

Exponent®
Engineering & Scientific Consulting

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Professional Profile

Elaine Freeman, DrSc, DABT, is a senior managing scientist in Exponent's Chemical Regulation & Food Safety practice with over 20 years of experience in regulatory toxicology, human health risk assessment, and chemical safety. She advises manufacturers, law firms, and regulatory affairs teams on pesticide registration, TSCA compliance, veterinary medicine registration, safety of substances added to food for regulatory submissions, and toxicological hazard evaluation, with particular depth in mode-of-action assessment and expert witness support.

Human Health Hazard & Risk

Dr. Freeman advises clients on the full spectrum of human health hazard identification and risk characterization for pesticides, industrial chemicals, food and feed ingredients, dietary supplements, consumer products, and veterinary medicines. Her work encompasses point-of-departure selection, margin-of-safety analysis, and the design of chemical-specific adjustment factors (CSAFs) based on pharmacokinetic and pharmacodynamic data. She develops hazard-based classification and screening systems, including prioritization frameworks for oil and gas, consumer products, and industrial chemicals, that help clients make defensible, risk-informed decisions under regulatory scrutiny.

Dr. Freeman conducts human health hazard and risk assessments for a broad range of chemical classes, including pesticide active ingredients and inerts, industrial chemicals, consumer products, cosmetics and personal care, fragrance compounds, nanomaterials, and pet and veterinary products. She has extensive experience with the Environmental Protection Agency's Endocrine Disruptor Screening Program (EDSP), including submission of other scientifically relevant information (OSRI), Tier I study monitoring, data evaluation reports, and weight-of-evidence submissions. Her evaluations address the full range of endocrine pathways — hypothalamic-pituitary-gonadal (HPG), hypothalamic-pituitary-thyroid (HPT), hypothalamic-pituitary-adrenal (HPA), somatotropic, vitamin D, PPAR, and retinoid signaling axes — as well as ToxCast and EDSP21 high-throughput screening (HTS) data interpretation.

Dr. Freeman prepares alternative approaches (waivers) from toxicological testing requirements under FIFRA, grounded in weight-of-evidence evaluations, structural analogy, and risk-based justifications, reducing unnecessary animal testing while satisfying EPA data requirements. She also advises clients on GHS/Globally Harmonized System classification and labeling under both U.S. OSHA Hazard Communication and international frameworks.

Toxicology

Dr. Freeman provides comprehensive toxicological consulting across the regulatory lifecycle of chemicals and products. Her expertise spans repeated-dose systemic toxicity, reproductive and developmental toxicity, immunotoxicity, neurotoxicity, genotoxicity, and carcinogenicity assessment. She applies the

IPCS Human Relevance Framework to evaluate mode-of-action (MOA) hypotheses for tumor findings in rodents, including thyroid, liver, eye, and lung tumors, and prepares mechanistic study designs and monitoring protocols to support those assessments.

She conducts and evaluates quantitative structure-activity relationship (QSAR) modeling for impurity and metabolite-of-concern assessments, new product development, and re-registration support. Dr. Freeman also prepares maximum tolerated dose (MTD) assessments, evaluates threshold of toxicological concern (TTC) frameworks, and refines inter- and intraspecies uncertainty factors using pharmacokinetic and pharmacodynamic data.

Safety of Substances Added to Food

Dr. Freeman supports clients seeking regulatory approval for food and color additives, regulatory submissions for food contact substances, and GRAS (Generally Recognized as Safe) conclusions and notifications. Her work includes preparing GRAS dossiers, presenting genotoxicity weight-of-evidence evaluations to the Food and Drug Administration, identifying surrogate compounds for toxicological assessment, and representing clients directly in FDA meetings. She has supported dietary and user safety assessments to determine acceptable daily intake (ADI) levels for veterinary active pharmaceutical ingredients (APIs) and has evaluated the toxicological implications of novel food-contact materials and devices, including compliance with FDA, EPA TSCA, and CPSC Federal Hazardous Substances Act (FHSA) requirements.

Recall Support and Health Hazard Evaluation

Dr. Freeman has led health hazard evaluations (HHEs) involving undeclared allergens, food and dietary supplement ingredients, pharmaceutical impurities, and microbial contaminants. She has applied exposure assessment, toxicological hazard characterization, epidemiological and clinical evidence review, and comparison to regulatory and literature-based safety thresholds to characterize potential health risks. She develops clear, scientifically supported conclusions and recommendations for clients addressing product safety concerns, regulatory inquiries, recall actions, consumer complaints, due diligence assessments, and legal proceedings.

Expert Reports & Witness

Dr. Freeman has served as an expert witness in toxicology and pesticide- and personal-care-related litigation and regulatory proceedings, including toxic tort, personal injury, and environmental matters. She prepares technically rigorous expert reports that translate complex toxicological data, including dose-response relationships, MOA findings, and epidemiological evidence, into clear, defensible conclusions for legal and regulatory audiences. Her testimony experience spans deposition proceedings in personal injury matters, and her written work product has supported regulatory submissions, arbitration, and agency hearings involving EPA, FDA, and CPSC.

Academic Credentials & Professional Honors

Dr.Sc, Regulatory Science, University of Southern California, 2026

M.S., Pharmacology and Toxicology, Duquesne University, 1998

B.S., Microbiology, University of Pittsburgh, 1994

Prior Experience

Regional Manager North America - Expert Network, SAP, 2010-2011

Global Toxicology Leader / Product Stewardship Leader, Celanese, 2008-2010

Toxicologist, Chemtura, 2004-2008

Product Safety Representative / Toxicologist, Bayer Material Science, 2002-2004

Professional Affiliations

ToxForum, 2021-present

Allegheny-Erie Society of Toxicology (AESOT), 1995-2004; 2010-present: Past-President and Counselor 2024-2025, President 2023, President-Elect 2023, Executive Committee 2003, Counselor 2011-present, Awards Chairperson 2003, Education Committee 1998-2002, Communication Committee 1999-2001

National Society of Toxicology (SOT), 2005-present Full Member, 1999-2005 Associate Member, 1996 Student Member; Risk Assessment Specialty Section Member 2010-present; Regulatory Specialty Section 2010-present; Women in Toxicology Member; Food Safety Section

Genetic Toxicology Associations (GTA), 2025-present. Member.

Crop Life America Human Health Working Groups, Human Health and Risk Assessment Committee (HARC, HHRAC), 2005-2008; 2011-present

American College of Toxicology (ACT), 2005-2009, 1999-2002 Associate Member, 1996 Student Member

International Society for Regulatory Pharmacology and Toxicology (ISRTP), 2011-present; Counselor 2015-2016; Treasurer 2016-2024

American Chemistry Council (ACC) Regulatory Advocacy Information Network (RAIN), 2008-2010

Society for Chemical Hazard Communication (SCHC), 1995-2000; 2008-present; Assistant Chair Professional Development Committee 2010-2021

Formaldehyde Council (FCI) and FormaCare, 2008-2010

Vinyl Acetate Council, 2008-2010

Publications

Morris-Schaffer K, Dahlberg S, Johann E, Murphy, MM, Tran NL, Freeman E. 2026. "Preclinical safety evaluation of sodium l-methylfolate," Food and Chemical Toxicology. https://doi.org/10.1016/j.fct.2025.115822

Freeman E, Pressman P, Hayes AW, Gukasyan H, Clemens R. 2025. "A review and critique of safety standards for dietary supplements," Nutrition Today. https://doi.org/10.1097/NT.0000000000000764

Freeman E, Rhiner M, Nahar M, Balachandran R, Tran N, LaCombe J. 2025. "A toxicological assessment of tri-betahydroxybutyrin for use as a novel food ingredient," Food and Chemical Toxicology. https://doi.org/10.1016/j.fct.2025.115638

Morris-Schaffer K, Farrington H, Dahlberg S, Llewellyn C, Freeman E. 2025. "A systematic literature

review and weight of evidence evaluation of the genotoxicity potential of atrazine," Journal of Toxicology and Regulatory Policy. https://doi.org/10.69982/JTRP-25-0007

Faulhammer F, Rooseboom M, Aygun Kocabas N, Arts JHE, Cordova A, Freeman E, Higgins LG, Nahar M, Richmond E, Schneider S, Morris-Schaffer K. 2024. "Xylene: Weight of evidence approach case study to determine the need for an extended one generation reproductive study with a developmental neurotoxicity animal cohort," Critical Reviews in Toxicology. 2024;54(10):925-952. https://doi.org/10.1080/10408444.2024.2413073

Chrysostomou P, Freeman E, Murphy MM, Chaudhary A, Siddiqui N, Daoust J. 2024. "A toxicological assessment of Ganoderma lucidum and Cordyceps militaris mushroom powders," Frontiers in Toxicology. http://dx.doi.org/10.3389/ftox.2024.1469348

Chrysostomou P, Freeman E, Murphy M, Pereira R, Esdaile DJ, Keohane P. 2024. "A toxicological assessment of spermidine trihydrochloride produced using an engineered strain of Saccharomyces cerevisiae," Food and Chemical Toxicology. https://doi.org/10.1016/j.fct.2023.114428

Freeman E, Ward R, Murphy MM, Wang T, Ryder J. "Comprehensive safety assessment of serendipity berry sweet protein produced from Komagataella phaffii," Regulatory Toxicology and Pharmacology. https://doi.org/10.1016/j.yrtph.2024.105562

Thiffault C, Freeman E, Williams GM, Tran NL. 2024. "Lack of genotoxicity potential and safety assessment of 4-(2-hydroxyethyl) morpholine present as an impurity in pharmaceuticals and nutritional supplements," Food and Chemical Toxicology. https://doi.org/10.1016/j.fct.2023.114352

Staveley JP, Freeman EL, McArdle ME, Ortego LS, Coady KK, Bone A, Lagadic L, Weltje L, Weyers A, Wheeler JR. "Current testing programs for pesticides adequately capture endocrine activity and adversity for protection of vertebrate wildlife," Integrated Environmental Assessment and Management. 2023;19(4):1089-1109. https://doi.org/10.1002/ieam.4732

Mealey KL, Owens KG, Freeman E. "Canine and feline P-glycoprotein deficiency: What we know and where we need to go," J Vet Pharmacol Therap. 2022;00:1–16. https://doi.org/10.1111/jvp.13102

Parsons P, Freeman E, Weidling R, Williams GL, Gill P, Byron N. "Using existing knowledge for the risk evaluation of crop protection products in order to guide exposure driven data generation strategies and minimise unnecessary animal testing," Critical Reviews in Toxicology Volume 51, 2021 - Issue 7. https://doi.org/10.1080/10408444.2021.1987384

Talyor AA, Freeman EF, van der Ploeg MJC. "Regulatory developments and their impacts to the nano-industry: A case study for nano-additives in 3D printing," Ecotoxicology and Environmental Safety 207 (2021) 111458. https://doi.org/10.1016/j.ecoenv.2020.111458

Loccisano AE, Freeman E, Riffle B, Doi A, Frericks M, Ferger I, Fabian E. 2021. "Afidopyropen: Challenges and impact of a toxicokinetic study designed to identify a point of inflection for dose-proportionality," Reg Tox and Pharm. 124. https://doi.org/10.1016/j.yrtph.2021.104962

McArdle ME, Freeman EL, Staveley JP, Ortego LS, Coady KK, Weltje L, Weters A, Wheeler KR, Bone AJ. "Critical Review of Read□Across Potential in Testing for Endocrine□Related Effects in Vertebrate Ecological Receptors," Environmental Toxicology and Chemistry—Volume 39, Number 4—pp. 739–753, 2020. https://doi.org/10.1002/etc.4682

Koblis KM, Kierski MW, Staveley JP, Freeman EL. 2014. "A Chemical Risk Prioritization Scoring Process for the Oil and Gas Exploration and Production Industry," SPE International Conference on Health, Safety, and Environment. http://dx.doi.org/10.2118/168326-ms

Published OECD IATA

Freeman E, Wilson K, Hilton GM, Wolf DC, Goetz A. OECD (2024). Case Study on the Use of Integrated Approaches for Testing and Assessment (IATA) for Chronic Toxicity and Carcinogenicity of Agrichemicals with Exemplar Case Studies - Ninth Review Cycle (2023). OECD Series on Testing and Assessment No. 402. OECD Publishing, Paris. Organisation for Economic Co-operation and Development 2024 https://doi.org/10.1787/c3b9ac37-en

Dissertation

Freeman EL. "Evaluating the FDA's Direct Food Ingredient Program: A Focus on GRAS Regulation, Industry Compliance, and Regulatory Outcomes from an Industry Perspective," Doctor of Regulatory Science Dissertation, University of Southern California, 2026. https://doi.org/10.25549/usctheses-oUC11399O24H

Project Experience

Dr. Freeman's project experience spans regulatory toxicology consulting for pesticide registrants, chemical manufacturers, food and consumer product companies, and veterinary pharmaceutical developers. The following examples are organized by her primary target work areas.

Human Health Hazard & Risk

Dr. Freeman has led human health hazard and risk assessments across dozens of engagements involving pesticides, industrial chemicals, consumer products, and oil and gas sector chemicals, applying both quantitative risk methods and regulatory frameworks including FIFRA, TSCA, FDA, and international equivalents.

- Conducted TSCA worker exposure assessments for new and existing chemicals, evaluating occupational health risks in support of EPA new chemical review and existing chemical risk evaluation programs.
- Designed and implemented a relative risk ranking system for a major oil and gas operator to prioritize chemicals used across the exploration and production lifecycle, integrating both hazard and exposure data for occupational and environmental receptors.
- Designed hazard-based classification and screening systems for internal and publicly available prioritization projects covering industrial chemicals, pesticide inerts, and consumer products.
- Assessed the product stewardship and regulatory implications of locating a 3D printer in an office setting, evaluating potential chemical exposures from nanomaterial-containing filaments and applicable regulatory frameworks under TSCA, OSHA, and consumer product safety statutes.
- Conducted strategic review and evaluation of ToxCast and EDSP21 high-throughput screening (HTS) data in support of international registration review for industrial and crop protection chemicals, advising clients on the weight-of-evidence implications for endocrine activity findings.
- Led project management and toxicological support for inert pesticide submissions under FIFRA, coordinating regulatory strategy, data gap analysis, and submission preparation.
- Managed global toxicological testing for an international biopesticide registration, including dossiers for Australia and New Zealand, a waiver from toxicological testing requirements for the European Union, and study placement and monitoring.
- Conducted regulatory toxicology assessments and developed registration strategies for microbial and biochemical pesticides, including evaluation of toxicology, infectivity, pathogenicity, allergenicity, secondary metabolites, and data waiver opportunities under FIFRA.

Toxicology

Dr. Freeman has provided toxicological consulting across the full regulatory lifecycle of pesticides, industrial chemicals, veterinary APIs, and consumer products, with particular depth in mode-of-action assessment, QSAR modeling, and mechanistic study design.

- Placed, monitored, and/or reviewed and evaluated global pesticide active ingredients toxicology studies. Selection of points of departure (PODs) as endpoints for human health risk assessment, including selection of safety factors and retention of FQPA safety factors.
- GLP Study Monitoring.
- Onsite CRO audit and in study laboratory visits for veterinary medicine assessments.
- Study director for veterinary medicine target animal safety (companion animal) study.
- Conducted multiple assessments of the mode of action (MOA) and human relevance of thyroid and liver tumors in rats using the IPCS Human Relevance Framework, including mechanistic study design, monitoring, and risk-based evaluation of the need for comparative thyroid assays.
- Authored multiple OECD Integrated Approach to Testing and Assessment (IATAs) submissions including the Rethinking Carcinogenicity Assessment for Agrochemicals Project (ReCAAP), Human Non-Relevance of Tyrosine-related Eye Effects with HPPDi Chemicals, and Exposure-led weight-of-evidence approach for agrochemicals.
- Conducted modeling and reviewed QSAR outputs to assess the toxicological relevance of impurities and metabolites of concern for FIFRA registration submissions.
- Evaluated toxicological data from literature, regulatory reports, publicly available databases, and internal sources for fragrance compounds, identifying NOAELs for oral repeated-dose systemic toxicity, acute and subchronic inhalation toxicity, and reproductive toxicity for use in threshold of toxicological concern (TTC) evaluations.
- Designed and supported dermal triple-pack testing (in vivo rat, in vitro rat, and in vitro human) to derive a refined dermal equivalent dose for pesticide risk assessment, reducing conservatism in occupational and residential exposure estimates.
- Conducted toxicological re-analysis and statistical modeling for a veterinary API safety assessment, supporting regulatory submission and label claims.
- Reviewed and evaluated guideline toxicology studies to assess whether effects on mammalian and ecological endocrine biological pathways, including HPG, HPT, HPA, somatotropic, vitamin D, PPAR, and retinoid signaling axes, were adequately characterized.
- Developed chemical-specific adjustment factors (CSAFs) based on human, rat, dog, and mouse pharmacokinetic data in support of EPA FIFRA pesticide reevaluation, enabling a more refined and scientifically defensible point of departure than default uncertainty factors.
- Prepared waivers from immunotoxicity and neurotoxicity testing requirements under FIFRA, grounded in review of the existing toxicological database, structural analogy to similar compounds, and margin-of-safety analysis in dietary and occupational health risk assessments.
- Advised clients on the selection, conduct, and regulatory application of acute toxicity New Approach Methodologies (NAMs), including OECD-accepted in vitro methods for skin and eye irritation, skin sensitization, and emerging approaches for respiratory toxicity assessment in support of TSCA and FIFRA submission.

Safety of Substances Added to Food

Dr. Freeman has supported multiple clients through FDA food safety regulatory processes, including GRAS determinations, food contact substance notifications, and dietary risk assessments for veterinary APIs.

- Provided toxicological support for FDA GRAS and food contact submissions, including representation of a client at FDA meetings to discuss the toxicological database, presentation of genotoxicity weight-of-evidence evaluations to FDA, participation in GRAS panel meetings, preparation of toxicological sections of GRAS dossiers, and identification of surrogate compounds for toxicological assessment.
- Placed, monitored, and/or reviewed and evaluated toxicological data packages for global registrations of human and pet food ingredients, including color additives.
- Conducted a weight-of-the-evidence review of the applicability of the Delaney Clause to an additive by reviewing the appropriate historical control data and applying statistical analyses.
- Review of the potential for genotoxicity and application of a threshold of toxicological concern (TTC) for an impurity in pharmaceuticals and nutritional supplements.
- Conducted a dietary risk assessment to determine the level of detection and influence on the acceptable ADI for a veterinary API, supporting regulatory approval of a food-producing animal product.
- Reviewed and evaluated a disposable device for measuring gluten in foods, assessing its components for compliance with FDA, EPA TSCA, CPSC Federal Hazardous Substances Act (FHSA), EPA waste regulations, and state-specific requirements, as well as product stewardship considerations.

Recall Support and Health Hazard Evaluation

Dr. Freeman has conducted multiple health hazard evaluations (HHEs) for a variety of products and contaminants/impurities.

- Led a health hazard evaluation of undeclared whey protein isolate in a liquid collagen supplement, including allergen exposure assessment, comparison to published milk allergen threshold doses, risk characterization, and development of recommendations supporting regulatory and legal decision-making.
- Conducted a health hazard evaluation of undeclared soy food allergens in finished food products, integrating consumption estimates, clinical allergen threshold data, and population risk considerations to support recall and risk management decisions.
- Evaluated the safety implications of undeclared ingredients and formulation discrepancies in dietary supplements through exposure assessment, toxicological review, and comparison to established safety benchmarks and regulatory guidance values.
- Assessed pharmaceutical impurities and manufacturing-related contaminants by integrating toxicological, pharmacological, and exposure information to characterize potential human health risks and support product quality and compliance assessments.
- Performed health hazard evaluations of microbial contamination events in consumer products and dietary supplements, including hazard characterization of identified organisms, exposure assessment, and development of scientifically defensible risk conclusions.

- Evaluated chemical contaminants and impurity findings in food and dietary supplement products using a weight-of-evidence approach that incorporated analytical data, exposure estimates, toxicological benchmarks, and regulatory precedent.
- Developed technical risk assessments and health hazard evaluations to support product recalls, regulatory inquiries, consumer complaint investigations, product stewardship programs, and litigation matters involving food, dietary supplement, and consumer product safety.
- Prepared expert reports and scientific opinions addressing alleged health risks associated with contaminants, undeclared ingredients, and product quality concerns for legal, regulatory, and commercial applications.

Expert Reports & Deposition Testimony

Dr. Freeman has prepared expert reports and provided deposition testimony on matters involving toxicology and pesticide safety, translating complex scientific data into clear, defensible conclusions for legal and regulatory audiences.

- Assessed labeling requirements for over-the-counter pet products under the Consumer Product Safety Act, the Federal Hazardous Substances Act (FHSA), and FHSA regulations, including evaluation of the necessity for child-protective packaging.
- Provided deposition testimony in a personal injury matter involving toxicology and pesticide-related claims.
- Served as toxicology lead for global regulatory toxicology and due diligence review in connection with the due diligence for acquisition of a FIFRA-registered active ingredient, assessing current and future regulatory risk associated with the asset.
- Prepared expert reports for data compensation of toxicology studies.
- Provided expert reports regarding the regulatory and safety of personal care products regulated under the Modernization of Cosmetics Regulation Act (MOCRA).

Peer Reviews

Regulatory Toxicology and Pharmacology

Research in Veterinary Science