Fundamentals of Human Health Risk Assessment with a Case Study Approach

Continuing Education Course AM05

Teresa L. Leavens, Chairperson
Jennifer Orme-Zavaleta, Co-Chairperson

Teresa L. Leavens
Gary Foureman
Harvey Clewell III
Elaine Cohen Hubal
Michael Gargas

8:15 AM-12:00 NOON
Sunday, March 25, 2007
Charlotte Convention Center
Charlotte, North Carolina

Fundamentals of Human Health Risk Assessment with a Case Study Approach

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Chairpersons: Teresa Leavens, Ph.D., CIIT Centers for Health Research, Research Triangle Park, North Carolina, and Jennifer Orme-Zavaleta, Ph.D., NHEERL/ US EPA, Research Triangle Park, North Carolina

Endorsed by: Risk Assessment Specialty Section, Biological Modeling Specialty Section, and Regulatory and Safety Evaluation Specialty Section

This course will provide a general overview of the process of human health risk assessment to educate students and post doctorates interested in careers in risk assessment and researchers who may be interested in how their work can impact and strengthen the science upon which the assessments are based. Risk assessment is a process that encompasses a broad range of disciplines and continues to evolve as basic research provides new technologies, information, and models. The process is used by toxicologists to estimate the likelihood of an adverse event from exposure to a hazardous agent. In 1983 the National Academy of Sciences-National Research Council published "Risk Assessment in the Federal Government: Managing the Process" in which the process of risk assessment was outlined into 4 components including hazard identification, dose-response assessment, exposure assessment, and risk characterization. This course will focus on each of these 4 components and will use vinyl chloride, especially the U.S. EPA IRIS assessment, as a case study to illustrate the development and application of the 4 components. The presentations will cover historical studies incorporated into hazard identification including acute, subchronic, and chronic animal assays as well as epidemiology studies, in vitro assays, predictive models, and genomics research. Information will also be presented on determination of the mode-of-action from non tumor data, and how it may guide and direct the assessment process to reduce uncertainty in extrapolating effects. Various methods of dose-response assessment will be presented including statistical and mechanistic models used to extrapolate effects among doses and species. Available exposure factor data, exposure modeling tools, biomonitoring data, and potential sources of variability and uncertainty in exposure assessment will be highlighted. The final component, risk characterization, will address statistical and biological issues, such as appropriate models and target populations, as well as connect the process of risk assessment with risk management.

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Course Schedule

Sunday, March 25, 2007

8:15–8:20 AM	**Opening Remarks** Jennifer Orme-Zavaleta *National Health and Environmental Effects Research Laboratory/USEPA*
8:20-8:30 AM	**Introduction** Teresa L. Leavens *CIIT Centers for Health Research*
8:15-9:15 AM	**Hazard Identification** Gary L. Foureman *National Center for Environmental Assessment/USEPA*
9:15-10:00 AM	**Dose-Response Assessment** Harvey J. Clewell III *CIIT Centers for Health Research*
10:00-10:30 AM	BREAK
10:30-11:15 AM	**Exposure Assessment** Elaine A. Cohen Hubal *National Center for Computational Toxicology/US EPA*
11:15-12:00 PM	**Risk Characterization** Michael L. Gargas *The Sapphire Group, Inc.*

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