

#### Mark Harris, Ph.D., M.B.A.

CHIEF OPERATING OFFICER MANAGING PRINCIPAL SCIENTIST

#### CONTACT INFORMATION

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#### PROFESSIONAL PROFILE

Dr. Mark Harris is a cofounder of ToxStrategies and has more than 25 years of experience in the areas of toxicology, human health risk assessment, and risk-based site investigations. He routinely applies his skills as a toxicologist and human health risk assessor to many types of projects, including designing, placing, and overseeing toxicology laboratory studies; and developing state-of-the-science toxicity values via the application of both default and more rigorous approaches such as benchmark modeling, application of weight-of-evidence techniques, and consideration of mode-of-action information. Other project experience includes estimating human exposures using a variety of approaches, including designing, implementing, and using data from biomonitoring studies; using complex data sets such as NHANES and conducting studies to gather human exposure information; modeling uptake and exposure via a variety of exposure pathways; and conducting both screeninglevel and complex site-specific risk assessments to quantify human health risks, including conduct of probabilistic risk assessments. Dr. Harris has a strong understanding of a wide variety of regulatory guidance documents that focus on human health risk assessment. He has substantial experience in dealing with regulatory agencies, ranging from implementation of administrative orders to developing site cleanup standards. Additionally, Dr. Harris has extensive experience in developing risk-based site investigations for both industrial and residential sites and in conducting source identification studies using both chemical fingerprinting techniques and historical records searches.

Dr. Harris is a co-author of more than 65 scientific journal articles and has participated in numerous technical seminars. He is a peer reviewer for several scientific journals, including the *Journal of Soil and Sediment Contamination, Integrated Environmental Assessment and Management (IEAM)*, the *Journal of Air and Waste Management,* and *Environmental Science and Technology (ES&T).* 











#### EDUCATION AND DEGREES EARNED

- 1990 Texas A&M University, Ph.D., Toxicology
- 2000 Southern Methodist University, MBA
- 1986 Texas A&M University, B.S., Biochemistry

#### PROFESSIONAL ASSOCIATIONS

American Chemical Society (ACS) Society of Environmental Toxicology and Chemistry (SETAC) Society of Risk Analysis (SRA)

#### CERTIFICATIONS AND COURSES

2002	Texas Risk Reduction Pro	gram (GSI	Training Course)
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- 2000 Hazardous Waste Shipping, DOT Regulation Compliance
- 1997 Spanish Language Immersion (Thunderbird University)
- 1992 OSHA Hazardous Waste Operations
- 1988 Molecular Endocrinology/Hormone Action

#### PROFESSIONAL HONORS/AWARDS

1990–1991 Outstanding Doctoral Research Award, Texas A&M University
1990 Outstanding Graduate Student Award, College of Veterinary Medicine, Texas A&M University
1989 George T. Edds Award for Graduate Student Research, College of Veterinary Medicine, Texas A&M University

#### SCIENTIFIC ADVISORY PANELS, COMMITTEES, & WORKGROUPS

2000 United States Environmental Protection Agency (USEPA) Expert Panel to evaluate Chapter 9 (Toxic Equivalency Factors) and Integrated Risk Characterization and Summary Section of Dioxin Reassessment (prepared by USEPA, July 2000)



#### PROFESSIONAL EXPERIENCE

Provided an expert report evaluating potential health effects associated with inhalation exposure to diacetyl incurred by an employee of a flavor manufacturer.

Evaluated a risk assessment prepared by a regulatory agency involving volatile organic chemicals and metals and potential exposure via inhalation by individuals living and working near a waste-handling facility. Prepared a rebuttal expert report describing shortcomings of regulatory agency approach to evaluating potential health risks.

Co-investigator of a study evaluating the mode of action of hexavalent chromium following oral exposure in rodents.

Managed the preparation of a human health risk assessment evaluating exposure via the fish ingestion pathway. The site was a large river in the northeastern United States. Risks associated with metals, PAHs, pesticides, PCBs, and PCDD/Fs were determined.

Co-principal investigator on a large biomonitoring study designed to assess the levels of dioxin-like compounds in the blood serum of workers at a former secondary copper smelting facility. This involved overseeing the development of the study protocol and comprehensive exposure questionnaire, study implementation, development of applicable background blood levels, fingerprinting analyses, data analyses, and interpretation of study findings. In addition, this project involved coordinating with an external Science Advisory Board and an Institutional Review Board.

Managed the design, implementation, and data analysis of a wild and farm-raised catfish sampling program in southern Mississippi. Chemical analyses included PCDD/Fs, dioxin-like PCBs, total PCBs, and PBDEs.

Evaluated the human health risk associated with a consumer food product contaminated by a non-food-grade lubricant. Conducted assessments specific to children's exposure in multiple countries around the globe in which the food product was sold, to aid the client with their implementation of a health-protective strategy to eliminate exposure to the contaminated product.

Evaluated PCB surface soil contamination at six softball fields within a larger recreational facility in Texas. Made recommendations regarding the continued use of the softball fields given the presence of PCBs. Additionally, developed a statistically based soil sampling plan for other areas of the park that were found to contain PCBs.

Reviewed PCDD/F and metal analyses of soils collected outside of a major industrial facility in southern Mississippi following the landfall of Hurricane Katrina, to determine whether these chemicals/metals posed any threat to human health and the environment.

Managed a large, multi-site RI/FS/Remediation in the northeastern United States, which resulted in the expedited closure of 18 industrial sites that contained varying quantities and concentrations of hexavalent chromium. This project involved characterizing affected environmental media, including soils, groundwater, surface water, sediments, and air; conducting a site-specific exposure assessment; developing site-specific hexavalent chromium cleanup standards, and developing and implementing various innovative remediation technologies for addressing hexavalent chromium.

Conducted a county-wide PRP search for industrial dischargers into a former publicly owned treatment works (POTW), to assist the client with the cost of investigation and remediation of the POTW and surrounding land. This project involved the review of historical records, search of various electronic databases, and interviews with knowledgeable individuals from the time period when the POTW operated.

Participated in a third-party review of a human health risk assessment on a former pentachlorophenol wood preservative site in Arkansas. Reviewed the calculations, assumed exposure pathways and conclusions, and made recommendations to the client for modifications to improve the assessment.

Assisted a client on the U.S. West Coast in an environmental-damage lawsuit brought by the National Oceanic Atmospheric Administration (NOAA) involving the discharge of PCBs into a POTW. Specifically, this effort involved utilizing historical data to estimate the amount of PCBs discharged by the client to the POTW that actually reached the environment.

Assisted in the development of chemical fingerprints for various sources of polychlorinated dibenzo-p-dioxins in a large urban river in the eastern United States.

Developed a surface water sampling plan and prepared a preliminary human health risk assessment for pathogens (bacteria, viruses, and parasites) discharged from a combined sewer overflow in a large urban river in the eastern United States.

Provided an expert report evaluating potential health effects associated with alleged exposure to benzene and hydrogen sulfide by employees of a wastewater treatment plant.

Prepared an expert report evaluating PCDD/F concentrations in surface soils adjacent to a large lake in East Texas. Compared the PCDD/F data to known local background concentrations of PCDD/Fs to demonstrate that the surface soils adjacent to the lake were not impacted by industrial operations.

#### MANUSCRIPTS

Thompson CM, Proctor DM, **Harris MA**. 2023. Letter to "Chepelev et al. Establishing a quantitative framework for regulatory interpretation of genetic toxicity dose-response data: Margin of exposure case study of 48 compounds with both in vivo mutagenicity and carcinogenicity dose-response data." Environ Mol Mutagen 64(4):259–260; DOI: <u>10.1002/em.22537</u>.

Bhat VS, Cohen SM, Gordon EB, Wood CE, Cullen JM, **Harris MA**, Proctor DM, Thompson CM. 2020. An adverse outcome pathway for small intestinal tumors in mice involving chronic cytotoxicity and regenerative hyperplasia: A case study with hexavalent chromium, captan, and folpet. Crit Rev Toxicol (open access), <a href="https://doi.org/10.1080/10408444.2020.1823934">https://doi.org/10.1080/10408444.2020.1823934</a>.

Thompson CM, Donahue DA, Hobbs C, Costecalde Y, Franzen A, Suh M, Proctor DM, Harris MA. 2020. Exposure to environmentally-relevant concentrations of hexavalent chromium does not induce ovarian toxicity in mice. Regul Toxicol Pharmacol 116, open access: <u>https://doi.org/10.1016/j.yrtph.2020.104729</u>.

Chappell G, Rager J, Wolf J, Babic M, Leblanc, Ring C, **Harris MA**, Thompson CM. 2019. Comparison of gene expression responses in the small intestine of mice following exposure to three carcinogens using the S1500+ gene set informs a potential common adverse outcome pathway. Toxicol Pathol 47(7):851–864, https://doi.org/10.1177/0192623319873882.

Klaren WD, Ring C, **Harris MA**, Thompson CM, Borghoff S, Sipes NS, Hsieh J-H, Auerbach SS, Rager JE. 2018. Identifying attributes that influence *in vitro*-to-*in vivo* concordance by comparing *in vitro* Tox21 bioactivity versus *in vivo* DrugMatrix transcriptomic responses across 130 chemicals. Toxicol Sci kfy220, available at <a href="https://doi.org/10.1093/toxsci/kfy220">https://doi.org/10.1093/toxsci/kfy220</a>.

Thompson CM, Kirman CR, Hays SM, Suh M, Harvey SE, Proctor DM, Rager JE, Haws LC, **Harris MA**. 2018. Integration of mechanistic and pharmacokinetic information to derive oral reference dose and margin-of-exposure values for hexavalent chromium. J Appl Toxicol 38:351–365. doi: 10.1002/jat.3545.

Bichteler A, Wikoff DS, Loko F, Harris MA. 2017. Estimating serum concentrations of dioxin-like compounds in the U.S. population effective 2005–2006 and 2007–2008: A multiple imputation and trending approach incorporating NHANES pooled sample data. Environ Int 105:112–125. doi: 10.1016/j.envint.2017.05.003.

Thompson CM, Wolf, JC, McCoy A, Suh M, Proctor DM, Kirman CR, Haws LC, **Harris MA**. 2017. Comparison of toxicity and recovery in the duodenum of B6C3F1 mice following treatment with intestinal carcinogens captan, folpet, and hexavalent chromium. Toxicol Pathol 45(8):1091–1101. DOI: 10.1177/019262331yy4324.

Thompson CM, Suh M, Proctor DM, Haws LC, **Harris MA**. 2017. Ten factors for considering the mode of action of Cr(VI)-induced gastrointestinal tumors in rodents. Mut Res/Genetic Toxicol Environ Mutagen 823:45–57.

Thompson CM, Young RR, Dinesdurage H, Suh M, Harris MA, Rohr AC, Proctor DM. 2017. Assessment of the mutagenic potential of hexavalent chromium in the duodenum of big blue® rats. Toxicol Appl Pharmacol 330(1):48-52.

Rager JE, Ring CL, Fry RC, Suh M, Proctor DM, Haws LC, **Harris MA**, Thompson CM. 2017. High-throughput screening data interpretation in the context of *in vivo* transcriptomic responses to oral Cr(VI) exposure. Toxicol Sci kfx085. doi: 10.1093/toxsci/kfx085.

Thompson CM, Wolf JC, Elbekai RH, Paranjpe MG, Seiter JM, Chappell MA, Tappero RV, Suh M, Proctor DM, Bichteler A, Haws LC, **Harris MA**. 2015. Duodenal crypt health following exposure to Cr(VI): micronucelus scoring, γ-H2AX immunostaining, and synchrotron x-ray fluorescence microscopy. Mut Res 789–790:61–66.

Thompson CM, Young RR, Suh M, Dinesdurage HR, Elbekai RH, **Harris MA**, Rohr, AC, Proctor DM. 2015. Assessment of the mutagenic potential of cr(VI) in the oral mucosa of big blue® transgenic f344 rats. Environ Mol Mutagen. 56(7):621–628. doi: 10.1002/em.21952.

Thompson, CM, Seiter J, Chappell MA, Tappero RV, Proctor DM, Suh M, Wolf JC, Haws LC, Vitale R, Mittal L, Kirman CR, Hays SM, **Harris MA**. 2015. Synchrotron-based imaging of chromium and γ-H2AX immunostaining in the duodenum following repeated exposure to Cr(VI) in drinking water. Toxicol Sci 143(1):16–25.

Suh M, Thompson C, Kirman C, Carakostas M, Haws LC, **Harris M**, Proctor D, Abraham L, Hixon JG. 2014. High concentrations of hexavalent chromium in drinking water alter iron homeostasis in F344 rats and B6C3F1 mice. Food Chem Toxicol 65:381–388.

Urban JD, Wikoff DS, Bunch ATG, **Harris MA**, Haws LC. 2014. A review of background dioxin concentrations in urban/suburban and rural soils across the United States: Implications for site assessments and the establishment of soil cleanup levels. Sci Tot Environ 466–467: 586–597.

Bunch AG, Perry CS, Abraham L, Wikoff DS, Tachovsky JA, Hixon JG, Urban JD, **Harris MA**, Haws LC. 2013. Evaluation of impact of shale gas operations in the Barnett Shale region on volatile organic compounds in air and potential human health risks. Sci Tot Environ 468–469(2014): 832–842.

Kirman CR, Aylward LL, Suh M, Harris MA, Thompson CM, Haws LC, Proctor DM, Lin SS, Parker W, Hays SM. 2013. Physiologically based pharmacokinetic model for humans orally exposed to chromium. Chem Biol Interact 204:13–27. doi:pii: S0009-2797(13)00082-3. 10.1016/j.cbi.2013.04.003

O'Brien T, Ding H, Suh M, Thompson C, Parsons BL, **Harris MA**, Winkelman WA, Wolf JC, Hixon JG, Schwartz AM, Myers MB, Haws LC, Proctor DM. 2013. Assessment of K-Ras mutant frequency and micronucleus incidence in the mouse duodenum following 90-days of exposure to Cr(VI) in drinking water. Mutat Res 754:15–21. pii: S1383-5718(13)00075-2. doi: 10.1016/j.mrgentox.2013.03.008

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Thompson CM, Kirman CR, Proctor DM, Haws LC, Suh M, Hays S, Hixon JG, Harris MA. 2013. A chronic oral reference dose for hexavalent chromium-induced intestinal cancer. <u>J Appl Toxicol</u> 34:525–536.

Kirman CR, Hays SM, Aylward LL, Suh M, Harris MA, Thompson CM, Haws LC, Proctor DM. 2012. Physiologically based pharmacokinetic model for rats and mice orally exposed to chromium. Chem Biol Interact 200(1):45–64.

Kopec AK, Kim S, Forgacs AL, Zacharewski TR, Proctor DM, **Harris MA**, Haws LC, Thompson CM. 2012. Genome-wide gene expression effects in B6C3F1 mouse intestinal epithelia following 7 and 90 days of exposure to hexavalent chromium in drinking water. Toxicol Appl Pharmacol 259(1):1326.

Proctor DM, Suh M, Aylward LL, Kirman CR, **Harris MA**, Thompson CM, Gürleyük H, Gerads R, Haws LC, Hays SM. 2012. Hexavalent chromium reduction kinetics in rodent stomach contents. Chemosphere 89(5):487–493.

Thompson CM, Fedorov Y, Brown DD, Suh M, Proctor DM, Kuriakose L, Haws LC, Harris MA. 2012. Assessment of Cr(VI)-induced cytotoxicity and genotoxicity using high content analysis. PLoS ONE 7(8):e42720.

Thompson CM, Hixon JG, Proctor DM, Haws LC, SuhM, Urban JD, **Harris MA**. 2012. Assessment of genotoxic potential of Cr(VI) in the mouse duodenum: An in silico comparison with mutagenic and nonmutagenic carcinogens across tissues. Regul Toxicol Pharmacol 64(1):68–76.

Thompson CM, Proctor DM, Suh M, Haws LC, Hebert CD, Mann JF, Shertzer HG, Hixon JG, **Harris MA**. 2012. Comparison of the effects of hexavalent chromium in the alimentary canal of F344 rats and B6C3F1 mice following exposure in drinking water: Implications for carcinogenic modes of action. Toxicol Sci 125(1):79–90.

Thompson CM, Proctor DM, Haws LC, Hebert CD, Grimes SD, Shertzer HG, Kopec AK, Hixon JG, Zacharewski TR, Harris MA. 2011. Investigation of the mode of action underlying the tumorigenic response induced in B6C3F1 mice exposed orally to hexavalent chromium. Toxicol Sci 123(1):58–70.

Thompson CM, Haws LC, **Harris MA**, Gatto NM, Proctor DM. 2011. Application of the U.S. EPA mode of action framework for purposes of guiding future research: A case study involving the oral carcinogenicity of hexavalent chromium. Toxicol Sci 119(1):20–40.

Tachovsky JA, Urban JD, Wikoff DS, Haws LC **Harris MA**. 2010. Reduction of a large fish tissue analyte database: Identifying and assessing data specific to a remediation site for risk assessment application. Chemosphere 80(5):481–488.

Urban J, Tachovsky JA, Haws L, Wikoff Staskal D, **Harris M**. 2010. Response to Mugdan et al.'s comment on Urban et al. "Assessment of human health risks posed by consumption of fish from the Lower Passaic River, New Jersey." Sci Tot Environ 408(6):1468–1470.

Urban JD, Tachovsky JA, Haws LC, Staskal DF, **Harris MA**. 2010. Response to Buchanan et al.'s comment on Urban et al. "Assessment of Human Health Risks Posed by Consumption of Fish from the Lower Passaic River, New Jersey." Sci Total Environ 408(8): 2004–2007.

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Urban JD, Tachovsky JA, Staskal DF, Haws LC, **Harris MA**. 2009. Assessment of human health risks posed by consumption of fish from the Lower Passaic River, New Jersey. Sci Tot Environ 408(2):209–224.

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Henry KS, Petura JC, Brooks S, Dentico S, Kessel SA, **Harris M**. 2007. Preventing surface deposition of chromium with asphalt caps at chromite ore processing residue sites: A case study. Canad Geotech J 44:814–839.

Ferriby LL, Knutsen JS, **Harris M**, Unice KM, Scott P, Nony P, Haws LC, Paustenbach D. 2007. Evaluation of PCDD/F and dioxin-like PCB serum concentration data from the 2001–2002 National Health and Nutrition Examination Survey of the United States Population. J Exp Anal Env Epidemiol 17:358–371.

Paustenbach DJ, Fehling K, Scott P, Harris M, Kerger B. 2006. Identifying soil clean-up criteria for dioxin in urban residential soils: How have 20 years of research and risk assessment experience affected the analysis? J Toxicol Environ Health, Part B. 9:87–145.

Haws L, Su S, Harris M, DeVito M, Walker N, Farland W, Finley B, Birnbaum L. 2006. Development of a refined database of mammalian relative potency estimates for dioxin-like compounds. Toxicol Sci 89(1): 4–30.

Proctor D, Panko J, Liebig E, Mundt K, Buczynski M, Barnhart R, **Harris M**, Morgan R, Finley B, Paustenbach D. 2002. Workplace concentrations of airborne hexavalent chromium for the Painesville, Ohio chromate production plant. Appl Occup Environ Hyg J 18(6):430–449.

Scott P, Petura J, **Harris M**. 2002. Derivation of a liquid to solid ratio for ASTM method D3987 85 for soils containing chromite ore processing residue using selected unsaturated zone models. Soil Sed Contam 12(4): 443–480.

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Scott P, Finley B, Harris M, Rabbe D. 1997. Determination of background airborne hexavalent chromium concentrations in industrial areas. J Air Waste Manage Assoc 47:592–600.

Costa M, Zhitkovich A, Harris M, Paustenbach D, Gargas M. 1997. DNA-protein crosslinks produced by various chemicals in cultured human lymphocytes. J Toxicol Environ Health 50:433–449.

Gargas M, Norton R, Harris M, Paustenbach D, Finley B. 1994. Urinary excretion of chromium following ingestion of chromite ore processing residue in humans: Implications for biomonitoring. Risk Anal 14(6): 1019–1024.

**Harris M**, Zacharewski T, Safe S. 1993. Comparative potencies of Aroclors 1232, 1248, 1254, and 1260 in male Wistar rats—Assessment of the toxic equivalency factor (TEF) approach for polychlorinated biphenyls (PCBs). Fund Appl Toxicol 20:456–463.

Copeland TL, Paustenbach DJ, **Harris MA**, Otani J. 1993. Comparing the results of a Monte Carlo analysis with EPA's reasonable maximum exposed individual (RMEI): A case study of a former wood treatment site. Regul Toxicol Pharmacol 18: 275–312.

Zacharewski T, Harris M, Biegel L, Morrison V, Merchant M, Safe S. 1992. 6-Methyl-1,3,8-trichlorodibenzofuran (MCDF) as an antiestrogen in human and rodent cancer cell lines: Evidence for the role of the Ah receptor. Toxicol Appl Pharmacol 113: 311–318.

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Safe S, Harris M, Biegel L, Zacharewski T. 1991. Mechanism of action of TCDD as an antiestrogen in transformed human breast cancer and rodent cell lines. Banbury Report 35: Biological basis for risk assessment of dioxins and related compounds. Cold Spring Harbor Laboratory Press, pp. 367–377.

Zacharewski T, **Harris M**, Safe S. 1991. Evidence for a possible mechanism of action of the 2,3,7,8tetrachlorodibenzo-p-dioxin-mediated decrease of nuclear estrogen receptor levels in wild-type and mutant hepa 1c1c7 cells. Biochem Pharmacol 41:1931–1939.

Piskorska-Pliszczynska J, Astroff B, Zacharewski T, **Harris M**, Rosengren R, Morrison V, Safe L, Safe S. 1991. Mechanism of action of 2,3,7,8-tetrachlorodibenzo-p-dioxin antagonists: Characterization of 6-[125l] methyl-8iodo-1,3-dichlorodibenzofuran-Ah receptor complexes. Arch Biochem Biophys 284(1): 193–200.

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#### BOOKS AND BOOK CHAPTERS

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#### ABSTRACTS AND PRESENTATIONS

Choksi NY, Fitch S, **Harris MA**, Thompson CM, Wikoff DS. Reliability assessment of guideline-based studies using systematic review critical appraisal tools. Poster presented at Society of Toxicology Annual Meeting, Nashville, TN, March 2023.

Thompson CM, Wikoff DS, Proctor DM, **Harris MA**. An evaluation of risk assessments on hexavalent chromium [Cr(VI)]: The past, present, and future of mode of action research. Poster presented at Society of Toxicology Annual Meeting, Nashville, TN, March 2023.

Chappell G, Wolf JC, **Harris MA**, Thompson CM. Variation in transcriptomic responses in the crypt and villus of mouse small intestine following oral exposure to hexavalent chromium. Poster presented at Society of Toxicology Annual Meeting, San Diego, CA, March 2022.

Thompson CM, Chappell GA, Mittal L, Gorman B, Proctor DM, Haws LC, **Harris MA**. Use of targeted mode-ofaction research to inform human health risk assessment of hexavalent chromium. Poster presented at Society of Toxicology Annual Meeting, San Diego, CA, March 2022.

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