

Future Research for Improving Risk Assessment Methods

Of Mice, Men, and Models

August 16–18, 2000

*Snowmass Village
Aspen, Colorado*

National Institute for Occupational Safety and Health
National Institute of Environmental Health Sciences
U.S. Environmental Protection Agency
Chemical Manufacturers Association
United Auto Workers



U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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Workshop Overview

Risk assessment has become an essential tool for developing occupational and environmental health and safety standards and other policies to protect workers and the public from hazardous exposures. Risk Assessment is a relatively new discipline and the currently available data and methods are often inadequate and/or controversial. The lack of consensus on what are appropriate methods for risk assessment has frequently led to acrimonious debates, which have been an impediment to the development of appropriate and expedient responses to environmental and occupational hazards. The source of the controversies are generally related to either the methods used for developing the toxicologic (e.g., mice) or epidemiologic (e.g., men) databases or to the methods used to develop mathematical predictions (e.g., models) from these databases. Thus research is needed to develop methods that will enhance the relevance of toxicologic and epidemiologic data, and the credibility of models of the results from these studies for predicting the consequences from exposures to occupational and environmental hazards. The resulting improvements in the methodology used for risk assessments should lead to the greater acceptance of the results from risk assessments, and ultimately to improvements in the development of standards and policies designed to protect workers and the public from exposure to hazardous substances.

Workshop Goals

- Develop a national agenda for research targeted towards improving risk assessment methods.
- Foster the development of an interdisciplinary approach to research on risk assessment methods.
- Identify problems with current methods used in epidemiologic and toxicologic studies that limit their usefulness for risk assessment.
- Identify problems with current methods used in models for predicting doses and risks associated with exposure to occupational and environmental hazards.
- Identify research that may resolve some of the problems associated with current methods used in toxicology, epidemiology and modeling.
- Identify mechanisms and funding resources for the support of targeted research to resolve methodological problems with risk assessment.
- Develop partnerships and mechanisms for increasing stakeholder and community input.

Who Should Attend?

Risk assessors, researchers, policy makers, grants program administrators, labor, industry organizations, public advocacy and community groups.

PRELIMINARY WORKSHOP PROGRAM

TUESDAY, AUGUST 15TH

4:00 p.m.–7:00 p.m. Early Bird Registration

WEDNESDAY, AUGUST 16TH

7:00 a.m. Registration and Continental Breakfast

8:00 a.m. **WELCOME**

Paul Schulte, National Institute for Occupational Safety and Health

8:20 a.m. **WORKSHOP CHARGE:**

Current Problems and Opportunities in Risk Assessment Methods Research

Leslie Stayner, National Institute for Occupational Safety and Health

8:40 a.m.–10:00 a.m. **PLENARY SESSION I:**

Current Perspectives on Issues in Risk Assessment Methods

Chair: A. John Bailer, Miami University and National Institute for Occupational Safety and Health

Adam Finkel, Occupational Safety and Health Administration

Bernard Goldstein, Robert Wood Johnson School of Medicine

Roger McClellan, Chemical Industry Institute for Toxicology

Frank Mirer, United Auto Workers

Ellen Silbergeld, Environmental Defense Fund

Herman Gibb, U.S. Environmental Protection Agency

10:00 a.m. Open Discussion

10:20 a.m. Break

10:40 a.m.–12 noon

PLENARY SESSION II:

Epidemiologic Issues

Chair: Kyle Steenland, National Institute for Occupational Safety and Health

10:40 a.m. **Environmental Epidemiology and Risk Assessment**

Joel Schwartz, Harvard School of Public Health

11:00 a.m.

Issues in Exposure and Dose Assessment for Epidemiology and Risk Assessment

Tom Smith, Harvard School of Public Health

PRELIMINARY WORKSHOP PROGRAM (continued)

11:20 a.m. **Biologic Markers and Epidemiologic Risk Assessment**
Paul Brandt-Rauf, Columbia University

11:40 a.m. Open Discussion

12 noon-1:00 p.m. Lunch

1:00 p.m.-2:20 p.m. **PLENARY SESSION III:**
Toxicologic Issues
Chair: Mark Toraason, National Institute for Occupational Safety and Health

1:00 p.m. **Use of Toxicological Data in Estimating Reference Values for Risk Assessment**
Carole Kimmel, U.S. Environmental Protection Agency

1:20 p.m. **Linking Pharmacokinetic and Biomarker Data to Mechanism of Action In Risk Assessment**
James Swenberg, University of North Carolina at Chapel Hill

1:40 p.m. **Genomics, Transcriptomics, Proteomics, and Human Health Risk Assessments**
Kevin Morgan, GlaxoWellcome

2:00 p.m. Open Discussion

2:20 p.m. Break

2:40 p.m.-4:30 p.m. **PLENARY SESSION IV:**
Statistical and Biologic Models of Dose and Response
Chair: Dale Hattis, Clark University

2:40 p.m. **Simplicity Versus Complexity in the Design of Statistical Models for Dose-Response Assessment**
Dan Krewski, University of Ottawa

3:00 p.m. **Innovative Use of Mechanistic Considerations in Forming Quantitative Risk Assessment Models**
Chris Portier, National Institute of Environmental Health Sciences

3:20 p.m. **Toxicokinetic Models: Where We Have Been and Where We Need to Go From Here**
Mel Andersen, University of Colorado

3:40 p.m.-4:30 p.m. Open Discussion



PRELIMINARY WORKSHOP PROGRAM (continued)

THURSDAY, AUGUST 17TH

7:00 a.m.-8:00 a.m. Registration and Continental Breakfast

8:00 a.m.-4:30 p.m. **BREAKOUT GROUP SESSIONS (CONCURRENT)**

Group 1: Epidemiology and Risk Assessment

Chair: Harvey Checkoway, University of Washington

Rapporteur: Herman Gibb, U.S. Environmental Protection Agency

Group 2: Toxicology and Risk Assessment

Chair: Clayton Frederick, Rohm and Haas

Rapporteur: Elaine Faustman, University of Washington

Group 3: Models of Dose and Response

Chair: Lauren Zeiss, State of California

Rapporteur: Dale Hattis, Clark University

8:00 a.m. Introductory Remarks and Charge for the Group

Breakout Chairs

8:30 a.m. Breakout Group Identification and Discussions of Issues

10:00 a.m. Break

10:20 a.m. Continuation of Breakout Group Identification and Discussions of Issues

12 noon Lunch

1:00 p.m. Breakout Group Identification of Research Priorities for Resolving Issues

7:00 p.m. Banquet Dinner



PRELIMINARY WORKSHOP PROGRAM (continued)

FRIDAY, AUGUST 18TH

7:00 a.m.	Registration and Continental Breakfast
8:00 a.m.-12 noon	PLENARY SESSION V: Conclusions
8:00 a.m.	Presentation of Epidemiology Workgroup <i>Rapporteur: Herman Gibb, U.S. Environmental Protection Agency</i>
8:20 a.m.	Open Discussion
8:40 a.m.	Presentation of Toxicology Workgroup <i>Rapporteur: Elaine Faustman, University of Washington</i>
9:00 a.m.	Open Discussion
9:20 a.m.	Presentation of the Dose and Response Models Workgroup <i>Rapporteur: Dale Hattis, Clark University</i>
9:40 a.m.	Open Discussion
10:00 a.m.	Break
10:20 a.m.-12 noon	PLENARY SESSION VI: Opportunities for Funding of Research in Risk Assessment Methodology <i>Chair: Michael Attfield, National Institute for Occupational Safety and Health</i> <i>Roy Fleming, National Institute for Occupational Safety and Health</i> <i>Steven C. Lewis, Chemical Manufacturers Association</i> <i>Peter Preuss, U.S. Environmental Protection Agency</i> <i>Anne Sassaman, National Institute of Environmental Health Sciences</i>
11:00 a.m.	Open Discussion
11:30 a.m.-12 noon	Final Synthesis and Closing Remarks <i>Leslie Stayner, National Institute for Occupational Safety and Health</i>

REGISTRATION INFORMATION

Registration Desk

The registration desk will be open during the following hours:

Tuesday, August 15 th	4:00 p.m. to 7:00 p.m.
Wednesday, August 16 th	7:00 a.m. to 4:30 p.m.
Thursday, August 17 th	7:00 a.m. to 4:30 p.m.
Friday, August 18 th	7:00 a.m. to 12 noon

Hotel Accommodations

Silvertree Hotel
P.O. Box 5009
Snowmass Village, CO 81615-5009
Telephone: (970) 923 3520
Fax: (970) 923-5192

Wildwood Lodge
P.O. Box 5037
Snowmass Village, CO 81615-5037
Telephone: (970) 923-3550
Fax: (970) 923-4844

A block of rooms has been reserved at the Silvertree Hotel at the rate of \$140.00 (plus tax) per night, single or double occupancy and at the Wildwood Lodge at the rate of \$99.00 (plus tax) per night, single or double occupancy. Reservations must be made directly with the hotel/lodge by **July 7, 2000**, to ensure availability. To receive the conference rate you must inform the reservation staff that you are calling for the NIOSH Conference.

Reservations may be canceled up to 72 hours before the arrival date without penalty; please ask the reservation desk for a cancellation number.

Check-in time is 3:00 p.m.
Check-out time is 11:00 a.m.

Travel Arrangements

TRAVEL-ON, the official travel agency for the NIOSH Conference - Future Research for Improving Risk Assessment Methods, has negotiated discounted airfares for all meeting attendees with United Airlines. Make your reservations early to receive the best rates. To make reservations, call (800) 333-1225, or (301) 589-5100 between 9:00 a.m. and 4:00 p.m. (EST), fax: (301) 589-8179, or e-mail: patriciao@tylon.com. Please refer to the NIOSH Conference.

Transportation From the Airport

Shuttle service to and from the Aspen Airport is about a 15 minute trip. At the Aspen Airport go to the Ground Transportation Board in baggage claim to call the hotel for pickup. Please note the shuttle buses will have either the Silvertree Hotel or the Wildwood Lodge in large silver letters on the side of the shuttle, so whatever shuttle arrives first, you will be able to go to either location.

REGISTRATION FORM

Future Research for Improving Risk Assessment Methods of Mice, Men, and Models

The Silvertree Hotel and Wildwood Lodge, Snowmass Village, CO

August 16-18, 2000

REGISTRATION IS LIMITED TO 150 ATTENDEES.

Mr. Ms. Mrs. Dr.

Name _____
Last _____ First _____ Mi _____ Degrees _____

Title _____

Name to appear on badge _____

Address _____

City _____ State _____ Zip _____

Telephone _____ Fax _____

E-mail _____

Any special needs _____

Wednesday night Rodeo and BBQ

A rodeo and BBQ is held every Wednesday and Saturday night. The cost for this event is \$31.00 per person inclusive. Each individual event cost is as follows: Rodeo \$16.00, BBQ \$15.00.

There will be a reception style buffet dinner on Thursday evening for all invited conference participants. The reception/buffet is sponsored by the Chemical Manufacturers Association. For additional guest, the cost is \$45.00 per person.

Tickets for both events can be purchased at the Silvertree Hotel upon arrival.

Please check if you plan to attend the dinner.
 Please check if bringing guest(s). How many? _____

Breakout Session Selection (Thursday and Friday)

Please rank your first and second choice selections for attendance at the breakout groups. Attempts will be made to honor your first choice, although assignments to these groups will be subject to space availability. Each room will hold up to 50 participants.

____ Group 1: Epidemiology and Risk Assessment
____ Group 2: Toxicology and Risk Assessment
____ Group 3: Models of Dose and Response

Please fax your completed form to:

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The KEVRIC Company, Inc.
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