

TOM JONAITIS, B.SC., DABT

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EXPERIENCE

Founder and Principal Consultant •

RegTox Solutions Inc. | August 2018–Present

Provide senior-level toxicology, product safety, and regulatory consulting services to companies in the food and food ingredient, dietary supplement, cosmetic, consumer product, and related sectors. Advise clients on regulatory strategy, product development, market access, and compliance in the United States, Canada, Australia, and other jurisdictions.

Services include regulatory and product feasibility evaluations; scientific literature reviews and hazard assessments; safety and exposure assessments; preparation and critical review of pre-market safety, quality, and regulatory dossiers for novel food and dietary supplement ingredients; label and claims compliance; and derivation of health-based exposure limits from preclinical and clinical data.

Provide specialized California Proposition 65 consulting for the food, beauty and personal care, consumer product, and building material industries. Services include formulation and product screening, exposure assessment, analytical testing strategy and interpretation, risk characterization, and derivation of chemical-specific No Significant Risk Levels and Maximum Allowable Dose Levels for listed carcinogens and reproductive toxicants.

Manager, Toxicology & Regulatory Affairs •

Intertek Scientific & Regulatory Consultancy • 2014 – August 2018

Intertek Cantox • 2010 – 2013¹

Cantox Health Sciences Inc. • 2005 – 2010

Subject-matter expert and client contact for matters related to California Proposition 65, including presenting webinars/presentations. Conducted human exposure assessments in relation to chemicals in food, dietary supplements, consumer products and cosmetics, as well as deriving exposure limits for carcinogens, reproductive/developmental or other toxins using traditional and benchmark dose modeling approaches.

Conducted regulatory feasibility assessments, compiled regulatory submissions and provided guidance for clients, including reviewing registration requirements, gathering required information, compiling exposure/safety data, writing read-across arguments in support of data gaps, preparing proper documentation and submitting applications to government agencies for novel food and dietary supplement ingredients, as well as animal feed ingredients (Canada [Health Canada], US [US FDA], EU [European Commission], Australia [TGA, FSANZ]). Review and evaluate the results of *in vitro* and *in vivo* toxicological studies in support of the above tasks. Conducted comprehensive scientific literature research: search, summarize, and interpret relevant information to address safety concerns for issues related to food ingredients/contaminants, cosmetics, and consumer products.

Other areas of experience include: pesticide/agricultural chemical regulation (Canada, US); workplace hazard classifications (e.g., GHS); spray foam human health risk assessments (CAN/ULC-S774); TRA/LHAMA assessments.

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Research Assistant • Center for Addiction and Mental Health, Department of Neuroscience • 2004 – 2005

Integral member of the research team, involved in collecting large amounts of raw data, coding/input/ statistical data analysis, and drafting report on research results.

CERTIFICATIONS

Diplomate of the American Board of Toxicology (DABT); Certified in November 2017. Re-certified until 2027.

EDUCATION

B.Sc. (Honours), Specialist Degree in Toxicology • 2005 • University of Toronto

PROFESSIONAL SOCIETIES/ASSOCIATIONS

Society of Toxicology – Full Member and Member of “Risk Assessment” and “Regulatory and Safety Evaluation” Specialty Sections; Member and Past-President of Lake Ontario Regional Chapter.

Society of Risk Analysis – Full Member, and member of Exposure Assessment Specialty Section.

PAPERS AND PUBLICATIONS

Jonaitis, T., Ulmann, M., Wiesler, G., & Lukasik, K. V. (2026). Comprehensive safety assessment of novel dicholine folate vitamin. *Toxicology Reports*, 17, 102315.

<https://doi.org/10.1016/j.toxrep.2026.102315>

Jonaitis, T., Lewis, E., Lourens, N., *et al.* (2022). Subchronic feeding, allergenicity, and genotoxicity safety evaluations of single strain bacterial protein. *Food and Chemical Toxicology*. Vol. 162.

<https://www.sciencedirect.com/science/article/pii/S0278691522000758?via%3Dihub>

Haighton L, Roberts A, **Jonaitis T**, Lynch B (2019). Evaluation of aspartame cancer epidemiology studies based on quality appraisal criteria. *Reg Tox Pharm* Vol 103: 352-362.

<https://www.sciencedirect.com/science/article/pii/S0273230019300418>

Card JW, **Jonaitis T** (2015). Nanomaterials in cosmetics: regulatory and safety considerations. In: Overbeek R, Rosen MR, editors. *Harry's Cosmetology Focus Books: Achieving Global Cosmetic Market Access: Issues and Approaches, 9th edition*. Los Angeles (CA): Chemical Publishing Company, pp. 150-162.

Magnuson BA, **Jonaitis TS**, Card JW (2011). A brief review of the occurrence, use, and safety of food-related nanomaterials. *J Food Sci* 76(6):R126-R133. Available at:

<http://onlinelibrary.wiley.com/doi/10.1111/j.1750-3841.2011.02170.x/pdf>.

¹ Cantox Health Sciences Inc., was acquired by Intertek Group plc in April 2010.

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Card JW, **Jonaitis TS**, Tafazoli S, Magnuson BA (2011). An appraisal of the published literature on the safety and toxicity of food-related nanomaterials. Crit Rev Toxicol 41(1):22-51.

Jonaitis T, Card J, Magnuson B (2010). Concerns regarding nano-sized titanium dioxide dermal penetration and toxicity study. Toxicol Lett 192(2):268-269.

Reich ES (2011). Nano rules fall foul of data gap: Incomplete nanotoxicology research is hampering efforts to introduce regulation [Review of JW Card, **TS Jonaitis**, S Tafazoli, BA Magnuson, 2011. Crit Rev Toxicol 41(1): 22-51]. Nature 480(7376): 160-161. doi: 10.1038/480160a.

POSTER PRESENTATIONS (LEAD/CO-AUTHOR)

2018 • Development of a No Significant Risk Level for Furfuryl Alcohol and Assessment of Exposures from Coffee Consumption for Compliance with California Proposition 65

- San Antonio Texas

Presented at the 57th Society of Toxicology Annual Meeting (Lead Author)

2017 • Alternative Approach in the Safety Assessment of Plant-Based Proteins Intended for Use as Novel Ingredients in Food

- Baltimore, Maryland

Presented at the 56th Society of Toxicology Annual Meeting (Co-author)

2016 • Assessment of Dietary Exposures to Inorganic Arsenic from Rice and Compliance with California Proposition 65

- New Orleans, Louisiana

Presented at the 55th Society of Toxicology Annual Meeting (Co-author)

2014 • Proposed Novel Method for Assessing Risks of Inhaled Titanium Dioxide from Cosmetics

- Phoenix, Arizona

Presented at the 53rd Society of Toxicology Annual Meeting (Lead Author)

2013 • Deriving Dermal Safe Harbor Levels for DEHP Relevant to Consumer Products for Adults

- San Antonio, Texas

Presented at the 52nd Society of Toxicology Annual Meeting (Lead Author)

2010 • A Method to Assess the Quality of Studies that Examine the Toxicity of Engineered Nanomaterials

- Chicago, Illinois

Presented at IFT Annual Meeting and Food Expo (Co-author)

COURSES AND TRAINING

2024 • Navigating the OECD QSAR Toolbox

ToxNavigation, LLC, UK. January 2024; [online]

2021 • U.S. Cosmetics Labeling and GMP Compliance Seminar.

EAS Consulting Group, LLC. December 2021; [online]

2021 • Dose-Response Modeling - EPA Standard Benchmark Dose Modeling Approaches Using The Newest Version of EPA/NIOSH BMDS Software including BMDS-Online

Society for Risk Analysis, Annual Meeting Workshop. December 5, 2021.

2020 • An Introduction to New Approach Methodologies (NAMs) and Understanding Their Potential to Support Regulatory Decisions

Society of Toxicology Continuing Education Course, May 15; [online]

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2020 • Advances in CRISPR-Cas9 Tools and Applications for Toxicologists

Society of Toxicology Continuing Education Course, May 15; [online]

2020 • Introduction to Open-Access Computational Toxicology Tools

Society of Toxicology Continuing Education Course, April 3; [online]

2019 • Industrial Application of Computational Toxicology

Society of Toxicology Continuing Education Course, Baltimore, Maryland

2019 • Current Dose-Response Modeling Strategies and Applications in Chemical Risk Assessment

Society of Toxicology Continuing Education Course, Baltimore, Maryland

2014 • Methodologies in Human Health Risk Assessment

Society of Toxicology Continuing Education Course, Phoenix, Arizona

2014 • Epidemiology for Toxicologists: What the Numbers Really Mean

Society of Toxicology Continuing Education Course, Phoenix, Arizona

2013 • Advances in Nanotoxicology: Challenges

Society of Toxicology Continuing Education Course, San Antonio, Texas

2013 • Basic Principles of Human Risk Assessment

Society of Toxicology Continuing Education Course, San Antonio, Texas

2013 • “Food Safety and Risk Assessment” and “Qualitative and Quantitative Risk Assessment” (Online Courses)

Joint Institute for Food Safety and Applied Nutrition (JIFSAN)

WEBINARS/PRESENTATIONS/LECTURES

Numerous webinars on California Proposition 65 for general industry audiences, as well as collaboratively with various industry associations (e.g., Chemical Watch “Food Contact Regulations USA Summit”; Consumer Health Products Association) and different law firms.

Food and Drug Law Institute (FDLI) Introduction to Food Law and Regulation workshop: “Framework for Food Ingredient Regulation; Food Additives Amendment of 1958”. March 2021 and 2022.

Guest Lecturer; University of Toronto. Department of Pharmacology and Toxicology. First Year Graduate Course. Topic: Regulatory Affairs as a Consulting Toxicologist. March 4, 2020.

Joint Webinar with Frost Brown Todd LLC (law firm). My topic: “Cannabidiol: Data Requirements for Pathways to Market in the US”; April 27, 2020.

Lake Ontario Regional Chapter Webinar. “Recreational Cannabis: Current Safety Considerations.” February 28, 2020.

OTHER

Scientific manuscript reviewer for several reputable food and toxicology journals.