Kenneth T. Bogen, Dr.P.H., DABT

Principal Consulting Toxicologist
Quantitative Environmental Exposure & Health Risk Assessment Expert

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Professional Profile

Board-certified toxicologist with nationally recognized expertise in environmental health risk assessment and related exposure, pharmacokinetic, dose-response, statistical, uncertainty analysis, and chemical-threat biosurveillance methods development.

30+ years of experience and expertise in human exposure and health risk assessment addressing dose response, chemical carcinogen risk, carcinogen mode-of-action, organic-chemical dermal absorption, toxicokinetics, physiologically based pharmacokinetic (PBPK), biologically based, toxicodynamic, statistical modeling, data analysis, and chemical biosurveillance, pertaining to chemical exposure scenarios in occupational, consumer-product, medical-device, California Proposition 65, atmospheric dispersion, and groundwater contamination contexts. Authored/co-authored >100 related (including 3 award-winning) peer-reviewed scientific journal publications, 24 key technical reports, 9 book chapters, and 2 monographs. Expert, litigation-support (including expert deposition), regulatory evaluation, scientific experimental design, and technical-analysis services. Projects, publications, scientific research, and services have addressed a broad range of chemicals, radiation, and human health endpoints,[1] as well as atmospheric chemical dispersion and threat-zone prediction/modeling, organophosphate PBPK models/methods/applications, and environmental health risk management, worldwide terrorism, and chemical threat biosurveillance methods development.

Member, National Academy of Sciences/National Research Council (NRC) committees that issued *Science and Judgment in Risk Assessment* (1994) and *Review of the Army's Technical Guides on Assessing and Managing Chemical Hazards to Deployed Personnel* (2004); chaired the U.S. Consumer Product Safety Commission's Chronic Hazards Advisory Panel on Diisononyl Phthalate (DINP) (2000–2001); chaired the Metabolism and Mode of Action Panel, *Naphthalene State of the Science Symposium* (NS^3), Monterey, CA (2006); and served as expert panelist at the NRC Standing Committee on Risk Analysis Issues and Reviews, Workshop on Uncertainty in Cancer Risk Based on Bioassay Data (2007). President (1995) and Councilor (2004–2006) of the Northern California Chapter of the Society for Risk Analysis (SRA); Chair-Elect and Chair of SRA Dose-Response Specialty Group (2016–2017). Winner, 2020 Wolfram Innovator Award.

Academic Credentials and Professional Certification

Dr.P.H., Environmental Health Science, University of California, Berkeley, 1986

M.P.H., Environmental Health Science, University of California, Berkeley, 1982

M.A., Science, Technology, and Public Policy, George Washington University, 1979

A.B., Biology, Princeton University, 1978

Diplomate of the American Board of Toxicology (DABT); 5-year certification awarded October 2008 (2009–2013), 5-year recertifications awarded Nov 2012, Nov 2017 (2014–2023)

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[1] Including: acetylcholinesterase inhibition, allergic contact dermatitis, arsenic, asbestos, benzene, captan, cancer endpoints, cooked-meat carcinogens (PhIP, etc.), Cs-137, chromium, dermal exposure, 1,3-dichloropropanol, dibenzo[*a*,*l*]pyrene, diethanolamine, dimethoate, furfuryl alcohol, formaldehyde, hydrogen sulfide, lead, malathion, 3-methylchloropropanol, 4-methylimidazole, methyl isobutyl ketone (MIBK), methyl tert-butyl ether (MTBE), musks, beta myrcene, naphthalene, nickel, paperboard packaging chemical contaminants and migration, phthalates, radionuclides, radon, reproductive/developmental toxicity, transuranic elements (uranium, plutonium), and VOCs.

Employment

Principal Consulting Toxicologist, ktbogen.com, Silver Spring, MD (Jan 2018 – Mar 2019, Sep 2020 – present, full time). Primary project in 2018-2019 focused on acetamide pharmacokinetic analysis and modeling as part of team focusing on acetamide cancer risk assessment for a Gates Foundation-funded research project conducted by the Michigan Research Institute

Senior Specialist – Toxicology, Cadmus Group LLC, providing contract support to the U.S. Department of Homeland Security (DHS) National Biosurveillance Integration Center (NBIC) (Apr 2019 – Sep 2020, full time; $115,000/year, TS-level USDOD Security Clearance 3/2020). Senior Scientist NBIC project role: development of NBIC capability for chemical threat surveillance using its Biofeeds system for detecting and integrating worldwide open-source threat information; to facilitate NBIC biosurveillance operations using quasi-real-time Biospatial platform Emergency Medical Services (EMS) data, also conceptualized, designed, wrote, and helped to illustrate operational application of *Mathematica*® software enabling automated location- and syndrome-specific characterization of trends and anomalies in U.S. state and county-specific sets of EMS data.

Managing Scientist and Consulting Toxicologist, Exponent Health Sciences Practice, Oakland, CA (Sept 2007 – Dec 2017 full time; 2017 salary $150,000/year; Jan 2018 – Mar 2019, part time). See Appendix for project details, also described in related publications listed below

Environmental Scientist, Energy and Environment Directorate L-396, University of California, Lawrence Livermore National Laboratory, USDOE Q Security Clearance (June 1986 – Sept 2007 full time; 2007 salary ~$105,000/year). Projects described in related publications (see below)

Program Analyst, U.S. Environmental Protection Agency Region 9, Office of Policy, Technical and Resource Management (Jun–Aug 1982 full time summer position)

Science Policy Analyst (GS 11 career tenure), U.S. Library of Congress, Congressional Research Service, Science Policy Research Division (1980–1981 full time)

Graduate Research Assistant, U.S. Environmental Protection Agency, Office of Radiation Programs, Crystal City, VA (1979 part time)

Science Advisory Boards/Panels

U.S. Environmental Protection Agency (EPA), National Exposure Research Laboratory (NERL) (September 5–12, 2016). Chaired external peer consultant panel evaluating NERL probabilistic exposure and dose modeling to support development of a Household Action Limit (HAL) under the revised EPA Lead and Copper Rule (LCR).

National Academy of Sciences, National Research Council (NRC), Subcommittee on the Toxicological Risks to Deployed Military Personnel, member (2002-2004). Issued report: *Review of the Army's Technical Guides on Assessing and Managing Chemical Hazards to Deployed Personnel*, 2004

U.S. EPA, Draft Framework for Cumulative Risk Assessment, peer consultant (U.S. EPA Risk Assessment Forum, EPA/630/R-01/005, April 2002; contributed to final framework, https://www.epa.gov/risk/framework-cumulative-risk-assessment)

U.S. Consumer Product Safety Commission (CPSC). Chronic Hazard Advisory Panel (CHAP) on Diisononyl Phthalate (DINP), Chairman (nominated by the President of the National Academy of Sciences; 2000–2001; CHAP report to USCPSC issued in June 2001, https://www.cpsc.gov/s3fs-public/pdfs/dinp.pdf)

U.S. EPA, Ambient Water Quality Criteria Methodology: Human Health, panel member (1999)

U.S. EPA, Carcinogenicity, Reproductive/Developmental Toxicity and Systemic Toxicity of Drinking Water Disinfectant By-Products, panel member (1998)

National Academy of Sciences, National Research Council (NRC), Committee on Risk Assessment of Hazardous Air Pollutants, member (1991–1994); issued the report: *Science and Judgment in Risk Assessment*, 1994. Student edition: Taylor and Francis, Washington DC, 1996.

International Life Sciences Institute (ILSI), Dose-Response Working Group (1991–1992)

Academic Appointment

Member, University of California Davis Cancer Center, 2002–2007

Patents Co-inventor on five University of California/LLNL DNA-technology patents

Key Capabilities

- Applied toxicology, including mechanistic, chemical carcinogen mode of action, and quantitative dose-response analysis
- Exposure assessment, including for dermal and multi-route issues
- Physiologically based pharmacokinetic (PBPK) and biokinetic modeling
- Quantitative risk/uncertainty characterization, statistics/biostatistics, mathematical modeling, data analysis (30+ years of *Mathematica*® programming expertise)
- Experimental and assessment-methods development and validation evaluation and guidance
- California Proposition 65 compliance assessment
- Expert deposition and litigation support experience (toxicology, chemical exposure, groundwater statistics)

Key Projects Since 2008 (see Appendix)

Key Areas of Scientific Research and Expertise[2]

Quantitative Risk Assessment Methods. While at LLNL I served as a Member of the National Academy of Sciences/National Research Council (NRC) committees that issued *Science and Judgment in Risk Assessment* (1994, reprinted in 1996 as a student edition) and *Review of the Army's Technical Guides on Assessing and Managing Chemical Hazards to Deployed Personnel* (2004). The *Science and Judgment in Risk Assessment* report, known as "the Blue Book"—the second NRC report to focus on regulatory (particularly U.S. EPA environmental carcinogen) risk assessment methodology—was prepared by NRC at Congressional request in the Clean Air Act Amendments of 1990 as a follow-up to NRC's first report on this topic, *Risk Assessment in the Federal Government: Managing the Process* (1986), known as the "Red Book." The *Science and Judgment* report recommended systematic distinction between and appropriate analysis of uncertainty and inter-individual variability in environmental health risk analysis, citing and adopting nomenclature and mathematical (e.g., nested Monte Carlo) approaches I developed for this purpose in my UCB SPH doctoral dissertation and related publications (see Bogen 1986 dissertation; Bogen & Spear 1987 *Risk Anal*; Bogen & McKone 1988 *Risk Anal*; Bogen 1990 book; McKone & Bogen 1991 *Environ Sci Technol*, 1992 *Regul Toxicol Pharmacol*; Bogen 1995 *Risk Anal*). At LLNL and Exponent, I continued to develop methods for uncertainty and inter-individual variability analysis applications to exposure and health risk assessment and management (see Bogen 1995 *Risk Anal*; Robison et al. 1997 *Health Phys*; Bogen et al. 1997 *Health Phys*; Daniels et al. 2000 *Water Air Soil Pollut*; Bogen 2005 *Risk Anal*; Bogen & Gouveia 2008 *J Hazard Mater A*; Bogen et al. 2009 *Toxicol Sci*).

Cooked-Meat Carcinogen Exposure Assessment & Epidemiology. As a project co-investigator in a 5-year NCI/NCI-P01-funded study centered at LLNL, I focused on heterocyclic amine (HA) cooked-meat mutagen carcinogenic potency and human dietary exposure characterization (the principal HA, PhIP, was first identified at LLNL) (see Bogen 1994 *Mutat Res*; Bogen 1994 *Food Chem Toxicol*; Bogen 1995 *Molec Environ Mutagen*; Layton et al. 1995 *Carcinogenesis*). As co-investigator in a 5-year follow-up study funded by a NCI/NCI-P01 grant centered at LLNL, I led an epidemiological study in collaboration with Professor Elizabeth Holly at the UCSF School of Medicine that investigated associations between prostate cancer screening outcome and dietary HA exposures in African-American men screened at a

[2] Cited publications are listed below in **Publications in Scientific Journals**.

clinic in Oakland, CA, for which I co-designed and supervised in-person administration of a dietary HA-intake questionnaire to study participants and directed all multi-institution IRB-approval aspects of the study (see Keating et al. 2000 *Cancer Causes Control*; Bogen & Keating 2001 *J Environ Sci Health*). As principal investigator of a follow-up 3-year expanded epidemiology study funded by the U.S. Department of Defense Prostate Cancer Research Program, I continued leading the same multi-institution collaborative team and succeeded in detecting a significant HA-exposure-related elevation in screening indices of prostate cancer in our clinic-based study population (see Bogen et al. 2007 *Prostate Cancer Prostatic Dis*). I also collaborated on follow-up HA-risk-related studies (see Keating et al. 2007 *J Am Dietetic Assoc*; Louis et al. 2007 *J Toxicol Environ Health*, 2008 *Neuroepidemiol*).

New Experimental Methods to Measure Dermal Uptake Kinetics, Ultra-Low Occupational ^{238}Pu Exposures, and Low-Dose Radiogenic Cell Killing. My experimental work at LLNL examined *in vivo* dermal uptake of organics into hairless guinea pigs, and I explored unexpected observations from that study by pioneering the application of accelerator mass spectrometry (AMS) to real-time dermal penetration kinetics research using human surgical tissue, leading to a surprising hypothesis that uptake-rates measured using *in vivo* methods generally and substantially exceed estimates based on conventional *in vitro* diffusion-cell methods (see Bogen et al. 1992 *Fund Appl Toxicol*; Bogen 1994 *J Expos Anal Environ Epidemiol*; Bogen et al. 1998 *J Expos Anal Environ Epidemiol*). Follow-up analysis at Exponent considerably strengthened this conclusion (Bogen 2013 *Risk Anal*). At LLNL I pioneered two additional experimental methods: (1) AMS-based ultrasensitive reconstruction of historical plutonium-238 dose to plutonium workers over a 20-year period at LLNL using archived alpha-spectrometry plates that previously had yielded only apparent background-level counts (see LLNL report: Bogen et al. 2004); and (2) application of gel-microdrop flow cytometry to assess hypersensitivity-related non-monotonic reduction in cell survival after gamma radiation exposure in collaboration with scientists at the Cross Cancer Institute in Alberta, Canada (see Bogen et al. 2001 *Toxicol*; Enns et al. 2004 *Molec Cancer Res*). At LNLN I was co-inventor on five patents awarded to the University of California.

PBPK-Based Environmental and Occupational Exposure Assessment. At LLNL I developed novel, efficient approaches to physiologically based pharmacokinetic (PBPK) model applications (see Bogen 1988 *Regul Toxicol Pharmacol*; Bogen & Hall 1989 *Regul Toxicol Pharmacol*; Daniels et al. 2000 *Water Air Soil Pollut*; Bogen 2006 *Risk Anal*), and applied those approaches to chemical-specific health risk assessment reports LLNL prepared on behalf of federal and state agencies such the California Department of Health Services and California Environmental Protection Agency (see LLNL Reports: Reed et al. 1987; Bogen et al. 1987, 1988, 1992a-b; Layton et al. 1987; Daniels et al. 1998; Bogen 2001). At LLNL and Exponent I continued to develop and apply PBPK-based approaches to environmental carcinogen and occupational (dermal pesticide) exposure assessment, to facilitate biologically based health risk assessment (see Bogen & Gold 1997 *Regul Toxicol Pharmacol*; Bogen & Singhal 2016 *J Environ Sci Health B*; Bogen & Heilman 2015 *Crit Rev Toxicol*).

Mechanistic Models of Tumorigenesis, Cancer Risk, and Low-Dose Dose Response. Chemical and radiogenic tumorigenesis and cancer risk assessment and associated risk policy issues have been continuing research interests of mine (Bogen 1980 *J Law Technol*; Bogen 1983 *J Health Politics Policy Law*; Lichtenberg et al. 1989 *J Environ Econ Management*; Bogen 1989 *J Natl Cancer Inst*; Bogen 1990 *Fund Appl Toxicol*;. Bogen 1994 *Mutat Res*; Layton et al. 1995 *Carcinogenesis*; Bogen 1995 *Molec Environ Mutagen*; Bogen et al. 1997 *Health Phys*; Bogen & Gold 1997 *Regul Toxicol Pharmacol*; Bogen 1998 *Hum Exper Toxicol*; Bogen 2001 *Hum Ecol Risk Assess*; Bogen & Witschi 2002 *Carcinogenesis*; Enns et al. 2004 *Molec Cancer Res*; Bogen 2008 *Risk Anal* [**SOT RASS Top-10 Publication Award**]; Bogen 2014 *Dose-Response*; Bogen 2014a-b *Risk Anal*; Bogen & Heilman 2015 *Crit Rev Toxicol*; Bogen 2016 *Risk Anal* [**SRA Best Paper of the Year Award**]; Bogen et al. 2017 *Toxicol Reports* [EPRI-funded research on low-dose dose-response for arsenic-induced cytotoxicity, on which I collaborated with Prof. Samuel Cohen at the University of Nebraska Medical Center]; Bogen 2017 *Risk Anal*; Bogen 2017 *Dose-Response*; Kerger 2017a-b *Human Ecol Risk Assess*; Bogen 2018 *Nucl Receptor Res*). As part of this

research focus, I proposed a new, epigenetic dysregulation-driven model of tumorigenesis and considered its dose-response implications (Bogen 2013 *Med Hypoth*; Bogen 2017 *Adv Molec Toxicol*). Related to this research focus, I served during 2016–17 as Chair-Elect and Chair of the Society for Risk Analysis Dose-Response Specialty Group.

Occupational, Environmental, Ecological, and Consumer Chemical Exposure & Risk Assessment. I have collaborated on published assessments of occupational, environmental, consumer-product, and ecological exposures to chemicals including benzene, formaldehyde, and pesticides (Sheehan et al. 2010, 2017 *Risk Anal*; Bogen & Reiss 2012 *Risk Anal*; Bogen & Sheehan 2014 *Risk Anal*). For the California Department of Justice I developed a screening-level assessment of hazards to children posed by multi-route exposure to six phthalates from consumer products regulated under California A.B. 1108 and Proposition 65 (Bogen and Goswami 2013 *report to CalDOJ*). As part of this research focus, I also developed the first published approach for quantitative assessment of sensitizer-specific risks of allergic contact dermatitis (ACD) elicitation in sensitized individuals, in relation to applied dermal load of a metallic or organic sensitizer, based on a new analysis of previously published clinical patch test data (Bogen & Garry 2017 *Risk Anal*). This new approach has broad potential applications to characterizing ACD-elicitation risks for occupational, medical-device, and consumer-product exposures (e.g., via sustained dermal contact incurred using wearable technologies—a burgeoning industry that already has experienced incidents of unexpected product-associated ACD elicitation).

Publications in Scientific Journals

Nault R, Bals B, Teymouri F, Black MB, Andersen ME, McMullen PD, Krishnan S, Kuravadi N, Paul N, Kumar S, Kannan K, Jayachandra KC, Alagappan L, Patel BD, Bogen KT, Gollapudi B, Klaunig JE, Zacharewski TR, Bringi V. A toxicogenomic approach for the risk assessment of the food contaminant acetamide. Toxicol Appl Pharmacol 2020; 388(Feb. 1):114872. doi: 10.1016/j.taap.2019.114872.

Bogen KT, Lewis RC, Singhal A, Sheehan PJ. Development of a novel method for estimating dermal contact with hand-applied cleaning solutions. Environ Monit Assess 2020; 192:157. doi: 10.1007/s10661-019-7929-7.

Bogen KT, Sheehan PJ, Valdez-Florez C, Li AA. Reevaluation of historical exposures to ethylene oxide among U.S. sterilization workers in the national institute of occupational safety and health (NIOSH) study cohort. Int J Envir Res Public Health 2019; 16:1738. doi: 10.3390/ijerph16101738.

Bogen KT. Inflammation as a cancer co-initiator: New mechanistic model predicts low/negligible risk at noninflammatory carcinogen doses. Dose-Response 2019; 17(2):1-12. doi: 10.1177/1559325819847834.

Bogen KT. Biphasic hCAR inhibition-activation by two aminoazo liver carcinogens. Nucl Receptor Res 2018b; 5:101321. doi: 10.11131/2018/101321.

Sheehan P, Singhal A, Bogen KT, MacIntosh D, Kalmes RM, McCarthy J. Potential exposure and cancer risk from formaldehyde emissions from installed Chinese manufactured laminate flooring. Risk Anal 2018; 38(6):1128–1142. doi: 10.1111/risa.12926.

Bogen KT, Garry MR. Risks of allergic contact dermatitis elicited by nickel, chromium, and organic sensitizers: Quantitative models based on clinical patch test data. Risk Anal 2018a; 38(5):1036–1051. doi: 10.1111/risa.12902.

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Kerger BD, Bogen KT, Loccisano AE, Lamb JC. Liver tumor potency indicators for technical toxaphene and congeners simulating weathered toxaphene. Human Ecol Risk Assess 2018a; 24(3):830–846. doi: 10.1080/10807039.2017.1401450.

Bogen KT. Low-dose dose-response for *in vitro* Nrf2-ARE activation in human HepG2 cells. Dose-Response 2017d; 15(2): 1559325817699696. doi: 10.1177/1559325817699696.

Bogen KT. Linear-no-threshold default assumptions are unwarranted for cytotoxic endpoints independently triggered by ultrasensitive molecular switches. Risk Anal 2017c; 37(10):1808–1816. doi: 10.1111/risa.12813.

Bogen KT, Arnold LL, Chowdhury A, Pennington KL, Cohen SM. Low-dose dose-response for reduced cell viability after exposure of human keratinocyte (HEK001) cells to arsenite. Toxicol Reports 2017b; 4:32–38. doi: 10.1016/j.toxrep.2016.12.003.

Bogen KT. A new theory of chemically induced tumorigenesis: Key molecular events and dose–response implications. Adv Molec Toxicol 2017a; 10:1–53. doi: 10.1016/B978-0-12-804700-2.00001-5.

Bogen KT, Singhal A. Malathion dermal permeability in relation to dermal load: Assessment by physiologically based pharmacokinetic modeling of *in vivo* human data. J Environ Sci Health, Part B 2016b; 52(2):138–146. doi: 10.1080/03601234.2016.1248150.

Bogen KT. Linear-no-threshold default assumptions for noncancer and nongenotoxic-cancer risks: A mathematical and biological critique. Risk Anal 2016a; 36(3):589–604. Open access: http://onlinelibrary.wiley.com/doi/10.1111/risa.12460/epdf **[Society for Risk Analysis Best Paper of the Year Award (2016)]**

Bogen KT, Heilman JM. Reassessment of MTBE cancer potency considering modes of action for MTBE and its metabolites. Crit Rev Toxicol 2015; 45 Suppl 1:1–56. doi: 10.3109/10408444.2015.1052367.

Bogen KT. Stem cell division, mutations, and cancer risk. Science 2015; 26 Jan [online comment]. http://comments.sciencemag.org/content/10.1126/science.1260825

Bogen KT. Unveiling variability and uncertainty for better science and decisions on cancer risks from environmental chemicals. Risk Anal 2014; 34(10):1795–1806. doi: 10.1111/risa.12290.

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Sheehan PS, Brorby GP, Berman DW, Bogen KT. Protecting good science. Ann Occup Hyg 2014; 58(2):267–268. doi: 10.1093/annhyg/met079.

Bogen KT. Mechanistic models fit to ED001 data on >40,000 trout exposed to dibenzo[*a*,*l*]pyrene indicate mutations do not drive increased tumor risk. Dose Response 2014; 12(3):386–403. doi: 10.2203/dose-response.13-019.Bogen. eCollection 2014.

Bogen KT, Sheehan PS. Dermal versus total uptake of benzene from mineral spirits solvent during parts washing. Risk Anal 2014; 34(7):1336–1358. doi: 10.1111/risa.12166.

Bogen KT. Efficient tumorigenesis by mutation-induced failure to terminate microRNA-mediated adaptive hyperplasia. Medical Hypotheses 2013; 80(1):83–93. doi: 10.1016/j.mehy.2012.10.017.

Bogen KT. Dermal uptake of 18 dilute aqueous chemicals: *In vivo* disappearance-method measures greatly exceed *in vitro*-based predictions. Risk Anal 2013; 33(7):1334–1352. doi: 10.1111/j.1539-6924.2012.01901.x.

Brorby GP, Sheehan PJ, Berman DW, Bogen KT, Holm SE. Exposures from chrysotile-containing joint compound: Evaluation of new model relating respirable dust to fiber concentrations. Risk Anal 2013; 33(1):161–176.

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Bogen KT, Reiss R. Generalized Haber's law for exponential concentration decline, with application to riparian-aquatic pesticide ecotoxicity. Risk Anal 2012; 32(2):250–258.

Sheehan PJ, Brorby GP, Berman DW, Bogen KT, Holm SE. Chamber for testing asbestos-containing products: validation and testing of re-created chrysotile-containing joint compound. Ann Occup Hyg 2011; 55(7):797–809.

Bogen KT, Brorby G, Berman DW, Sheehan P, Floyd M. Measuring mixed cellulose ester (MCE) filter mass under variable humidity conditions. Ann Occup Hyg 2011; 55(5):485–494.

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Bogen KT. Generic Hockey-Stick model for estimating benchmark dose and potency: performance relative to BMDS and application to anthraquinone. Dose-Response 2011; 9(2):182–208.

Sheehan P, Bogen KT, Hicks J, Goswami E, Brorby G, Lau EC, Ott B. Benzene inhalation by parts washers: new estimates based on measures of occupational exposure to solvent coaromatics. Risk Anal 2010; 30(8):1249–1267.

Bogen KT, Goswami E. Screening-Level Hazard Assessment for Six Phthalates Under A.B. 1108 and Proposition 65 (Rev. 1). Technical Report prepared by Exponent, Inc., for the Environment Section, Office of the Attorney General, California Department of Justice (CalDOJ), May 2009 (made public by CalDOJ, August 2009). Exponent Doc. no. 0800736.000 0601 0509 KB01. Exponent, Inc., Oakland, CA, 97 pp.

Bogen KT, Cullen AC, Frey HC, Price PS. Probabilistic exposure analysis for chemical risk characterization. Toxicol Sci 2009; 109(1):4–17.

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Bogen KT. High voltage electric power transmission lines: Impact on public and environmental health. Report No. 80-199. U.S. Library of Congress, Congressional Research Service, Washington, DC, 1980.

Presentations at Scientific Meetings

Dr. Bogen was first author or a contributing coauthor of presentations made at a total of 75 scientific meetings held during 1987–2019, including meetings held by the Society of Toxicology, the Society of Toxicology Contemporary Concepts in Toxicology (CCT–Toxicoepigenetics), the Society for Risk Analysis, the International Dose-Response Society, the American Industrial Hygiene Association, the Electric Power Research Institute (EPRI) and Air & Waste Management Association (A&WMA) Environmental-Vision (ENV-VISION) Conference, SETAC North America, the International Society of Exposure Science, the American Chemical Society (AGRO), the Northern California Chapter of the Society of Toxicology, the U.S. Department of Defense Prostate Cancer Research Program, the American Association for Cancer Research, the National Research Council Standing Committee on Risk Analysis Issues and Reviews, the 8th International Conference on Greenhouse Gas Technologies (GHGT8), the International Symposium on Site Characterization for CO_2 Geological Storage (CO2SC 2006), the American Geophysical Union, the 51st Annual Radiobioassay and Radiochemical Measurements Conference, the University of California Davis Health System Future Fair, the Health Physics Society 41st Midyear Topical Meeting, the University of California Davis Cancer Center Annual Cancer Research Symposium, the International Conference on Accelerator Mass Spectrometry, the International Society for Environmental Epidemiology (ISEE), the U.S. Department of Energy Office of Biological and Environmental Research Low Dose Radiation Research Program, the DOE/NASA Radiation Investigators' Workshop, and the Air Pollution Control Association. Complete list available at www.ktbogen.com.

UC/LLNL Key Research Projects

As a University of California environmental scientist at Lawrence Livermore National Laboratory (LLNL), Dr. Bogen served as PI and/or project leader of the following studies pertaining to environmental carcinogen risk assessment:

- PI, "Mode-of-Action uncertainty for dual-mode carcinogens: Lower bounds for naphthalene-induced nasal tumors in rats implied by PBPK and 2-stage stochastic cancer risk models," ORNL funded by USEPA ORD (2007). Project comprised drafting a white paper of USEPA regulatory interest addressing treatment of uncertainty in cancer risk estimated from animal bioassay data.

- PI, “PSA-Based Screening Outcome, Dietary Heterocyclic Amine Exposure, and Prostate Cancer Risk in African Americans,” DOD Prostate Cancer Res. Prog. competitive award W81XWH-05-1-0153 (2005-2007). A LLNL-led 3-year, partially overlapping supplement/extension of the 5-year clinic-based epidemiological study described just below, to expand the study to 700 men through 2007 and to add an additional (percent-free) PSA measure to the other prostate-cancer screening tests performed as described below. Collaborating investigators were based at Alta Bates Summit Hospital (Oakland, CA) and UC San Francisco Medical School.
- Project Leader, “Determining the Carcinogenic Significance of Heterocyclic Amines, Project 5: Prostate cancer screening and dietary HA exposure in African-Americans,” NIH/NCI P01 grant 2 NIH P01 CA55861-09A2 (2002-2006). A LLNL-led 5-year clinic-based epidemiological study of association between dietary exposure to cooked-meat (heterocyclic amine) mutagens (particularly, PhIP) and screening indicators of prostate cancer risk in 500 African-Americans. Collaborating investigators were based at Alta Bates Summit Hospital (Oakland, CA) and UC San Francisco Medical School.
- Co-investigator, “Environmental Epidemiology of Essential Tremor,” NIH/NINDS grant R01 NS03422 (2006-2010). This 5-year study of environmental and occupational risk factors for essential tremor, led by Dr. Elan Louis, M.D. of Columbia University Medical School, uses an LLNL-developed dietary meat-intake questionnaire and corresponding data analysis for 900 subjects planned over the period of study. In this work, a total of 1,235 meat questionnaires will be provided to Columbia University in annual lots, together with initial training on questionnaire interpretation and administration, and annual analysis of resulting data on estimated daily dietary intake of total heterocyclic amines (HAs), including the primary dietary HA (PhIP), for each participant completing a questionnaire.
- PI, “Retrospective Plutonium Biodosimetry by Modeling Urinary ^{239}Pu from Archived Occupational Samples,” 3-year LLNL competitively awarded RandD project 01-ERD-108 (2001-2003). This project successfully developed and demonstrated the application of accelerator mass spectrometry (AMS)--which is ~20- to 40-fold more sensitive than traditional alpha spectrometry methods for the purpose of Pu-exposure assessment--to analyze archived alpha-spectrometry urinalysis disks obtained from LLNL Pu workers in accordance with an approved LLNL IRB protocol. This study showed that AMS can be used to recover otherwise inaccessible information on urinary Pu excretion patterns over 10- to 20-year periods.
- PI, “DNA Damage vs. Cell Killing by Low-Dose-Rate Radiation: Ultrasensitive Measures, and Implications for Mechanistically Modeled Cancer Risk,” USDOE Low Dose Res. Prog. and Cross Cancer Institute, Alberta Cancer Board (2000-2002). This 3-year study developed and applied a gel-microdrop flow cytometry assay to assess low-dose dose-response of gamma-radiation-induced cell killing in human cells *in vitro*. This study showed that a previously well characterized “hyper-radiosensitivity” (HRS) low-dose dose-response phenomenon is induced very early after radiation exposure and that its underlying molecular mechanism involves dose-induced suppression of p53-triggered “apoptosis” or programmed cell death.

Research Awards & Honors

Wolfram Innovator Award (2020), Wolfram Research (www.Wolfram.com); see https://www.businesswire.com/news/home/20201009005493/en/Wolfram-Research-Announces-Innovator-Award-Winners-for-2020,https://www.wolfram.com/events/technology-conference/innovator-award/2020/

Society for Risk Analysis Best Paper Award (2016), for: Bogen KT. Linear-no-threshold default assumptions for noncancer and nongenotoxic-cancer risks: A mathematical and biological critique. Risk Anal 2016; 36(3):589–604.

Society of Toxicology, Risk Assessment Specialty Section, Top 10 Publications in 2008 Demonstrating an Application of Risk Assessment (2008), for: Bogen KT. An adjustment factor for mode of action uncertainty with dual-mode carcinogens: The case of naphthalene-induced nasal tumors in rats. Risk Anal 2008; 28(4):1033–1051.

Society for Risk Analysis Best Paper Award, Decision Science (2006), for: Bogen KT, Jones ED. Risks of mortality and morbidity from worldwide terrorism: 1968–2004. Risk Anal 2006; 26(1):45–59.

Scientific Journal Editorial & Review

- *Adv Water Resources* (Reviewer)
- *Chemosphere* (Reviewer)
- *Crit Rev Toxicol* (Reviewer)
- *Dose Response* (Reviewer)
- *Environmental and Molecular Mutagenesis* (Reviewer)
- *Fd Chem Toxicol* (Reviewer)
- *J Expos Sci Environ Epi* (Reviewer)
- *Int J Oral Science* (Reviewer)
- *Med Hypotheses* (Reviewer)
- *Risk Anal* (Editorial Board member, May 2008 – May 2013; Reviewer)
- *Toxicol Sci* (Reviewer)
- *Water Resources Res* (Reviewer)

Professional Affiliations

- Society of Toxicology (Full Member, 2008–present)
- Society for Risk Analysis (1984–present)
- Toxicology Forum (2008–2012)
- American Association for Advancement in Science (1979–present)

Appendix
Key Projects Involving Dr. K.T. Bogen (2008–2019)[3]

Acetamide Biokinetic Modeling & Toxicity Assessment (2018–2019). Retained by the Michigan Biotechnology Institute (MBI) to perform acetamide biokinetic modeling and toxicity assessment to support regulatory evaluation of nutrient-boosting livestock feed-modification methods designed to ameliorate world hunger, as part of an R&D project funded by Gates Foundation. Using custom *Mathematica*® software, modeled and fit a large set of experimental data obtained by MBI pertaining to the biokinetics of excess acetamide appearing in plasma (sampled periodically) and in liver (at terminal sacrifice) of male and female Wistar rats after daily oral gavage exposure to six different acetamide doses for 1 or 28 days. Also developed and applied a novel approach to characterize dose-response patterns for altered gene expression in Wistar rats administered acetamide for 28 days.

Historical occupational Exposure to Ethylene Oxide (2018–2019). Collaborated on developing and implementing an Exponent historical occupational exposure assessment for ethylene oxide industry workers from the late 1930s to 1978, a critical comparison of these assessment results to predictions made by a published model developed by the National Institute for Occupational Safety and Health (NIOSH) during the 1990s, and assessment of implications of this comparison on the scientific credibility of ethylene oxide exposure assumptions used by NIOSH and the U.S. Environmental Protection Agency to evaluate conditions incurred by a large NIOSH epidemiological study cohort of workers exposed historically to ethylene oxide. This work was subsequently published (Bogen et al. 2019 *Int J Envir Res Public Health*).

Allergic Contact Dermatitis Risk Assessment (2013–2017). At Exponent designed and directed development of new capability to quantify risk of allergic contact dermatitis (ACD) elicited by sustained dermal contact with chemical or metallic allergens (sensitizers), based on a novel analysis of published human clinical patch test data (Bogen & Garry 2017 *Risk Anal*). In contrast to previous that classify relative potency for the first (*sensitization*) phase of the two-phase ACD (i.e., delayed, or Type IV hypersensitivity) immune reaction, the new approach is the first and only method allowing quantitative assessment of risk for inducing the second and more sensitive (*elicitation*) phase of ACD in sensitized individuals, and has been applied by Exponent to inform U.S. wearable-technology manufacturers after detecting one or more sensitizers in product-specific leach tests.

Benzene from Parts-Washing and Gasket-Removal Solvents (2007–2009, 2017). At Exponent developed novel approach to estimate litigation-related average occupational inhalation, dermal, and total benzene exposures incurred during parts washing, using: a) data on historical concentrations of benzene in recycled parts-washing solvent (PWS); b) models fit to measures of benzene and toluene volatilization from PWS over time; c) statistical analysis of paired measurements of benzene and other aromatic compounds in PWS and in worker air during parts-washing activities that were measured by the National Medical Advisory Service at 16 parts washing facilities; d) a collaborative application of the universal functional activity coefficient (UNIFAC) thermodynamic equation-of-state approach to estimate activity as a function of mole fraction for non-ideal binary solutions volatilized from an PWS-like hydrocarbon blend; and e) a two-process model of benzene uptake from dermally contacted PWS that developed using results from IRB-approved experiments that measured rates of PWS uptake into human skin *in vivo* (Sheehan et al. 2010, 2017 *Risk Anal*; Bogen & Sheehan 2014 *Risk Anal*).

Furfuryl Alcohol Cancer Risk (2016). At Exponent funded by a U.S. food manufacturer, developed proposed no-significant risk level (NSRL) values for furfuryl alcohol, identified as a carcinogen under California Proposition 65 (Prop 65) addressing National Toxicology Program (NTP) cancer bioassay data

[3] Citations below refer to publications listed in my resume.

involving elevated rates of nasal tumors in male rats and kidney tumors in male mice, analyzed using U.S. EPA Benchmark Dose software.

***Tert*-Butyl Alcohol Carcinogenicity** (2016). Retained at Exponent by the American Petroleum Institute (API) to prepare and to submit to the U.S. Environmental protection Agency (EPA) IRIS TBA public docket a response to that Agency's IRIS Toxicology Review of *tert*-butyl alcohol (TBA). The resulting comments ("Technical Comments Submitted to U.S. EPA Docket ID No. EPA-HQ-ORD-2013-0111 Concerning the IRIS Draft Toxicological Review of *tert*-Butyl Alcohol: Relevance of Rat Kidney and Mouse Thyroid Tumors," 24 pp.) were submitted to EPA on July 15, 2016.

Arsenic-Induced Cytotoxicity Dose Response (2015). At Exponent obtained funding by the Electric Power Research Institute (EPRI) for a ~$250K collaborative research project with Professor Samuel Cohen at the University of Nebraska Medical Center to investigate high-resolution low-dose dose-response for reduced viability of cells exposed to inorganic arsenic *in vitro*—work later published (Bogen et al. 2017 *Toxicol Reports*).

Formaldehyde Exposure Characterization (2014–2016). Contributed to Exponent assistance to a U.S. manufacturer of formaldehyde-emitting laminated flooring products in its meetings with the U.S. Consumer Product Safety Commission and in product-related litigation support. To address potential exposure concerns, the manufacturer had tested the largest-ever set of measured formaldehyde emission rates from samples of new laminated flooring, using standard small chamber test methods; after obtaining residents' consent, this manufacturer also gathered the largest-ever set of in-home measures of formaldehyde in air and corresponding small-chamber-test measures of rates of formaldehyde emission rates from samples of previously installed laminated flooring. I supervised the analysis of this combined data set at various stages of data acquisition; I fit the final combined set of measured formaldehyde emission rates in relation to time since flooring installation; and, using home survey data also obtained, I developed a stochastic flooring-attributable household formaldehyde concentration model and implemented this model using Monte Carlo methods to calculate corresponding variability distributions of inhaled formaldehyde and associated potential cancer risk. This work was later published (Sheehan et al. 2017 *Risk Anal*).

Prop 65 Compliance for Chemicals Migrated from Paperboard Food Packaging Products (2012–2015). Exponent developed and delivered for use by American Forest and Paper Association (AF&PA) members an Excel-based Computer Tool for determining maximum concentrations that comply with California Proposition 65 (Prop 65) for a wide array of chemicals that all are listed as reproductive toxins and/or carcinogens under Prop 65 and that may be present in an array of different types of paperboard products manufactured by AF&PA members for food/beverage packaging applications. Designed the physico-chemical regression modeling approach that was, in a competitive review process, selected by AF&PA to serve as the basis for developing this Tool. Derived the entire suite of empirically based physico-chemical regressions and temperature-dependent models of chemical-specific vapor pressure that the Tool incorporates to predict mass-transport of chemicals from paperboard to contacted food later ingested, to skin, and to inhaled air. Collaborated on model application by the Tool to product-category-specific multi-route exposure scenarios for consumers/workers who contact such products and/or ingest product-contained foods. The Tool is now used by AF&PA members to evaluate Prop 65 compliance of existing and proposed paperboard packaging products, and periodically has been updated to address >120 chemicals that may occur in paperboard food/beverage packaging products. Co-authored related journal manuscripts.

Development of Human Biokinetic Model for Ni (2012–2018). Exponent was retained by a Minnesota medical-device manufacturer to do a biokinetic analysis of nickel released from each of a series of nitinol cardiac plug medical devices *in vivo* and *in vitro*. To support this effort, modified previously published human biokinetic models for nickel, fit this new model to previously published human biokinetic data for nickel using custom *Mathematica*® software, and applied the model to predict rates of nickel release

expected to occur after *in vivo* surgical implantation of each device considered. Later retained by the Nickel Producers Environmental Research Association (NiPERA) to further develop and then validate the nickel model using additional unpublished human data obtained by NiPERA, apply this model to evaluate individual occupational exposures to nickel, and prepare a related journal manuscript.

Characterization of Asbestos Exposure from Joint Compound (2007–2014). Contributed to experimental designs for and provided statistical and modeling analysis of data from Exponent experiments performed for a U.S. manufacturer to reconstruct historical human exposures to chrysotile asbestos contained historically in joint compound—work subsequently published (Brorby et al. 2011 *J Occup Environ Hyg*; Bogen et al. 2011 *Ann Occup Hyg*; Sheehan et al. 2011 and 2014 *Ann Occup Hyg*; Berman et al. 2012 *Ann Occup Hyg*; Brorby et al. 2013 *Risk Anal*).

Lead Exposure Characterization Under Prop 65 (2012–2016). At Exponent developed a *Mathematica*® software implementation of a human biokinetic model for lead published by Leggett in 1993 that predicts age-specific blood lead levels over time in relation to user-specified, time-specific, oral and/or inhalation exposure(s) to defined amounts of lead. I later implemented a *Mathematica*® software version of a Leggett-model update called the Leggett+ human physiologically based pharmacokinetic (PBPK) model for lead reported in 2013 by the California Environmental Protection Agency, Office of Environmental Health Hazards Assessment (OEHHA). Later retained by the California Chamber of Commerce to evaluate the accuracy of the OEHHA Leggett+ model, which had been implemented by OEHHA in MatLab® software—an analysis that identified a coding error in initially released OEHHA Leggett+ software that later was corrected by OEHHA.

Low-Dose Dose Response (2013–2014). At Exponent I prepared a manuscript to address mathematical and biological problems raised by the National Research Council (2009) *Science and Decisions* report recommendation to apply default low-dose linear assumptions for noncancer endpoints, and further developed this manuscript with funding by the Arsenic Task Force. The resulting published paper (Bogen 2016 *Risk Anal*) received a *Society for Risk Analysis Best Paper of the Year* award.

Neurotoxicity Risk of Zinc from Nasal Gel (2012). At Exponent was retained by an Arizona manufacturer of a zinc-containing nasal cold-remedy gel to predict the likelihood of a key neurotoxic endpoint (anosmia), involving olfactory receptor neuron (ORN) cells located relatively high in the nasal cavity that are required for the sense of smell, after single or repeated use of the gel product applied in a manner consistent with package instructions. Adapted a mathematical model of the human nasal cavity and mucous-covered surface epithelium adapted from a highly detailed (>500,000-vertex) 3D anatomical model estimated from MRI images of 30 male and female patients, and using this model applied a grid-based surface-diffusion algorithm implemented in *Mathematica*® software to realistically reflect zinc-ion diffusion into mucosal fluid covering the rather complex surface geometry of the human nasal cavity. ORN toxicity likelihood predicted by combining this model with a) data obtained from experiments conducted to quantify the droplet size distribution of gel dispensed from the product dispenser, b) published data on location and dispersion of nasally inhaled droplets, and c) a toxic-load model fit to published data on olfactory neurotoxicity vs. zinc concentration and exposure duration.

Household MTBE Exposure After Gasoline Tank Leak (2012). At Exponent was retained as a designated expert toxicologist in the civil lawsuit *Ayala et al. v. The Carroll Independent Fuel Company et al.* before the Circuit Court for Frederick County, Maryland, concerning alleged chronic human exposures primarily to the gasoline additive (fuel oxygenate) chemical methyl *tert*-butyl ether (MTBE) in groundwater. I prepared a 328-page expert report providing opinions addressing MTBE absorption, distribution, metabolism, and excretion; genotoxicity of MTBE and its metabolites; tumorigenicity of MTBE and its metabolites; modes of action for tumors associated with exposure to MTBE and/or its metabolites; and characterization of MTBE cancer potency. The case was settled just prior to scheduled deposition, but expert report was adapted and published as 134-page article in a leading toxicology journal (Bogen & Heilman 2015 *Crit Rev Toxicol*).

Diethanolamine Cancer Risk (2012). Lead author of an Exponent technical report to a U.S. manufacturer proposing no-significant risk level (NSRL) values for diethanolamine and a related chemical that in 2012 were identified as California Proposition 65 (Prop 65) carcinogens based on National Toxicology Program (NTP) cancer bioassay data indicating elevated liver tumors and marginally elevated kidney tumors in mice (but not rats) after chronic dermal administration. Based on a detailed analysis of dose-response and carcinogenic mode-of-action (MOA) data, different NSRL levels were proposed using alternative genotoxic and nongenotoxic MOA assumptions, the latter being concluded as more likely in view of available mechanistic evidence.

4-MEI Cancer Risk (2011–2012). Authored two Exponent technical reports to the American Beverage Association and International Technical Caramel Association addressing Proposition 65 compliance issues concerning the chemical 4-methylimidazole (4-MEI) in caramel food coloring. These reports hypothesized a novel, nongenotoxic mode of action (MOA) for mouse lung tumors induced by 4-MEI and propose a no-significant risk level (NRSL) for 4-MEI in view of MOA considerations.

Post-Spill Inhalation & Dermal Exposure Assessment (2011). Contributed to Exponent assessments of dermal and respiratory exposures that arose from the British Petroleum oil spill, including development and application of real-time wind-direction data to show that real-time air monitoring data collected during the event were inconsistent with hypothesized event-caused increases in concentrations of onshore event-related chemicals measured in air. Also contributed to assessments of dermal exposures to event-related beach-deposited chemicals, by deriving chemical-specific permeability coefficients and applying these to estimate corresponding chemical exposures associated with conservative dermal contact scenarios.

Phthalate and Formaldehyde Exposure from Children's Playwear and Sleepwear (2008). At Exponent was retained as Defendant's expert toxicologist in a California litigation matter, *Laurie M. Montanez and Jehan Hughes v. Gerber Childrenswear*, concerning dermal exposure to and absorption of phthalate formaldehyde chemicals from tagless labels on children's playwear and sleepwear clothing. Prepared related Declaration and was deposed in this matter.

Cobalt Risk from a Medical Device (2008). Lead author of an Exponent technical report ("Potential Chronic Toxicity of Tungsten Carbide and Cobalt Residue from the Next Generation SilverHawk") addressing potential U.S. FDA regulatory concerns of interest to a California medical-device manufacturer about cobalt residues released by their newly designed surgical cutting device. This report addressed potential toxicity and cancer risk posed by systemically distributed particulate cobalt residue, and results from applications of an adaptation of a published human biokinetic model for cobalt implemented using *Mathematica*® software.