

# Ann E. Bradley

## Senior Consultant



### Education and Credentials

M.P.H., Environmental and Occupational Health Sciences, Risk Assessment Concentration, University of Washington, Seattle, Washington, 2004

B.S., Biological Sciences, minor Environmental Sciences, Carnegie Mellon University, Pittsburgh, Pennsylvania, 2000

### Continuing Education and Training

Project Manager Boot Camp Training, PSMJ Resources Inc. (2015)

Hazardous Waste Operations and Emergency Response 40-Hour Certification (2009; 8-Hour refresher 2010)

### Professional Affiliations

Member, Product Stewardship Society (2015 to present)

Member, Society for Toxicology (2011 to present)

Member, Society for Risk Analysis (2005 to 2010)

Member of Society for Environmental Toxicology and Chemistry (2009 to 2010)

Member, International Society for Exposure Science (2007 to 2009)

Board Member, National Capitol Area Chapter, Society for Risk Analysis (2005 to 2008)

## Professional Profile

Ms. Ann Bradley is a toxicologist and risk assessor with more than 15 years of experience in the health and environmental science fields. Her particular areas of expertise include site- and chemical-specific risk assessments and toxicological assessments. As lead human health risk assessor and toxicologist on her projects, Ms. Bradley provides leadership and direction in all aspects of human health risk assessment under CERCLA and other regulatory programs. She has extensive experience evaluating the potential health impacts of metals, pesticides, PCBs, dioxins, and PAHs through multi-media exposures. Ms. Bradley also leads exposure and toxicological assessments of chemicals in consumer products to support regulatory compliance, including under Proposition 65 (Prop 65). Her work has included the design and implementation of both deterministic and probabilistic (i.e., Monte Carlo) risk assessments aimed at understanding the influences of uncertainty and variability in exposure patterns and risk results.

Ms. Bradley is skilled in conducting toxicological evaluations to develop health-based criteria used to derive cleanup goals. She has successfully petitioned to alter such criteria, and has proposed new criteria for chemicals without established criteria. Her professional interests include determining methods for integrating findings of divergent data types to inform decision-making.

## Relevant Experience

### Risk Assessment

***Human Health Risk Assessment for Extended Floodplain, New York***—Leading human health risk assessment activities for an extended river floodplain area in New York State where PCBs have been identified. The 100-year floodplain of the river extends into approximately 2,500 individual properties, including parks, public land, residential parcels, schools, undeveloped land, agricultural properties, and commercial/industrial areas. Developing strategic approaches and overseeing the execution of the human health risk assessment.

***Risk Assessment for a Former Wood Treatment Facility under CERCLA, Mississippi***—Led human health risk assessment for a former wood treatment facility under CERCLA. Created plan for



multi-incremental sampling of dioxin in residential areas and evaluated the data using human health criteria to inform yard removals.

***Risk Assessment for a Former Wood Treatment Facility under RCRA, Mississippi***—Led human health risk assessment for a former wood treatment facility under RCRA. Developed a plan for sampling to fill data gaps and oversaw project team in conducting and reporting human health risks for the facility and off-facility areas.

***Risk Assessment for a Former Wood Treatment Facility, North Carolina***—Leading a human health risk assessment for a former wood treatment facility under CERCLA. Work includes developing sampling strategies for the collection of data needed to perform risk assessments and performing risk assessments.

***Risk Assessment for a Watershed, New Jersey***—Completed human health risk assessment for an RI/FS conducted for the Berry's Creek watershed, a Superfund site located in the Meadowlands. Chemicals of interest included mercury and other metals and PCBs.

***Risk Assessment of PCB Residues at a Former Natural Gas Facility, Texas***—Led risk assessment of PCBs in soils at a former natural gas facility in Texas. Soils from the former facility had migrated to adjoining ranch land that was actively used for grazing. The focus of the risk assessment was to assess whether the PCBs could be taken up by vegetation and enter the food chain of the grazing cattle and native species. The risk assessment predicted potential human exposures and helped to support management decisions for the site.

***Human Health Risk Assessment, San Jacinto River Waste Pits, Harris County, Texas***—Led project team in conducting the baseline human health risk assessment to support remediation efforts at the San Jacinto River Waste Pits Superfund site. The site is a closed facility for storage of bleached kraft pulp mill waste deposited in the 1960s. Chemicals of concern include dioxins and furans and PCBs. The completed risk assessment relied on threshold-based toxicity criteria to describe dioxin cancer toxicity. Site-specific fish ingestion rates were developed based on regionally available information.

***Risk Assessment, Former Mining Site, Illinois***—Developed sample planning documents to support risk assessment and remedial planning. Constituents of concern include lead and other metals. Residential sampling was planned in accordance with EPA's *Superfund Lead-Contaminated Residential Sites Handbook*. Completing human health risk assessments for residential properties, recreational ball field, and adjacent areas using EPA's IEUBK model and ALM.

***Risk Assessment and Evaluation of Liability, Fox Point Park, Wilmington, Delaware***—Participating in the site investigation and leading the human health risk assessment being conducted in the area of the Delaware River adjacent to Fox Point State Park. The state park was created historically using industrial fill material and later was used for the storage and stockpiling of sewage sludge. Constituents of concern include metals, PCBs, and PAHs. Completed an evaluation of liabilities associated with the remediation at the state park. Participated in



developing sampling strategies and approaches for human health risk assessment to be completed for the site.

***Risk Assessment, Cut Bank, Montana***—Completed human health risk assessment for an old oil refinery and transportation and storage terminal. Constituents of concern included petroleum hydrocarbons and PAHs. The risk assessment was completed under Montana’s Comprehensive Environmental Cleanup and Responsibility Act.

***Evaluation of Industrial Complex, Henderson, Nevada***—Provide technical and strategic support to address human health risks associated with groundwater and surface soil contamination at an industrial complex. Site-related constituents include pesticides, asbestos, PCBs, dioxins, and volatile chemicals. Participated in the development of the risk assessment work plan and conducted data usability evaluation. Ongoing work includes fate, transport, and exposure modeling; toxicity evaluation; and uncertainty analysis.

***Sample Planning for Industrial Complex, Henderson, Nevada***—Developed sampling plans to support risk assessment and remedial planning for site surface and subsurface soils. Reviewed EPA guidance on sample design and environmental data collection. Performed statistical calculations to determine adequate sample size.

***Formerly Used Defense Site Inspections***—Performed and reviewed screening level human health and ecological risk assessments for more than 25 sites. Compounds of concern were munitions-related constituents. Assessed the adequacy of risk screening levels and the appropriateness of toxicological surrogates to fill gaps in chemical-specific, risk-based screening levels.

***Probabilistic Risk Assessment for Fish Consumption, Portland, Oregon***—Evaluated uncertainty and variability for risks associated with fish consumption using probabilistic techniques. Contaminant of concern was PCBs. Researched uncertainty and variability in key parameters, including fish consumption and losses to PCBs via various cooking techniques to determine appropriate distributions for assessment. Completed risk modeling with Monte Carlo software.

***West Nile Virus, Suffolk County, New York***—Calculated exposure point concentrations for human health risk assessments of various vector control agents used in Suffolk County, New York. Reviewed methodologies and calculations for various components of human health and ecological risk assessments.

***Brownfields Redevelopment, West Virginia***—Provided risk assessment support for multiple redevelopment sites. Performed risk calculations for worker and residential exposure scenarios. Employed EPA’s Johnson and Ettinger model to evaluate vapor intrusion of volatile compounds. Calculated preliminary remediation goals for groundwater using human health methodologies.

***Former Pesticide Facility, California***—Assembled toxicity values for constituents of concern. Performed risk calculations for worker and residential exposure via routes of dermal absorption and ingestion. Performed uncertainty analysis for upper bound risks.



***Metal Smelter Risk Assessment, South America***—Completed toxicological profiles for metals including arsenic, lead, copper, and thallium. Provided assistance in performing human health risk calculations for chemicals of concern in indoor and outdoor dust, soil, drinking water, and air.

***Upper Columbia River, Washington***—Critically reviewed risk assessment for recreational beach use. Examined risk assessment methodologies, assumptions, calculations, and risk communication.

***Smelter Site, British Columbia***—Prepared toxicological profile for arsenic. Reviewed literature related to inhalation, oral, and dermal routes of arsenic exposure. Assessed strengths and weaknesses of studies to inform the residential risks being evaluated at the site.

***Dioxin Risk Assessment***—Reviewed literature on dioxin risk assessment methodologies to inform human health risk assessments. Examined literature on the half-life of dioxin and dioxin-like compounds in humans and mice to determine the appropriateness of the scaling factor used to account for relative differences in species half-lives. Prepared materials for National Academy of Sciences public meetings regarding the dioxin reassessment.

***Coeur d'Alene Superfund Site, Idaho***—Participated in the review of the Lake Coeur d'Alene basin public health assessment. Integrated information from current scientific literature on lead toxicity into the assessment. In response to community concerns, addressed residential exposure to heavy metals surrounding The Trail of the Coeur d'Alenes.

## **Toxicology**

***Carcinogenicity Assessment of Lindane and Isomers and Petition to Change Regulatory Toxicity Criteria***—Performed technical review of toxicological literature for three hexachlorocyclohexane (HCH) isomers (lindane, alpha-HCH, beta-HCH) with the aim of determining the critical effect and deriving scientifically based toxicity criteria with which to regulate human health. The assessment included the critical review of more than 200 studies from the primary literature, an evaluation of the most sensitive target endpoint, a review of the carcinogenicity, and an assessment of the mode of action by which each isomer elicits toxicity. Synthesized the weight of evidence for the carcinogenic potential and the mode of action for toxicity using principals and frameworks set forth by EPA and the International Programme on Chemical Safety. Toxicity criteria were determined using several approaches including EPA's benchmark dose modeling software. Criteria were reviewed and accepted by the Nevada State regulatory agency for use.

***Surrogate Toxicity Development, Former Pesticide Facility, Nevada***—Developed human health toxicological criteria for two organic acids that are of concern in groundwater. Performed extensive literature search to identify potential surrogate candidates. Evaluated biochemical mechanisms of action, structure activity relationships, and available *in vivo* and *in vitro* toxicological data. Criteria were reviewed and accepted by the Nevada State regulatory agency for use.

***Critical Review of the Toxicity of p-Toluic Acid to Inform Regulatory Standard, North Carolina***—Conducted a technical review of the toxicity basis for regulatory standard for *p*-toluic acid. Review



utilized a weight-of-evidence approach that evaluated *in vivo* and *in vitro* test results, chemical surrogates, and metabolically relevant compounds.

***Sulfolane Toxicology Review, Confidential Location***—Reviewed and summarized published literature and state regulations regarding potential human health effects from sulfolane in groundwater. Provided technical support for the development of groundwater cleanup levels.

***1,2,3-Trichloropropane (TCP) Toxicity Assessment***—Performed critical review of EPA’s toxicological review for 1,2,3-TCP. Evaluated the application of risk assessment principles including benchmark dose and cancer risk assessment methodologies.

***Arsenic Toxicity Assessment***—Critically reviewed Agency for Toxic Substances and Disease Registry’s *Draft Arsenic Toxicological Profile*. Evaluated peer-reviewed literature to determine adequacy for inclusion in the toxicological profile. Evaluated strength of evidence for health effects related to arsenic exposure.

***DDT Toxicity Assessment***—Compiled and critically reviewed literature on the reproductive toxicity and bioaccumulation of DDE in bird species. Assigned rankings regarding the usability of literature based on outlined study criteria. Performed statistical analysis and summarized reproductive toxicity information for individual bird species.

***BEHP Toxicity Assessment***—Performed critical review of bis(2-ethylhexyl)phthalate (BEHP) toxicity to aquatic invertebrates. Evaluated research and data needs.

***Thallium Toxicity Assessment***—Completed a critical review of EPA’s draft toxicological review for thallium and compounds. Evaluated the appropriateness of the selection of biologically significant endpoints for establishing reference dose concentrations. Reviewed sources of uncertainty and their impacts on the established toxicity criteria.

## **Product Stewardship and Consumer Safety**

***Exposure Evaluation of Metals from Products Manufactured with Metal Alloys***—Leading a project team to evaluate exposure to lead that potentially leaches from products manufactured with metal alloys. Assessment involves the review of data that evaluates leaching over time and considers ingestion, hand-to-mouth, and dermal absorption pathways.

***Human Health Metric***—Worked with a chemical industry-led consortium to establish a metric that can be used to communicate to the public the health impacts of chemicals. Work included review of concepts and specific data sources that fed into the established metric.

***Proposition 65 Regulatory Compliance Evaluation, California***—Participated in an evaluation of a carpet tile product to determine its compliance with California’s Prop 65. Determined that exposures to any of the Prop 65 chemicals present in the carpet tile did not pose a health concern and that the product did not require Prop 65 labeling.



***Exposure Assessment of Chemicals in Sporting Goods for Compliance with Proposition 65, California***—Contributed to the assessment of constituents present in client’s sporting goods to determine whether they were subject to California’s Prop 65. For those chemicals on the Prop 65 list, an exposure assessment was conducted to confirm that they were present below the safe harbor levels and, therefore, not subject to labeling.

***Evaluation of Turf Components in Playing Fields, New York***—Completed an exposure and risk evaluation of constituents in synthetic turf fields. Summary supported school district decision for field installation.

***Carbon Black Regulatory Toxicology***—Completed critical review of EPA’s new chemical exposure limit for carbon black particles, formed under TSCA. Evaluated the applicability of the studies to regulating worker exposures to carbon black particles with different properties.

***Pharmaceuticals and Personal Care Products Toxicity Database***—Created, populated, and maintained a relational database in Microsoft® Access housing data quality observations, study methodologies, and dose-response data for five classes of pharmaceuticals and personal care products. Applied database content to inform the development of toxicity reference values.

## **Litigation Support**

***Litigation Support Regarding PCBs, Multiple Locations***—Providing technical support for data exposure assessment and toxicology for multiple litigation projects related to PCBs in buildings. The work includes analysis of blood serum data as a biomarker of exposure. The primary focus of the human health risk assessments is exposure to PCB volatiles in indoor air. This project is ongoing.

***Soil Contamination, Contribution Assessment, Kentucky***—Evaluating potential contribution of industrial processes to measured soil contamination. Chemicals of concern include mercury, PCBs, and volatile organic compounds. Reviewing manufacturing processes and historical facility documents to understand potential releases.

***Sediment Contamination, Contribution Assessment, Louisiana***—Evaluated potential contribution of an industrial facility to measured sediment contamination through several lines of evidence. Contaminants of interest included PCBs, mercury, and dioxins. Reviewed historical facility documents including process documents, permits, and monitoring data to understand potential releases. Developed models to estimate relative mass contributions to the bayou from the facility to resolve mass balance. Models were run using probabilistic techniques, which accounted for the probability of events that might lead to a release of PCB contaminants from electrical equipment. Results provided insight on the likelihood that a given mass might reach the contaminated source. Conducted forensic assessments to evaluate sources and patterns of contamination for PCBs and dioxins.

***Arsenic Litigation, New York***—Prepared report regarding potential for risk associated with residential exposure to arsenic in an area surrounding a pesticide manufacturing site.



*Consulting Support for Petroleum Spill, Alaska*—Assessed historical state of knowledge regarding the fate, transport, and natural damages associated with a petroleum spill.

## **Public Health**

*School Health Finance Evaluation, Colorado*—Led a multiyear study to assess the financial implications of implementing changes aimed at increasing the healthfulness of nutritional offerings in a school district’s cafeterias to the food service budget. Evaluated the cost structure of the food service budget as a function of planned changes and identified cost control strategies.

*School Health Nutrition Intervention, Colorado*—Investigated à la carte programs and their impact on school lunch nutrition and lunch program finances at middle schools in the Roaring Fork Valley of Colorado. Final study report was shared with Colorado State Department of Education, who disseminated it to all middle school nutrition directors in the state of Colorado.

*Lead Biomonitoring Study, Rico, Colorado*—Conducted fieldwork for blood lead biomonitoring study. Performed statistical analysis to characterize blood lead and predictive exposure pathways and behavior patterns. Assessed seasonal patterns in environmental media and blood lead using multiphase data. Prepared data report.

*Angler Survey Development, New Jersey*—Designed survey to evaluate fishing patterns and behavior of anglers.

## **Database Management**

*HCH Toxicity Literature Database*—Designed and maintained Microsoft® Access database to house critiques of more than 200 primary literature sources. Database was designed to facilitate the comprehensive review of the carcinogenicity and mode of action of three HCH isomers.

*Toxicity Reference Value Database*—Designed Microsoft® Access database to house aquatic toxicity data for more than 100 chemicals, including metals, pesticides, PCBs, dioxins, and volatile chemicals. The database was used to derive species sensitivity distributions to aid in interpretation of exposure estimates for ecological receptors in a baseline ecological risk assessment.

*Sediment Groundwater Chemical Correspondence*—Maintained Microsoft® Access databases for large sets of sediment and groundwater data used for chemical correspondence evaluation. Developed summaries and tables of constituents detected in both media.

*Stressor Evaluation, Delaware River*—Created and maintained a database in Microsoft® Access housing literature and summaries of available data to be used in a comprehensive assessment of chemical, biological, and physical stressors on the Delaware River.

*DDT Toxicity Database*—Created and maintained a relational database in Microsoft® Access housing toxicity literature, data quality evaluations, and dose-response data. Created summaries of available literature by usability rankings, species, and reproductive endpoints evaluated.



## Risk Assessment Methodologies

**Weight-of-Evidence Approach**—Reviewed approaches used by government and academic institutions for evaluating and using multiple lines of evidence in decision making. Collaborated with multiple stakeholders to formulate a framework to be used in a weight-of-evidence evaluation to determine party's responsibility for site toxicity. Facilitated evaluations of scientific findings using the weight-of-evidence framework.

**Uncertainty Factors**—Analyzed the use and adequacy of uncertainty factors in the current risk assessment process. Studied the potential uses and limitations surrounding probabilistic determinations of overall uncertainty.

**Expert Elicitation**—Planned and coordinated a seminar series on the use of expert elicitation in risk assessment. Reviewed cases in which expert elicitation has been used for estimating various parameters within a risk assessment.

**Environmental Burden of Disease**—Assessed current methodologies used by several organizations in determining the environmental burden of disease. Developed material explaining the concept and its use for EPA's *Report on the Environment*.

## Environmental Audits

**Maryland Port Administration, Maryland**—Completed multimedia environmental audits at port terminals participating in a voluntary disclosure program. Aided in designing audit checklists detailing federal and Maryland State Regulations under Clean Air Act, Clean Water Act, EPCRA, FIFRA, RCRA, and TSCA. Prepared reports detailing facility overviews and audit findings.

## Professional Interests and Research Projects

**Nanotechnology**—Track environmental health and safety findings, the development of risk assessment approaches, and the regulatory status of nanomaterials. Participated in planning a workshop sponsored by the Society for Risk Analysis titled Nano Risk Analysis: Advancing the Science of Nanoscale Material Management.

**Impact and Policy Implications of Genomic Information in Regulation**—Assessed the implications of genetic information on regulation and policy. Quantified and described the influence of genetic polymorphisms on the metabolism, toxicity, and population response to organophosphate pesticides. Analyzed the ability of currently available genetic information to inform regulation within the regulatory framework for organophosphate pesticides. Attended EPA Emerging Issues Seminar Series on the use of genomic information. Participated in EPA case study assessing the use of genomic information in determining toxicity values.

## Publications

Bradley, A.E., J.L. Shoenfelt, and J.L. Durda. 2016. Carcinogenicity and mode of action evaluation for alpha-hexachlorocyclohexane: Implications for human health risk assessment. *Regul. Toxicol. Pharmacol.* 76(2016):152–173.



Lutter, R., L. Abbott, R. Becker, C. Borgert, A. Bradley, G. Charnley, S. Dudley, A. Felsot, N. Golden, G. Gray, D. Juberg, M. Mitchell, N. Rachman, L. Rhomberg, K. Solomon, S. Sundlof, and K. Willett. 2015. Improving weight of evidence approaches to chemical evaluations. *Risk Anal.* 35(2):186–192.

Shatkin, J.A., L.C. Abbott, A.E. Bradley, R.A. Canady, T. Guidotti, K.M. Kulinowski, R.E. Löfstedt, G. Louis, M. Macdonell, and A.D. Maynard. 2010. Nano risk analysis: advancing the science for nanomaterials risk management. *Risk Anal.* 30(11):1680–1687.

Gil, O.D., T. Sakurai, A.E. Bradley, M.Y. Fink, M.R. Cassella, J.A. Kuo, and D.P. Felsenfeld. 2003. Ankyrin binding mediates L1CAM interactions with static components of the cytoskeleton and inhibits retrograde movement of L1CAM on the cell surface. *J. Cell Biol.* 162(4):719–730.

## **Presentations/Posters**

Bradley, A., J. Lape, and J. Durda. 2017. Human health risk assessment for the Berry's Creek Study Area: A data-driven, site-specific assessment. Platform presentation. Battelle Sediments Conference, January, New Orleans, LA.

Bradley, A. 2013. Developing toxicity criteria for the use in human health risk assessment. AEHS Fall Conference, October, Amherst, MA.

Session organizer and chair. Weight-of-evidence frameworks: design and case study applications. SRA Annual Conference, December 2009, Baltimore, MD.

Neuber, K., J. Durda, and A. Bradley. 2009. Development of human health toxicological criteria for five organic acids. SRA Annual Conference, December, Baltimore, MD.

Bradley, A., J. Durda, and L. Brzuzny. 2009. A weight-of-evidence framework for reaching scientific consensus on causality. Platform presentation. SETAC Annual Conference, November, New Orleans, LA.

Bradley, A., A. Cárdenas, C. Curl, and R. Schoof. 2007. Developing and utilizing questionnaire data in building an exposure model for lead. Poster presentation. ISEA Annual Conference, October, Durham, NC.

Sampson, J., B. Day, A. Bradley, V. Fagerness, M. Tritt, and E. Spalt. 2007. Understanding the ecological significance of sediment recontamination: A case study of bis(2-ethylhexyl)phthalate. Poster presentation. Fourth International Conference on Remediation of Contaminated Sediments, January, Savannah, GA.

Neuber, K., A. Bradley, and J. Durda. 2006. Comparative sensitivity of bird species of the Gulf Coast to environmental DDT contamination: A meta-analysis of existing dose-response data for egg residue of DDE and eggshell thinning. Poster presentation. SRA Annual Conference, December, Baltimore, MD.



Bradley, A.B., A.C. Cullen, W. Burke, and E.M. Faustman. 2004. Impact and policy implications of genetic information in regulation: A case study of organophosphate pesticides. Poster presentation. SRA Annual Conference, December, Palm Springs, CA.

