

EPA/CDC Workshop on State-of-the-Science for the Determination and Application of Dose-Response Relationships in Microbial Risk Assessment
April 21 - 23, 2009

CDC Tom Harkin Global Communications Center
Atlanta, Georgia

AGENDA

Day 1: Tuesday, April 21, 2009

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| 8:00 – 8:30 a.m. | Registration |
| 8:30 – 9:00 a.m. | Welcome
<i>Cynthia Sonich-Mullin, U.S. Environmental Protection Agency (EPA)</i> |
| 9:00 – 9:30 a.m. | Keynote Address: “MRA Dose-Response Challenges”
<i>Cynthia Chappell, University of Texas School of Public Health</i> |
| 9:30 – 9:45 a.m. | Participant Feedback and Discussion |
| 9:45 – 10:05 a.m. | Break |
| 10:05 – 11:30 a.m. | Mission Needs for Dose-Response
<i>Tonya Nichols, EPA</i>
<i>Michael Bell, Centers for Disease Control and Prevention (CDC)</i>
<i>David Oryang, U.S. Food and Drug Administration</i>
<i>Janell Kause, U.S. Department of Agriculture</i> |
| 11:30 – 12:00 p.m. | Participant Feedback and Discussion |
| 12:00 – 1:00 p.m. | Lunch |
| 1:00 – 1:30 p.m. | Dose-Response Extrapolations <ol style="list-style-type: none">1. How is uncertainty and variability addressed in extrapolating dose-response data (e.g., extrapolating across host species, exposure levels, routes of exposure, durations of exposures, pathogen strains or species, endpoints, and/or sensitive populations)?2. Is it appropriate to group studies, animal models or host species, and/or pathogen strains or species in dose-response modeling of multiple data sets?
<i>Margaret Coleman, Syracuse Research Corporation</i>
<i>Charles Haas, Drexel University</i>
<i>Laurie Waisel, Concurrent Technologies Corporation</i>
<i>Mary Alice Smith, University of Georgia</i> |

Day 1: Tuesday, April 21, 2009 (continued)

1:30 – 2:30 p.m.

Participant Feedback and Discussion

2:30 – 3:00 p.m.

Break

3:00 – 3:30 p.m.

Physiological-Based Modeling

1. What overall assumptions are necessary for valuable physiological models to predict human consequences?
2. What is the minimum data set required (i.e., what level of detail needs to be modeled for acceptable human predictions (e.g., whole species models, organ-specific models, and/or cellular or toxin activity models)?)

Sarah Taft, EPA

Jeff Gearhart, The Henry M. Jackson Foundation for the Advancement of Military Medicine

Michael Lumpkin, Syracuse Research Corporation

3:30 – 4:30 p.m.

Participant Feedback and Discussion

4:30 – 4:45 p.m.

Preview of Day 2

Day 2: Wednesday, April 22, 2009

8:30 – 8:45 a.m.

Day 2 Opening Remarks

8:45 – 9:45 a.m.

Dose-Response Method Comparisons: Classical, Bayesian, Epidemiology, and Benchmark Dose Modeling

1. Is the dose-response statistical method utilized empirical or mechanistic?
2. Is the method applicable for low-dose extrapolations?
3. Can the method accommodate data pooling and/or the use of correction factors?
4. How is the calculated dose-response relationship verified and validated?
5. How is model uncertainty adjusted for and communicated to risk managers?

Classical – *Tim Bartrand, Clancy Environmental Consultants*

Bayesian – *Jade Mitchell-Blackwood, Drexel University*

Epidemiology Modeling – *Thomas Whalen, Georgia State University*

Benchmark Dose Modeling – *Jeff Gift, EPA*

9:45 – 10:05 a.m.

Break

Day 2: Wednesday, April 22, 2009 (continued)

10:05 – 11:45 a.m.	Participant Feedback and Discussion
11:45 – 12:00 p.m.	Closing Comments From Stimulus Presenters
12:00 – 1:00 p.m.	Lunch
1:00 – 1:30 p.m.	Stimulation Activity: Going Beyond the Dose-Response Curves!
1:30 – 3:45 p.m.	Breakout Activity (4 teams)
3:45 – 4:45 p.m.	Teams Report Back
4:45 – 5:00 p.m.	Discussion on Playback Reports

Day 3: Thursday, April 23, 2009

8:30 – 8:45 a.m.	Day 3 Opening Remarks
8:45 – 9:15 a.m.	Dose-Response Applications for Vaccines and Therapeutics 1. How are biomarkers utilized in dose-response modeling of infection and/or disease? 2. Can dose-response thresholds be estimated for vaccines and/or therapeutics? <i>Conrad Quinn, CDC</i> <i>Louise Pitt, U.S. Army Medical Research Institute of Infectious Diseases</i> <i>Martin Meltzer, CDC</i>
9:15 – 10:30 a.m.	Participant Feedback and Discussion
10:30 – 11:00 a.m.	Next Steps
11:00 a.m.	Adjournment