

## Isabel Lea, Ph.D.

DIRECTOR, HEALTH SCIENCES  
SENIOR MANAGING SCIENTIST

### CONTACT INFORMATION

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### PROFESSIONAL PROFILE

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Dr. Isabel Lea is a toxicologist in ToxStrategies' Health Sciences practice with more than 20 years of experience evaluating scientific evidence related to diverse chemicals and their potential impacts on human health. Her work focuses on hazard identification and the systematic evaluation of toxicological and mechanistic evidence to support regulatory decision-making and risk-based assessments. Dr. Lea has extensive experience synthesizing multiple lines of evidence, including *in vivo*, *in vitro* (including high-throughput screening), and *in silico* data, to characterize potential health hazards across a wide range of chemical classes.

Dr. Lea has supported clients navigating regulatory requirements for the identification of endocrine disruptors. She has experience applying frameworks developed by the European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA) for pesticide and biocide assessments and has evaluated evidence across estrogen, androgen, thyroid, and steroidogenesis (EATS) pathways. This expertise has been used to prepare submissions under the endocrine disruptor provisions of the EU Classification, Labelling, and Packaging (CLP) Regulation, which requires a comprehensive evaluation of mechanistic and apical evidence and the integration of findings into a clear, weight-of-evidence assessment aligned with regulatory expectations.

Dr. Lea also conducts International Agency for Research on Cancer (IARC) readiness evaluations to help clients understand and proactively manage the potential carcinogenic hazard profile of substances prior to formal IARC review. She evaluates the scientific literature to anticipate how evidence may be interpreted by an IARC Working Group and identifies key strengths, limitations, and data gaps. Dr. Lea has experience organizing mechanistic evidence using the key characteristics of carcinogens (KCCs) and integrating these data with *in vivo*, *in vitro*, and high-throughput screening results within a mode-of-action framework to assess biologically plausible pathways linking exposure to carcinogenic outcomes.

Dr. Lea also has extensive experience developing, managing, and curating toxicological databases. She possesses in-depth knowledge of major publicly available toxicology data platforms, including the National Toxicology Program's Chemical Effects in Biological Systems (CEBS) database and the Integrated Chemical Environment (ICE) database developed by the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). Through this work, she has developed a strong understanding of the structure and interpretation of large toxicology datasets, enabling her to efficiently identify relevant data sources, interpret complex datasets, and integrate information across platforms to support hazard identification and weight-of-evidence evaluations.

Dr. Lea has authored and co-authored publications in peer-reviewed journals, served as a reviewer for scientific manuscripts, and regularly participates in professional conferences and scientific meetings. She is a certified Project Management Professional (PMP) with extensive experience leading multidisciplinary teams and managing complex scientific projects, ensuring the timely delivery of high-quality work products while maintaining strong client engagement and satisfaction.

## EDUCATION, DEGREES, AND CERTIFICATIONS

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Ph.D. Molecular and Cell Biology, London University and the Zoological Society of London, UK

B.S. Microbiology, London University, London, UK

P.M.P. Project Management Professional (2019), Project Management Institute

## SELECTED PROFESSIONAL EXPERIENCE

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### *Toxicology*

Conducted a weight-of-evidence endocrine disruption assessment of phthalates using ECHA/EFSA guidance, synthesizing data from >100 studies, high-throughput assays, and *in silico* analyses to conclude whether phthalates met criteria for endocrine disruptors across estrogen, androgen, and steroidogenesis pathways.

Conducted an IARC readiness assessment for automotive gasoline and oxygenates by systematically reviewing human, animal, and mechanistic evidence and applying the Key Characteristics of Carcinogens (KCC) framework to evaluate carcinogenic hazard.

Performed a systematic weight-of-evidence evaluation of low and no calorie sweetener carcinogenicity, critically reviewing data from animal studies, and applying mechanistic endpoints using Key Characteristics of Carcinogens to conclude on human carcinogenic hazard.

Evaluated the applicability of the Threshold of Toxicological Concern (TTC) approach to PFAS by integrating NOAEL data for PFAS into the Munro dataset, demonstrating comparable Cramer Class III distributions and supporting TTC as a resource-efficient screening tool for PFAS risk prioritization.

Composed chapter "Electrolytes, Blood Gases, and Acid-Base Balance" for third edition of *The Clinical Chemistry of Laboratory Animals* (<https://doi.org/10.1201/9781315155807>).

Prepared four OSRI (Other Significantly Relevant Information) reports for four chemicals identified for Endocrine Disruptor Screening Program Tier 1 screening for use in their weight-of-evidence assessments for determination of Tier 2 testing.

## Data Science

Managed NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) Integrated Chemical Environment (ICE) database in support of developing alternative test methods. Integrated *in vivo*, *in vitro*, and *in silico* data from quantitative structure-activity relationship (QSAR) and *in vitro*-to-*in vivo* extrapolation (IVIVE) modeling. Established the use of controlled vocabularies to facilitate data selection and improve the user experience for ICE users.

Led team and performed a key role in redesigning and managing NTP's toxicological testing database (CEBS), working with NTP to develop standard data import procedures, perform statistical data analysis, and develop standardized reports for *in vivo* and *in vitro* data, single- and multigenerational studies, and multiple endpoints. Developed workflows to analyze multi-well plate data and a website to allow users to interact with the data.

## Project Management

Managed, expanded, and delivered a program handling a portfolio of up to 10 projects and developing services simultaneously. Allocated and scheduled resources while leading a multidisciplinary team comprising direct employees and subcontractors.

Monitored staff and provided comprehensive oversight of scientific team efforts, and guided development of reports and other written work products, including manuscripts for publication, CMMI level 3 documentation and processes, and software performance quality documents.

## MANUSCRIPTS

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**Lea IA**, Rivera B, Rogers S, Borghoff SJ. 2026. Assessment of the carcinogenic potential of automotive gasoline in humans based on mechanistic evidence. *Curr Res Toxicol* 10(Feb 12):100284; doi: [10.1016/j.crttox.2026.100284](https://doi.org/10.1016/j.crttox.2026.100284).

Borghoff SJ, Rivera B, Fitch S, Buerger AN, Choksi N, Franzen A, Vincent MJ, Covington T, ..., **Lea IA**. 2025. Systematic evaluation of the evidence base on methyl tert-butyl ether supporting a lack of concern for carcinogenic hazard in human based on animal cancer studies and mechanistic data. *Curr Res Toxicol* 8(Feb 16):100224; doi: [10.1016/j.crttox.2025.100224](https://doi.org/10.1016/j.crttox.2025.100224).

**Lea IA**, Buerger AN, Feifarek D, Mihalchik A, Heintz MM, Haws LC, Nyambego H, Goyak K, et al. 2025. Evaluation of the endocrine disrupting potential of Di-isononyl phthalate. *Curr Res Toxicol* 8(Feb 1):100220; doi: [10.1016/j.crttox.2025.100220](https://doi.org/10.1016/j.crttox.2025.100220). Corrigendum 8:100233; doi: [10.1016/j.crttox.2025.100233](https://doi.org/10.1016/j.crttox.2025.100233).

**Lea IA**, Feifarek D, Mihalchik A, Heintz M, Haws L, Nyambego H, Goyak K, Palermo C, Borghoff SJ. 2025. Evaluation of the endocrine disrupting potential of Di-isodecyl phthalate. *Curr Res Toxicol* 8(Feb 2):100221; doi: [10.1016/j.crttox.2025.100221](https://doi.org/10.1016/j.crttox.2025.100221).

Rivera BN, **Lea IA**, Fitch S, Choksi N, Franzen A, Bus J, Rushton E, Borghoff SJ. 2025. Systematic evaluation of the evidence base on ethyl *tert*-butyl ether and *tert*-butyl alcohol for carcinogenic potential in humans: Lack of concern based on animal cancer studies and mechanistic data. *Curr Res Tox* 10(Nov 10):100270; doi: [10.1016/j.crttox.2025.100270](https://doi.org/10.1016/j.crttox.2025.100270).

Rogers JM, Buerger AN, Heintz MM, Palermo CM, Haws LC, **Lea IA**. 2025. Evaluation of a hypothesized Sertoli cell-based adverse outcome pathway for effects of diisononyl phthalate on the developing testis. *Curr Res Toxicol* 8(Feb 1):100219; doi: [10.1016/j.crttox.2025.100219](https://doi.org/10.1016/j.crttox.2025.100219).

Borghoff SJ, Cohen SS, Jiang X, **Lea IA**, Klaren WD, Chappell GA, Britt JK, Rivera BN, et al. 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).

- Lea IA**, Pham LL, Antonijevic T, Thompson C, Borghoff SJ. 2022. Assessment of the applicability of the threshold of toxicological concern for per- and polyfluoroalkyl substances. *Regul Toxicol Pharmacol* 133(Aug):105190; doi: [10.1016/j.yrtph.2022.105190](https://doi.org/10.1016/j.yrtph.2022.105190).
- 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(Aug-Sept):503389; doi: [10.1016/j.mrgentox.2021.503389](https://doi.org/10.1016/j.mrgentox.2021.503389).
- Gentry R, Greene T, Chappell G, **Lea I**, Borghoff S, Yang C, Rathman J, Ribeiro JV, et al. 2021. Integration of evidence to evaluate the potential for neurobehavioral effects following exposure to USFDA-approved food colors. *Food Chem Toxicol* 151(May):112097; doi: [10.1016/j.fct.2021.112097](https://doi.org/10.1016/j.fct.2021.112097).
- Gentry R, Rodricks J, Clewell H, Greene T, Chappell G, **Lea I**, Borghoff S, Yang C, et al. 2021. RE: Response to the Office of Environmental Health Hazard Assessment on comments related to Gentry et al. (2021). *Food Chem Toxicol* 152(Jun):112202; doi: [10.1016/j.fct.2021.112202](https://doi.org/10.1016/j.fct.2021.112202).
- 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(July 22):2:254–271; doi: [10.1016/j.crttox.2021.07.002](https://doi.org/10.1016/j.crttox.2021.07.002).
- Bell S, Abedini J, Ceger P, Chang X, Cook B, Karmaus AL, **Lea I**, Mansouri K, et al. 2020. An integrated chemical environment with tools for chemical safety testing. *Toxicol in Vitro* 67(Sep):104916; doi: [10.1016/j.tiv.2020.104916](https://doi.org/10.1016/j.tiv.2020.104916).
- Jackson MA, Yang L, **Lea I**, Rashid A, Kuo B, Williams A, Lyn Yauk C, Fostel J. 2017. The TGx-28 65 biomarker online application for analysis of transcriptomics data to identify DNA damage-inducing chemicals in human cell cultures. *Environ Mol Mutagen* 58(7):529–535; doi: [10.1002/em.22114](https://doi.org/10.1002/em.22114).
- Lea IA**, Gong H, Paleja A, Rashid, A, Foster J. 2017. CEBS: A comprehensive annotated database of toxicological data. *Nucleic Acids Res* 45(D1):D964–D971; doi: [10.1093/nar/gkw1077](https://doi.org/10.1093/nar/gkw1077).
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- Lea IA**, Jackson MA, Dunnick JK. 2009. Genetic pathways to colorectal cancer. *Mutat Res* 670(1–2):96–98; doi: [10.1016/j.mrfmmm.2009.06.011](https://doi.org/10.1016/j.mrfmmm.2009.06.011).
- Lea IA**, Jackson MA, Li X, Bailey S, Peddada SD, Dunnick JK. 2007. Genetic pathways and mutation profiles of human cancers: Site- and exposure-specific patterns. *Carcinogenesis* 28(9):1851–1858; doi: [10.1093/carcin/bgm176](https://doi.org/10.1093/carcin/bgm176).
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O'Rand MG, **Lea IA**. 1997. Designing an effective immunocontraceptive. *J Reprod Immunol* 36(1–2):51–59; doi: [10.1016/S0165-0378\(97\)00052-1](https://doi.org/10.1016/S0165-0378(97)00052-1).

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**Lea IA**, Adoyo P, O'Rand MG. 1997. Autoimmunogenicity of the human sperm protein Sp17 in vasectomized men and identification of linear B cell epitopes. *Fertil Steril* 67(2):355–361; doi: [10.1016/S0015-0282\(97\)81923-1](https://doi.org/10.1016/S0015-0282(97)81923-1).

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## BOOK CHAPTERS

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**Lea IA**, Borghoff S, Travlos GS. 2018. Electrolytes, blood gases and acid-base balance. In: Kurtz DM, Travlos GS (eds): *The Clinical Chemistry of Laboratory Animals* (3rd edition). CRC Press:Boca Raton, FL.

## ABSTRACTS AND PRESENTATIONS

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Buerger AN, **Lea IA**, Vincent MJ, Rivera BN, Choksi NY, Britt J, Fitch S, Rogers S, et al. Systematic evaluation of the carcinogenic potential of di-isononyl phthalate in humans. Abstract 3314, Society of Toxicology 65<sup>th</sup> Annual Meeting, San Diego, CA, March 2026.

**Lea I**, Rivera B, Rogers S, Borghoff SJ. Assessment of the carcinogenic potential of automotive gasoline in humans based on mechanistic evidence. Abstract 5206, Society of Toxicology 65<sup>th</sup> Annual Meeting, San Diego, CA, March 2026.

Borghoff SJ, Rivera BN, Fitch S, Buerger A, Choksi N, Franzen A, Bus J, Rushton EK, **Lea I**. Systematic evaluation of the evidence base on methyl tert-butyl ether for carcinogenic potential in humans; Low concern based on animal cancer studies and mechanistic data. Abstract 4702, Society of Toxicology 64<sup>th</sup> Annual Meeting, Orlando, FL, March 2025.

**Lea IA**, Holt J, Bunnage E, Long M, Chew R, Bell S, Edwards S, Sayre R, et al. Integrated computational approaches in systematic evidence mapping: Bridging human expertise and machine learning for advanced toxicological assessments. Abstract 3409, Society of Toxicology 64<sup>th</sup> Annual Meeting, Orlando, FL, March 2025.

Rivera BN, **Lea IA**, Fitch S, Choksi N, Franzen A, Bus J, Rushton EK, Borghoff SJ. Systematic evaluation of the evidence base on ethyl tert-butyl ether and tert-butyl alcohol for carcinogenic potential in humans: Low concern based on animal cancer studies and mechanistic data. Abstract 4697, Society of Toxicology 64<sup>th</sup> Annual Meeting, Orlando, FL, March 2025.

Holt JR, Chew RF, Bunnage E, **Lea I**, Borghoff SJ, Sayer R, et al. Categorizing articles for environmental health systematic evidence mapping: A zero-shot machine learning approach using large language models. American Society of Cellular and Computational Toxicology Annual Meeting, Research Triangle Park, NC, October 2024.

**Lea IA**, Borghoff SJ, Chew R, Bell S, Edwards S, Vasko J, et al. Leveraging computational tools for enhanced human-in-the-loop systematic literature reviews. American Society of Cellular and Computational Toxicology Annual Meeting, Research Triangle Park, NC, October 2024.

**Lea IA**, Feifarek D, Mihalchik A, Heintz M, Haws L, Nyambego H, Goyak K, Borghoff SJ. Evaluation of the endocrine disrupting potential of di-isodecyl phthalate. Abstract 3930, Society of Toxicology 63<sup>rd</sup> Annual Meeting, Salt Lake City, UT, March 2024.

Borghoff SJ, Feifarek D, Mihalchik A, Heintz M, Haws L, Nyambego H, Goyak K, **Lea IA**. Evaluation of the endocrine disrupting potential of di-isodecyl phthalate. Abstract 3931, Society of Toxicology 63<sup>rd</sup> 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 63<sup>rd</sup> Annual Meeting, Salt Lake City, UT, March 2024.

**Lea IA**, Heintz MM, Feifarek D, Haws LC, Borghoff SJ. Weight-of-evidence evaluation of endocrine activity for di-isodecyl phthalate (DIDP) and di-isononyl phthalate (DINP). Poster presented at Society of Toxicology 62<sup>nd</sup> Annual Meeting, Nashville, TN, March 2023.

Mihalchik AL, Choksi NY, **Lea I**, Wood ML. Modern strategies to evaluate drug impurities. Session presented at Society of Toxicology 62<sup>nd</sup> Annual Meeting, Nashville, TN, March 2023.

Wikoff D, Edwards S, Angrish M, Baumgartner, Bever R, Borghoff S, Chappell G, Chew R, Fitch S, Hench G, Hamernik K, Henderson D, Kirk A, **Lea I**, Mandel M, Payne L, Shapiro S, Urban J, Williams D, Markey K. Application of systematic methods to characterize thyroid adverse outcome pathways (AOPs). Presented at American Society for Cellular and Computational Toxicology 10<sup>th</sup> Annual Meeting, Virtual, October 2021.

Bell S, Mansouri K, Phillips J, Chang X, Abedini J, Karmaus AL, **Lea I**, Rai R, Allen DG, Casey W, Kleinstreuer NC. NCEATM computational tools and resources supporting alternative test method development and evaluation. Abstract #2976-P607, Society of Toxicology 59<sup>th</sup> Annual Meeting, Anaheim CA, March 2020.

Sheridan E, Moose J, Liu Y, Martini C, **Lea I**, Fostel J. NTP high-level summary data collections in the Chemical Effects in Biological Systems (CEBS) database. Poster PS01-0606, 15th International Congress of Toxicology, Honolulu, HI, July 2019.

Bhawana B, **Lea I**, Liu Y, Martini C, Fostel J. Access to National Toxicology Program histopathology lesion collection in Chemical Effects in Biological Systems (CEBS) database. Poster P040, 38th Annual Symposium of Society for Toxicologic Pathology, Raleigh, NC, June 2019.

**Lea I**, Liu Y, Sheridan E, Motti D, Martini C, Fostel J, Auerbach S. Hallmark gene set annotation for NTP toxicogenomic studies. Abstract #1743-P119, Society of Toxicology 58th Annual Meeting, Baltimore, MD, March 2019.

Martini C, Liu Y, Motti D, Johnson J, McCormick K, **Lea I**, Fostel F. Integrating assay datasets into Chemical Effects in Biological Systems (CEBS). Abstract #1749-P125, Society of Toxicology 58th Annual Meeting, Baltimore, MD, March 2019.

Sheridan ER, Jackson M, Paleja A, Martini C, Rashid A, **Lea I**, Fostel J. Improved searching in the Chemical Effects in Biological Systems (CEBS) database leads to greater utility of NTP data. Abstract 2525-P887, Society of Toxicology 57th Annual Meeting, San Antonio, TX, March 2018.

Sheridan E, Raghuraman A, Brown P, Jackson M, Martini C, **Lea I**, Smith-Roe S, Witt K, Fostel J. Genetic toxicology data in the Chemical Effects in Biological Systems (CEBS) database. Poster P3, Environmental Mutagenesis and Genomics Society 48<sup>th</sup> Annual Meeting, San Antonio, TX, September 2018.

**Lea I**, Yang L, Rashid A, Fostel JM. Chemical Effects in Biological Systems (CEBS) Database: Treatment-related findings. Abstract 2918-P412, Society of Toxicology 56<sup>th</sup> Annual Meeting, Baltimore, MD, March 2017.

Martini C, Rashid A, Paleja A, **Lea I**, Fostel JM. Chemical Effects in Biological Systems (CEBS) database: Treatment-related findings. Abstract 1381-P119, Society of Toxicology 56<sup>th</sup> Annual Meeting, Baltimore, MD, March 2017.

Sheridan E, Martini C, Shaw M, Shockley K, Brix A, Rashid A, **Lea I**, Fostel J. Using the Chemical Effects in Biological Systems (CEBS) database to answer pathology questions. Poster P035, Society for Toxicologic Pathology 36<sup>th</sup> Annual Symposium, Montreal, Quebec, Canada, June 2017.

Jackson M, Yang L, Yauk CL, **Lea I**, Kuo B, Williams A, Rashid A, Fostel J. The TGx-28.65 biomarker — A web-based application using transcriptomics to identify DNA damage-inducing chemicals. Abstract 1224, Environmental Mutagenesis and Genomics Society 48<sup>th</sup> Annual Meeting, Raleigh, NC, September 2017.

**Lea I**, Rashid A, Favaro C, Fostel J. Chemical Effects in Biological Systems (CEBS) database: Advanced histopathology search applications. Abstract 2195-P410, Society of Toxicology 54<sup>th</sup> Annual Meeting, San Diego, CA, March 2015.