10:00 to 11:00

Safe Harbor Levels and Exposure Assessments: Best Practices in Assessing Prop. 65 Compliance

Moderator: **Judith Praitis**, Partner, Faeger Drinker Biddle & Reath

Panel: **Steven Boomhower**, Principal Scientist, Gradient

Renee Kalmes, Principal, Exponent

Martha Sandy, Chief, Reproductive & Cancer Hazard Assessment Branch, OEHHA

Margaret Whittaker, Managing Director and Chief Toxicologist, ToxServices

Bios

Judith Praitis
Partner, Faegre Drinker Biddle & Reath

Judith Praitis counsels clients on environmental transactional issues and on air, water and waste management permitting, compliance, release reporting and enforcement issues under California and federal law. With decades of experience in environmental law, Judith is a trusted source of legal and business guidance for clients working to develop and implement environmental management systems, audit compliance protocols, and anticipate and adapt to emerging regulatory environments. Judith has particular experience managing complex environmental matters for distressed entities, or those with material legacy environmental liabilities, to orchestrate a controlled resolution of such obligations. She is particularly adept at crafting novel settlements with governmental regulators and prosecutors.

Judith advises clients on compliance with and, if necessary, litigation of, Proposition 65 matters, particularly those involving the food and supplement industries and other consumer products. She assists clients with compliance under many of California's product- and chemical-specific regulatory regimes, including the Green Chemistry Initiative.

Judith's Proposition 65 representations include some of the most significant and complex matters involving the legislation, including several prosecuted by the Office of the Attorney General of the State of California. Her Proposition 65 work includes cases involving:

· Bottled water
· Chocolate
· Ginseng
· Progesterone creams
· Brass fixtures
· Children's vitamins
· Dietary supplements
· Supplements containing alcohol
· Meal replacement bars
· Textiles
·Glassware
·Electrical cords
·Plastic and vinyl products
·Alleged exposures at hotels

Education

Harvard Law School
J.D. in Law, cum laude (1988)
University of Chicago
A.B. in Political Science, with honors, Phi Beta Kappa (1985)

Professional Associations

·Environmental Law Institute — Leadership Council Member
·American Bar Foundation — Fellow
·Proposition 65 Advisory Board
·Annual California Cliff Conference — Co-chair
·2016 Proposition 65 Clearinghouse Annual Conference — Chair

Steven Boomhower
Principal Scientist, Gradient

Dr. Boomhower is a principal scientist at Gradient and has worked on multiple projects involving the application of principles and methods in toxicology, exposure science, and risk assessment to assess compliance with Proposition 65. His scientific work related to Proposition 65 has been recognized by the Risk Assessment Specialty Section of the Society of Toxicology. Dr. Boomhower also teaches courses in toxicology and pharmacology as an instructor at Harvard University, and he has served as an invited adjunct lecturer at Georgetown University.

Renee Kalmes
Principal, Exponent

Ms. Kalmes is a certified industrial hygienist with over 25 years of experience. In this role, she is responsible for designing, conducting, and managing technical studies addressing community, occupational and consumer exposure to chemical agents, including studies to simulate and reconstruct potential worker and residential historical exposures to asbestos, nanoparticles, benzene, formaldehyde, styrene, silica, carbon monoxide, phthalates, lead, metals, and a variety of volatile organic compounds (VOCs).

Ms. Kalmes also specializes in conducting and directing studies to assess potential exposure to consumer and personal care products, including evaluation of lead, cadmium, phthalates, silica, trace constituents (i.e., solvents, benzene, toluene, ethyl benzene), diethanolamine (DEA), arsenic, formaldehyde, bisphenol A (BPA), bisphenol S (BPS), PFAS and flame retardants. She has developed sampling protocols to evaluate FDA, CPSC, and Proposition 65 claims, specifically addressing dermal contact and incidental ingestion associated with hand-to-mouth activities. She has provided exposure assessment and toxicology support for consumer product recall claims. Ms. Kalmes has assisted numerous companies in establishing programs to address Proposition 65, restricted chemical listings, and green chemistry initiatives.

Ms. Kalmes has performed comprehensive health investigations related to industrial settings, environmental contamination, and indoor air quality, including indoor air quality assessments evaluating building material emissions, groundwater vapor intrusion and carbon monoxide exposure. She has conducted industrial hygiene surveys, environmental audits for the public and private sector, and provided recommended strategies for worker health and safety compliance programs, including preparation and review of Safety Data Sheets (SDSs) for silica, beryllium, PFAS and formaldehyde-containing products. Ms. Kalmes' evaluations included review of safe chemical handling procedures, spill and leak procedures, use of personal protective equipment, ventilation, and employee training and chemical inventory procedures. Ms. Kalmes has developed and conducted more than 100 hazard communication training programs.

Ms. Kalmes has taught numerous courses on risk assessment, industrial hygiene, and toxicology at the University of California Extension Program. Ms. Kalmes has been an invited speaker at numerous professional conferences and is frequently invited to speak and lecture on exposure assessment methods. Ms. Kalmes often interacts with local and state regulatory agencies and has testified as an expert in the area of exposure assessment, industrial hygiene, Proposition 65, Hazard Communication, and human health risk assessment.

Academic Credentials: M.S., Air and Industrial Hygiene, University of North Carolina, Chapel Hill, B.S., Purdue University

Martha Sandy

Chief, Reproductive & Cancer Hazard Assessment Branch, OEHHA

Dr. Sandy is Chief of the Reproductive and Cancer Hazard Assessment Branch in the California Environmental Protection Agency's (Cal/EPA) Office of Environmental Health Hazard Assessment (OEHHA). Dr. Sandy's Branch conducts scientific evaluations to identify, assess, and characterize cancer and reproductive hazards, and, together with California's Departments of Public Health and Toxic Substances Control, implements the State's chemical biomonitoring program. Prior to joining OEHHA, Dr. Sandy's research included investigations of biochemical and molecular mechanisms of carcinogenicity and cytotoxicity, and as well as biochemical and genetic susceptibility factors in Parkinson's disease. She has served on scientific committees for the National Toxicology Program, the U.S. Environmental Protection Agency, the National Academy of Sciences, and the International Agency for Research on Cancer. Dr. Sandy has a Ph.D. and an M.P.H. in Environmental Health Sciences, with an emphasis in Toxicology, from the University of California, Berkeley's School of Public Health.

Margaret Whittaker

Managing Director and Chief Toxicologist, ToxServices

Dr. Margaret "Meg" Whittaker is the Managing Director and Chief Toxicologist of ToxServices LLC. She is an accomplished human health risk assessor, chemical hazards assessor, and alternatives assessor. Dr. Whittaker performs quantitative exposure and risk assessments for projects including California Proposition 65 safe harbor assessments, medical device extractables and leachables assessments, consumer product safety assessments, and cosmetics/personal care product assessments, among others. Dr. Whittaker is a Diplomate of the American Board of Toxicology who earned a Ph.D. in Toxicology from The University of Maryland, Baltimore and an M.P.H. in Environmental Health from The University of Michigan. Dr. Whittaker is a U.K./EuroTox Registered Toxicologist, as well as a Chartered Biologist and Fellow of the U.K. Royal Society of Biology. Meg has served as an officer on multiple SOT Specialty Section and Regional Chapters, including the Metals Specialty Section, Mixtures Specialty Section, Sustainable Chemicals for Contemporary Toxicology (SCCT) Specialty Section, and the National Capital Area Chapter of SOT. She served as a member of the SOT Nominating Committee from 2021- 2023, and has served as an SOT Roving Reporter since 2014.