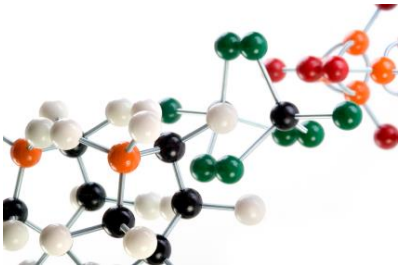
Beyond Science and Decisions:
From Problem Formulation to Risk Assessment

February 26 & 27, 2019
Texas Commission on Environmental Quality
Austin, Texas



Workshop Co-Chairs:
Mark S. Johnson, US Army Public Health Center
Kimberly White, American Chemistry Council

Workshop Coordinators:
Angela Curry, TCEQ
Valerie Ayers, TERA

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Workshop Information and Sponsors

Workshop X Title Beyond Science and Decisions: From Problem Formulation to Comprehensive Risk Assessment

Workshop X Site Texas Commission on Environmental Quality,
Room 191 Building D, 12118 N IH-35, Austin, TX

Workshop X Dates February 26 & 27, 2019

Since 2010, a number of organizations have sponsored this workshop series through endorsement, in-kind donations, or grants. For a partial list of these sponsors see: https://tera.org/Alliance%20for%20Risk/ARA_Dose-Response_Sponsors.htm.

Current Sponsors/Endorsements for Workshop X

- American Chemistry Council
- Center for Food Safety and Applied Nutrition of the US Food and Drug Administration
- Consortium for Environmental Risk Management LLC (CERM)
- E Risk Sciences, LLP
- Exponent
- Georgia Pacific
- Gradient
- International Association of Plumbing and Mechanical Officials, Research and Testing
- The LifeLine Group
- Lucy Fraiser Toxicology Consulting LLC
- National Institute of Occupational Safety and Health
- National Institute of Environmental Health Sciences
- Nickel Producers Environmental Research Association
- Ramboll
- Summit Toxicology
- Texas Commission on Environmental Quality
- Toxicology Excellence for Risk Assessment
- US Army Public Health Center

Background & Purpose

Background

The Alliance for Risk Assessment (*ARA*) sponsors a series of workshops titled *Beyond Science & Decisions: From Problem Formulation to Comprehensive Risk Assessment*. Building on the ideas of the National Academy of Sciences' *Science & Decisions: Advancing Risk Assessment* (2009), nine workshops were conducted from 2010 to 2015 that brought together over 60 organizations seeking to clarify and advance the NAS recommendations (see: https://tera.org/Alliance%20for%20Risk/ARA_Dose-Response.htm). A total of 40 research case studies were presented at these workshops, which provided a real-time compendium of practical, problem-driven approaches for "fit for purpose" risk assessments. Specifically, the compendium links novel and evolving scientific methods and approaches with specific problems faced by risk assessors and risk managers in a variety of organizations (e.g., local, regional and federal governments, academia, private sector).

Purpose

Due to continued demand for the types of work products achieved by these workshops, the workshop series is continuing in 2019 and will expand upon the discussion set forth by *Science and Decisions: Advancement of Risk Assessment* (NAS, 2009). These workshops will be conducted under the aegis of the Alliance for Risk Assessment (*ARA*), a broad-based coalition (see: https://tera.org/Alliance%20for%20Risk/index.htm).

Workshop Objectives

- Improve the risk assessment process by developing an updated and ongoing compendium of practical, problem-driven approaches for "fit for purpose" risk assessments, linking methods with specific problem formulations (e.g., prioritization, screening, and in-depth assessment) for use by risk assessors and managers at a variety of levels (e.g., states, regional managers, people in a variety of agencies, and in the private sector).
- Implement a multi-stakeholder approach to share information, ideas, and techniques in support of developing practical problem-driven risk assessment methods.
- Identify effective and meaningful problem formulation, and useful hazard identification, dose-response, exposure assessment, and risk characterization techniques for specific issues, including consideration of relevant data, description of assumptions, strengths, and limitations, and how the techniques address key considerations in risk assessment and decision-making. These techniques should appropriately reflect the relevant biology (including the biology of thresholds), mode of action information, and exposure variability at a level of appropriate detail.
- Provide methods to explicitly address human variability in assessments, including explicit consideration of underlying disease processes and exposure conditions, as appropriate for the relevant risk assessment context.
- Identify methods for calculating the probability of response for noncancer endpoints, as appropriate for the relevant risk assessment context.
- Identify useful decision-making approaches that incorporate risk information and uncertainty analysis.
- Develop a risk methods compendium that will serve as a resource for regulators and scientists on key considerations for applying selected dose-response or exposure assessment techniques for various problem formulations, with suggested techniques and resources.

Listing of Research Case Studies

The recommended framework for the workshops and research case studies is currently being restructured. For access to any of the prior research case studies, please see https://tera.org/Alliance%20for%20Risk/Workshop/Framework/ProblemFormulation.html, or contact Michael Dourson with Toxicology Excellence for Risk Assessment (TERA) at dourson@tera.org.

COMMITTEES OF THE ALLIANCE FOR RISK ASSESSMENT

- The Alliance for Risk Assessment **Steering Committee** (SC) will provide guidance and oversight of the workshop series and research case study selection. The Steering Committee will have the final decision on charge questions after consultation with the Risk Assessment Advisory Committee, and will have the final decision on members of the Expert Panel after a review of all nominations. The SC consists of state, tribal, and federal governments, academia, and environmental NGO:
    - Annette Dietz, Portland State University
    - Michael Dourson, Toxicology Excellence for Risk Assessment
    - Michael Honeycutt, Texas Commission on Environmental Quality
    - Moiz Mumtaz, Agency for Toxic Substance & Disease Registry
    - Ralph Perona, Neptune & Company, Inc. [representing tribal interests]

- The **Risk Assessment Advisory Committee** (RAAC) will be composed of state, federal, industry, and NGO representatives. This group will represent the various sponsors in the development of workshop structure, charge questions, development of Panel nominations, and the recruitment of presenters. The RAAC will have the final decision on workshop structure, presenters, and content, after consultation with the *ARA* Steering Committee. Members include:
    - James Bus, Exponent
    - Danielle Carlin, NIEHS
    - Michael Dourson, TERA
    - Suzanne Fitzpatrick, FDA
    - Mark S. Johnson, US ARMY
    - Sabine Lange, TCEQ
    - Kimberly White, ACC
    - Pamela Williams, E Risk Sciences, LLP

- The Beyond Science and Decisions **Science Panel** (SP) provides input on research case study methods being proposed to enhance the risk framework. Panel members also provide input on the utility of the research case study methods to address specific problem formulations, and identify areas for additional development of the research case study and/or method. Inclusion of a method or research case study in the framework as an illustration of a useful technique does not imply panel acceptance of the chemical-specific outcome. Core panel members will serve for 2-3 years; members may be added to the standing panel to ensure expertise on specific topics.

- Panel members are selected from a diversity of affiliations and areas of expertise, particularly biology/toxicology, exposure assessment, epidemiology, risk assessment, and statistical/modeling. Members include:
    - James Bus, Exponent
    - Chris Chaisson, The Lifeline Group
    - Harvey Clewell, *ad hoc* member, Ramboll
    - Scott Cormier, *ad hoc* member, Medxcel
    - Michael Dourson, TERA
    - Annie Jarabek, U.S. EPA
    - Judy LaKind, LaKind Associates LLC
    - Sabine Lange, *ad hoc* member, TCEQ
    - Bette Meek, University of Ottawa
    - Greg Paoli, Risk Sciences International

Presentations

Presentations will be available at the Workshop.

Workshop X Agenda & Purpose:

To advance the recommendations in the NAS (2009) report concerning issue identification (problem formulation) and all aspects of risk assessment and management, through selection of illustrative research case studies for further development

Day 1: Tuesday, February 26th

Chair: **Dr. Mark S. Johnson**, US Army Public Health Center

Welcome (8:30 to 8:45)

- **Commissioner Emily Lindley**, Texas Commission on Environmental Quality
- **Dr. Pamela Williams**, E Risk Sciences, LLP, Member of the Risk Assessment Advisory Committee
- **Dr. Michael Dourson,** TERA, Member of the Science Panel

Keynote Talk (8:45 to 9:15)

- **Dr. Michael Honeycutt**, Texas Commission on Environmental Quality

Wastewater Cleaning: A preliminary method adapted from the trenches (9:15 to 10:15)

- **Mr. Kelly Houston,** AEI, LLC
- Discussion by the Science Panel
- Comments from Observers

Morning Break (10:15 to 10:45)

Assessing Influence of Confounding Variables in Low Dose Lead Dose Response (10:45 to noon)

- **Drs. Cynthia Van Landingham and Rosalind Schoof,** Ramboll
- Discussion by the Science Panel
- Comments from Observers

Lunch (noon to 1:00)

Data Derive Extrapolation Factors for Developmental Toxicity: A Case Study with PFOA (1:00 to 3:00)

- **Drs. Bernard Gadagbui and Michael Dourson** TERA
- Discussion by the Science Panel

Afternoon Break (3:00 to 3:30)

Data Derive Extrapolation Factor Case Study Continued (3:30 to 5:00)

- Discussion by the Science Panel
- Comments from Observers
- Chair's Summary

Social TBA-open to all attendees (dinner portion hors d'oeuvres, 6:30 to 9:00)

Day 2: Wednesday, February 27th

Chair: **Dr. Kimberly White**, American Chemistry Council

Physiologically based pharmacokinetic (PBPK) modeling of inhaled aerosol (8:30 to 10:00)

- **Drs. Aditya Reddy Kolli**, **Florian Martin, Arkadiusz Kuczaj** of PMI Research and Development
- Discussion by the Science Panel

Morning Break (10:00 to 10:30)

PBPK Research Case Study continued (10:30 to 12:30)

- Discussion by the Science Panel
- Comments from Observers
- Chair's Summary

Lunch (12:30 to 1:30)

Ongoing Activities (1:30 to 3:00)

Weight of Evidence Methodology

- **Dr. Bette Meek**, University of Ottawa

Bayesian Benchmark Dose Analysis for Probabilistic Risk Assessment – Another Revolution in Dose-Response

- **Dr. Kan Shao**, Indiana University, Bloomington, Indiana.

Fetal Cardiac Findings in Rats Exposed to TCE in Drinking Water

- **Dr. James Bus,** Exponent, Midland, Michigan.

Afternoon Break (3:00 to 3:30)

Ongoing Activities continued (3:30 to 4:30)

Going beyond basic QSARs to support Pre-Manufacturing Notices

- **Dr. Alexandra Maertens**, Consortium for Environmental Risk Management

Probabilistic exposure models for industrial hygiene applications

- **Dr. Tom Armstrong,** TWA8HR Occupational Hygiene Consulting, LLC

Summary of the Workshop (4:30 to 5:00)

- **Drs. Kimberly White and Mark S. Johnson**

Adjourn (5:00)

Biographical Sketches of Workshop Coordinators, Co-Chairs, Speakers, Presenters, & Science Panelists

Dr. Thomas W. Armstrong is the Principal Investigator at his sole proprietor consulting company, TWA8HR Occupational Hygiene Consulting, LLC established in 2008. Tom has his Bachelor of Science in Chemistry, Master of Science in Environmental Health, and PhD in Environmental Engineering, all from Drexel University, Philadelphia, PA. He is certified in the comprehensive practice of industrial hygiene (CIH), and is a Fellow of the American Industrial Hygiene Association. Tom is a longtime member of the American Industrial Hygiene Association and the Society for Risk Analysis. Before he retired from ExxonMobil Biomedical Sciences in 2008, he was a Senior Scientific Associate in Exposure Sciences. His career in anticipating, recognizing, evaluating, controlling and confirming control of occupational health risks spans over 40 years in multiple industries. His ongoing activities include exposure assessment for epidemiology studies, mathematical methods to estimate exposures to chemicals, quantitative risk assessments for Legionella and Legionnaires' disease and risk assessments for other hazards. He has over 30 peer reviewed publications, and has published chapters in books on exposure assessment strategies, mathematical modeling to estimate exposures, and risk assessment approaches. He has been the lead instructor for American Industrial Hygiene Association (AIHA) professional development courses on mathematical modeling to assess chemical exposures, and Monte Carlo Simulation techniques in exposure assessment.

Ms. Valerie Ayers has served as the Executive Assistant at the 501c3 nonprofit organization Toxicology Excellence for Risk Assessment (TERA) since 2006. Valerie has extensive experience in office management, purchasing, and document editing. Previous positions include Purchasing Agent for AmeriLink Corporation, Text Editor for the Ohio CLE, the continuing legal education arm of the Ohio Bar Association, and Senior Administrative Assistant at Seattle University in Seattle Washington.

Dr. **James S. Bus** is a Senior Managing Scientist in the Health Sciences Group of Exponent, Inc. (May 2013-present). Dr. Bus retired from The Dow Chemical Company as Director of External Technology and Fellow in the Toxicology and Environmental Research and Consulting unit (1989-2013). Prior to Dow, he was Associate Director of Toxicology and Director of Drug Metabolism at The Upjohn Company (1986-1989); Senior Scientist at the Chemical Industry Institute of Toxicology (CIIT, 1977-1986); and Assistant Professor of Toxicology, University of Cincinnati (1975-1977). Dr. Bus has been an advisor to a variety of institutions including ILSI, ILSI-HESI, The Hamner Institutes (formerly CIIT), American Chemistry Council Long-Research Initiative, and on advisory boards of the EPA (BOSC and Chartered SAB), FDA (NCTR), the National Toxicology Program, the National Academy of Sciences (BEST), and BELLE. He has served as President of the Society of Toxicology, The American Board of Toxicology, and the Academy of Toxicological Sciences, and in editorial roles including *Toxicology and Applied Pharmacology*, *Environmental Health Perspectives*, and *Regulatory Toxicology and Pharmacology*. Dr. Bus has received the Society of Toxicology Achievement (1987) and Founders (2010) awards, the Toxicology Forum George Scott Award (2013), Rutgers University Robert A. Scala Award (1999), the Michigan State University K.E. Moore Outstanding Alumnus Award, the International Society of Regulatory Toxicology and Pharmacology International Achievement Award (2015), and the International Dose-Response Society Outstanding Leadership Award (2018). He received a B.S. in Medicinal Chemistry from the University of Michigan (1971) and PhD in pharmacology from Michigan State University (1975), and currently is an Adjunct Professor in the Dept. Pharmacology and Toxicology at that institution. He has authored/co-authored over

130 publications, books, and scientific reviews. His primary research interests include modes of toxic action of industrial chemicals and pesticides including the role of non-linear toxicokinetics as a key consideration for improving the human relevance of *in vitro* and *in vivo* toxicity test findings.

Dr. Harvey J. Clewell is a research scientist with over forty-five years of experience in environmental quality and toxicology research, chemical risk assessment and hazardous materials management. He is currently a Principal Consultant with Ramboll. He received a Masters Degree in Chemistry from Washington University, St. Louis, and a PhD in Toxicology from the University of Utrecht, the Netherlands. He is a Diplomate of the American Board of Toxicology and a Fellow of the Academy of Toxicological Sciences, and holds the position of Visiting Scientist at the University of Utrecht in the Netherlands. He has authored more than 200 peer-reviewed scientific publications and a number of book chapters. He has gained an international reputation for his work on the incorporation of mechanistic data and mode of action information into chemical risk assessments, having played a role in the first uses of physiologically based pharmacokinetic (PBPK) modeling in cancer and non-cancer assessments by EPA, ATSDR, OSHA, and FDA. Dr. Clewell has served on external peer review panels for a number of EPA guidelines, including those for cancer risk assessment, risk characterization, benchmark dose modeling, and dermal absorption, and has participated in chemical-specific reviews conducted by the EPA Scientific Advisory Board and the FIFRA Scientific Advisory Panel. He also served as a member of the ECVAM Scientific Advisory Panel from 2012 to 2016. Over the years he has performed research for a wide variety of clients, including the EPA, FDA, NIEHS, ATSDR, Health Canada, TCEQ, ACC, CEFIC, Pfizer, DuPont, Dow Corning, EPRI, NIPERA, Syngenta and Cosmetics Europe. In 2007 the Society of Toxicology recognized Dr. Clewell with the Arnold J. Lehman Award for major contributions to chemical safety and risk assessment.

Angela Curry has been a Toxicologist in the Toxicology, Risk Assessment, & Research Division of the Texas Commission on Environmental Quality (TCEQ) for 17 years. During that time as a regulatory toxicologist and risk assessor, she has worked on a great variety of environmental issue projects (e.g., remediation, chemical and baseline risk assessment, air permitting, air monitoring, and risk assessment guidelines), including many projects directly relevant to chemical risk assessment and the derivation of toxicity factors. She has conducted dose-response assessments and derived toxicity factors for methyl amyl ketone, methyl ethyl ketone, formaldehyde (24-hour), trimethylbenzene, and acetone. She has also participated in the review of many other chemical assessments. Angela has served as a mentor in various STEM programs and participates in career days and regional science fairs at local universities and public schools. Additionally, Angela serves as the Division's web page coordinator.

Angela graduated from Texas Southern University with a M.S. in Environmental Toxicology and graduated with a B.S. in Biology/Chemistry from Huston-Tillotson University.

Dr. Michael Dourson has a PhD in toxicology from the University of Cincinnati, College of Medicine, and is a board-certified toxicologist (i.e., DABT) serving as the Director of Science at the 501c3 nonprofit organization Toxicology Excellence for Risk Assessment (TERA). Prior to this, he was Senior Advisor in the Office of the Administrator at the US EPA. Before this, he was a Professor in the Risk Science Center at the University of Cincinnati, College of Medicine and also worked at TERA and US EPA. He has been awarded the Arnold J. Lehman award from the Society of Toxicology, the International Achievement Award by the International Society of Regulatory Toxicology and Pharmacology, and 4 bronze medals from the U.S. Environmental Protection Agency. He has been elected as a Fellow of the Academy of Toxicological Sciences (i.e., FATS) and as a Fellow for the Society for Risk Analysis (i.e., FSRA). He has co-published

more than 150 papers on risk assessment methods or chemical-specific analyses, and co-authored well over 100 government risk assessment documents, many of them risk assessment guidance texts. He has made over 150 invited presentations to a variety of organizations, and has chaired over 150 sessions at scientific meetings and independent peer reviews. He has been elected to multiple officer positions in the American Board of Toxicology (including its President), the Society of Toxicology (including the presidency of 3 specialty sections), the Society for Risk Analysis (including its Secretary), and is currently the President of the Toxicology Education Foundation, a nonprofit organization with a vision to help our public understand the essentials of toxicology. In addition to numerous appointments on government panels, such as EPA's Science Advisory Board, he is a current member on the editorial board of Regulatory Toxicology and Pharmacology and Human and Experimental Toxicology.

Dr. Michael E. Honeycutt is the director of the Toxicology Division of the Texas Commission on Environmental Quality (TCEQ). He has been employed by the TCEQ since 1996 and has managed the division of 14 toxicologists since 2003. His responsibilities include overseeing health effects reviews of air permit applications, overseeing the review of the results of ambient air monitoring projects, and overseeing the reviews of human health risk assessments for hazardous waste sites. Dr. Honeycutt spearheaded the updating of TCEQ's method for deriving chemical toxicity factors, which has been through two independent external scientific peer reviews and multiple rounds of public comment (http://www.tceq.texas.gov/toxicology/esl/guidelines/about.html). He has overseen the development of inhalation toxicity factors for over 100 chemicals using this process and has published numerous articles on chemical risk assessment. Dr. Honeycutt serves as a technical resource in the areas of chemical toxicokinetics and toxicodynamics, and human health and environmental risk assessment, particularly as they relate to issues concerning air and water quality, drinking water contamination, and soil contamination. Dr. Honeycutt is an adjunct professor in two departments at Texas A&M University, serves or has served on numerous external scientific committees, participated in and helped organize international scientific conferences, and has provided invited testimony at several Congressional hearings. He currently serves as chairman of USEPA's Science Advisory Board. He also serves as an expert witness in public and state legislative hearings, participates in public meetings, and has conducted hundreds of media interviews.

Kelly K. Houston, B.A., M.A is the Principle and Director of Aerosolization Equity Investments, LLC; a patent licensing company. Mr. Houston holds US Patents #8,926,792, #9,890,057, #9,926,209, #14/519,163, #14/671,366 and US Trademark #505096668 clustered around the medically understood "System and Method of On-Site Aerosolization of All Leachates and Wastewaters, Aerosolization of Alternative Daily Cover (ADC), and Aerosolization of Aqueous Solutions".

Annie M. Jarabek currently serves as the Senior Science Advisor in the immediate office of the National Center for Environmental Assessment (NCEA) at its Research Triangle Park (RTP) Division, within the U.S. Environmental Protection Agency's Office of Research and Development (ORD), following recent service as the Deputy Director of the Human Health Risk Assessment (HHRA) national research program in ORD. Annie has significant experience and training in inhalation toxicology in both laboratory and clinical environments, dosimetry modeling, risk assessment, and decision analysis. She was principal author of the Agency's *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry*. Annie has worked on risk assessments, dosimetry models or analysis methods across all media and routes of exposure. She was the lead for the Agency's risk assessment of ingested perchlorate and some of her other work addressed several priority, interdisciplinary Agency assessments including: inhaled particulate matter, vinyl acetate, manganese, and asbestos. Her current research efforts focus on multi-scale

dosimetry modeling, including approaches for *in vitro* to *in vivo* extrapolation (IVIVE) of inhalation exposures to advance the application of emerging methods for translation and evidence integration across various experimental platforms. Annie has received three awards for best manuscript in risk assessment application from the Risk Assessment Specialty Section (RASS) of the Society of Toxicology, along with several best abstract presentation awards. She also received a Lifetime Achievement Award from the University of Massachusetts, the Risk Practitioner of the Year award from the Society of Risk Analysis, the Superfund National Notable Achievement Award, and several award medals (gold, silver and bronze) and technical or special service awards from the Agency.

Dr. Mark S. Johnson currently serves as the Director of Toxicology, US Army Public Health Center at Aberdeen Proving Ground, MD where he is responsible for the operational and technical arm of the Army Surgeon General and the Assistant Secretary of the Army for toxicological matters. He has worked extensively in the evaluation of the toxicity of military unique compounds and development and evaluation of a phased approach to the gathering toxicity data for new compounds under development. He has authored over 100 peer-reviewed publications, book chapters, and technical reports. He has been a member of Society of Environmental Toxicology and Chemistry (SETAC) since 1997 and is a Steering Group Member of the Wildlife Toxicology World Interest Group, chair of Ecological Risk Assessment World Interest Group, and a member of the Science Committee for SETAC North America. Dr. Johnson is also the Chair of the Tri-Service Toxicology Consortium (TSTC), past Steering Committee Chair of the Joint Army-Navy-NASA-Air Force (JANNAF) Propulsion Committee, Subcommittee on Safety and Environmental Protection, the past chair of the Terrestrial Toxicity Subcommittee of the Biological Fate and Effects Committee of the American Society for Testing and Materials (ASTM), and the past president of the American Board of Toxicology (ABT).

Dr. Aditya Reddy Kolli is a Scientist in the Department of Systems Toxicology at Philip Morris International R&D in Neuchatel, Switzerland. Aditya has obtained his Bachelors of Pharmacy from Osmania University, India in 2006 and received his PhD in Chemistry from University of Central Florida, Orlando, FL in 2014. He was a postdoctoral fellow in Drug Safety and Metabolism at AstraZeneca in Waltham, MA from 2015 to 2017. His research interests are to develop mathematical models describing cellular signaling dynamics, methodologies for quantitative translation of microphysiological systems readouts to in vivo outcomes and physiologically based pharmacokinetic models for toxicity assessment.

Dr. Arkadiusz K. Kuczaj earned his PhD (2006) in the field of Applied Mathematics from the University of Twente, the Netherlands. As Manager of Aerosol Research and Dosimetry, he is currently leading aerosol delivery and characterization, *in vitro* exposure, and *in vivo* inhalation research in the Biomedical Research Department at Philip Morris International R&D in Neuchatel, Switzerland. Since 2013 he also holds an Associate Professor position in Industrial Computational Modeling at the Department of Applied Mathematics of the University of Twente.

Dr. Kuczaj graduated with MSc (1999) in Applied Physics at the Military University of Technology in Warsaw, Poland, where he continued his research (2000-2002) in the Department of Explosives and Physics of Explosion. In parallel, he completed postgraduate Software Engineering program (2000-2002) in Computer Science at the Jagiellonian University in Cracow, Poland. In 2003 he started his PhD-project on direct numerical simulations and modelling of turbulent fluid-flow phenomena, investigating fundamental aspects of turbulence as part of Fundamental Research on Matter (FOM, the Netherlands) program. In 2006 he conducted research on interaction of rotation and turbulence in the Center of Nonlinear Studies at the Los

Alamos National Laboratory, USA. He worked as R&D Consultant (2007-2009) at the Nuclear Research and Consultancy Group (NRG) in Petten, the Netherlands. In 2009 he joined Philip Morris International R&D working on innovation, development and assessment of the potentially Reduced Risk Products.

Dr. Kuczaj primary scientific interests include experimental and computational aerosol research along with computational physics, fluid dynamics and high-performance computing. His work spans from fundamental aerosol dynamics investigations, through development and assessment of novel experimental and computational techniques for characterization of aerosol generation, transport, and deposition in the laboratory systems, to establishment of aerosol dosimetry models ultimately aimed at exposure-dose translations for toxicological risk assessment. He published and co-authored more than 30 technical papers in the field of computational physics, fluid dynamics and aerosol research.

Dr. Judy S. LaKind, President of LaKind Associates, LLC, and Adjunct Associate Professor, Department of Epidemiology and Public Health, University of Maryland School of Medicine is a health and environmental scientist with expertise in exposure science, assessment of human health risks, biomonitoring, scientific and technical analysis for regulatory support, and state-of-the-science and systematic reviews. Dr. LaKind has spoken and published extensively on exposure- and risk-related issues, including children's exposures to environmental chemicals, the implications of uncertainty in the risk assessment process, weighing potential risks and benefits related to chemical use, and environmental chemicals in human milk. She has developed risk assessments for a variety of urban industrial sites, military bases, and firing ranges. Dr. LaKind has taught graduate level courses at The Johns Hopkins University and the University of Maryland in risk assessment and aquatic chemistry. She serves on the editorial boards of the Journal of Toxicology and Environmental Health and Environment International and is Past President of the International Society of Exposure Science.

Dr. Sabine Lange is the section manager for the Toxicology Division at the Texas Commission on Environmental Quality (TCEQ). Dr. Lange's responsibilities include overseeing health effects risk assessments of air permit applications, ambient air monitoring projects, and hazardous waste sites; overseeing the development of chemical toxicity factors; and conducting and overseeing systematic reviews and independent analyses of risk assessments. Dr. Lange serves as a technical resource for the State and citizens of Texas for human health and environmental risk assessment, especially related to air and water quality. Dr. Lange's research interests include the toxicology of criteria air pollutants, and risk assessment methods used for derivation of toxicity factors. Dr. Lange received a Bachelor's degree from the University of Western Ontario in Canada, and completed a Ph.D. and post-doctoral training in biochemistry and molecular carcinogenesis at the University of Texas at Houston and MD Anderson Cancer Center. Dr. Lange is a Diplomate of the American Board of Toxicology.

Dr. Bette Meek is the Associate Director of Chemical Risk Assessment at the McLaughlin Centre for Risk Science, Faculty of Medicine, University of Ottawa. Previously, she contributed to and managed several chemical risk assessment programs within Health Canada. With colleagues internationally, she has contributed to or led initiatives in developing methodology in chemical risk assessment, including mode of action, chemical specific adjustment factors, physiologically-based pharmacokinetic modeling, combined exposures and predictive modeling. These initiatives have involved collaborations with a range of international organizations and national Agencies, including the World Health Organization International Programme on Chemical Safety, the Organization for Economic Cooperation and Development, the U.S. Environmental Protection Agency, the European Joint Research Centre and the Agency for Food,

Environmental and Occupational Health and Safety of France (ANSES). She has authored approximately 200 publications in this area and received several awards for contribution in this domain.

Dr. Alexandra Maertens is the head of the Green Toxicology, Read-Across and Big Data initiative at the Johns Hopkins Center for Alternatives to Animal Testing. Dr. Maertens has an extensive publication record on the use of high-content and high-throughput in vitro data, including transcriptomics and metabolomics, for establishing molecular mechanism of toxicity, as well as increasing regulatory acceptance of data-driven read-across approaches, and machine-learning approaches for predictive toxicology. Additionally, Dr Maertens is the Senior Toxicologist at the Consortium for Environmental Risk Management, where she developed a suite of models for screening level human health hazard assessments. Dr. Maertens also serves as part-time faculty at the Brandeis University School of Graduate and Professional Studies where she teaches Whole Genome Expression Analysis and Biomarker Discovery.

Dr. Florian Martin is Principal Mathematician at Philip Morris International R&D in Switzerland. Florian obtained his PhD in theoretical mathematics in 2003 from the University of Neuchatel, Switzerland; and holds two masters, in mathematics and in statistics. Florian has >15 years of experience in the field of mathematical modeling, computational biology and biostatistics. His current research focus in systems toxicology is on the development of novel network based mathematical models and computational methodologies aiming at elucidating the mechanisms of disease and toxicity

Dr. Greg Paoli's career has spanned a wide spectrum of public risk management domains. This has included the safety of food, drinking water, air quality, consumer products, drugs, medical devices and the blood supply, engineered devices, transportation of dangerous goods, museum collections, emergency management for natural and man-made disasters, and climate change impacts on infrastructure. Due to the diversity of this experience, Greg was commissioned by the University of Pennsylvania Law School to prepare a discussion paper on "The Analytical Capabilities of a Best-in-Class Regulator" as part of its international Best-in-Class Regulator Project.

Greg has served on a number of expert committees devoted to the risk sciences. He was a member of the U.S. National Academy of Sciences committee that issued the 2014 report, *A Framework to Guide the Selection of Chemical Alternatives*, and the 2009 report, *Science and Decisions: Advancing Risk Assessment*. He was invited to serve as a member of an expert peer review panel for the US EPA's Framework for Human Health Risk Assessment to Inform Decision Making. He has served on numerous expert committees convened by the World Health Organization and the Food and Agriculture Organization of the United Nations. He recently served a three-year term on the Scientific Advisory Committee for Health Canada's Chemical Management Plan.

Greg completed a term as Councilor of the Society for Risk Analysis (SRA) and served two terms as a member of the Editorial Board of the journal Risk Analysis. In 2011, he was awarded the Distinguished Lectureship Award by the Society for Risk Analysis and the scientific society, *Sigma Xi*.

Dr. Rosalind Schoof is currently a Principal at Ramboll US Corporation. She received a Ph.D. in toxicology from the University of Cincinnati, has been a diplomate of the American Board of Toxicology since 1986, and is a Fellow of the Academy of Toxicological Sciences. Her practice has focused on risk assessment, with more than 35 years' experience assessing human health effects and exposures from chemical substances in a variety of settings, such as contaminated sites, commercial/ industrial/agricultural/residential projects,

product uses, dietary exposures and general home and community exposures. Her projects have included numerous formal health risk assessments conducted under various US and international regulatory settings, as well as regulatory, research and litigation projects. Dr. Schoof is an internationally recognized expert on evaluation of arsenic and metals in the environment and in the diet, and on the bioavailability of metals from soil. She has over 35 peer-reviewed publications and has served on numerous peer review panels for US agencies and Canadian ministries as well as several National Research Council committees. She is currently a member of the US Department of Defense Strategic Environmental Research and Development Program (SERDP) Science Advisory Board. Prior to her consulting career, Dr. Schoof worked for a pharmaceutical company conducting safety assessments for new drugs, and designing and directing toxicity studies. She also worked in the Office of Toxic Substances at USEPA.

Dr. Kan Shao is an Assistant Professor of Environmental and Occupational Health at Indiana University School of Public Health, where he primarily works on human health risk assessment research and education. He received a dual Ph.D. degree in Civil & Environmental Engineering and Engineering & Public Policy from Carnegie Mellon University in 2011 and was a postdoctoral fellow at the National Center for Environmental Assessment at the US EPA from 2011 to 2014. Dr. Shao's research mainly focuses on advancing modeling and quantitative methods to support chemical risk assessment. His major contributions to the field of quantitative chemical risk assessment include the development of the BMD methodology, improvement of toxicological study design for BMD estimation, and various methods (especially Bayesian approaches) to quantify different types of uncertainties and to promote the framework of probabilistic risk assessment. Currently, he is the PI or co-PI on a number of externally (by NIH) and internally supported research projects to improve the efficiency and effectiveness of dose-response modeling, and to employ quantitative risk assessment methodologies to solve practical problems, such as arsenic in rice and water safety after natural disaster. His research work has been published in a number of high-impact journals. One of the publications was selected as "Top Five" Best Published Papers Advancing the Science of Risk Assessment by the SOT-RASS in 2014 and another was nominated for the CDC 2016 Charles C. Shepard Science Award. Dr. Shao is also actively involved in professional societies and currently serve as the Secretary/Treasurer of SOT Risk Assessment Specialty Group. Previously, he served as Vice-Chair, Chair and Past-Chair for the SRA Dose-Response Specialty Group from 2012 to 2016 successively.

Cynthia Van Landingham currently works as a Senior Science Advisor at Ramboll US Corporation. Cynthia received a Masters Degree in Computer Science from Louisiana Tech University where her application area was statistical analysis. She began her career working with Dr. Kenny Crump and Dr. Annette Shipp on risk assessment projects including dose-response modeling. She was a contributor or lead programmer on several dose-response software packages that were developed in the late 80's and early 90's by the KS Crump Group including TOX_RISK and Global86 which were used for many dose-response assessments by the USEPA and OEHHA. During the early 2000's, Ms. Van Landingham and her team updated a program for the Office of Pesticides Programs of the USEPA that includes database management for animal bioassay data, statistical analysis and dose-response modeling that is still in use today. She has also served as an informal tester of the USEPA benchmark dose software (BMDS) program and coded the first version of the multitumor (MS_COMBO) model which was first added to BMDS in version 2.12 in 2010. Ms. Van Landingham's work experience in risk assessment include dose-response modeling, statistical analysis, biologically based pharmacokinetic modeling, and the use of Monte Carlo techniques. She has performed statistical analysis of data from clinical trial data, animal bioassays, epidemiology studies, and complex surveys, and has conducted dose-response modeling for many of these. She has more than 40

publications in peer reviewed journals and has presented research at both the Society for Risk Analysis and the Society of Toxicology's annual meetings.

Dr. Kimberly Wise White is a Senior Director in the Chemical Products and Technology Division at the American Chemistry Council. In this position she works with multiple stakeholders to conduct scientific research that informs human health hazard assessments and implement approaches to improve the chemical assessment process. Dr. White received a BS and MS in Biology and a PhD in Environmental Toxicology from Texas Southern University. She is a member of the Society of Toxicology and serves on the Board of Directors for the Toxicology Forum. Dr. White has a diverse background having worked as a laboratory researcher focusing on neurotoxicity, an environmental sustainability and compliance manager and as a scientific advisor. For the past 10 years, she has been actively involved in supporting scientific research and chemical assessments that are firmly based on up-to-date scientific knowledge and are evaluated in accordance with the most relevant scientific approaches. Dr. White has also coauthored publications on weight of evidence frameworks, problem formulation in chemical assessment and understanding potency information associated with human exposures.