Ethylene Oxide Peer Reviewers

RSC independently selected the following six experts to provide independent peer review of the TCEQ EtO DSD. Each has been screened for conflict of interest. None of the selected experts has a conflict of interest with the review of this document.

Bruce Allen

Bruce C. Allen is a biomathematician and works as an independent consultant. Previously Mr. Allen held manager and senior scientist positions with Environ International; ICF Consulting, KS Crump Group; and RAS Associates. He received his M.S. in Biomathematics with a Statistics minor from North Carolina State University. Mr. Allen's areas of expertise are dose response analysis, biologically-motivated modeling, and statistics, particularly applied to human health risk assessment. His primary interest is in the quantitative aspects of risk analysis, including dose-response analysis; statistical appraisal of data, models, and modeling results; and with developing rigorous approaches to decision making in risk assessment contexts. In particular, Mr. Allen has conducted research to study dose-response modeling approaches for developmental toxicants and cancer dose-response, and the estimation of risks from epidemiological data. He has over 50 peer-reviewed publications on quantitative risk assessment and is a frequent peer reviewer of risk assessment documents. Over the past five years, Mr. Allen has consulted on a paid basis for the U.S. EPA (through contractors Lockheed Martin, CSRA, and GDIT), the University of Cincinnati RSC, Toxicology Excellence for Risk Assessment, Ramboll Corporation, ICF Consulting, and 3M.

Mr. Allen recently was a co-author of a paper[1] published in 2017 on dose and temporal evaluation of ethylene oxide-induced mutagenicity in lungs of mice. The paper was based on research performed under a CRADA with the FDA, with funding from Ethylene Oxide and Derivatives Producers' Association and Lower Olefins Sector Group of the European Chemical Industry Association (CEFIC). This government/industry collaborative project addressed the MOA for EtO-induced lung tumors in mice, which is not an issue relevant to the TCEQ ethylene oxide assessment. Mr. Allen (as a sub-contractor to TERA) contributed dose-response analysis to the project and publication. Mr. Allen's work on this project does not constitute a conflict of interest and will not interfere with Mr. Allen's ability to be impartial with this peer review, because the work is completed, no other work is anticipated, and it is not relevant to the current assessment. For the U.S. EPA, Mr. Allen is currently working on several projects (as a subcontractor to a government contractor), including dose-response analyses for arsenic and development of benchmark dose software. Since 2015 he has worked for 3M (a company that produces sterilization equipment using EtO) on dose-response and pharmacokinetic modeling of PFAS and related compounds (some of that work done as a subcontractor through a consulting firm). These projects are unrelated to EtO, do not create a conflict interest, and will not interfere with Mr. Allen's ability to provide an impartial, technically sound, and objective review of the subject matter.

Harvey Checkoway

Harvey Checkoway has been a Professor since 2013 and Vice Chair for Research since 2014 at the University of California, San Diego (UCSD), in the Department of Family Medicine and Public Health. He

[1] Manjanatha, Mugimane G; Shelton, Sharon D; Chen, Ying; Parsons, Barbara L; Myers, Meagan B; McKim, Karen L; Gollapudi, B Bhaskar; Moore, Nigel P; Haber, Lynne T; Allen, Bruce; Moore, Martha M 2017. Dose and temporal evaluation of ethylene oxide-induced mutagenicity in the lungs of male big blue mice following inhalation exposure to carcinogenic concentrations. Environmental and molecular mutagenesis, 58 3, 122-134.

has had a joint appointment as a Professor in the UCSD Department of Neurosciences since 2015. Previously he was a professor in the Departments of Environmental and Occupational Health Sciences and Epidemiology at the University of Washington (1987-2013) and an assistant professor (1979-86), and associate professor (1987) at the University of North Carolina. He earned his Ph.D. in epidemiology from the University of North Carolina and an M.P.H. from Yale University. His research has focused on epidemiologic investigations of occupational and environmental risk factors for chronic diseases, especially cancers and neurodegenerative disorders. His research has included assessments of biomarkers in occupational epidemiological investigations and methodological research on study design and research validity considerations, as well as evaluation of the quality of epidemiological research data for applications to risk assessments. Dr. Checkoway has served on many advisory committees and peer review panels for state, federal, and international government agencies, unions, and private companies. For the National Academy of Sciences he has served on committees addressing military personnel at atmospheric tests of nuclear weapons, low-dose ionizing radiation, IRIS formaldehyde risk assessment, and asbestos. Dr. Checkoway also served as a Visiting Scientist at the International Agency for Research on Cancer (IARC) in 2006, and for 1-3-month periods as a Visiting Professor in the Department of Occupational and Environmental Medicine at the University of Turin in 2017, and as a Visiting Scientist at Bologna University Institute of Advanced Studies in 2019. Dr. Checkoway is the lead author of a major textbook on research methods in occupational epidemiology and is a journal editor and reviewer. He has over 250 peer-reviewed publications, and has written 25 book chapters.
During the last five years Dr. Checkoway has received grants or funding from NIEHS, NIOSH, National Cancer Institute, National Multiple Sclerosis Society, National Institute for Neurological Diseases and Stroke, National Health Lung and Blood Institute, Alpha Foundation for the Improvement of Mine Safety and Health, and the National Institute of Aging. As a consultant, he has also received funding from the Foundation for Chemistry Research and Initiatives, Electric Power Research Institute, American Chemistry Council, University of Minnesota, Aluminum Company of America, Dupont Company, American Journal of Epidemiology, Materion, Ramboll Environ Corporation, Hellenic Center for Disease Control and Prevention, Department of Justice Canada, Exponent, and Monsanto Corporation.

Dr. Checkoway recently received funding from the American Chemistry Council to review epidemiology literature on formaldehyde and non-Hodgkin's lymphoma (2017) and from the Monsanto Corporation to review epidemiological literature on polychlorinated biphenyls and non-Hodgkin's lymphoma (2016-19). These projects do not create a conflict interest and will not interfere with Dr. Checkoway's ability to provide an impartial, technically sound, and objective review of the subject matter.

Kenny Crump

Kenny S. Crump is retired and works as a private consultant. He has a Ph. D. in mathematics from Montana State University. Dr. Crump was a Professor of mathematics at Louisiana Tech from 1966 through 1980. Later he held positions in several companies, including K S Crump and Company, Inc. and Environ International Corporation. Dr. Crump's research has primarily involved development and application of statistical methodologies for quantitative assessment of health risks, primarily cancer, from exposures to toxic substances. The U. S. EPA has for many years used a statistical model developed by Dr. Crump to quantify cancer risk from toxic chemicals. Dr. Crump also initiated the "benchmark approach" for setting exposure standards for toxic chemicals that is now widely used in the U.S. and abroad. Dr. Crump is an author of more than 150 peer-reviewed scientific publications and book chapters. Many of these deal with risks to human health from specific substances, notably dioxin, asbestos, and diesel exhaust.

Dr. Crump has served as an advisor and on advisory committees for various bodies, including the USEPA's Science Advisory Board and Science Advisory Panel, the National Center for Toxicological Research's Science Advisory Board, the Mickey Leland National Urban Air Toxics Research Center's Science Advisory Panel, the National Institute of Environmental Health Sciences Board of Scientific Counselors, and the National Toxicology Program Board of Scientific Counselors. He has served on six National Academies of Science Committees and has been an official advisor to the World Health Organization, Health Canada, and the Province of Ontario. Dr. Crump is an elected Fellow of the American Statistical Association and the Society for Risk Analysis, and has received distinguished achievement awards from both of these organizations. During the past five years Dr. Crump has received funding from the Engine Manufacturers Association, the Canadian National Railroad, Tox-Strategies, and the U.S. EPA (Science Review Board on glyphosate).

Dr. Crump is not currently working on ethylene oxide; however, in 1983 he reviewed an OSHA quantitative risk assessment on EtO and presented his independent findings in an OSHA hearing. He has stated that his previous work on ethylene oxide was over 30 years ago and will not interfere with his objective evaluation of the ethylene oxide assessment. For the U.S. EPA, Dr. Crump served on a Science Review Board on glyphosate. This activity does not create a conflict interest and will not interfere with Dr. Crump's ability to provide an impartial, technically sound, and objective review of the subject matter.

Bette Meek

M.E. (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 in Health Canada, most recently the assessment of Existing Substances under the Canadian Environmental Protection Act (CEPA). Dr. Meek received her Ph.D. in risk assessment from the University of Utrecht, the Netherlands and earned a M.Sc. in Toxicology from the University of Surrey, U.K. Dr. Meek 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. She has co-authored approximately 200 peer-reviewed publications and more than 75 government publications. She has served on panels and/or as an advisor for national and international agencies and organizations, including Health Canada, U.S. EPA, U.S. National Academy of Sciences, World Health Organization, International Labour Organization, the European Joint Research Centre and the Agency for Food, Environmental and Occupational Health and Safety of France (ANSES). Dr. Meek received the Arnold J. Lehman Award from the Society of Toxicology. She has twice received the highest award of excellence of the Public Service of Canada, and several Health Canada Excellence in Science Awards. During the past five years, Dr. Meek has received external funding from the World Health Organization and Health Canada.

Dr. Meek contributed to the 2001 Health Canada assessment on ethylene oxide while managing the Priority Substances Program at Health Canada and was a contributing author on a resulting published manuscript and a 2003 World Health Organization Concise International Chemical Assessment Document. Dr. Meek has stated that the Health Canada EtO assessment was conducted in 2001 and that the relevant database and methodology has likely moved on significantly since then; therefore, she is confident that she can objectively review and comment on the TCEQ assessment. Dr. Meek has no conflicts of interest for this peer review.

David Savitz

David A. Savitz is Professor of Epidemiology and Interim Chair of the Department of Epidemiology in the School of Public Health at Brown University, with joint appointments in Obstetrics and Gynecology and Pediatrics in the Alpert Medical School. Previously, he was a professor at Mount Sinai School of Medicine and at the University of North Carolina, and an Assistant Professor at the University of Colorado School of Medicine. Dr. Savitz earned a Ph.D. in Epidemiology from the University of Pittsburgh Graduate School of Public Health. His epidemiological research has addressed environmental hazards in the workplace and community, reproductive health outcomes, and environmental influences on cancer. He has done extensive work on health effects of nonionizing radiation, pesticides, drinking water treatment by-products, and perfluorinated compounds. He is the author of nearly 350 papers in professional journals and editor or author of three books. He was President of the Society for Epidemiologic Research and the Society for Pediatric and Perinatal Epidemiologic Research. Dr. Savitz is an elected member of the National Academy of Medicine (NAM) where he has served on more than a dozen committees, five of which he chaired. He currently chairs the Health Effects Institute Research Committee and the NAM Committee to Review the Long-Term Effects of Antimalarial Drugs. From 2013-2017 he served as Vice President for Research at Brown University. During the past five years, Dr. Savitz has received research grants from the National Institutes of Health, the Department of Defense, and the Agency for Toxic Substances and Disease Registry (subcontract with RTI). He has also served as a consultant on several legal cases. None of these involved ethylene oxide.

Dr. Savitz has collaborated professionally with Dr. Kyle Steenland on several projects and publications, but not on ethylene oxide. Dr. Savitz has stated that his professional association with Dr. Steenland will not interfere with his objective evaluation of the ethylene oxide assessment. Dr. Savitz has no conflicts of interest for this peer review.

Rita Schoeny

Rita Schoeny retired from the U.S. EPA in 2015 after 30 years and is currently serving as a consultant in risk assessment and science policy. Her most recent positions at U.S. EPA were as Senior Science Advisor for the Office of Science Policy, Office of Research and Development; and as the Director of the Risk Assessment Forum in EPA's Office of the Science Advisor. Dr. Schoeny received her Ph.D. in microbiology from the University of Cincinnati. She regularly lectures at colleges and universities, and has given training and lectures on risk assessment, science policy and toxicology in many areas of the world. She has been responsible for major assessments and programs in support of legislative mandates including the Safe Drinking Water Act, Clean Water Act, Clean Air Act, and Food Quality and Protection Act. Dr. Schoeny has published in the areas of toxicity of PCBs, PAHs, mercury, and drinking water contaminants (including disinfectant byproducts and microbes); assessment of complex environmental mixtures; and principles and practice of human health risk assessment. Recent work includes frameworks for human health risk assessment, interpretation of DNA adduct data for risk assessment, evaluation of episodic and less-than-lifetime exposure to carcinogens, new approaches to dose response assessment (including application of benchmark and other modeling procedures to chemicals including carcinogens), OECD guidelines for genetic toxicity testing, quantitative approaches to genetic toxicology, Adverse Outcome Pathways and Mode of Action, and approaches to cancer risk assessment. She has served on WHO committees and a National Academy of Sciences committee on risk assessment of complex mixtures. Dr. Schoeny is the recipient of numerous awards including EPA's Science Achievement Award for Health Sciences and the FDA Teamwork Award for publication of national advice on mercury-contaminated fish. She is an elected Fellow of the Society for Risk Analysis.

During the past five years, Dr. Schoeny has consulted on a paid basis with the American Chemistry Council Adverse Outcome Pathways project, Procultivos ANDI, the University of Cincinnati RSC, and Health Canada (subcontract with University of Cincinnati). She also does unpaid work for Save EPA, Environmental Protection Network, and other groups. This unpaid work has included contributing to discussions of current U.S. EPA published assessments in support of TSCA, as well as reviewing comments made by several retired U.S. EPA scientists and managers.

Dr. Schoeny worked for 30 years for the U.S. EPA, but she did not work on ethylene oxide. She has done some consulting work for the American Chemistry Council on Adverse Outcomes Pathways, but none of that work has been on ethylene oxide. None of her unpaid work has involved ethylene oxide, and Dr. Schoeny notes that her affiliation with these groups does not influence her scientific opinion on ethylene oxide or other chemicals. Dr. Schoeny has recently shared personal opinions about the U.S. EPA in a public blog. Regarding this, she notes: "A few years ago I contributed to a blog of the Union of Concerned Scientists. In this post I called into question the stated intention of the current administration to overturn or not enforce regulations promulgated by the U.S. EPA. I noted the lack of process in this endeavor by contrast to the established, iterative process for review, comment, and stakeholder involvement in issuing environmental regulations as well as the scientific evaluations in support of risk management choices. I state that as scientists we need to 'insist on the validity and thoroughness of our discipline'. I continue to uphold this opinion, and I here note that as part of this stance I have offered critiques of science based solely on the data available and my best scientific judgement. I note that my publications reflect this." Dr. Schoeny has stated that her previous employment by the U.S. EPA and consulting work with the American Chemistry Council and others will not bias her review and will not interfere with her objective evaluation of the ethylene oxide assessment. Dr. Schoeny has no conflicts of interest for this peer review.

Risk Science Center

The UC RSC evaluated the potential for conflict of interest for RSC as an organization and for RSC personnel. The following activities related to ethylene oxide and relationships with the interested parties were identified.

- When she was an employee of Toxicology Excellence for Risk Assessment (TERA), Dr. Lynne Haber of the RSC was the lead of a project that investigated the mode of action for ethylene oxide-induced lung tumors in male mice. The project was conducted through a Cooperative Research and Development Agreement (Grant Number: CRADA E7229.11) between the National Center for Toxicological Research (NCTR) of the U.S. Food and Drug Administration and TERA. Funding for TERA and support for NCTR under the CRADA was provided by Ethylene Oxide and Derivatives Producers' Association and Lower Olefins Sector Group of the European Chemical Industry Association (CEFIC). This funding paid for materials at NCTR and Dr. Haber and other's time to work with NCTR on study design, interpretation of results, and preparation of publications. Dr. Haber coauthored two papers with the project team.

- In a second project while with TERA, Dr. Haber worked with Environ, with funding from CEFIC, to use the modified Hill criteria to integrate all of the MOA data, including the data obtained by NCTR, for an overall MOA evaluation. The focus of this work was MOA for lung cancer in mice.

These two projects were completed by 2014 while Dr. Haber was employed by TERA, and the RSC has had no work on ethylene oxide. Because Dr. Haber's projects are completed and no other work is planned, the RSC and Dr. Haber have no financial conflict of interest with this peer review work order.

The MOA of EtO-induced mouse lung tumors is not an issue or outstanding question for the current ethylene oxide assessment, and the work Dr. Haber did is not directly relevant to the human cancer dose-response assessment that is the subject of this peer review. Therefore, this prior work does not create a situation that would cause Dr. Haber (or the RSC) to have a bias regarding the ethylene oxide DSD.

- Dr. Michael Dourson previously worked for the RSC and was a member of the EPA Science Advisory Board (SAB) for several years. He may have been involved in discussions of EPA's ethylene oxide work as an SAB member. Dr. Dourson left the RSC in 2017.

- A recent publication on ethylene oxide that is cited in the TCEQ DSD was co-authored by two individuals who previously worked for the RSC (Melissa Vincent and Andy Maier). None of the work for that publication took place while they were employed by the RSC. The RSC collaborates with Ms. Vincent and Dr. Maier on other projects unrelated to ethylene oxide. The RSC does not believe that these collaborations will cause the RSC staff to be biased regarding the ethylene oxide DSD or in conducting this peer review.

The RSC worked on two peer review projects in the last five years related to ethylene glycols (which are made from ethylene oxide).

- For the American Chemistry Council Ethylene Oxide/Ethylene Glycols Panel (which provided comments on the proposed DSD), Ms. Patterson of the RSC organized a panel of experts to perform a quality assurance review of two publications that derived risk values for diethylene glycol (DEG) and ethylene glycol (EG) for inclusion on the International Toxicity Estimates for Risk (ITER) database. This review project was completed in April 2019 with loading of the summaries on the ITER database.

- For Health Canada, the RSC (under a contract held by Toxicology Excellence for Risk Assessment) organized a letter peer review of a screening assessment on ethylene glycol ethers. The review was completed in June 2016.

These review projects did not involve ethylene oxide and involved peer review. No other work on ethylene glycols is planned.