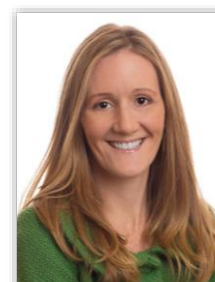


Daniele (Staskal) Wikoff, Ph.D.

CHIEF SCIENTIFIC OFFICER

SENIOR VICE PRESIDENT, HEALTH SCIENCES

PRINCIPAL SCIENTIST



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PROFESSIONAL PROFILE

Dr. Daniele Wikoff is ToxStrategies' Chief Scientific Officer, as well as Senior Vice President of the firm's Health Sciences practice. She specializes in using evidence-based methods to support hazard and risk assessment applications. Dr. Wikoff has led the firm's initiatives to integrate evidence-based methods as part of safety assessments for a broad spectrum of substances, including food ingredients, cosmetic ingredients, dietary supplements and botanicals, industrial chemicals, environmental contaminants, and pharmaceuticals. She has successfully implemented a turn-key process for conducting systematic assessments involving an experienced multidisciplinary team and systematic review software, including AI-facilitation tools. She has experience applying these methods to different types of data (epidemiological, experimental animal, mechanistic) and to a variety of health outcomes for causation and risk assessment purposes. Dr. Wikoff routinely engages with risk communication efforts regarding hazard and risk assessment topics with diverse audiences, including international regulators and non-technical audiences.

Dr. Wikoff has experience applying systematic mapping (scoping reviews) and systematic reviews to develop health-based benchmarks and pathway-based analyses. She regularly employs both qualitative (e.g., AOP-based integration, biological plausibility) and quantitative integration techniques (e.g., meta-analyses, Bayesian/meta-regression) to characterize hazards, causal relationships, points of departure, estimates of relative potency, and dose-response relationships. Her expertise extends to topic-specific application of various organizational concepts for mechanistic data, including key characteristics, adverse outcome pathways, and modes of action. Dr. Wikoff has a particular interest in methods development related to defining and evaluating data quality, and how elements of internal, construct, and external validity can be used to transparently inform conclusions and provide critical information to decision makers. Her expertise also includes performing qualitative and quantitative assessments of confidence and uncertainty to characterize hazard and dose-response relationships with both toxicological and epidemiological data.

Dr. Wikoff is active in the scientific community, highlighted by her service to academic journals in the toxicology field. She currently serves as Co-Editor-in-Chief of the peer-review journal *Regulatory Toxicology and Pharmacology*, as Associate Editor at *Toxicological Sciences*, and on the editorial boards of *Food and Chemical Toxicology* and *Current Opinion in Toxicology*. She has also served as an appointed member of the Society of Toxicology's Scientific Program Committee, and has held elected positions with the Risk Assessment Specialty Section and Food Safety Specialty Section.

In addition, Dr. Wikoff is involved in multiple global collaborations to advance evidence-based toxicology. She is both a member of the Board of Trustees and Chair of the Science Advisory Council for the Evidence-Based Toxicology Collaboration (EBTC), as well as a member of National Academy of Sciences committees, and co-author on the World Health Organization's systematic review framework. She has been an invited speaker and panel participant at the National Academies of Sciences, the European Food Safety Authority, and the U.S. Environmental Protection Agency. She has also taught multiple continuing education courses on systematic review and risk assessment, and has authored numerous guidance documents and book chapters.

EDUCATION AND DEGREES EARNED

2005 Ph.D., Toxicology, University of North Carolina at Chapel Hill
2000 B.S., Chemistry and Biology, Buena Vista University

PROFESSIONAL ACTIVITIES

Co-Editor-in-Chief, *Regulatory Toxicology and Pharmacology*

Associate Editor (Systematic Reviews; Risk Assessment), *Toxicological Sciences*

Board of Trustees Member, Evidence-Based Toxicology Collaboration, Johns Hopkins University

Chair, Science Advisory Council, Evidence-Based Toxicology Collaboration, Johns Hopkins University

Member/Author, World Health Organization Systematic Review Framework

Member, USEPA Science Advisory Board; review of the Draft IRIS Assessment on Arsenic

Member, National Academies of Science and Engineering (NASEM); review of the Department of Veterans Affairs presumption decision process

Member (ad-hoc), USEPA Science Advisory Committee on Chemicals; review of the draft Proposed Principles of Cumulative Risk under the Toxic Substances Control Act, and draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act

Member (ad-hoc), USEPA Science Advisory Committee on Chemicals, review of the Draft TSCA Systematic Review Protocol

Toxicology Forum, Board of Trustees (Elected)

Member (appointed), Society of Toxicology's Scientific Program Committee

Past President (Elected), Society of Toxicology's Risk Assessment Specialty Section

Past President (Elected), Ethical, Legal, and Social Issues Specialty Section, Society of Toxicology

Past Councilor (Elected), Food Safety Specialty Section, Society of Toxicology

Past Secretary/Treasurer (Elected), Risk Assessment Specialty Section, Society of Toxicology

Associate Editor, *Current Opinions in Toxicology*

International Editorial Board, *Food and Chemical Toxicology*

Member, GRADE Environmental Health Project Group and Dose-Response Project Group

Member, National Academies of Science (NAS), Review of the IRIS Protocol for Inorganic Arsenic

U.S. Department of Agriculture — Scientific Quality Reviewer (ARS project plans)

National Institute of Environmental Health Sciences — Virtual Consortium for Translational/Transdisciplinary Environmental Research (ViCTER) Consortium (R01 grant reviews)

Health Canada Expert Reviewer — Review of Biomonitoring Equivalents: Derivation of Biomonitoring Equivalents for Pentabromodiphenylether (PBDE-99)

EPA External Review Panel — An Exposure Assessment of Polybrominated Diphenyl Ethers (External Review Draft)

Co-Chair, International Symposium on Halogenated Persistent Organic Pollutants, DIOXIN 2010

Professional Associations

Evidence-Based Toxicology Collaboration

Society of Toxicology (SOT), North Carolina Regional Chapter

Society for Risk Analysis (SRA)

Toxicology Forum

AWARDS

Lead author of abstract named one of the Top 10 Abstracts of 2025 (out of 250 submissions) by the Society of Toxicology Risk Assessment and Specialty Section (RASS)

Lead author of article named Best Paper of the Year for 2018 by the Regulatory and Safety Evaluation Specialty Section of the Society of Toxicology

Lead author of article named Best Paper of the Year for 2017 by Editors of *Food and Chemical Toxicology*

INVITED AND GUEST LECTURES / CONTINUING EDUCATION

Invited Speaker: Philippine Chamber of Food Manufacturers, Inc. (PCFMI), Manila, April 2025. "Risk & hazard assessment in food safety—How should we review food regulations?"

Invited Speaker: Food Industry Asia (FIA)-Empowering Evidence Based Food Policies in Indonesia, Jakarta, April 2025. "Application of risk and hazard assessment in shaping informed food policies and regulations."

Keynote Speaker: International Forum on Food Safety and Health/International Union of Food Science and Technology (IUFOST), Beijing, China, April 2024. "Mystery of sweetener safety."

Continuing Education Speaker: Society of Toxicology, March 2023. "Tailoring off-the-shelf systematic review methods to the identification and evaluation of mechanistic data."

Presenter: Society of Toxicology, March 2023. "Continuing towards best practices in organizing, assessing, and applying mechanistic data in hazard characterization and risk assessment."

Session Chair: Society of Toxicology, March 2022. “Mode of action, adverse outcome pathways, and key characteristics (KCs): Proposed steps forward and mid-course corrections.”

Session Co-Chair: Society of Toxicology, March 2022. “How does your study measure up? The evolution of study quality evaluations in toxicology and risk assessment.”

Presenter: Society of Toxicology, March 2022. “Bridging the past, present, and future of study quality evaluations in toxicology: A summary of recommendations to researchers for the conduct and reporting of toxicological studies.”

Co-Presenter: Society of Toxicology, March 2022. “Picking the right tool: Using evidence-based toxicology to evaluate mechanistic data in KC, AOP, and MoA constructs.”

Guest Lecture: University of North Carolina, Chapel Hill, Toxicology Curriculum, November 2021. “Using systematic review for risk assessment.”

Guest Lecture: Johns Hopkins Center for Clinical Trials and Evidence Synthesis, October 2021. “Survey of evidence-based toxicology applications: use of systematic mapping and systematic review to evaluate adverse effects and risk assessment.”

Continuing Education Speaker: EUROTOX 2021. “Advances in conducting systematic reviews for chemical assessment: Automation, uncertainty assessment, and synthesis.”

Continuing Education Speaker: Institute for the Advancement of Food and Nutrition Sciences, LNCS Practitioner Webinar Series, July 15, 2021. “The acceptable daily intake (ADI) for low- and no-calorie sweeteners (LNCS): Origin, interpretation, and application.” Available at: <https://iafns.org/acceptable-daily-intake-adi-for-lncs/>

Invited Speaker: OECD EAGMST Initiative on Systematic Methods in AOP Development, March 2021. “Systematic methods in AOPs: Success is dependent on problem formulation.”

Continuing Education Speaker: Society of Toxicology, 2019. “Conducting systematic review in toxicology – Why, when, how?”

Invited Speaker: EPA Systematic Review Community of Practice (SR CoP), July 2018. “Evidence integration.”

Invited Speaker, EPA Advancing Systematic Review Workshop, 2018.

GUIDANCE DOCUMENTS AND BOOK CHAPTERS

National Academies of Sciences, Engineering, and Medicine [reviewer]. 2024. The role of seafood consumption in child growth and development. Washington, DC: The National Academies Press. <https://doi.org/10.17226/27623>.

Wikoff D, Fitch S. 2024. Systematic reviews and evidence-based methods in toxicology. In: Wexler P (ed), Encyclopedia of Toxicology. Elsevier, pp. 875–882

Wikoff D, Fitch S. 2024. Evidence-based methods in toxicology: Systematic review and systematic evidence mapping. Chapter 32 in: Paustenbach DJ (ed), Human and Ecological Risk Assessment: Theory and Practice, Third Edition, pp. 1133–1148. [Wiley](https://www.wiley.com), ISBN: 978-1-119-74296-8.

Principal Investigator, FDA contract to develop a protocol for assessing safety of cosmetic ingredients

World Health Organization [drafting author]. 2021. Framework for the use of systematic review in chemical risk assessment.

Fitzgerald L, **Wikoff DS**. 2014. Persistent organic pollutants. In: Wexler, P (ed), Encyclopedia of Toxicology, 3rd edition, vol 3. Academic Press, pp. 820–825.

Staskal DF, Birnbaum LS. 2011. Health effects of brominated flame retardants. In: The Handbook of Environmental Chemistry, vol. 16 — Brominated Flame Retardants. Springer.

Staskal DF, Birnbaum LS, Haws LC. 2009. Application of a relative potency factor approach in the assessment of health risks associated with exposures to mixtures of dioxin-like compounds. In: The Principles and Practice of Mixtures Toxicology. Wiley.

Staskal DF, Birnbaum LS. 2007. Brominated flame retardants. In: Maxcy-Rosenau-Last Public Health and Preventive Medicine, 15th Edition, John Wiley & Sons.

PEER-REVIEWED PUBLICATIONS

Brorby G, Franzen A, Thompson C, **Wikoff D**, Doecker C. 2025. Human health risk assessment of three smoke flavoring primary products. Food Chem Toxicol 115490; doi: [10.1016/j.fct.2025.115490](https://doi.org/10.1016/j.fct.2025.115490). Online ahead of print May 2, 2025. PMID: 40320068.

Diemar MG, Giusti A, Michel-Caillet C, Leme DM, **Wikoff D**, Bloch D, Sass J, Beekmann K, et al. 2025. How to organize a successful toxicology workshop? A participant perspective on the Collaboration to Harmonise the Assessment of Next Generation Evidence (CHANGE) workshop in Oslo, 18-20 June 2024. Arch Toxicol; doi: [10.1007/s00204-025-04064-6](https://doi.org/10.1007/s00204-025-04064-6). Online ahead of print May 15, 2025. PMID: 40372420.

Kennedy SB, Heintz MM, Klaren WD, **Wikoff DS**, Haws LC, Fitch SE. 2025. An integrated ecotoxicological study reliability framework for use in toxicity value development. Environ Tox Chem 44(4):1142-1153; doi: [10.1093/etoxnl/vgaf030](https://doi.org/10.1093/etoxnl/vgaf030). PMID: 39873747.

Wikoff DS, Vincent MJ, Heintz MM, Pastula ST, Reichert H, Klaren WD, Haws LC. 2025. Application of a quantitative uncertainty assessment to develop ranges of plausible toxicity values when using observational data in risk assessment: A case study examining associations between PFOA and PFOS exposures and vaccine response. Toxicol Sci 204(1):96-115; doi: [10.1093/toxsci/kfae152](https://doi.org/10.1093/toxsci/kfae152). PMID: 39792025.

DeVito M, Bokkers B, van Duursen MBM, van Ede K, Feeley M, Antunes Fernandes Gáspár E, **Haws L**, Kennedy S,... **Wikoff DS**, et al. 2024. The 2022 World Health Organization reevaluation of human and mammalian toxic equivalency factors for polychlorinated dioxins, dibenzofurans and biphenyls. Regul Toxicol Pharmacol 146 (Jan):105525; doi: [10.1016/j.yrtph.105525](https://doi.org/10.1016/j.yrtph.105525).

Fitch S, Blanchette A, Haws LC, Franke K, Ring C..., **Wikoff DS**. 2024. Systematic update to the mammalian relative potency estimate database and development of best estimate toxic equivalency factors for dioxin-like compounds. Regul Toxicol Pharmacol 147(Feb)105571; doi: [10.1016/j.yrtph.2024.105571](https://doi.org/10.1016/j.yrtph.2024.105571).

Mathisen GH, Bearth A, Jones LB, Hoffmann S, Vist GE, Ames HM,... **Wikoff D**, Wright F, Whaley P. 2024. Editorial: Time for CHANGE: System-level interventions for bringing forward the date of effective use of NAMs in regulatory toxicology. Arch Toxicol 98(8):2299-2308; doi: [10.1007/s00204-024-03802-6](https://doi.org/10.1007/s00204-024-03802-6). PMID: 38877155.

Mattes RD, Rivera BN, Rutigliani GR, Rogers S, Mendoza ID, Wang L, Beckemeier K, **Wikoff D**. 2024. A review of low- and no-calorie sweetener safety and weight management efficacy. Nutrition Today 59(6):261-288; doi: [10.1097/NT.0000000000000723](https://doi.org/10.1097/NT.0000000000000723).

Mihalchik AL, Choksi NY, Roe AL, Wisser M, Whitaker K, Seibert D, Deore M, Pavlick L, **Wikoff DS**. 2024. Safety evaluation of 8 drug degradants present in over-the-counter cough and cold medications. Regul Toxicol Pharmacol 149(May):105621; doi: [10.1016/j.yrtph.2024.105621](https://doi.org/10.1016/j.yrtph.2024.105621).

Vincent MJ, Fitch S, Bylsma L, Thompson C, Rogers S, Britt J, **Wikoff D**. 2024. Assessment of associations between inhaled formaldehyde and lymphohematopoietic cancer through the integration of epidemiological and toxicological evidence with biological plausibility. *Toxicol Sci* 199(2):172–193; doi: [10.1093/toxsci/kfae039](https://doi.org/10.1093/toxsci/kfae039).

Borghoff SJ, Cohen SS, Jiang X, Lea IA, Klaren WD, Chappell GA, Britt JK, Rivera BN, Choksi NY, **Wikoff DS**. 2023. Updated systematic assessment of human, animal and mechanistic evidence demonstrates lack of human carcinogenicity with consumption of aspartame. *Food Chem Toxicol* 172(Feb):113549; doi: [10.1016/j.fct.2022.113549](https://doi.org/10.1016/j.fct.2022.113549).

Ring C, Blanchette A, **Klaren WD**, **Fitch S**, **Haws L**, Wheeler MW, DeVito M, Walker N, **Wikoff D**. 2023. A multi-tiered hierarchical Bayesian approach to derive toxic equivalency factors for dioxin-like compounds. *Regul Toxicol Pharmacol* 143(Sep):105464; doi: [10.1016/j.yrtph.2023.105464](https://doi.org/10.1016/j.yrtph.2023.105464).

Wikoff D, Ring C, DeVito M, Walker N, Birnbaum L, **Haws L**. 2023. Development and application of a systematic and quantitative weighting framework to evaluate the quality and relevance of relative potency estimates for dioxin-like compounds (DLCs) for human health risk assessment. *Regul Toxicol Pharmacol* 145(Dec):105500; doi: [10.1016/j.yrtph.2023.105500](https://doi.org/10.1016/j.yrtph.2023.105500).

Meek ME, **Wikoff D**. 2023. The need for good practice in the application of mechanistic constructs in hazard and risk assessment. *Toxicol Sci* 194(1):13–22; <https://doi.org/10.1093/toxsci/kfad039>.

Doepker C, Movva N, Cohen SS, **Wikoff DS**. 2022. Benefit-risk of coffee consumption and all-cause mortality: A systematic review and disability adjusted life year analysis. *Food Chem Toxicol* 170:113472; doi: [10.1016/j.fct.2022.113472](https://doi.org/10.1016/j.fct.2022.113472).

Hoffmann S, Aiassa E, Angrish M, Beausoleil C, Bois FY... **Wikoff D**, et al. 2022. Application of evidence-based methods to construct mechanism-driven chemical assessment frameworks. *ALTEX* 39(3):499–518; doi: [10.14573/altex.2202141](https://doi.org/10.14573/altex.2202141).

Chappell GA, Heintz MM, Borghoff SJ, Doepker CL, **Wikoff DS**. 2021. Lack of potential carcinogenicity for steviol glycosides — Systematic evaluation and integration of mechanistic data into the totality of evidence. *Food Chem Toxicol* 150:112045; <https://doi.org/10.1016/j.fct.2021.112045>.

Chappell GA, **Wikoff DS**, Thompson CM. 2021. Assessment of mechanistic data for hexavalent chromium-induced rodent intestinal cancer using the key characteristics of carcinogens. *Toxicol Sci* 180(1):38–50; <https://doi.org/10.1093/toxsci/kfaa187>.

de Vries RBM, Angrish M, Browne P, Brozek J, Rooney AA, **Wikoff DS**, Whaley P, Edwards SW, Morgan RL, Druwe IL, Hoffmann S, Hartung T, Thayer K, Avey MT, Beverly BEJ, Falavigna M, Gibbons C, Goyak K, Kraft A, Nampo F, Qaseem A, Sears M, Singh JA, Willett C, Yost EY, Schünemann H, Tsaioun K. 2021. Applying evidence-based methods to the development and use of adverse outcome pathways. *ALTEX* 38(2):336–347; doi: [10.14573/altex.2101211](https://doi.org/10.14573/altex.2101211).

Fitch SE, Payne LE, van de Ligt JLG, Doepker C, Handu D, Cohen SM, Anyangwe N, **Wikoff D**. 2021. Use of acceptable daily intake (ADI) as a health-based benchmark in nutrition research studies that consider the safety of low-calorie sweeteners (LCS): A systematic map. *BMC Public Health* 21(1):956; doi: [10.1186/s12889-021-10934-2](https://doi.org/10.1186/s12889-021-10934-2).

Heintz MM, Doepker CL, **Wikoff DS**, Hawks SE. 2021. Assessing the food safety risk of ochratoxin A in coffee: A toxicology-based approach to food safety planning. *J Food Sci* 86(11):4799–4810; doi: [10.1111/1750-3841.15938](https://doi.org/10.1111/1750-3841.15938).

Jaeschke H, Murray FJ, Monnot AD, Jacobson-Kram D, Cohen SM, Hardisty JF, Atillasoy E... **Wikoff D**, et al. 2021. Assessment of the biochemical pathways for acetaminophen toxicity: Implications for its carcinogenic hazard potential. *Regul Toxicol Pharmacol* 120(March):104859; doi: [10.1016/j.yrtph.2020.104859](https://doi.org/10.1016/j.yrtph.2020.104859).

- Lea IA, Chappell GA, **Wikoff DS**. 2021. Overall lack of genotoxic activity among five common low- and no-calorie sweeteners: A contemporary review of the collective evidence. *Mutat Res Genet Toxicol Environ Mutagen* 868–869:503389; doi: 10.1016/j.mrgentox.2021.503389. PMID: 34454695.
- Palermo CM, Foreman JE, **Wikoff DS**, Lea I. 2021. Development of a putative adverse outcome pathway network for male rat reproductive tract abnormalities with specific considerations for the androgen sensitive window of development. *Curr Res Toxicol* 22:2:254–271; doi: 10.1016/j.crtox.2021.07.002. PMID: 34401750; PMCID: PMC8350458.
- Whaley P, Blaauboer BJ, Brozek J, Cohen Hubal EA, Hair K, Kacew S, Knudsen TB, Kwiatkowski CF, Mellor DT, Olshan AF, Page MJ, Rooney AA, Radke E, Shamseer L, Tsaion K, Tugwell P, **Wikoff D**, Woodruff TJ. 2021. Improving the quality of toxicology and environmental health systematic reviews: What journal editors can do. *ALTEX* 38(3):513-522; <https://www.altex.org/index.php/altex/article/view/2307>.
- Chappell GA, **Wikoff DS**, Doepker CL, Borghoff SJ. 2020. Lack of potential carcinogenicity for acesulfame potassium — Systematic evaluation and integration of mechanistic data into the totality of the evidence. *Food Chem Toxicol* 141:111375; doi: <https://doi.org/10.1016/j.fct.2020.111375>.
- Eichenbaum G, Yang K, Gebremichael Y, Howell BA, Murray FJ, Jacobson-Kram D, Jaeschke H, Kuffner E, Gelotte CK, Lai JCK, **Wikoff D**, Atillasoy E. 2020. Application of the DILIsym® Quantitative Systems Toxicology drug-induced liver injury model to evaluate the carcinogenic hazard potential of acetaminophen. *Regul Toxicol Pharmacol* 118:104788.
- Urban JD, **Wikoff DS**, Chappell GA, Harris C, Haws LC. 2020. Systematic evaluation of mechanistic data in assessing in utero exposures to trichloroethylene and development of congenital heart defects. *Toxicology* 436:152427; doi: 10.1016/j.tox.2020.152427. PMID: 32145346.
- Whaley P, Aiassa E, Beausoleil C, Beronius A, Bilotta, G, Boobis A, de Vries R, Hanberg A, Hoffman S, Hunt N, Kwiatkowski CF, Lam J, Lipworth S, Martin O, Randall, N, Rhomberg L, Rooney AA, Holger J, Schünemann HJ, **Wikoff D**, Wolffe T, Halsall C. 2020. Recommendations for the conduct of systematic reviews in toxicology and environmental health research (COSTER). *Environ Int* 143:105926; <https://doi.org/10.1016/j.envint.2020.105926>.
- Wikoff DS**, Bennett DC, Brorby GP, Franke KS. 2020. Evaluation of potential human health risk associated with consumption of edible products from livestock fed ration supplemented with Red Lake Diatomaceous Earth. *Food Addit Contam Part A*; 37(5):804-814; doi: 10.1080/19440049.2020.1727963.
- Wikoff D**, Lewis JR, Erraguntla N, Franzen A, Foreman J. 2020. Facilitation of risk assessment with evidence-based methods — A framework for use of systematic mapping and systematic reviews in determining hazard, developing toxicity values, and characterizing uncertainty. *Regul Toxicol Pharmacol* 118:104790; [https://authors.elsevier.com/sd/article/S0273-2300\(20\)30216-6](https://authors.elsevier.com/sd/article/S0273-2300(20)30216-6).
- Wikoff DS**, Urban JD, Ring C, Britt J, Fitch S, Haws LC. 2020. Development of a range of plausible non-cancer toxicity values for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) based on effects on sperm count: Application of systematic review methods and quantitative integration of dose response using meta-regression. *Toxicol Sci* 179(2):162-182; <https://doi.org/10.1093/toxsci/kfaa171>.
- Chappell GA, Borghoff SJ, Pham L, Doepker CL, **Wikoff DS**. 2019. Lack of potential carcinogenicity for acesulfame potassium — Systematic evaluation and integration of mechanistic data into the totality of the evidence. *Food Chem Toxicol* 141:111375; doi: <https://doi.org/10.1016/j.fct.2020.111375>.
- Suh M, **Wikoff D**, Lipworth L, Goodman M, Fitch S, Mittal L, Ring C, Proctor D. 2019. Hexavalent chromium and stomach cancer: A systematic review and meta-analysis. *Crit Rev Toxicol* 49(2):140–159; doi: 10.1080/10408444.2019.1578730.

- Wikoff DS**, Chappell GA, Fitch S, Doepker CL, Borghoff SJ. 2019. Lack of potential carcinogenicity for aspartame – Systematic evaluation and integration of mechanistic data into the totality of the evidence. *Food Chem Toxicol* 135:110866; doi: <https://doi.org/10.1016/j.fct.2019.110866>.
- Wikoff D**, Haws L, Ring C, Budinsky R. 2019. Application of qualitative and quantitative uncertainty assessment tools in developing ranges of plausible toxicity values for 2,3,7,8-tetrachlorodibenzo-p-dioxin. *J Appl Toxicol* 39(9):1293–1310; doi: <https://onlinelibrary.wiley.com/doi/full/10.1002/jat.3814>.
- Doepker C, Franke K, Myers E, Goldberger JJ, Lieberman HR, O'Brien C, Peck J, Tenenbein M, Weaver C, **Wikoff D**. 2018. Key findings and implications of a recent systematic review of the potential adverse effects of caffeine consumption in healthy adults, pregnant women, adolescents, and children. *Nutrients* 10:1536; doi: 10.3390/nu10101536.
- Wikoff D** (contributing author). EFSA (European Food Safety Authority) and EBTC (Evidence-Based Toxicology Collaboration). 2018. EFSA Scientific Colloquium 23. Evidence integration in risk assessment: The science of combining apples and oranges. EFSA Supporting Publication 2018:15(3):EN-1396; doi: [10.2903/sp.efsa.2018.EN-1396](https://doi.org/10.2903/sp.efsa.2018.EN-1396).
- Wikoff D**, Miller G. 2018. Systematic reviews in toxicology. *Toxicol Sci* 163(2):335–337; doi: 10/1093/toxsci/kfy109.
- Wikoff DS**, Rager JE, Chappell GA, Fitch S, Haws L, Borghoff SJ. 2018. A framework for systematic evaluation and quantitative integration of mechanistic data in assessments of potential human carcinogens. *Toxicol Sci* 167(2):322–335; doi: <https://doi.org/10.1093/toxsci/kfy279>.
- Wikoff DS**, Thompson C, Rager J, Chappell G, Fitch S, Doepker C. 2018. Benefit-risk analysis for foods (BRAFO): Evaluation of exposure to dietary nitrates. *Food Chem Toxicol* 120(2018):709–723.
- Wikoff D**, Urban JD, Harvey S, Haws LC. 2018. Role of risk of bias in systematic review for chemical risk assessment: A case study in understanding the relationship between congenital heart defects and exposures to trichloroethylene. *Int J Toxicol* 37(2):125–143; doi: 10.1177/1091581818754330.
- 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(2017):112–125.
- Hoffmann S, de Vries RBM, Stephens ML, Beck NB, Dirven HAAM, Fowle JR III, Goodman JE, Hartung T, Kimber I, Lalu MM, Thayer K, Whaley P, **Wikoff D**, Tsaoun K. 2017. A primer on systematic reviews in toxicology. *Arch Toxicol* 91(7):2551–2575; doi: 10.1007/s00204-017-1980-3.
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- Wikoff DS**, Rager JE, Haws LC, Borghoff SJ. 2016. A high dose mode of action for Tetrabromobisphenol A-induced uterine adenocarcinomas in Wistar Han rats: A critical evaluation of key events in an adverse outcome pathway framework. *Regul Toxicol Pharmacol* 77:143–159; doi: 10.1016/j.yrtph.2016.01.018.
- Borghoff SJ, **Wikoff D**, Harvey S, Haws L. 2016. Dose- and time-dependent changes in tissue levels of tetrabromobisphenol A (TBBPA) and its sulfate and glucuronide conjugates following repeated administration to female Wistar Han rats. *Toxicol Rep* 3:190–201; doi:10.1016/j.toxrep.2016.01.007.
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PROTOCOLS

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- Fitch S, **Wikoff D**, Britt J, Lea I, Brown L, Borghoff S, et al. 2022. Systematic literature review and critical appraisal of mammalian reproductive studies evaluation potential effects associated with microplastics. OSF | Systematic Literature Review and Critical Appraisal of Mammalian Reproductive Studies Evaluation Potential Effects Associated with Microplastics.
- Franke K, Payne L, Franzen A, **Wikoff D**, Henderson R. 2021. Cannabidiol literature scoping review protocol. OSF | Cannabidiol Literature Scoping Review Protocol.
- Lalu M, Jeffers M, Moher D, Sena E, Macleod MR, Avey M, ... **Wikoff D**. 2020. PRISMA extension for preclinical in vivo animal experiments. OSF | PRISMA Extension for Preclinical In Vivo Animal Experiments.
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SELECTED SCIENTIFIC MEETING PRESENTATIONS

Fitch S, **Wikoff D**, Foreman J, Buerger A, Haws L, Palmero C. Assessment of relative potency factors for six phthalates. Abstract 4235, Society of Toxicology 64th Annual Meeting, Orlando, FL, March 2025.

Wikoff D. An introduction to evidence integration. Workshop Session, Abstract 1333, Society of Toxicology 64th Annual Meeting, Orlando, FL, March 2025.

Wikoff D, Fitch S, Vincent M, Southall MD, Atillasoy E, Weinstein RD, Ejaz SD, Rhoden JD, Choksi N. Biological plausibility assessment of acetaminophen and occurrence of developmental neurological outcomes in humans. Abstract 4768, Society of Toxicology 64th Annual Meeting, Orlando, FL, March 2025. (*Honored as one of the Risk Assessment Specialty Section's Top 10 Abstracts*)

Wikoff D. Pragmatic solutions for better using evidence-based methods to integrate observational data in food safety assessments. Toxicology Forum 2025 Winter Meeting, Raleigh, NC, February 2025.

Wikoff D. Use cases of strategic application of ML/AI in the risk assessment process. Toxicology Forum 2025 Winter Meeting, Raleigh, NC, February 2025.

DeVito, Bokkers B, van Duursen M, van Ede K, Feeley M,... Haws L,... **Wikoff D**, et al. The 2022 WHO reevaluation of human and mammalian toxic equivalency factors for polychlorinated dioxins, dibenzofurans and biphenyls. Abstract 3626, Society of Toxicology 63rd Annual Meeting, Salt Lake City, UT, March 2024.

Fitch S, Ellis-Hutchings R, Rogers J, Marty S, Rushton E,... **Wikoff D**. Study quality evaluation of literature reporting plastic microparticle exposure against reproductive and developmental toxicity endpoints. Abstract 5159, Society of Toxicology 63rd Annual Meeting, Salt Lake City, UT, March 2024.

Franke K, Vincent M, Rogers S, Rivera B, **Wikoff D**. Assessment of non-occupational exposures to cleaning products and the incidence of asthma and respiratory disease. Abstract 3393, Society of Toxicology 63rd Annual Meeting, Salt Lake City, UT, March 2024.

Lynn SG, Lea IA, Urban J, Borghoff SJ, **Wikoff D**, Fitch S, Perry C, Choksi N, Britt J, Heintz M, Klaren W, et al. Development and application of systematic approach to inventory and interrogate thyroid hormone network information. Abstract 4357, Society of Toxicology 63rd Annual Meeting, Salt Lake City, UT, March 2024.

Thompson CM, Heintz MM, Rogers SI, Fitch SE, Rivera BN, Klaren WD, Vincent MJ, **Wikoff DS**, Haws LC. Evidence identification and appraisal supporting development of an updated toxicity value for HFPO-DA. Abstract 3654, Society of Toxicology 63rd Annual Meeting, Salt Lake City, UT, March 2024.

Urban JD, Covington TR, Fitch SE, **Wikoff DS**. Dioxin-like compounds in soils: A pilot survey updating background soil TEQ. Abstract 5147, Society of Toxicology 63rd Annual Meeting, Salt Lake City, UT, March 2024.

Vincent M, Fitch S, Bylsma L, Thompson C, Rogers S, Britt J, **Wikoff D**. Integration of toxicological and epidemiological information to evaluate biological plausibility and causality of associations between inhaled formaldehyde (FA) and lymphohematopoietic (LHP) cancers. Abstract 5157, Society of Toxicology 63rd Annual Meeting, Salt Lake City, UT, March 2024.

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 62nd Annual Meeting, Nashville, TN, March 2023.

Fitch S, Rogers J, Marty S, Ellis-Hutchings R, Becker R, **Wikoff D**. Development of a study quality tool for use in a systematic review of literature reporting microplastic exposure and reproductive and developmental toxicity. Poster presented at Society of Toxicology 62nd Annual Meeting, Nashville, TN, March 2023.

Franzen AC, Thompson CM, Brorby GP, **Wikoff DS**, Ilkbahar Z, Doepker C. Risk assessment of three smoke flavoring primary products currently under re-evaluation by EFSA. Poster presented at Society of Toxicology 62nd Annual Meeting, Nashville, TN, March 2023.

Rivera BN, Svetlik A, Klaren WD, **Wikoff DS**, Henderson RG. Scoping review of the immunomodulatory effects of cannabidiol: Effects within T cells. Poster presented at Society of Toxicology 62nd 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 62nd Annual Meeting, Nashville, TN, March 2023.

LaPlaca SB, Heintz MM, **Wikoff D**, Haws LC. Multi-step integration of ecotoxicological study reliability in ecological risk assessment. Poster at Society of Environmental Toxicology and Chemistry ([SETAC](#)), Philadelphia, PA, November 2022.

Fitch S, Klaren WD, Payne L, **Wikoff D**. Comparison of public and private literature databases for toxicological investigations. Poster presented at Society of Toxicology 61st Annual Meeting, San Diego, CA, March 2022.

Panel Discussion Moderator: “Systematic review in the risk assessment community—Highlights of key utilities, challenges, and opportunities for path forward.” The Toxicology Forum, Virtual Summer Meeting, July-August 2021.

Wikoff D, Fitch S, Borghoff S. Case-study applications using evidence-based approaches to assess endocrine activity for risk assessment. Invited speaker (Wikoff). Society for Birth Defects Research & Prevention 61st Annual Meeting, Virtual, June 2021.

Wikoff D, Franzen A, Chappell G, Harris M, Thompson C. Systematic characterization of hexavalent chromium and potential female reproductive outcomes: Application of US EPA critical appraisal tools and stepwise inclusion of mechanistic data. Poster for Society of Toxicology, 59th Annual Meeting, Virtual, 2020, <https://eventpilotadmin.com/web/page.php?page=Session&project=SOT20&id=P3209>.

Henderson RG, Franzen A, Franke K, Payne L, Schmitt D, **Wikoff D**. Creating a literature database for cannabidiol (CBD): Systematic evidence mapping. Poster for Society of Toxicology, 59th Annual Meeting, Virtual, 2020, <https://eventpilotadmin.com/web/page.php?page=Session&project=SOT20&id=P1236>.

Ring C, Fitch S, Haws L, Harris M, **Wikoff D**. Quantitative integration of dose-response data for relative potency estimates of dioxin-like chemicals. Poster for Society of Toxicology, 59th Annual Meeting, Virtual, 2020, <https://eventpilotadmin.com/web/page.php?page=Session&project=SOT20&id=P3385>.

Wikoff D, Erranguntla N, Lewis J, Foreman J. A fit-for-purpose framework for use of systematic methods in risk assessment. Poster at Evidence Integration in Chemical Assessments: Challenges Faced in Developing and Communicating Human Health Effect Conclusions. National Academies of Sciences, Engineering, and Medicine, Washington, DC, June 2019.

Borghoff S, Fitch S, Britt J, Franke K, **Wikoff D**. Application of the EFSA/ECHA endocrine disruption guidance as a framework for evidence integration in a weight-of-evidence (WoE) analysis for oxybenzone (BP-3). Poster at Evidence Integration in Chemical Assessments: Challenges Faced in Developing and Communicating Human Health Effect Conclusions. National Academies of Sciences, Engineering, and Medicine, Washington, DC, June 2019.

Urban J, **Wikoff D**, Haws L. Three-tiered approach to integrating evidence streams assessing gestational trichloroethylene exposure and congenital heart defects (TCE-CHD). Poster at Evidence Integration in Chemical Assessments: Challenges Faced in Developing and Communicating Human Health Effect Conclusions. National Academies of Sciences, Engineering, and Medicine, Washington, DC, June 2019.

Urban J, **Wikoff D**, Suh M, Britt J, Harvey S, Chappell G, Haws L. Comparison of NTP OHAT and US EPA TSCA study quality criteria: Trichloroethylene (TCE) and congenital heart defects (CHDs) as a case study. Poster at Society of Toxicology 58th Annual Meeting, Baltimore, MD, March 2019.

Borghoff SJ, Fitch S, Huggett, **Wikoff D**. A hypothesis-driven weight-of-evidence analysis to evaluate potential endocrine disrupting properties of perfluorohexanoic acid (PFHxA). 2019. Poster at Society of Toxicology 58th Annual Meeting, Baltimore, MD, March 2019.

Ring CL, Urban J, **Wikoff D**, Thompson C, Budinsky RA, Haws LC. Application of systematic review and quantitative evidence integration methods to support risk assessment: Characterization of the dose-response relationship between exposure to dioxin-like compounds (DLC) and sperm count. Poster at Society of Toxicology 58th Annual Meeting, Baltimore, MD, March 2019.

Wikoff D. Problem formulation: Lessons and tools from practical applications involving systematic review of mechanistic data. Presented at Strategies and Tools for Conducting Systematic Reviews of Mechanistic Data to Support Chemical Assessments, National Academies of Sciences, Engineering, and Medicine. Washington, D.C., December 2018.

Borghoff S, **Wikoff D**, Urban JD, Rager JE. A systematic approach to identify plausible mode-of-actions (MOA) for an increased incidence of lung tumors in mice with chronic exposure to 4-methylimidazole (4-MEI). Society of Toxicology 57th Annual Meeting, San Antonio, TX, March 2018.

Wikoff D. Moving beyond theory to the use of systematic review to support regulatory decision making for evidence-based risk assessment. Society of Toxicology 57th Annual Meeting, San Antonio, TX, March 2018.

Urban JD, Harvey S, Haws LC, **Wikoff D**. Assessment of study quality (risk of bias) in understanding the relationship between congenital heart defects (CHDs) and exposures to trichloroethylene (TCE). Society of Toxicology 57th Annual Meeting, San Antonio, TX, March 2018.

Wikoff D, Goodrum P, Haws L, Budinsky R. Application of quantitative approaches to assess uncertainties in the development of toxicity values: A case study involving the reference dose (RfD) for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). Society of Toxicology 57th Annual Meeting, San Antonio, TX, March 2018.

Wikoff DS, Welsh BT, Henderson R, Brorby G, Britt J, Myers E, Goldberger J, Lieberman HR, O'Brien C, Doepker C. Application of systematic reviews in the evaluation of caffeine safety: Potential adverse effects of caffeine consumption in healthy adults, pregnant women, adolescents, and children. Society of Risk Analysis Annual Meeting, Arlington, VA, December 2017.

Wikoff DS, Rager JE, Harvey S, Haws L, Chappell G, Borghoff S. Development and refinement of a framework for quantitative consideration of study quality and relevance in the evaluation of mechanistic data based on Key Characteristics of Carcinogens. Society of Risk Analysis Annual Meeting, Arlington, VA, December 2017.

Wikoff DS, Rager J, Harvey S, Haws L, Chappell G, Borghoff S. Framework for quantitative consideration of study quality and relevance in the systematic evaluation of mechanistic data per the Ten Key Characteristics of Carcinogens. Poster presented at Society of Toxicology 56th Annual Meeting, Baltimore, MD, March 2017.

Suh M, Harvey S, **Wikoff D**, Mittal L, Ring C, Goodmanson A, Proctor D. Meta-analysis of hexavalent chromium and stomach cancer. Poster presented at Society of Toxicology 56th Annual Meeting, Baltimore, MD, March 2017.

Chappell G, Welsh B, Harvey S, Harris M, **Wikoff D**. Validation and application of a text mining tool in the identification and categorization of mechanistic data: A case study in improving problem formulation of carcinogenicity assessments. Poster presented at Society of Toxicology 56th Annual Meeting, Baltimore, MD, March 2017.

Doepker D, Tyndall K, Lane R, **Wikoff D**, Thompson C, Harvey S, Schmitt D. A proposed ADI for nitrate. Poster presented at Society of Toxicology 56th Annual Meeting, Baltimore, MD, March 2017.

Wikoff D, White MC, Borghoff SJ, Haws LC. Evaluation of tetrabromobisphenol A (TBBPA)-induced endocrine-related target gene activity using high-throughput screening data from ToxCast. Presented at Society of Toxicology 54th Annual Meeting, San Diego, CA, March 2015.

Borghoff SJ, **Wikoff D**, White MC, Thompson C, Haws LC. Identification of the molecular initiating event (MIE) for TBBPA induced uterine tumors in the framework of an adverse outcome pathway (AOP). Presented at Society of Toxicology's 54th Annual Meeting, San Diego, CA, March 2015.

Haws LC, Thompson C, Perry C, White M, Fitzgerald L, Borghoff S, **Wikoff D**. Development of non-cancer based toxicity factors and daily dose estimates for TBBPA. Presented at Society of Toxicology 53rd Annual Meeting, Phoenix, AZ, March 2014.

Wikoff D, Thompson C, Perry C, White M, Fitzgerald L, Borghoff S, Haws LC. Development of an oral cancer slope factor and lifetime average daily dose estimates for TBBPA. Presented at Society of Toxicology 53rd Annual Meeting, Phoenix, AZ, March 2014.

Haws L, Fitzgerald L, Burkhalter K, **Wikoff D**. US EPA's proposed toxicity values for TCDD: Implications for decision-making regarding the safety of foods in the United States. Presented at Society of Toxicology 51st Annual Meeting, San Francisco, CA, March 2012.

Wikoff D, DeVito M, Walker N, Hixon G, Harris M, Tachovsky A, Birnbaum L, Haws L. Application of machine learning in the development of a weighting framework for evaluating estimates of relative potency for dioxin-like compounds. Presented at Society of Toxicology 51st Annual Meeting, San Francisco, CA, March 2012.

Diliberto JJ, Sirinek L, Burkhalter B, **Wikoff DS**, Hixon G, Becker J, Patterson DG, Turner W, Tachovsky JA, Birnbaum LS, Haws LC. Endometriosis in a cohort of women living in the Kanawha River Valley in West Virginia: Blood levels of non-dioxin-like PCBs and relationship with BMI and age. Presented at Dioxin 2011, Brussels, Belgium, August 2011.

Haws LC, DeVito MJ, Walker NJ, Harris MA, Tachovsky JA, Birnbaum LS, Farland WH, **Wikoff DS**. Development of a consensus-based weighting framework for evaluating estimates of relative potency for dioxin-like compounds that includes consideration of data from human cells. Presented at Dioxin 2011, Brussels, Belgium, August 2011.

Haws LC, Fitzgerald L, Burkhalter B, Harris M, **Wikoff DS**. Assessment of the US EPA's proposed toxicological values for TCDD for regulation of dioxin-like compounds in foods: Bridging the science divide in a global market. Presented at Dioxin 2011, Brussels, Belgium, August 2011.

Rowlands JC, Urban J, **Wikoff DS**, Budinsky R. The presence and estimated functional effect of single nucleotide polymorphisms at the AIP, ARNT, HSP90AA1, AND HSP90AB1 loci in the human population. Presented at Dioxin 2011, Brussels, Belgium, August 2011.

Wikoff DS, Thompson C, Walker N, DeVito M, Harris M, Birnbaum L, Haws L. Derivation of relative potency estimates using benchmark dose modeling: a case study with TCDF. Presented at Dioxin 2011. Brussels, Belgium, August 2011.

Fitzgerald L, Burkhalter B, Urban J, **Staskal D**, Harris M, Haws L. VOC serum levels in the general U.S. population: An analysis of the 2003-2004 NHANES dataset. Presented at Society of Toxicology 50th Annual Meeting, Washington, DC, March 2011.

Staskal-Wikoff D, Budinsky R, Rowlands JC. Single nucleotide polymorphisms in the human aryl hydrocarbon receptor interacting protein (AIP) gene from six ethnic populations. Presented at Society of Toxicology 50th Annual Meeting, Washington, DC, March 2011.

Urban J, Fitzgerald L, Burkhalter B, **Staskal D**, Harris M, Haws L. BTEX serum levels in the general U.S. population: An analysis of 2003-2004 NHANES dataset. Presented at Society of Toxicology 50th Annual Meeting, Washington, DC, March 2011.

Harris M, Tachovsky JA, **Staskal-Wikoff D**, Aylward L, Burkhalter B, Simon T, Haws L. Serum concentrations of dioxin-like compounds in a population in Midland Michigan: An evaluation of the impact of soil exposures. Presented at Dioxin 2010, San Antonio, TX, September 2010.

Harris M, Tachovsky JA, **Staskal-Wikoff D**, Simon T, Burkhalter B, Urban J, Haws L. Assessment of the impact of various soil cleanup levels on serum concentrations of dioxin-like compounds in humans. Presented at Society of Toxicology 49th Annual Meeting, Salt Lake City, UT, March 2010.

Haws L, Tachovsky JA, **Staskal-Wikoff D**, Aylward L, Burkhalter B, Urban J, Simon T, Harris M. An evaluation of the influence of different soil cleanup levels on the concentration of dioxin-like compounds in human serum. Presented at Dioxin 2010, San Antonio, TX, September 2010.

Staskal-Wikoff D, Burkhalter B, Stapleton H, Harris M. PBDEs in Newark Bay sediments. Presented at Dioxin 2010, San Antonio, TX, September 2010.

Staskal DF, Birnbaum LS. Screening-level assessment of risk associated with exposure to PBDEs in Vehicles. Society for Toxicology 48th Annual Meeting, Baltimore, MD, March 2009.

Urban JD, Tachovsky JA, **Staskal DF**, Haws LC, Harris MA. Human health risk assessment of consumption of fish from the Lower Passaic River. Society for Toxicology 48th Annual Meeting, Baltimore, MD, March 2009.

Urban JD, Haws LC, Scott LF, Scott PS, **Staskal DF**, Tachovsky AT, Unice KM, Harris MA. A framework for evaluating serum dioxin data derived from biomonitoring studies. Society for Toxicology 47th Annual Meeting, Seattle, WA, March 2008.

Haws LC, Scott LLF, **Staskal DF**, Harris MA, Finley BL. Evaluation of biomonitoring data for dioxin-like compounds in workers at a primary magnesium production facility. Society for Risk Analysis, San Antonio, TX, December 2007.

Staskal DF, Donovan EP, Haws LC, Roberts JD, Unice KM, Finley BL, Harris MA. A quantitative microbial risk assessment for exposure to pathogens in waters and sediments of the Lower Passaic River. Society for Risk Analysis, San Antonio, TX, December 2007.

Staskal DF, Donovan E, Roberts J, Unice K, Finley B, Harris M. Human health risk associated with exposure to pathogen-contaminated sediments. Society of Toxicology 46th Annual Meeting, Charlotte, NC, March 2007.

Diliberto JJ, **Staskal DF**, Hakk H, Birnbaum LS. Differential urinary protein binding of PBDEs in mice. Society of Toxicology 46th Annual Meeting, Charlotte, NC, March 2007.

Emond C, Raymer J, Garner E, Diliberto J, **Staskal D**, Birnbaum LS. A physiologically-based pharmacokinetic model for developmental exposure to PBDE-47 in rodents. Society of Toxicology 46th Annual Meeting, Charlotte, NC, March 2007.

Nguyen LM, **Staskal DF**, Ferriby LL, Williams ES, Luksemburg WJ, Haws LC, Birnbaum LS, Paustenbach DJ, Harris MA. Dietary intake of PBDEs based on consumption of catfish in southern Mississippi. Society of Toxicology 46th Annual Meeting, Charlotte, NC, March 2007.

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