several new projects have been initiated to support the Agency's evolving needs and external advice



## ***RAF New Projects***

- Human Health Risk Assessment Colloquium- internal EPA
  - October 2010
- Computational Tools Training
- Ecosystem Services
- Strengthening Consideration of Ecological Effects in Decision-making
- Cross-EPA Ecological Risk Assessment Community of Practice



# ***Human Health Colloquium- Internal EPA***

## **Goal**

- Bring Agency risk assessors and managers together to work toward advancing risk assessment, focusing on:
  - Recommendations presented in recent National Research Council (NRC) reports including 2009 *Science and Decisions*
  - SAB reports
  - EPA Administrator's priorities
  - Recommendations from other external advisory bodies and stakeholders



## ***Human Health Colloquium- Internal EPA***

- The Colloquium will be a drawing in/taking stock of existing guidance
- The agenda will be developed by a Planning Committee, with guidance from the RAF Executive Committee, to include discussions of the Agency response and proposed follow-up to recommendations addressing similar issues and those identified in pre-Colloquium discussions with anticipated participants



# ***Human Health Colloquium- Internal EPA***

## **Anticipated Results**

- An evaluation of the consolidated recommendations from multiple external advisory reports and a plan for addressing the recommendations
  - It is anticipated that follow-up work on specific subject areas and recommendations will need to occur, likely through small, focused workgroup meetings and analyses in 2010-2011
- An evaluation of Agency human health risk assessment data gaps and guidance needs and a plan for addressing the needs



## ***Computational Tools Training Development***

- Following publication of the 2007 NRC's *Toxicity Testing in the 21st Century*, EPA continued to make a substantial investment in molecular and computer sciences to enhance the ability to more effectively manage chemical risks
- In the Agency's 2009 Strategic Plan for Evaluating the Toxicity of Chemicals, training was noted as essential in implementing any new toxicity testing /assessment approach
- RAF has developed internal training courses in genomics but additional resources and training programs are critical
- RAF is collaborating with ORD's Computational Toxicology Program to develop a training program focused on new developments in computational tools for risk assessment including 'omics' technologies, (Q)SAR modeling, *in vitro* high throughput profiling, mode of action or toxicity pathway analysis



# *Computational Tools Training Development*

- Three target audiences:
  - **Risk assessors:** on computational tools and their potential application in risk assessment
  - **Computational toxicology research scientists:** on risk assessment and potential applications of computational tools in decision making
  - **Managers:** on the utility and application of computational tools in risk assessment in their decision making process
- A Planning Committee is developing the training scope and approach (e.g., lectures, web-based materials, computer modeling labs), and implement the training events for each of the target audiences



## ***Using Ecosystem Service Endpoints in Ecological Risk Assessment***

- Ecosystem services are defined as the products of ecological functions and processes that directly or indirectly contribute to human well being
- ORD has an extensive research program on ecosystem services, however, ERA is not considered explicitly in that research
- Incorporating ecosystem service endpoints into ERA could benefit EPA and the risk assessment community by providing an improved means of communicating risk and informing decisions, including considerations of contributions to human well-being through quantification of service losses or gains
- RAF is thus undertaking a project to develop general principles and a case study on incorporating ecosystem service endpoints into ERA



## ***Enhancing the Utility of Ecological Risk Assessment Information in Decision Making***

- Recent reports (SAB October 2007, NRC 2009) urge the Agency to make better use of ecological risk assessment findings
- An RAF Technical Panel is being formed to will explore the utility of Ecological Risk Assessments in Agency decision making
- Potential multiple products:
  - Summary of planned surveys/interviews of ecological risk assessors and decision makers on ERAs, their presentation, and utility
  - Depending on the results of the findings, the panel may develop:
    - Guidance to risk assessors on how to present ERA information in a manner that makes it useful to decision makers
    - Informational materials for managers and decision makers on the nature of ecological risks, ERA information and its utility in support of decision making



## ***Key Recent SAB & NAS Studies/Reports Relevant to EPA Risk Assessment Overall***

- SAB
  - Science Integration for Decision Making (in process)
  - Valuing the Protection of Ecological Systems and Services and Consultation on EPA's Implementation of the Ecosystem Services Research Program (2009)
  - Advice to EPA on Advancing Science and Applications of Ecological Risk Assessment in Environmental Decision Making (2007)
  - Consultation on Enhancing Risk Assessment Practices and Updating EPA's Exposure Guidelines (2007)
  - Commentary on EPA's Initiatives to Improve Human Health Risk Assessment (2005)
- NRC
  - Science and Decisions: Advancing Risk Assessment (2009)
  - Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008)
  - Toxicity Testing in the 21st Century: A Vision and a Strategy (2007)
- NAS/IOM
  - Decision Making Under Uncertainty (in process)



## ***Coordinated Agency Response to Recent NRC and SAB Reports***

- RAF developed table of NRC recommendations, potential implementation mechanisms, and potential groups to lead efforts
  - RAF considering advisory recommendations, discussed at March and May All-RAF meetings
    - RAF members from Program Offices and Regions asked to consider recommendations and identify their relevant on-going activities in their Program or Region
    - Convening RAF Technical Panel to examine NRC recommendations from Science and Decisions Chapter 5 (Unified Approach to Dose-Response) and Chapter 6 (Use of Defaults) and potential RAF activities in response
    - Reinvigorating the Cumulative Risk Assessment Technical Panel, charging them with specifically reviewing NRC, SAB, and other relevant advisory recommendations on cumulative risk assessment
    - Products expected to be discussed at the Human Health Colloquium in October
- ORD/NCEA developing discussion papers for Human Health Colloquium <sup>48</sup>



## ***Coordinated Agency Response to NRC and SAB Reports and the 2010 Human Health Colloquium***

- Ongoing discussions will be held to identify collaborations and recommendations to move the Agency forward
  - Expect to return to brief the SPC SC and SPC prior to the Colloquium to obtain feedback on RAF recommendations
- Discussions will include *Science and Decisions*, *Phthalates and Cumulative Risk*, *Toxicity Testing in the 21<sup>st</sup> Century*, and SAB reports
  - For *Phthalates and Cumulative Risk* focusing only on general cumulative risk assessment recommendations



## ***RAF Future Directions***

- SAB/EHHC feedback on RAF Priorities?