Allison C. Franzen, Ph.D.

SCIENTIST III

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Allison Franzen has 8 years of experience in human health risk assessment. Her areas of expertise include quantitative risk assessments, evidence integration, weight-of-evidence analysis, systematic reviews, hazard identification, toxicological and pharmacokinetic critical literature review and searching, physiologically based pharmacokinetic (PBPK) modeling, PBPK USEPA quality assurance project plan (QAPP) documentation, benchmark dose modeling, and exposure assessments. Dr. Franzen has performed large-scale toxicity systematic reviews and smaller literature reviews and assessments for numerous chemicals. She has performed multiple dose-response analyses using USEPA's noncancer and cancer methods, and she has worked with biologically based interaction models to understand the interactions of the chemical mixture and its potential impact, with an exposure analysis of potential health effects.

Dr. Franzen has conducted literature reviews to determine the most appropriate biomarkers of exposure and effect for multiple chemicals. She has expanded and created multiple PBPK models and has recently been working to convert models from the now-outdated ACSLX language to R. She has developed an adverse-outcome pathway (AOP) and applied AOPs to inform the mechanism of toxicity for chemicals. Dr. Franzen is currently working on a chemical assessment under the new Toxic Substances Control Act (TSCA) guidelines.

EDUCATION AND DEGREES EARNED

2017 University of Louisiana at Monroe, Ph.D., Toxicology and Pharmacology

2010 University of Louisiana at Monroe, B.S., Toxicology (Physics)

PROFESSIONAL ASSOCIATIONS AND HONORS

2011–present	Society of Toxicology (SOT) Member
2016–2017	North East Louisiana (NELA) Young Professionals Top 20 Under 40
2015–2017	SOT Graduate Student and Leadership Committee Executive Board Programming Chair
2015–2016	SOT Outstanding Graduate Student Award for exemplary service to the Society
2014–2016	SOT Risk Assessment Specialty Section Graduate Student Representative

SELECTED PROFESSIONAL EXPERIENCE

Toxicological Reviews

Participated on teams to complete various studies:

- Develop the toxicological portion of a large weight-of-evidence (WOE) analysis for chemical and multiple health outcomes, which included the review and synthesis of toxicological literature describing the non-acute health effects of exposure. Identified and reviewed the relevant published and unpublished literature, applied the data management tool DistillerSR, performed QA/QC of the data set, and created visual graphic representations of WOE results.
- Produced the toxicological portion of a WOE analysis to develop product standards for eight chemicals following oral exposure. Included critical review and synthesis of the toxicological literature describing the non-acute oral health effects following exposure. The project included identification and systematic review of the published literature on this topic, and creation of visual graphic representation of WOE results.
- Critical review of the mechanistic and pharmacokinetic literature review of selected chemicals to develop a biologically based interactions model. Modeling helped to understand the interactions of each chemical mixture and the potential impact of the mixtures, with an exposure analysis of potential health effects.
- Protocol development for a step-by-step approach to conducting a systematic review of the epidemiological, toxicological, and mechanistic data, including methods for transparency, documentation of literature searching, assessing study quality and risk of bias, and integrating the data to be used in hazard assessments and dose-response analysis.
- Large review on biomarkers of exposure and determination of the biomarker of exposure that would most accurately characterize a change in exposure for approximately 20 different chemicals. Project included identification of the relevant published data and the specific chemicals, as well as a critical review of the literature. Reviewed the statistical analyses (e.g., coefficient of variability, linear regression analysis, multiple linear regression analysis, Spearmen's and Pearson's correlations) to quantify the biomarker of exposure specific to each chemical and correlated most closely to a one-to-one relationship representing a more accurate change in exposure.
- Apply the IPCS framework to a chemical to understand the human relevance and biological plausibility of the proposed modes of action of a health outcome that were put forth in the published literature.

- Develop an adverse-outcome pathway (AOP) for nasal pharyngeal cancer. Project included a large-scale literature review, identification of potential molecular initiating events and key events, and defining their dose-response relationships and weight of evidence for these events in the AOP. Used the AOP in an example case study with formaldehyde and also participated in a critical review of another developed AOP for arsenic.
- Review and comments for submission to USEPA on multiple IRIS assessments.

Quantitative Risk Assessment

Participated on teams to complete various studies:

- Conducted an aggregated global human health risk assessment for both octamethylcyclotetrasiloxane (D_4) and decamethylcyclopentasiloxane (D_5). Consisted of harmonized assessments that addressed the requirements for substance-specific risk assessment by agencies, including USEPA and Health Canada; various independent scientific committees working on behalf of the European Commission; and guidance for chemical safety assessments under the REACH Regulation in Europe; as well as other relevant authoritative bodies.
- Quantitative risk assessment for methyl salicylate. This risk assessment induced a critical review of the toxicity literature for oral exposure to methyl salicylate and a study quality assessment of the literature to understand the mode of action of the chemical and determine what data to use in benchmark dose modeling of the most sensitive endpoint, for the purpose of developing a point of departure (POD).
- Read-across review and report of TOXCAST data for a fungicide producer. Work included evaluation of the available toxicity data for fungicide and conduct of a read-across evaluation to determine data gaps that would need to be filled for the re-reregistration process under USEPA's Office of Pesticide Programs, Pesticide Re-Evaluation Division, to deliver findings to the Agency.
- Multiple baseline ecological risk assessments for sites in Louisiana. Work included review and understanding of current available guidelines for ecological risk assessments, data analysis of ecotoxicological literature, and calculation of exposure-point concentrations for ecological receptors.

Exposure Assessment

Participated in an exposure assessment of different siloxanes from food, water, and air, as well as dermal exposure to various personal care products. The exposure population included infants, children, and adults. Concentration distributions in the food items, over-the-counter drugs, water, indoor and outdoor air, and personal care products were assessed, along with distributions for consumption and other exposure parameters from published literature and the client's internal reports, to comply with globally harmonized human health risk assessment requirements of the US, Canada, and Europe.

Participated in an exposure assessment of a chemical in foods using the NHANES database to establish potential reference ranges for a chemical that would be found in certain foods and food groups.

Pharmacokinetic/Benchmark Dose Modeling

Participated on teams to complete various studies:

- Multiple physiologically based pharmacokinetic (PBPK) modeling expansion projects, including one for benzo(a)pyrene and 1,3-butadiene. Work included literature searching, review of primary scientific literature, and identifying data needed for model development, working with ACSLX program for simulation runs of the model, sensitivity analysis, and debugging.

- Various benchmark dose modeling projects. The projects included review of the toxicological literature and determination of the most sensitive endpoints for multiple different chemicals, dose-response modeling, running BMDS software, organizing and formatting data output for client, and determining the POD.
- R model conversion projects and creation of training for clients to use in the translated models. Previous ACSLX models were converted to the R computer language to assist with a change in platforms, as ACSLX licensing became available.
- Multiple USEPA QAPP PBPK model documentation projects. Models were submitted to USEPA for determination of validity for use and application in risk assessments. Project work included meticulous model documentation of all source values, model files, and model code.

Litigation Support

Participated in a large toxic tort litigation support project. The work included literature searching, critical review of literature and content, development of draft summaries of findings to include in expert report, organization and coordination of data between offices, and review of methods of safety values and possible extrapolation of these values over time periods.

Assisted with several large environmental and toxic tort litigation support projects. The work included conducting web-based literature searches, performing data analysis, and summarizing depositions, complaints, interrogation transcripts, medical record and social security transcripts, and other case-related materials.

Site/Facility Support

Assisted in multiple facets of various efforts:

- Creation and submission of Tier II forms, and preparation of client materials.
- Coordination and creation of several notice-of-intent forms for facilities.
- Asbestos inspections in small rental homes associated with catastrophe relief projects (hurricanes Katrina and Rita) from a state database. Assisted with home inspections, report development, and review support.
- Permit modification and renewals for industrial and chemical stormwater and wastewater permits. The work included water sampling, and developing and reviewing discharge monitoring reports (DMRs). Also, familiar with netDMR reporting process.
- Due diligence activities, including Phase 1 environmental site assessments, literature searches for background information through Louisiana DEQ's EDMS database, and review of environmental database reports (EDRs), report development, and review support.
- Title V air permits and permit modifications, including data input and analysis in Title V air permit database, preparation of SipGaps and crosswalks for facilities, and creating and submitting Notice-of-Intent Forms.
- Tank Speciation permit, including data input, analysis, and review.
- Large-scale environmental review of flood sites for the state of Louisiana.

MANUSCRIPTS

Gentry R, Thompson CM, **Franzen A**, Salley J, Albertini R, Lu K, Greene T. 2020. Using mechanistic information to support evidence integration and synthesis: A case study with inhaled formaldehyde and leukemia. Crit Rev Toxicol 50(10):885–918, https://doi.org/10.1080/10408444.2020.1854678.

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 (in press), journal pre-press at https://authors.elsevier.com/sd/article/S0273-2300(20)30216-6.

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: https://doi.org/10.1016/j.yrtph.2020.104729.

Gentry R, **Franzen A**, Green T. 2019. Principles of risk assessment. In: Toxicology. Elsevier, in press.

Greene T, Rogers S, **Franzen A**, Gentry R. 2017. A critical review of the literature to conduct a toxicity assessment for oral exposure to methyl salicylate. Crit Rev Toxicol 47(2):98–120. DOI:10.1080/10408444.2016.1236071.

Franzen A, Greene T, Van Landingham C, Gentry R. 2017. Toxicology of octamethylcyclotetrasiloxane (D4). Toxicol Lett 279 Suppl 1:2–22. DOI:10.1016/j.toxlet.2017.06.007.

Gentry R, **Franzen A**, Van Landingham C, Greene T, Plotzke K. 2017. A global human health risk assessment for octamethylcyclotetrasiloxane (D4). Regul Toxicol Pharmacol 74(Suppl):S25–S43.

Franzen A, Van Landingham C, Greene T, Plotzke K, Gentry R. 2016. A global human health risk assessment for decamethylcyclopentasiloxane (D_5). Regul Toxicol Pharmacol 74:25–43.

Campbell J, **Franzen A**, Van Landingham C, Lumpkin M, Crowell S, Meredith C, Loccisano A, Gentry R, Clewell H. 2016. Predicting lung dosimetry of inhaled particle-borne benzo(a)pyrene using physiologically based pharmacokinetic modeling. Inhal Toxicol 28(11):520–535.

Gentry R, Clewell H, Greene T, **Franzen A**, Yager J. 2014. The impact of recent advances in research on arsenic cancer risk assessment. Regul Toxicol Pharmacol 69(1):91–104.

ABSTRACTS, POSTERS, PRESENTATIONS

Franzen A, Borghoff SJ. An adverse outcome pathway for renal tumors in male rats through chemical induction of αa2u-globuline (α2u) nephropathy (α2u-N). Poster for Society of Toxicology, Virtual Annual Meeting, 2020, https://eventpilotadmin.com/web/page.php?page=Session&project=SOT20&id=P1921.

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, Virtual Annual Meeting, 2020, https://eventpilotadmin.com/web/page.php?page=Session&project=SOT20&id=P1236.

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, Virtual Annual Meeting, 2020, https://eventpilotadmin.com/web/page.php?page=Session&project=SOT20&id=P3209.

CERTIFICATIONS AND TRAINING

The Hamner Institutes Physiologically Based Pharmacokinetic Modeling (PBPK) and Applications Course, 2013

OSHA 40-hour Hazardous Waste Operations & Emergency Response (HAZWOPER), 2011

USEPA Environmental Boot Camp Education Course, 2011