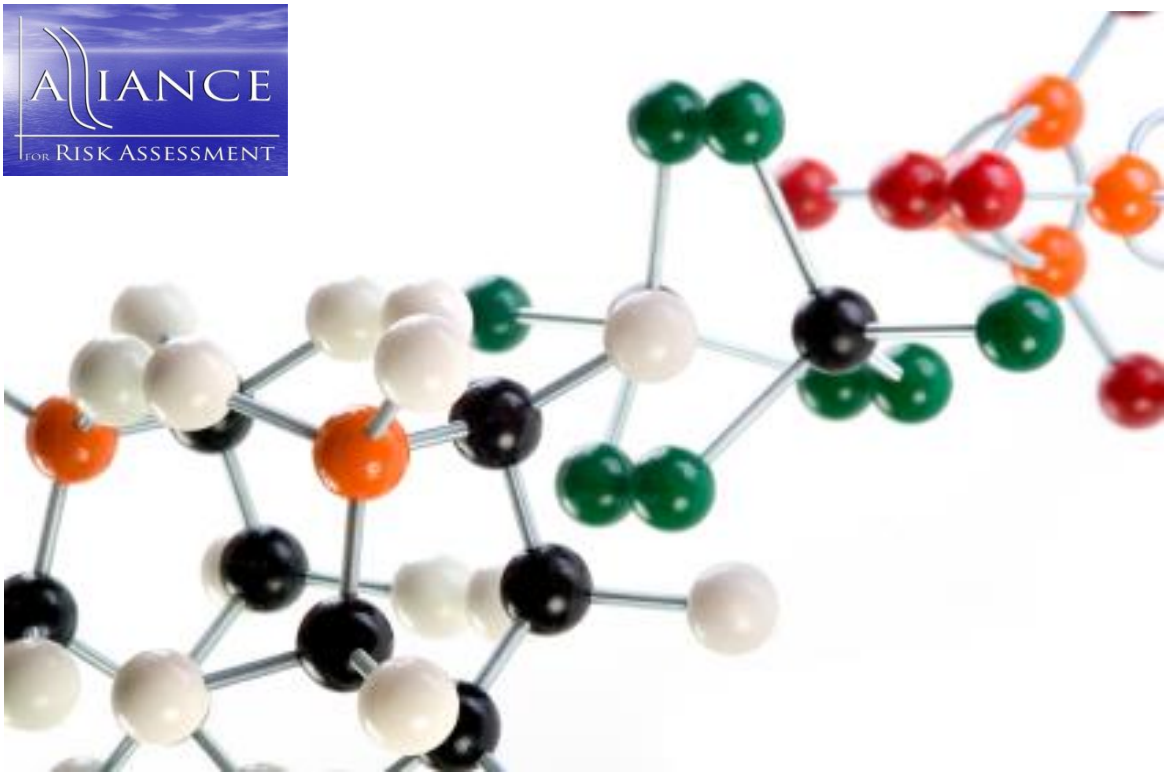

Beyond Science and Decisions:
From Problem Formulation to Dose-Response
Report from Workshop IX - Appendices

Workshop Held:
June 9-10, 2015
Cincinnati, Ohio
University of Cincinnati

Appendices

September 11, 2015

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Appendix 1. Biographies for Panel Members

Science Panel

Mike Dourson, Toxicology Excellence for Risk Assessment

Mike Dourson is the President of Toxicology Excellence for Risk Assessment (TERA), a nonprofit corporation dedicated to the best use of toxicity data in risk assessment. Before founding TERA in 1995, Dr. Dourson held leadership roles in the U.S. Environmental Protection Agency as chair of US EPA's Reference Dose (RfD) Work Group, charter member of the US EPA's Risk Assessment Forum and chief of the group that helped create the Integrated Risk Information System (IRIS). Dr. Dourson received his Ph.D. in Toxicology from the University of Cincinnati. He is a Diplomate of the American Board of Toxicology and a Fellow of the Academy of Toxicological Sciences. Dr. Dourson has served on or chaired numerous expert panels, including peer review panels for US EPA IRIS assessments, US EPA's Risk Assessment Forum, TERA's International Toxicity Estimates for Risk (*ITER*) independent peer reviews and consultations, FDA's Science Board Subcommittee on Toxicology, the NSF International's Health Advisory Board, and SOT's harmonization of cancer and non-cancer risk assessment. He served as Secretary for the Society for Risk Analysis (SRA) and has held leadership roles in specialty sections of SRA and SOT. He is currently on the editorial board of three journals. Dr. Dourson has published more than 100 papers on risk assessment methods, has co-authored over 100 government risk assessment documents, and has made over 100 invited presentations.

Annie M. Jarabek, U.S. EPA, Office of Research and Development

Annie M. Jarabek is a senior toxicologist in the immediate office of the National Center for Risk Assessment (NCEA) within the US EPA's Office of Research and Development (ORD). Annie is the principal author of the US EPA's Methods for Derivation of Inhalation Reference Concentrations (RfC) and Application of Inhalation Dosimetry, which introduced dosimetry and physiologically-based pharmacokinetic (PBPK) model structures and reduced forms into the RfC methods for interspecies adjustment. She has worked on several high-priority and interdisciplinary Agency assessments including the risk characterization of perchlorate ingestion and the inhalation of particulate matter (PM); and has served in an advisory capacity on other methods and assessments, including the guidance on body-weight scaling for harmonizing noncancer and cancer approaches for the interspecies adjustment of ingested chemicals. Her

current research efforts focus on multi-scale modeling of dose-response and decision analysis. Annie has twice received awards for best manuscript in risk assessment application from the Risk Assessment Specialty Section (RASS) of the Society of Toxicology (SOT), along with several best abstract awards. She has also received the Lifetime Achievement Award from the University of Massachusetts, the Risk Practitioner of the Year award from the Society of Risk Analysis (SRA), the Superfund National Notable Achievement Award, and several award medals (1 gold, 1 silver and 5 bronze) and "S awards" for scientific leadership from the Agency for her various contributions. Annie has served as an elected Councilor to the Society for Risk Analysis and as the vice-president/president of the SOT RASS. Annie has also served the SOT on its awards, communications, nominations, and scientific program committees. She is currently on the editorial board of the international journal "Dose-Response."

R. Jeffrey Lewis, ExxonMobil Biomedical Sciences, Inc.

Dr. R. Jeffrey Lewis is currently Section Head of the Epidemiology, Health Surveillance and Quality Assurance group at ExxonMobil Biomedical Sciences, Inc (EMBSI). In this position, Dr Lewis is responsible for managing EMBSI's Epidemiology and Health Surveillance group, the company's laboratory quality assurance program, and for providing support to ExxonMobil scientific programs related to 1,3-butadiene, naphthalene, asphalt, legislative/regulatory affairs and regulatory impact analysis (e.g., benefit-cost analysis). He has served on a number of industry trade association scientific committees (e.g., the American Chemistry Council's 1,3-butadiene Work Group), external science advisory boards (e.g., the Alliance for Risk Assessment Expert Science Panel) and is a member of the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) Committee. Dr. Lewis also has an adjunct faculty appointment at the University of Texas School of Public Health and is Past Treasurer for the Society for Risk Analysis. Dr. Lewis received his Bachelor of Science degree in biology from the University of Kansas in 1985 and a M.S. and Ph.D. in Epidemiology from the University of Texas School of Public Health in 1987 and 1990, respectively. In addition, he earned a Master of Business Administration degree from Rutgers University in 1997.

Bette Meek, McLaughlin Centre for Population Health Risk Assessment, University of Ottawa

Bette Meek has a background in toxicology receiving her M.Sc. in Toxicology (with distinction) from the University of Surrey, U.K. and her Ph.D. in risk assessment from the University of Utrecht, the Netherlands. She is currently the Associate Director of Chemical Risk Assessment at the McLaughlin Centre for Population Health Risk Assessment, University of Ottawa, completing an interchange assignment from Health Canada. She has extensive experience in the management of chemical assessment programs within the Government of Canada, most recently involving development and implementation of process and methodology for the health assessment of Existing Substances under the Canadian Environmental Protection Act (CEPA) and previously, programs for contaminants in drinking water and air.

With colleagues within Canada and internationally, she has contributed to or led initiatives to increase transparency, defensibility and efficiency in health risk assessment, having convened and participated in initiatives in this area for numerous organizations including the International Programme on Chemical Safety, the World Health Organization, the International Life Sciences Institute, the U.S. Environmental Protection Agency, the U.S. National Academy of Sciences and

the U.S. National Institute for Environmental Health Sciences. Relevant areas have included frameworks for weight of evidence analysis including mode of action, chemical specific adjustment factors, physiologically-based pharmacokinetic modeling, combined exposures and predictive modeling. She has also authored over 175 publications in the area of chemical risk assessment and received several awards for contribution in this domain.

Greg Paoli, Risk Sciences International

Greg Paoli serves as Principal Risk Scientist and COO at Risk Sciences International, a consulting firm specializing in risk assessment, management and communication in the field of public health, safety and risk-based decision-support. Mr. Paoli has experience in diverse risk domains including toxicological, microbiological, and nutritional hazards, air and water quality, climate change impacts, medical and engineering devices, as well as emergency planning and response for natural and man-made disasters. He specializes in probabilistic risk assessment methods, the development of risk-based decision-support tools and comparative risk assessment. Mr. Paoli has served on a number of expert committees devoted to the risk sciences. He was a member of the U.S. National Research Council committee that issued the 2009 report, *Science and Decisions: Advancing Risk Assessment*. He serves on the Canadian Standards Association Technical Committee on Risk Management, advisory committees of the National Roundtable on the Environment and the Economy, a US NRC Standing Committee on the Use of Public Health Data at the U.S. Food Safety and Inspection Service, and has served on several expert committees convened by the World Health Organization. Mr. Paoli completed a term as Councilor of the Society for Risk Analysis (SRA) and is a member of the Editorial Board of *Risk Analysis*. Recently, Mr. Paoli was awarded the Sigma Xi – SRA Distinguished Lecturer Award. He has provided training in risk assessment methods around the world, including the continuing education programs of the Harvard School of Public Health and the University of Maryland. Greg holds a Bachelors Degree in Electrical and Computer Engineering and a Master's Degree in Systems Design Engineering from the University of Waterloo.

Ad Hoc Science Panel

Barbara Beck, Gradient

Dr. Beck is expert in toxicology and in human health risk assessment for environmental chemicals,

especially metals and air pollutants. For her projects at Gradient, she has performed site-specific and

chemical-specific risk assessments, and developed exposure and risk assessment methodologies for

multiple chemicals. Dr. Beck has worked on risk assessment issues regarding arsenic for over 25 years. Her projects on arsenic have included: development of a probabilistic exposure model; performing a mode of action analysis on arsenic carcinogenicity, particularly with respect to the

role of cytotoxicity; and evaluating the potential role of arsenic on cardiovascular disease in US populations, considering mode of action issues.

Before joining Gradient, she was Chief of Air Toxics Staff for US EPA Region I. Prior to that she was a

Fellow in the Interdisciplinary, Programs in Health at the Harvard T.H. Chan School of Public Health. She has a Ph.D. in molecular biology and microbiology from Tufts University and an A.B. in biology

from Bryn Mawr College. Dr. Beck also holds certifications from the American Board of Toxicology, the Academy of Toxicological Sciences and the UK Register of Toxicologists. She is at present a Visiting Scientist in the Department of Environmental Health at the Harvard T.H. Chan School of Public Health.

Steve Edwards, US EPA

Stephen Edwards is a Systems Biologist within the U.S. Environmental Protection Agency's National Health and Environmental Effects Research Laboratory (EPA-NHEERL) in Research Triangle Park, N.C. Dr. Edwards is the EPA lead for an international effort to develop an Adverse Outcome Pathway (AOP) Knowledgebase, which is designed to house descriptions of the biological mechanisms underlying chemical toxicity in a structured manner. He is also leading an EPA effort to create computationally-predicted AOPs by integrating data from the published literature, omics databases, and HTS toxicity data. He serves as a senior advisor in the Office of Research and Development (ORD) on issues regarding the development of predictive toxicology models of disease using genomics, proteomics, and metabolomics. With a combination of experimental and computational experience, Dr. Edwards also serves as a liaison with the EPA's National Center for Computational Toxicology (NCCT) and has developed a flexible data management system to support systems biology research within the EPA. Dr.

Edwards received his bachelor of science in chemistry from the University of North Carolina at Chapel Hill and his doctorate in pharmacology from Vanderbilt University Medical Center. Before joining the EPA, he served as a senior research scientist and research fellow at Rosetta Inpharmatics (Merck & Co.), in Seattle, Washington, a recognized leader in computational and systems approaches to drug development.

Mike Jayjock, Jayjock Associates

Mike Jayjock has his own LLC (Jayjock Associates), he is also a Senior Analyst for The LifeLine Group. Mike has an M.S. and Ph.D. from Drexel University in Environmental Engineering & Science and he is board certified (ABIH) in the Comprehensive Practice of Industrial Hygiene. His primary research interest includes the development of better-estimating and more cost-efficient human exposure models. He has been active in the publication of his work and in participating on various committees of the EPA, International Society of Exposure Assessment, American Industrial Hygiene Association, the National Academy of Science and the European Union. He writes a weekly blog on Human Health Risk Assessment at: http://jayjock-associates.blogspot.com/

Joel Tickner, University of Massachusetts, Lowell

Dr. Joel Tickner is Associate Professor in the Department of Community Health and Sustainability at the University of Massachusetts Lowell where he also directs the Chemicals Policy and Science Initiative of the Lowell Center for Sustainable Production. He also directs the Green Chemistry and Commerce Council, a network of more than 70 companies and other organizations dedicated to accelerating the adoption of green chemistry across supply chains and sectors. He is an expert on chemicals regulation, regulatory science, and application of the alternatives assessment in science and policy. In particular, he has led efforts to build a scientific community of practice for alternatives assessment and has written extensively on alternatives assessment policy and practice. He served on the EPA's National Pollution Prevention and Toxics Advisory Committee as well as National Academy of Sciences Panels on the Future of Science at the Environmental Protection Agency and the Design of Safer Chemical Alternatives. He holds a Masters of Science degree in Environmental Studies from the University of Montana and a Doctor of Science Degree from the Department of Work Environment at University of Massachusetts Lowell.

Dan Villeneuve, US EPA

Dr. Daniel L. Villeneuve is a research toxicologist at the US EPA Mid-Continent Ecology Division (MED) in Duluth MN, USA. He earned a BS in Biology and Water Resources from the University of Wisconsin-Steven Point and a Ph.D. in Zoology/Environmental Toxicology from Michigan State University and has worked at MED since 2004. Dr. Villeneuve serves as a project lead for laboratory and field research aimed at the development adverse outcome pathway (AOP) knowledge and application of that knowledge to support regulatory toxicology. Dr. Villeneuve's research is focused on the use of systems biology approaches and application of the AOP framework to extend fundamental understanding of the ways in which chemical stressors can interact with the hypothalamic-pituitary-gonadal (HPG)-axis to produce reproductive toxicity in fish and other vertebrates. Dr. Villeneuve has over 15 years of experience conducting freshwater ecotoxicology research and has been recognized with 14 US EPA Scientific and Technological Achievement Awards, two Bronze Medal awards, and is a US National Academy of Sciences and Kavli Foundation Kavli Fellow. He has authored or co-authored over 130 peer-reviewed papers in the field of ecotoxicology and serves as an associate editor of Environmental Toxicology and Chemistry and an international expert advisor on Molecular Screening and Toxicogenomics to the Organization for Economic Cooperation and Development (OECD).

Standing Science Panel, Unable to Attend

Richard Beauchamp, Texas Department of State Health Services

Richard A. Beauchamp is the Senior Medical Toxicologist for the Texas Department of State Health Services (DSHS) with responsibility for providing advanced toxicological and risk assessment support for the Exposure Assessment, Surveillance, and Toxicology (EAST) Group. As cooperative agreement partners with the Agency for Toxic Substances and Disease Registry (ATSDR), Dr. Beauchamp and other EAST Group members are tasked with conducting Public Health Assessments at abandoned hazardous waste sites that are proposed and added to the Environmental Protection Agency's (EPA's) National Priority List (NPL) of Superfund sites in Texas. Dr. Beauchamp is also involved with conducting other medical and toxicological Public Health Consultations involving exposures to environmental hazardous substances.

After earning his medical degree at the University of Texas Health Science Center at San Antonio (1973-1977), Dr. Beauchamp completed a three year pediatric residency with the Austin Pediatric Education Program at Brackenridge Hospital in Austin, Texas (1977-1980) and began working at the Texas Department of Health as a Public Health Physician Epidemiologist (1980). Early in his career at the health department, he was tasked with developing risk assessment expertise that would be essential for the newly-formed Environmental Epidemiology Program in

the evaluation of environmental and chemical exposures. With an undergraduate degree in Electrical Engineering (U.T. Austin) and a strong background in mathematics and computer sciences, Dr. Beauchamp has applied the knowledge gained through participation at numerous risk assessment conferences, symposia, and seminars (sponsored by EPA, NGA, CDC, ASTHO, NIOSH, and others) to the development of his so-called "Risk Assessment Toolkit." Dr. Beauchamp's toolkit consists of a series of Excel® spreadsheets designed for the flexible and rapid evaluation of cancer and non-cancer risks resulting from exposures to a wide variety of environmental contaminants through all of the common exposure pathways. Risks are calculated incrementally using age-specific exposure parameters, including body weights, body surface areas, respiratory daily volumes, and EPA's early-life exposure factors. Risks are integrated over the exposure duration, using up to 46 different age intervals, to insure that childhood exposures are appropriately addressed.

James S. Bus, Exponent

James S. Bus is a Senior Managing Scientist in the Center for Toxicology and Mechanistic Biology in the Health Sciences Group of Exponent, a leading global consulting firm (May 2013-present). His primary responsibilities at Exponent are to provide toxicology expertise for addressing client product stewardship and regulatory needs associated with industrial and pesticide chemicals. Prior to joining Exponent, Dr. Bus retired from The Dow Chemical Company as Director of External Technology, Toxicology and Environmental Research and Consulting (1989-2013). He also previously held positions as 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 currently serves on the Boards of Directors of The Hamner Institutes (formerly CIIT) and the ILSI Research Foundation. He has also has served as Chair of the American Chemistry Council and International Council of Chemical Associations Long-Range Research Initiatives; the Board of Directors of ILSI-HESI; the USEPA Office of Research and Development Board of Scientific Counselors (1997-2003) and Chartered Science Advisory Board (2003-2009); the National Toxicology Program Board of Scientific Counselors (1997-2000); the FDA National Center for Toxicological Research Science Advisory Board (2004-2010); and the National Academy of Sciences/National Research Council Board on Environmental Studies and Toxicology (BEST; 2005-2011). He has served as an Associate Editor of *Toxicology and Applied Pharmacology*, and on the Editorial Boards of *Environmental Health Perspectives* and *Dose Response*. Dr. Bus is a member of the Society of Toxicology (serving as President in 1996-97), the American Society for Pharmacology and Experimental Therapeutics, the American Conference of Governmental and Industrial Hygienists, and the Teratology Society. He is a Diplomate and Past-President of the American

Board of Toxicology and a Fellow of the Academy of Toxicological Sciences (member of Board of Directors, 2008-present; President, 2010-2011). Dr. Bus received the Society of Toxicology Achievement Award (1987) for outstanding contributions to the science of toxicology; the Society of Toxicology Founders Award (2010) for leadership fostering the role of toxicology in improving safety decisions; Rutgers University Robert A. Scala Award (1999) for exceptional work as a toxicologist in an industry laboratory; and the K.E. Moore Outstanding Alumnus Award (Michigan State University, Dept. Pharmacol. And Toxicol.). He received his B.S. in Medicinal Chemistry from the University of Michigan (1971) and Ph.D in pharmacology from Michigan State University (1975) and currently is an Adjunct Professor in the Dept. Pharmacology and Toxicology at that institution. His research interests include mechanisms of oxidant toxicity, chemical and pesticide modes of action, defense mechanisms to chemical toxicity, relationships of pharmacokinetic and exposures information to expression of chemical toxicity, and general pesticide and industrial chemical toxicology. He has authored/co-authored over 100 publications, books, and scientific reviews.

Appendix 2. Meeting Agenda

Agenda
Date: June 9-10, 2015
Location: Cincinnati, Ohio

Purpose: To advance the recommendations of NAS (2009) and subsequent framework of *ARA* (2013) on problem formulation and dose-response analysis, through review of illustrative case studies for further development of methods

All times are Eastern Daylight Time.

Tuesday, June 9

Welcome (8:30)

- **Andrew Maier, Director, University of Cincinnati NIOSH Education and Research Center Continuing Education Program**

Introduction and Opening Remarks (8:35 to 8:50)

- **Members of the Advisory Committee and Science Panel**

Overview of AOPs and best practices and OECD wiki, (9:00 to 10:00**)**

- **Steve Edwards, U.S. Environmental Protection Agency**
- **Dan Villeneuve, U.S. Environmental Protection Agency**
- **Bette Meek, University of Ottawa**

Morning Break (10:00 to 10:30)

Review of Case Study: Vicinal Dithiol Binding Cancer Adverse Outcome Pathway: Case Study with Inorganic Arsenic (10:30 to 12:00)

- **Harvey Clewell, The Hamner Institute**
- **Science Panel discussion**

Lunch (12:00 to 1:00)

Vicinal Dithiol Binding Cancer Adverse Outcome Pathway: Case Study with Inorganic Arsenic (continued) (1:00 to 3:00)

- **Science Panel discussion (cont)**

Afternoon Break (3:00 to 3:30)

Review of Case Study: Vicinal Dithiol Binding NonCancer Adverse Outcome Pathway: Case Study with Inorganic Arsenic (3:30 to 5:30)

- **Robinan Gentry, Ramboll ENVIRON**
- **Science Panel discussion**

Observer Comments (5:30 to 6:00)

Reception (dinner portion hors d'oeuvres, 6:30 to 9:00)

Wednesday, June 10

Frameworks for evaluating chemical alternatives (8:00-8:30)

- **Joel Tickner, University of Massachusetts, Lowell**

Review of Case study: A systematic assessment methodology for flame retardants (FRs) based on hazard and exposure- the FR framework (8:30 -10:00)

- **Smadar Admon, ICL**
- **Science Panel discussion**

Morning Break (10:00 to 10:30)

Review of Case study: A systematic assessment methodology for flame retardants (FRs) based on hazard and exposure- the FR framework (continued) (10:30 – 12:30)

- **Science Panel discussion (cont)**

Lunch (12:30 to 1:30)

[1]Review of Case Study: AOP for a Mutagenic MOA for Cancer (AFB_1 and HCC) (1:30 - 3:30)

- **Lynn H. Pottenger, TERC, The Dow Chemical Company; Martha M. Moore, Ramboll ENVIRON, Rita Schoeny, U.S. EPA**
- **Science Panel discussion**

Observer Comments and Closing remarks (3:30 to 4:00)

Adjourn

[1](Break may be scheduled at the discretion of the cochairs.)

Appendix 3. List of Workshop Participants

In-Person Attendees

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