

2009 Workshops

Sunday, December 6

Full Day Workshops – 8:00 AM-5:00 PM

WK1: Probabilistic Risk Analysis with Hardly Any Data

Organizer: Scott Ferson

Preregistration: \$240, Onsite: \$290

This full-day tutorial introduces and compares methods for developing a probabilistic risk analysis when little or no empirical data are available to inform the risk model. The talks are organized around the basic problems that risk analysts face: not knowing the input distributions, not knowing their correlations, not being sure about the model itself, or even which variables should be considered. Possible strategies include traditional approximative methods and recent robust and bounding methods. Numerical examples are given that illustrate the use of various methods including traditional moment propagation, PERT, maximum entropy, uniformity principle, probability bounds analysis, Bayesian model averaging and the old work horse, sensitivity analysis. All of the approaches can be used to develop a fully probabilistic estimate useful for screening decisions and other planning. The advantages and drawbacks of the various approaches are examined. The discussion addresses how defensible decisions can be made even when little information is available, and when one should break down and collect more empirical data and, in that case, what data to collect. When properly formulated, a probabilistic risk analysis reveals what can be inferred from available information and characterizes the reliability of those inferences. In cases, where the available information is insufficient to reach dispositive conclusions, bounding probabilistic risk analysis provides a compelling argument for further empirical research and data collection. The presentation style of the tutorial will be casual and interactive.

WK2: Get More from Your Models- Use Sensitivity Analysis

Organizer: Amir Mokhtari

Preregistration: \$245, Onsite: \$295

This workshop will answer key questions faced by those who conduct, manage, or review probabilistic and sensitivity analysis of risk models.

When should you perform sensitivity analysis? What are the typical simulation techniques and software packages? What are the roles of uncertainty and sensitivity analyses as value added techniques in risk assessment? How do you prepare a model to facilitate sensitivity analysis? What are some typical sensitivity analysis methods and how can you select among them? How should particular sensitivity analysis methods be applied? How should the results of sensitivity analysis be presented and interpreted? This workshop will answer these questions.

The methods and case studies are based upon several years of research at NC State University and RTI regarding developing quantitative risk assessment models for environmental and microbial systems and also research at NCSU regarding transferring, applying, and adapting sensitivity analysis methods developed in other disciplines (e.g. complex engineering systems) to quantitative exposure and risk assessment models. Workshop participants will be provided with course notes, a copy of the guidance document, and a tutorial with examples for instructing attendees how to perform sensitivity analysis using common sensitivity analysis methods. The

basic concepts of probabilistic risk assessment will be illustrated during the course using software packages such as @Risk and Crystal Ball. The uncertainty and sensitivity analysis methods will also be illustrated with practical case studies. This workshop is aimed at practitioners, managers, or reviewers who wish to refine their knowledge regarding approaches in risk assessment and sensitivity analysis methods.

WK3: Decision Analysis for Risk Analysts

Organizer: Greg Parnell

Preregistration: \$300, Onsite: \$350

Decision analysis is the appropriate operations research technique to help decision makers facing decisions with multiple stakeholders, conflicting objectives, significant uncertainties, and complex alternatives. This workshop presents the fundamentals of decision analysis to help risk analysts understand a related discipline that offers important concepts and techniques that can be used by risk analysts to better meet the needs of their clients and key stakeholders. We present the methodology and art of single objective (usually net present value) and multiobjective decision analysis and introduce the philosophy of Value-Focused Thinking for creating value for customers that focuses on identifying stakeholder values, using values to generate new alternatives, and using values to evaluate the alternatives. Several decision analysis applications are presented including examples of the use of decision analysis and risk analysis concepts incorporated in an integrated analysis framework. In addition to the analytical concepts, the workshop compares three decision analysis approaches (analytic approach, decision conferences, and dialog decision process) to engaging decision makers and stakeholders.

WK4: Risk Management for Movers and Shakers

Organizer: N. Krishnamurthy

Preregistration: \$295, Onsite: \$345

The workshop is aimed at the planners and managers (movers and shakers), and all who are responsible for conducting risk assessment and implementing risk controls at the workplace. The workshop will focus on current workplace safety management practices in industry, particularly construction. Responsibilities of various stakeholders in the value chain for personnel safety will be highlighted. The elusive concept of 'safety culture' will be clarified. It will cover the basic principles of qualitative risk assessment by job safety analysis based on the likelihood of hazard occurrence and severity of its consequences, and combining them with a risk matrix. Extension to numerical rankings will be discussed. A major aim will be to address the increasing need for use of risk assessment as a proactive measure to reduce workplace accidents, both from legal and professional points of view, and at the same time convince the managers that safety is also good business. There will be a distinct international flavor to the presentation due to the extensive experience of the instructor in the United States, India, and Singapore. The study material will include a complimentary copy of the instructor's book: "*Introduction to Risk Management*", and his recent papers on the subject. No prior knowledge or experience of risk management will be expected from the participants. The course will start with the essential fundamentals and reach up to a working competency level. It will not get into scientific or mathematical abstractions, but deal with practical case studies and real-life everyday scenarios.

WK5: Introduction to the Benchmark Dose Methodology and Interactive Application of EPA's Benchmark Dose Software (BMDS), Version 2.1

Organizer: Allen Davis

Preregistration: \$250, Onsite: \$300

This daylong course is designed to provide participants with an interactive training workshop on the use of the U.S. EPA's Benchmark Dose Software, BMDS 2.1 and its application to risk assessment. The course will provide instruction in changes that have been implemented in version 2.1, including a new user interface that allows multiple run processing, the ability to save model option choices, and summary sheets for side-by-side comparison of model results. The course will provide an overview of the BMD process, including determination of data adequacy, model fitting, model comparison, selection of a benchmark response level, and modeling linear versus nonlinear responses. Attendees will also work on examples from chemical assessments and learn how to take advantage of the new features offered by version 2.1 of BMDS to prepare summary reports for insertion in their assessments. This workshop will cover all the BMD models available in the current version of BMDS—including the recently added dichotomous hill, background dose, and continuous exponential models. This course is an interactive training workshop in the features of BMDS 2.1 and it is therefore recommended that prior to this training students who are not familiar with BMD modeling take the online BMD training course (<http://www.epa.gov/ncea/bmds/training/index.html>) in order to ensure that they receive the maximum benefit from participating in the workshop. Participants need to bring their own laptops to the workshop with the latest version of BMDS 2.1 installed (with necessary administrative rights). The latest version of the software can be found at: <http://epa.gov/ncea/bmds/>.

WK6: Risk Analysis: Fundamental Concepts, Approaches, Issues and Applications

Organizer: David M. Hassenzahl

Preregistration: \$295, Onsite: \$345

Meetings and publications of the Society for Risk Analysis can be daunting to newcomers. More generally, risk analysis incorporates and spans many disciplines. It is often difficult for people, even those who work on some topic within risk analysis—be it toxicology, terrorist threat assessment or human behavior—to understand how their work fits into the risk analysis “big picture.” Likewise, disciplinary training does not prepare people to understand, much less converse with, fellow practitioners. This workshop, taught by experts with extensive histories in practice, government and academia, is designed to fill that gap. We introduce fundamental risk analysis concepts, terminology, applications and calculations. The workshop is suitable for first time Society for Risk Analysis Annual Meeting attendees, as well as all individuals new to risk analysis and those who have been involved in only a limited aspect of risk analysis. Participants should have an undergraduate degree in an area relevant to risk analysis, and / or relevant work experience. Upon completion of this course, students will gain a broader, holistic view and understand the origins, applications and controversies surrounding risk analysis. They will be prepared to evaluate risk analysis reports and presentations. Most importantly, they will be prepared to engage comfortably in the range of conversations that distinguish Society for Risk Analysis Annual Conferences. Lunch will be provided.

WK7: Spatial Decision Support Tools for Managing Multi-Criteria Environmental Contamination Problems

Organizer: Terry Sullivan

Preregistration: \$300, Onsite: \$350

Environmental contamination problems are often complex due to the need to incorporate many differing measures and views into the decision process. In addition, large environmental problems have a spatial component that impacts the decision. The objective of the workshop is to present the attendee with an overview of the types of software tools and supporting models that are commonly needed to address complex environmental contamination problems. The workshop is geared towards providing a fundamental level of understanding on the application and use of multi-criteria decision analysis tools for environmental problems with a spatial component. The course will begin with an overview of existing environmental Spatial Decision Support Tools and the many criteria (cost, ecological risk, environmental risk, societal values, etc.) that are part of the decision process. The concept of multi-criteria decision analysis tools will be introduced and the basic MCDA methods will be covered. The integration of GIS tools to examine spatial relationships in the problem, MCDA tools, and process models to predict risks, costs, etc will be discussed. The discussion of each component (GIS, MCDA, risk, etc.) will begin with an overview of the general capabilities and functionality of the models and progress to practical applications. The course will conclude with examples using the DECERNS software as a teaching aid of a few case studies that integrate the different components into the analysis within a consistent framework. Case study examples will include environmental resource allocation (maintaining habitat for endangered species) and land contamination problems.

WK8: Methods for Identifying Cost-Effective Risk Reduction Technologies for Controlling Animal Disease in Developing Countries

Organizer: Clare Narrod

Preregistration: \$350, Onsite: \$400

The emergence of HPAI and the threat of a global human pandemic have been issues of great concern in recent years. The problem is compounded by uncertainty regarding the timing, extent and severity of HPAI, and the risk of human infection. In addition to actual outbreaks, control strategies have significant economic and social costs, including direct costs of standard disease control measures – such as compensation, vaccination, eradication and bio-security – as well as indirect costs of building institutions and mechanisms to support those measures. Significant indirect costs stem from wide-spread market shocks, which place a heavy burden not only on poultry producers of all sizes, input suppliers, and others along the poultry value chain, but also on consumers. In many affected countries, poultry production is highly heterogeneous; hence, the effectiveness and efficiency of control and prevention strategies are likely to vary significantly across production units depending on their size and levels of bio-security. This workshop will illustrate methods that will help identify and evaluate different control and prevention strategies. The methods presented, when used by policy makers can aid them in their efforts to select a strategy that is most suitable for any given country. In many developing countries, a great majority of the rural and peri-urban poor are involved. The workshop will conclude with the presentation of two case studies illustrating how a multidisciplinary team of

risk assessors, economists, and sociologists went about identifying cost-effective control options to reduce the risk of HPAI in select countries in Africa and Asia.

WK9: Workshop on Scientific Methods for Evaluating EDSP Screening Data and Estimating Dose-Response for Endocrine Disruption

Organizer: Richard Belzer

Preregistration: \$495, Onsite: \$555

Law enacted in 1996 (codified at 21 U.S.C. 346a(p)) directs EPA to develop a screening program, using appropriate validated test systems and “other scientifically relevant information,” to determine whether certain substances may have adverse endocrine effects in humans. EPA’s Endocrine Disruptor Screening Program has proven challenging to implement for several reasons, including the difficulty of defining “adverse” endocrine effects in humans, and devising and validating appropriate toxicological test systems that are sufficiently sensitive and specific to achieve the statutory goal. EPA is implementing a two-tiered testing strategy. Tier 1 will screen for potential adverse effects, and Tier 2 will characterize human dose-response. EPA does not yet have a scientific weight-of-evidence framework for evaluating Tier 1 data and “other scientifically relevant information.” This workshop has two objectives. The morning session will evaluate the Tier 1 test battery to ascertain (1) whether Tier 1 data can satisfy statutory criteria; and (2) if so, how outputs from Tier 1 can be used to develop a (minimally) ordinal or (desirably) cardinal ranking that is scientific, transparent, reproducible, and objective. The afternoon session will focus on selecting and designing “appropriate validated test systems” for Tier 2, taking into account these statutory requirements. In part because no established methods now exist for estimating human endocrine dose-response, Tier 2 provides a novel opportunity for innovative scientific work in toxicology, modeling and biostatistics. Registrants will participate with invited experts in toxicology, endocrinology, and biostatistics. The workshop will produce a report suitable for peer review publication. Lunch is included in this course.

WK10: The Use of Decision Support Tools as an Aid in Making Cleanup Decisions for Sites Contaminated with Unexploded Ordnance (Workshop and Research Project)

Organizer: Laurie Haines

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Recently, DoD has implemented a program to clean up unexploded ordnance (UXO) on land no longer used for military training. Reaching a decision on an appropriate level of cleanup at these sites is often difficult because multiple stakeholders must reach consensus. To reach consensus, stakeholders must make difficult trade-offs between social, economic, political and technical considerations. Decision support tools such as benefit cost analysis (BCA) and multicriteria decision analysis (MCDA) are thought to facilitate decision making because they help decision makers: 1) structure the problem; 2) quantify uncertainty, 3) quantify preferences; and 4) evaluate alternatives. Workshop attendees will learn about decision support tools and participate in a research project. The research, which is being conducted as part of a dissertation project, is intended to evaluate whether the use of decision support tools at UXO sites results in better cleanup decisions or a more efficient decision making process. The workshop will consist of approximately 3 hours of lecture that introduces decision analysis concepts and presents an overview of the research project and the tools that will be tested. The remainder of the workshop

will consist of a hands-on exercise in which workshop attendees will be asked to use the decision support tools to reach consensus on an appropriate cleanup level for UXO at a hypothetical site. Three different decision support tools will be tested: 1) EPA's Munitions and Explosives of Concern Hazard Assessment (MEC HA); 2) BCA; and, 3) MCDA. Lunch will be provided.

Morning Half Day Workshops – 8:30 AM-12:30 PM

WK11: Cumulative Risk Assessment Part 1: Chemical Mixtures Component-Based Methods

Organizer: Linda Teuschler

Preregistration: \$195, Onsite: \$245

Public interest exists in understanding multiple-route environmental exposures to chemical mixtures in the presence of population vulnerability factors related to diet, behaviors, genetics, socio-economics, sensitivities, and nutritional status. Cumulative risk assessment (CRA) is “an analysis, characterization, and possible quantification of the combined risks to human health or the environment from multiple agents or stressors” (U.S. EPA, 2003). CRA provides the integrating foundation for linking multiple stressors, vulnerabilities and environmental fate across exposure settings to produce a population-based risk picture and inform health protection programs. This set of two independent, but related workshops highlights concepts, methods, and resources for CRA, including lectures and hands-on exercises. Part 1 presents information on chemical mixture component-based risk assessment methods, mixture exposures, toxic mode of action and risk characterization for evaluating chemical mixtures, including multiple route exposures, with a look forward to CRA. Part 2 presents basic concepts, methods and resources for scoping and conducting a population-based CRA, based on chemical mixtures risk assessment approaches; a central theme is the integration of information during CRA planning and scoping by grouping chemicals or stressors by exposure and toxicity factors and linking them with vulnerability factors characteristic of the exposed population for use in developing risk characterization information. These workshops target people interested in developing knowledge of CRA concepts, methods, and resources. Either or both workshops may be taken depending on the goals of the participant, but Part 1 is recommended prior to taking Part 2 for those who are unfamiliar with chemical mixtures risk assessment methods.

WK12: Use of Expert Elicitation to Inform Decisionmaking

Organizer: Cristina McLaughlin

Preregistration: \$250, Onsite: \$300

Decision makers must frequently rely on data or information that is incomplete or inadequate in one way or another. Judgment, often from experts, then plays a critical role in the interpretation and characterization of those data. But how experts are selected and their judgments elicited matters – they can also strongly influence the opinions obtained and the analysis on which they rely. Several approaches to eliciting expert judgments have evolved. The workshop will cover topics ranging from expert recruitment, elicitation protocol design, different elicitation techniques (e.g., individual elicitations, Delphi method, nominal group technique, etc.) to aggregation methods for combining opinions of multiple experts. The role of expert elicitation and its limitations, problems, and risks in policy analysis will also be addressed. The workshop will conclude with the presentation of two case studies. The first is from EPA on using expert

elicitation to determine the relationship between mortality and exposure to fine particulates. The second case study is a recent FDA study that evaluated the effectiveness of various practices for reducing *Salmonella* contamination risk in fresh and fresh-cut tomatoes through an expert elicitation. Both presentations will include a discussion of the expert selection process; elicitation protocol development, elicitation technique utilized, and the various issues that arose before, during, and after the elicitation process and the manner in which they were resolved.

Afternoon Half Day Workshops – 1:30-5:30 PM

WK13: Cumulative Risk Assessment Part 2: Concepts, Methods and Resources

Organizer: Linda Teuschler

Preregistration: \$195, Onsite: \$245

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WK14: Introduction to Environmental and Health Aspects of Nanotechnology

Organizer: Jo Anne Shatkin

Preregistration: \$350, Onsite: \$400

This course will provide participants with an overview of the emerging concerns regarding nanotechnology and nanomaterials and impacts for occupational and public health and the environment. The course introduces the topics of nanotechnology, nanotoxicology, environmental aspects of nanotechnology, and addresses ethical, legal, societal and regulatory perspectives. Through lectures and interactive sessions, participants will obtain a knowledge base for understanding the exposure, human health, and safety issues for nanomaterials and nanotechnologies and the potential impacts for workers, consumers, stakeholders, and the environment. Nanotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications.

Nanotechnology is emerging in all economic sectors, including: energy, medicine, food technology, imaging, manufacturing, electronics and air and water purification. Some of the current and potential future materials and technologies have the potential for significant impacts on health and the environment. This course introduces participants to the technological basis of nanoscale phenomena, the current and potential future uses of nanotechnology, explores the breadth of issues raised for health and the environment, and implications of current research and gaps on regulatory policy and societal impacts. At the conclusion of this course, the participants will have gained insights into (1) Key concerns regarding nanotechnology risks for employees, the public, and the environment; (2) Characteristics and properties of nanomaterials and nanotechnologies; (3) Nanotoxicology: state-of-the-science regarding the toxicity of nanomaterials and nanotechnologies; (4) Environmental aspects of nanotechnology; and (5) Risk assessment and risk management issues for nanomaterials and nanotechnologies.

WK15: Chemical-Specific Adjustment Factors: Avoiding Default Values for Inter- and Intraspecies Extrapolation

Organizer: John C. Lipscomb

Preregistration: \$200, Onsite: \$250

The World Health Organization's International Programme on Chemical Safety (IPCS), has established guidance for replacing default uncertainty factor values for interspecies extrapolation and intraspecies extrapolation in risk values such as Reference Doses (RfDs) and Tolerable Concentrations (TCs). It guides the evaluation and quantitation of data that can be used to replace defaults with chemical specific adjustment factors (CSAFs). The approach subdivides the uncertainty factors for interspecies differences (UFA) and human variability (UFH) into toxicokinetic (TK) and toxicodynamic (TD) components. Default values for any or all of these four subfactors can be replaced by CSAF values. In the absence of chemical-specific data, default values of 2.5 and 4.0 have been established for the TD and TK component of UFA, while the default values for the TD and TK components of UFH were each established at one-half order of magnitude (3.2). This framework enables the incorporation of quantitative data, reducing the uncertainties in dose extrapolation. This emerging approach has been used to support the U.S. EPA in deriving an RfD for boron and by Health Canada in deriving a TC for 2-butoxyethanol. This half-day workshop will review the use of uncertainty factors and present a historical perspective on the reliance on quantitative data to develop values for inter- and intraspecies extrapolation. The course will focus on the IPCS methodology for CSAF development, including the thinking process and steps used for evaluating data. Examples and classroom activities will be used as instructional aids. Participants should bring a calculator.

Thursday, December 10 & Friday, December 11

8:00 AM-5:00 PM

8:00 AM-1:00 PM

Joint IRAC-SRA-CBER-JIFSAN Symposium on New Tools, Methods and Approaches for Risk Assessment

Sponsored by: EPA/OW, FDA/CBER, FDA/CFSAN, JIFSAN SRA Biostressors Specialty Group, USDA/ARS, USDA/FSIS

Organizers: Steve Anderson and Marianne Milliotis

Preregistration \$75/Onsite \$100

A variety of approaches and methods are used in risk assessment. The Interagency Risk Assessment Consortium^[1], FDA's Center for Biologics Evaluation Research, the Society for Risk Analysis, and the Joint Institute for Food Safety and Applied Nutrition are cosponsoring a symposium on "New Tools, Methods and Approaches for Risk Assessment"^[2]. The goal of this symposium is to bring together a forum of risk assessment and other experts from a broad range of fields to discuss and share their insights in risk assessment and discuss common issues and novel approaches. The proposed topics to be discussed include:

- Current state of dose-response modeling approaches for use of animal model data and extrapolation to predict human dose-response for microbial pathogens.
- Application of proteomics and genomics to environmental, chemical/toxicological, food safety, drug and medical product risk assessments.
- Applying risk assessment methods to predicting the effects of immunotoxicants on immune function and susceptibility to infectious disease
- Metrics and tools used in risk and benefit analysis
- Use of different databases in risk assessment; e.g., data from microarray studies, single nucleotide polymorphism and whole genome analyses to identify biomarkers for diseases and adverse effects; medical informatics; and free web-based databases accessible at www.foodrisk.org.

For more information about the meeting, please contact Steve Anderson (steven.anderson@fda.hhs.gov) or Marianne Miliotis (marianna.miliotis@fda.hhs.gov).

^[1] For list of IRAC member agencies, go to: <http://foodrisk.org/IRAC/agencies.cfm>

^[2] We would like to thank the following organizations for the support of this workshop: "EPA/OW, FDA/CBER, FDA/CFSAN, JIFSAN, SRA Biostressors Specialty Group, USDA/ARS, USDA/FSIS