Seneca Fitch

DIRECTOR, HEALTH SCIENCES
SUPERVISING SCIENTIST

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Seneca Fitch, Director of ToxStrategies' Health Sciences practice, works as an information specialist and evidence analyst in support of systematic evaluations of substances associated with consumer products, food ingredients and additives, pharmaceuticals, and industrial chemicals. She has specialized expertise in facilitating the start-to-finish process of systematic reviews and evidence mapping according to several frameworks and utilizing software such as DistillerSR, HAWC, and SWIFTReview. Such work includes problem formulation and protocol development, definition of eligibility criteria (i.e., inclusion/exclusion), data extraction parameters, critical appraisal of study quality, and creation of evidence tables and data visualizations. Additionally, Ms. Fitch has strong working knowledge of developing database-specific syntax and executing search strategies for investigational and systematic literature queries in citation databases such as PubMed, Embase, and ToxPlanet. This work consists of formulating search strings according to structured and controlled vocabulary, such as PubMed's MeSH and Embase's Emtree, using Boolean search phrases, and using reference management software to organize and deliver query results. Ms. Fitch also has extensive experience designing and implementing literature prioritization methods to address the growing landscape of scientific literature. This includes application of machine learning techniques such as topic modeling—an approach that uses text mining to identify patterns and information clusters within a set of references.

Ms. Fitch has applied the principals of systematic review, together with the evaluation of endocrine-disrupting potential, for multiple compounds by applying guidance such as ECHA/EFSA's 2018 Guidance for the identification of endocrine disruptors. These efforts include developing a strategy to gather and assess all relevant information, assemble lines of evidence, and integrate evidence for estrogen, androgen, thyroid, or steroidogenesis-related endocrine activity in developing overall conclusions. Data extraction for endocrine evaluation is implemented using specific processes and modality-specific templates that require a working knowledge of endpoints associated with each endocrine modality, as well as assignment to biological levels of organization and categories/levels of strength based on study design. Ms. Fitch routinely assesses endocrine-related data, as well as other data types, for quality via risk-of-bias and other validity tools, including NTP-OHAT, USEPA-TSCA, SciRAP, and ToxRTool.

In an extension of systematic evaluation, Ms. Fitch developed and maintains several internal and external platforms that consult a wide range of sources to combine data and assist in managing the scientific landscape—a capability that allows for efficient and timely summarizing of large amounts of information in qualitative and quantitative capacities. These databases include guidance levels developed for food additives by several regulatory agencies (e.g., Acceptable Daily Intakes [ADIs]), regulatory status of such additives, and results of toxicity and carcinogenicity studies for more than 1,800 chemical exposure studies. In addition to her skills in systematic review and literature identification, Ms. Fitch also has experience in the conduct of hazard assessments for a range of products, such as herbal and natural products, essential oils, food additives, and microorganisms. This includes identification of toxicological data, as well as integration of regulatory considerations from both US and international agencies to ensure a comprehensive overview of the product.

EDUCATION, TRAINING, AND CERTIFICATION

May 2012	Texas Tech University, B.S., Biology
April 2020	DistillerSR Super User Certification
October 2019	EFSA/ECHA Guidance for Identifying Endocrine Disrupting Chemicals (Mainz, Germany)

PROFESSIONAL ACTIVITIES

2017–Present	Evidence Based Toxicology Collaboration Scientific Advisory Council (2019–2021) Tox21 Working Group Member
2015–2019	Air & Waste Management Association Young Professionals Coordinator (2016, 2017) Hot Air Topics Conference Planning Committee (2016) Annual Conference and Exhibition Planning Committee (2017)

SOFTWARE AND DATABASES

Systematic Review: DistillerSR, HAWC, SWIFT Review, SysRev

Data Visualization: Microsoft PowerBI, GraphPad Prism, Tableau, Microsoft Excel,

Literature Search: ToxPlanet, PubMed, Embase, *and others*

Reference Management: EndNote, Zotero, Mendeley

PROFESSIONAL EXPERIENCE

Designed and implemented a systematic evidence map case study using an AOP framework to characterize the potential estrogenicity of selected alkylphenols. The primary objective of this study was to characterize estrogen-mediated molecular initiating events, key events, key event relationships, and adverse outcomes for alkylphenols across evidence streams, species, and study designs.

Systematically evaluated potential endocrine activity (estrogen, androgen, thyroid, and steroidogenesis pathways) of oxybenzone, a common UV filter, across evidence streams using the EFSA/ECHA (2018) endocrine disruptor identification framework. This work included the use of the Microsoft Excel data extraction templates and line-of-evidence tables, to integrate data types for an overall characterization of evidence.

Collaborated in a weight-of-evidence analysis to evaluate the potential endocrine disruption activity across estrogen, androgen, thyroid, and steroidogenesis pathways of 6:2 FTOH and its degradant, PFHxA, by integrating *in vivo* studies and *in vitro* high-throughput screening data relative to the exposure required to elicit the potential responses.

Applied ECHA/EFSA (2018) guidance for evaluating endocrine disruptors to data sets for a variety of flame-retardants. The evaluations focused on identifying potential for activity along the estrogen, androgen, thyroid, and steroidogenesis pathways following exposure to these compounds, as well as any degradation products or metabolites.

Applied ECHA/EFSA (2018) guidance for evaluating endocrine disruptors to data sets for a proprietary insecticide to identify potential indicators of estrogen, androgen, thyroid, or steroidogenesis pathway disruption.

Implemented a scoping review based on the Joanna Briggs Institute framework (2015) to systematically map the literature landscape of when and how acceptable daily intakes of low-calorie sweeteners are compared to estimated intakes in nutrition research.

Systematically collected and updated relative potency estimates (REPs) for 29 dioxin-like compounds and designed a data selection hierarchy to identify highest quality data. The resulting database comprises >600 dose-response data sets (REPs) to facilitate the determination of TEFs quantitatively using all available data while accounting for quality, relevance, and a consistent approach.

Completed the analysis of multiple chemicals within SWIFT-Review to understand the efficiency with which the software organized and tagged the literature within specified toxicological categories.

Contributed to the development of multiple systematic review protocols, and their implementation, for a range of compounds (e.g., caffeine, TCE) across evidence streams (human, experimental animal, mechanistic). This included specific considerations such as establishing topic-specific search strategies, designating inclusion and exclusion criteria, study screening and characterization, and risk-of-bias assessment (e.g., internal validity). Protocols were developed according to the PROSPERO registration requirements to increase transparency and reduce bias in performing systematic reviews.

Developed a database to record and track ADI development by EFSA, JECFA, and FDA, and to benchmark values used to develop them. As a secondary initiative, subjective information, such as public opinion on the danger of such compounds, is also captured to provide a snapshot of the current landscape.

Collaborated in the development of a quantitative framework to evaluate the ten key characteristics of carcinogens, as described by Smith et al. (2016), in assessments of potential human carcinogens. In application, this framework involves applying a mathematical algorithm that allows for integration of data across characteristics and according to the quality, relevance, and activity to reach an overall conclusion about mechanistic data (as related to carcinogenicity).

Assisted in developing and implementing a search strategy to capture mechanistic data related to four common low-/no-calorie sweeteners. Data were then reviewed for relevance and extracted systematically, and an algorithm was applied to estimate carcinogenic potential relative to the ten key characteristics of carcinogens.

Formulated and conducted a systematic literature search to identify peer-reviewed literature pertaining to the carcinogenicity of a commonly used flame retardant. Screened literature by title and abstract and later organized results according to a framework utilized by IARC.

Regularly creates and pilots project-specific forms via DistillerSR, a proprietary software, according to the needs of title and abstract screening, full-text screening, data extraction, and risk of bias.

Regularly develops data visualizations using interactive software such as Tableau and PowerBI to support the characterization of project-specific literature landscapes.

Reviewed and extracted data from more than 600 publications to produce an index of data sets from *in vivo* and *in vitro* assays assessing the genotoxicity of 2-AAF, acrylamide, aflatoxin B_1, benzo(a)pyrene, butadiene, doxorubicin, MeIQx, PhIP, and vinyl chloride.

Assisted in compiling nonclinical pharmacology, pharmacokinetics, and toxicology data for the submission of a successful Investigational New Drug (IND) application filing.

Fit mathematical models to dose-response data using EPA's Benchmark Dose software to identify the benchmark dose level (BMDL) of a common flame retardant synergist.

Developed monographs for flavor additives and essential oils to identify relevant toxicology information and knowledge gaps for use in a large-scale systematic review of tobacco additives. Monographs included a review of available information, including physical and chemical properties, regulatory considerations, toxicological data, pyrolysis, and thermal degradation.

Wrote toxicology monographs identifying potential hazards of impurities and excipients at an anticipated exposure in patients for a pharmaceutical drug formulation. Assessments included physiochemical properties, regulated uses and limits, pharmacology, toxicology, immunology, pharmacokinetics, and in some cases, derivation of the toxicology-based exposure limit. Monographs were used to assess toxicity and formulate recommendations for necessary nonclinical studies.

Supported the update of an existing Superfund risk assessment using the EPA Risk Assessment Guidance for Superfund: Part D (RAGS D) tables to reflect potential new site usage.

Prepared a screening human health risk evaluation for indoor air measurements to assess the possibility of vapor intrusion of volatile organic compounds (VOCs) in subsurface soils adjacent to the property, and the potential public health risk of the current building and occupancy conditions. The data evaluation included comparison of indoor air concentrations to health-based screening levels and assessment of potential lifetime excess cancer risk and non-cancer hazard index of measured concentrations.

Formulated questions for a deposition pertaining to a potential occupational exposure to propane. Relevant questions were formed by an initial hazard characterization of propane, as well as site-specific information regarding the potential source of emission.

Calculated descriptive statistics of TBBPA and TBBPA-conjugate concentrations using GraphPad Prism to support analysis of the dose- and time-dependent changes of tissue levels in a repeat-dose toxicokinetic study.

Used the EPA IEUBK model to determine risk associated with soil concentrations of lead on a Superfund site in Pennsylvania for baseline and future/potential land-use scenarios.

Assisted in the development of a systematic review protocol and specific considerations, such as assessment of individual study risk of bias, or internal validity, as well as strength of evidence.

Conducted hazard assessments of natural products (e.g., chili peppers, marigold, etc.) intended for use in dietary supplements and other nutritional products. Assessments included review of traditional and current use, toxicological data, and various regulatory considerations from both US and international agencies.

Developed a chemical database for ToxStrategies that mines web data from more than 1,800 chemical exposure studies, facilitating trend analysis of continually accumulating intelligence pertaining to toxicity and carcinogenicity studies.

Assisted in generating receptor locations for air dispersion modeling of a chemical release, to obtain a data set that is sensitive to several possible exposure scenarios. Used this data set to compare identified air concentration limits, as well as values developed according to state guidance in a preliminary screening. Current emergency exposure limits were also evaluated in reference to the event in a preliminary health hazard assessment of the release.

Selected and compared defined Metropolitan Statistical Areas in the United States using data provided by the U.S. Census Bureau, to determine comparable cities based on similar demography and industrial workforce. These selected areas were used in an analysis of background health outcome levels to determine whether asthma and cancer rates are elevated among the cities of comparison.

Evaluated the geographic location of sediment samples along a shoreline with recreational access and assisted in identifying future sampling locations, to ensure an adequate amount of data to support future calculation of possible risks to visitors of the recreational sites.

BOOK CHAPTERS

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

MANUSCRIPTS

Fitch S, Blanchette A, Haws LC, Franke K, Ring C, DeVito M,… 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 147:105571; doi: 10.1016/j.yrtph.2024.105571.

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.

Borghoff SJ, **Fitch SE**, Black MVB, McMullen PD, Andersen ME, Chappell GA. 2021. A systematic approach to evaluate plausible modes of [action] for mouse lung tumors in mice exposed to 4-methylimidozole. Regul Toxicol Pharmacol 124:104977; DOI: 10.1016/j.yrtph.2021.104977.

Dirven H, Vist GE, Bandhakavi S, Mehta J, **Fitch SE**, Pound P, Ram R, Kincaid B, Leenaars CHC, Chen M, Wright RA, Tsaioun K. 2021. Performance of preclinical models in predicting drug-induced liver injury in humans: A systematic review. Nature, Scientific Reports; open access: https://doi.org/10.1038/s41598-021-85708-2.

Thompson CM, Gentry R, **Fitch S**, Lu K, Clewell HJ. 2020. An updated mode of action and human relevance framework evaluation for formaldehyde-related nasal tumors. Crit Rev Toxicol 50(10):919–952, https://doi.org/10.1080/10408444.2020.1854679.

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.

Wikoff DS, Chappel 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, https://doi.org/10.1016/j.fct.2019.110866

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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, DOI: 0.1177/1091581818754330.

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Wikoff D, Welsh BT, Henderson R, Brorby GP, Britt J, Myers E, Goldberger J, Lieberman HR, O'Brien C, Peck J, Tenebein M, Weaver C, **Harvey S**, Urban J, Doepker C. 2017. Systematic review of the potential adverse effects of caffeine consumption in healthy adults, pregnant women, adolescents, and children. Food Chem Toxicol 109(Pt1):585–648. https://doi.org/10.1016/j.fct.2017.04.002. E-pub Apr 21.

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.

ABSTRACTS AND PRESENTATIONS

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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.

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 Annual Meeting, Nashville, TN, March 2023.

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

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Fitch S, Goyak K, Green M, Grimm F, Wikoff D. AOP-based evidence integration in risk assessment: An evidence mapping case study on the estrogenicity of alkylphenols. Presentation for Society of Toxicology, Virtual Annual Meeting, 2020.

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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, Virtual Annual Meeting, 2020, https://eventpilotadmin.com/web/page.php?page=Session&project=SOT20&id=P3385.

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