

Rayetta G. Henderson, Ph.D.

DIRECTOR SENIOR MANAGING SCIENTIST

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Rayetta Henderson is a toxicologist and Director of ToxStrategies' Foods & Consumer Products Practice. She has experience in the assessment of food, feed, and dietary supplement ingredients, including a focus on the study of botanicals. Dr. Henderson's work includes developing materials to support regulatory submissions, such as Generally Recognized as Safe (GRAS) and New Dietary Ingredient (NDI) notifications to the US Food and Drug Administration (FDA). Since enactment of the 2018 Farm Bill, much of her work has focused on the assessment of cannabidiol (CBD) and other hemp-derived products for use in foods and dietary supplements, including safety assessment and toxicology testing programs.

Dr. Henderson has published academic and professional work in book chapters and peer-reviewed journals, has reviewed submissions for scientific journals, and regularly attends and presents at professional conferences and working groups. She also currently serves as an appointed member of the Organizing Committee for the Society of Toxicology (SOT) FDA Colloquia on Emerging Toxicological Science: Challenges in Food and Ingredient Safety.

Dr. Henderson has prior experience working for an international trade association, including aiding in the development of strategies for addressing regulatory and technical issues in the US and EU. In addition, in her previous role as technical manager of the global Nickel REACH Consortia, she managed the strategic planning and implementation of research programs to fulfill data requirements for nickel-containing substances for the EU's REACH Regulation.

After attending the North Carolina School of Science and Mathematics (Durham, NC), Dr. Henderson earned her B.S. in Biology from Eckerd College (St. Petersburg, FL) and her Ph.D. in Toxicology from the University of North Carolina at Chapel Hill.









EDUCATION AND DEGREES EARNED

2005 Ph.D., Toxicology and Interdisciplinary Program in Biomedical Sciences, University of North Carolina at Chapel Hill

2000 B.S., Biology (Spanish minor), Eckerd College

PROFESSIONAL ASSOCIATIONS

International Cannabinoid Research Society

North Carolina Chapter, Society of Toxicology

Society of Toxicology

Regulatory Affairs Professionals Society

Women in Nutraceuticals

PROFESSIONAL ACTIVITIES

	2024	Invited Speaker, Reproductive and Developmental Toxicity Evaluation of Cannabidiol to Support Risk Characterization. Symposium: Looking through the Haze: Is the Picture Any Clearer on the Effects of Cannabis and Cannabis-Related Products on Reproduction and Development? Society of Toxicology Annual Meeting.
	2023	Invited Witness — Expert testimony before the House Committee on Oversight and Accountability: Subcommittee on Health Care and Financial Services. Hemp in the Modern World: The Years-Long Wait for FDA Action.
2023-Present Appointed member, SOT FDA Colloquium Organizing Committee		
	2021	Invited Speaker, Best Practices: Generally Recognized as Safe (GRAS). Toxicology Workshop — Safety Considerations for NDI Notifications and GRAS Conclusions. Council for Responsible Nutrition.
2019-Present Participating member, Council for Responsible Nutrition, CBD Working Group 2019-Present Participating member, Council for Responsible Nutrition, Senior Scientific Advisory Council		t Participating member, Council for Responsible Nutrition, CBD Working Group
		t Participating member, Council for Responsible Nutrition, Senior Scientific Advisory Council
	2008–2009	Speaker and participant, HERAG Alloys Fact Sheet meeting at Finnish Institute of Occupational Health
	2005–2006	Student Councilor, Reproductive and Developmental Toxicology Specialty Section, Society of Toxicology
	2005	Invited Speaker, Organ System Maturation: The Lung. Middle Atlantic Reproduction and Teratology Association
	2004–2005	Student Representative, The Teratology Society Continuing Education Committee
	2004–2005	Student Representative, UNC-CH Curriculum in Toxicology Executive Committee
	1998–2000	Student Representative, Natural Science Collegium Senate, Eckerd College



PROFESSIONAL AWARDS

Best Paper of the Year (co-author), Food and Chemical Toxicology (2017)

Young Investigator Travel Award, The Teratology Society (2003, 2004, and 2005)

US EPA Bronze S-Award for Sustained Efforts (2004)

Marie Taubeneck Award, The Teratology Society (2004)

Graduate Student Travel Award, Society of Toxicology (2002)

SELECTED PROFESSIONAL EXPERIENCE

Foods & Consumer Products

Conducted systematic safety evaluations and extensive testing programs to support future regulatory submissions for hemp-derived products.

Performed extensive work in the safety evaluations of food, feed, and nutritional supplement ingredients, such as colors, sweeteners, fibers, pomaces, waxes, lecithins, and plant-based proteins; other examples include fatty acid esters, keto salts, eggshell membrane, and various plant and seed extracts.

Prepared numerous Generally Recognized as Safe (GRAS) dossiers with and without FDA notification.

Created a literature database and systematic evidence map for cannabidiol (CBD) safety.

Conducted data gap assessments and designed testing programs to support future GRAS determinations and/or New Dietary Ingredient Notifications (NDINs).

Managed project evaluating the identification, uses, and doses of ~100 essential oils used in cigarettes and e¬cigarettes.

Drafted a comprehensive review of the potential reproductive toxicity of a botanical-derived ingredient to be used in a personal care product; submitted by the client to Health Canada's Pest Management Regulatory Agency (PMRA)

Developed an original framework for safety testing of novel food compounds undergoing sensory testing.

Served as assessor for Systematic Review of the effects of caffeine intake during pregnancy.

Conducted data-gap analyses on various colors and sweeteners in anticipation of potential future Joint FAO/WHO Expert Committee on Food Additives (JECFA) and/or European Food Safety Authority (EFSA) evaluations.

Generated comments to be submitted to the FDA regarding labeling of a low-calorie sweetener as a food additive.

Coordinated and managed the development of an expert panel and comments on the US CPSC Chronic Hazard Advisory Panel Report on Phthalates.

REACH, CLP, and GHS

Evaluated available data and recommended hazard classification for Safety Data Sheets (SDSs) based on a metal in a mixture product according to the US OSHA Hazard Communication Standard (HCS; aligned with the UN GHS); co-wrote the supporting technical white paper.



Managed the strategic planning and implementation of research programs to fulfill data requirements under the REACH/CLP 2010 Registration on behalf of a global REACH Consortium.

Served as science team representative to industry stakeholders, including technical working groups and legal and financial subgroups.

Evaluated toxicology data, generated endpoint summaries, and assessed hazard classifications for nickel and nickel-containing substances and alloys.

Drafted dossiers for Proposal for Harmonised Classification and Labelling on behalf of a global metal-industry REACH consortium.

Developed and implemented an *in vitro* system for reading-across the toxicological properties of nickel compounds in order to reduce animal testing.

Conducted data-gap analysis and managed testing for human health, including 60+ OECD-guideline-compliant toxicity studies with contract laboratories.

Assisted in drafting reports regarding health issues for nickel compounds used in regulatory comments and submissions (e.g., technical guidance for read-across of metals toxicity for EU CLP Regulation).

Additional Metals

Drafted comments on the European Food Safety Authority's (EFSA) Opinion on Nickel in Feed; comments were submitted to EFSA for consideration.

Managed a complex multi-year study and drafted the corresponding peer-reviewed publication on an interlaboratory validation method for metals involving 12 different organizations. Following completion of this work, updated the standard operating procedure to assist with submission of a Test Method Submission to the European Union Reference Laboratory for alternatives to animal testing (EURL-ECVAM).

Contributing author to industry documents titled, *Guidance for Bio-elution Testing of Alloy and HERAG Alloys Fact Sheet: Hazard Identification and Classification of Alloys for Human Health Endpoints.*

BOOK CHAPTERS

Henderson RG, Nguyen H. 2022. Pathways to the US supplement market: New Dietary Ingredient Notification and Generally Recognized as Safe Determination. Chapter 19 in: Ruthsatz M, Wong AW (eds), Nutrition, Health, and Disease: Regulatory Policy Matters. Regulatory Affairs Professionals Society, E-Book, 427 pp., ISBN: 978-1-947493-82-7.

Verougstraete V, **Henderson R**, Mackie M, Newson T, Oller R. 2018. Human health (toxicity) assessment of complex inorganic materials. Chapter 8 in: Risk Management of Complex Inorganic Materials. Elsevier, ISBN 978-0-12-811063-8.

MANUSCRIPTS

Oller A, Barroso J, Prieto P, Verougstraete V, Heim K, **Henderson R**. 2024. Response to letter to editors submitted by PE Rasmussen, P Huntsman, TM Singer, MN Jacobs, and CC Trevithick-Sutton (Aug 2024). Regul Toxicol Pharmacol 105740; doi: 10.1016/j.yrtph.2024.105740. Online ahead of print 16 Nov 2024. PMID: 39557211.



Henderson RG, Vincent M, Rivera BN, Bonn-Miller MO, Doepker C. 2023. Cannabidiol safety considerations: Development of a potential acceptable daily intake value and recommended upper intake limits for dietary supplement use. Regul Toxicol Pharmacol 144:105482; doi: 10.1016/j.yrtph.2023.105482 [open access].

Kulpa J, **Henderson RG**, Schwotzer D, Dye W, Trexler KR, McDonald J, Lefever TW, Bonn-Miller MO. 2023. Toxicological evaluation and pain assessment of four minor cannabinoids following 14-day oral administration in rats. Cannabis Cannabinoid Res 8(S1):S25–S41 [open access].

Kulpa J, Lefever TW, Trexler KR, **Henderson RG**, MacNair L, Toth ML, Vanapalli SA, Rahman M, Gupta S, Bonn-Miller MO. 2023. Toxicity of cannabigerol: Examination of long-term toxicity and lifespan in *Caenorhabditis elegans* and 14-day study in Sprague Dawley rats. Cannabis Cannabinoid Res 8(S1):S62–S70; https://www.liebertpub.com/doi/10.1089/can.2023.0035.

Henderson RG, Franke KS, Payne LE, Franzen A. 2023. Cannabidiol safety data: A systematic mapping study. <u>Cannabis Cannabinoid Res</u> 8(1):34–40.

Henderson RG, Welsh BT, Trexler KR, Bonn-Miller MO, Lefever TW. 2023. Genotoxicity evaluation of cannabidiol. Regul Toxicol Pharmacol 142:105425.

Henderson RG, Welsh BT, Rogers JM, Borghoff SJ, Trexler KR, Bonn-Miller MO, Lefever TW. 2023. Reproductive and developmental toxicity evaluation of cannabidiol. <u>Food Chem Toxicol</u> 176:113778.

Henderson RG, Lefever TW, Heintz MM, Trexler KR, Borghoff SJ, Bonn-Miller MO. 2023. Oral toxicity evaluation of cannabidiol. Food Chem Toxicol 113778.

Franke K, Payne L, Franzen A, Wikoff D, **Henderson R**. 2021. Cannabidiol literature scoping review protocol. Center for Open Science, OSFHOME (May 20): https://doi.org/10.17605/OSF.IO/PDZ9S.

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.

Henderson RG, Verougstraete V, Anderson K, Arbildua JJ, Brock TO, Cappellini D, Delbeke K, Herting G, Hixon G, Wallinder IO, Rodriguez PH, Assche FV, Wilrich P, Oller AR. 2014. Interlaboratory validation of bioaccessibility testing in metals. Regul Toxicol Pharmacol 70(1):170–181.

Henderson RG, Durando J, Oller A, Merkel DJ, Marone PA, and Bates HK. 2012. Acute oral toxicity of nickel compounds. Regul Tox Pharmacol 62(3):425–432.

Henderson, RG, Cappellini D, Seilkop SK, Bates HK and Oller AR. 2012. Oral bioaccessibility testing and read-across hazard assessment of nickel compounds. Regul Tox Pharmacol 63(1):20–28.

Oller AR, Cappellini D, **Henderson RG**, Bates HK. 2009. Temperature effect on nickel release in ammonium citrate. J Environ Monit 11(9):1697–1699.

Oller AR, Cappellini D, **Henderson RG**, Bates HK. 2009. Comparison of nickel release in solutions used for the identification of water-soluble nickel exposures and in synthetic lung fluids. J Environ Monit 11(4):823–829.

Grasty RC, Bjork JA, Wallace KB, Wolf DC, Lau CS, Rogers JM. 2005. Effects of prenatal perfluorooctane sulfonate (PFOS) exposure on lung maturation in the perinatal rat. Birth Defects Res B Dev Reprod Toxicol 74(5):405–416.

Grasty RC, Grey BE, Wolf DC, Lau CS, Rogers JM. 2003. Prenatal window of susceptibility to perfluorooctane sulfonate-induced neonatal mortality in the Sprague-Dawley rat. Birth Defects Res (Part B) Dev Reprod Toxicol 68(6):465–471.



Smith DM, **Grasty RC**, Theodosiou NA, Tabin CJ, Nascone-Yoder NM. 2000. Evolutionary relationships between the amphibian, avian, and mammalian stomachs. Evol Dev 2(6):348–359.

ABSTRACTS AND PRESENTATIONS

Rivera BN, Svetlik A, Klaren WD, Wikoff DS, **Henderson RG**. Scoping review of the immunomodulatory effects of cannabidiol: Effects within T cells. Poster presented at Society of Toxicology Annual Meeting, Nashville, TN, March 2023.

Lefever TW, Trexler KR, **Henderson RG**, Bonn-Miller MO. Pre-clinical evaluation of cannabidiol toxicity in rats. Poster at the 32nd Annual International Cannabinoid Research Society Symposium on the Cannabinoids [presented by TL], Galway, Ireland, June 2022.

Lefever TW, Schwotzer D, Bonn-Miller MO, McDonald J, **Henderson RG**, Trexler KR. Novel data update on oral toxicity of phytocannabinoids in rats after 14-days repeated dosing. Carolina Cannabinoid Collaborative (CCC) Conference, Greenville, NC, November 2022.

Lefever TW, Trexler KR, **Henderson RG**, Bonn-Miller MO. Pre-clinical evaluation of cannabidiol toxicity in rats. Poster presented at the 32nd Annual International Cannabinoid Research Society Symposium on the Cannabinoids, Galway, Ireland, June 2022.

Lefever TW, Schwotzer D, Bonn-Miller MO, McDonald J, **Henderson RG**, Trexler KR. Novel data update on oral toxicity of phytocannabinoids in rats after 14-days repeated dosing. Carolina Cannabinoid Collaborative (CCC) Conference, Greenville, NC, November 2022.

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.

Henderson RG, Doepker C, Lopez JG. Safety evaluation of L-theanine administered via hard chew to dogs. Poster at Society of Toxicology Annual Meeting, Baltimore, MD, March 2019.

Henderson, R, Miller J, Lopez JG. Safety evaluation of daily oral administration of egg shell membrane via soft chew to male and female beagles. Presented at the Society of Toxicology's 57th Annual Meeting, San Antonio, TX, March 2018.

Wikoff DW; Welsh BT, **Henderson R**, Brorby G, Britt J, Myers E, Goldberger J, Lieberman HR, O'Brien C, Doepker C. Application of systematic review in the evaluation of caffeine safety: Potential adverse effects of caffeine consumption in healthy adults, pregnant women, adolescents, and children. Society of Risk Analysis Annual Meeting. Arlington, VA, December 2017.

Henderson R, Verougstraete V, Anderson K, Arbidua JJ, Brock TO, Brouwers T, Cappellini D, Delbeke K, Herting G, Hixon G, Odnevall Wallinder I, Rodriguez PH, Van Assche F, Wilrich P, Oller AR. Inter-laboratory validation of bioaccessibility test for metals. Presented at the Society of Toxicology's 53rd Annual Meeting. Phoenix, AZ, March 2014.

Henderson R, Verougstraete V, Anderson K, Arbildua JJ, Brock TO, Brouwers T, Cappellini D, Delbeke K, Herting G, Hixon G, Odnevall Wallinder I, Rodriguez PH, Van Assche F, Wilrich P, Oller AR. Interlaboratory comparison of bioaccessibility tests for metals. Annual meeting of the Belgian Society for Toxicology and Ecotoxicology (BelTox), 2013.

Oller A, **Henderson RG**. Bioaccessibility testing and its application to read-across for hazard assessment and risk characterisation of metals. Annual meeting of the Belgian Society for Toxicology and Ecotoxicology (BelTox), 2011.



Semeraro A, Patriarca M, Taylor A, **Henderson R**, Bates H. Nickel kinetics after oral exposure: Urinary excretion. IUPAC 4th International Symposium for Trace Elements in Food, 2011.

Henderson RG, Cappellini D, Seilkop S, Oller A, Bates H. 2011. Bioaccessibility-based read-across assessment of nickel compounds for oral systemic toxicity. Abstract 298. The Toxicologist (CD—An official journal of the Society of Toxicology) 120:S-2.

Grasty RC, Roberts N, Klinefelter G, Bjork JA, Wallace KB, Lau CS, Rogers JM. 2005. Effects of prenatal perfluoroctanesulfonate (PFOS) exposure on lung maturation in the perinatal rat. Birth Defects Res A Clin Mol Teratol 73:314.

Grasty RC, Roberts N, Grey BE, Lau C, Rogers JM. 2004. Effects of prenatal exposure to perfluorooctane sulfonate on the developing lung in the rat. The Toxicologist, 78(1-S):1916.

Grasty RC, Roberts N, Grey BE, Lau C, Rogers JM. 2004. Perfluorooctane sulfonate (PFOS) alters lung development in the neonatal rat. Birth Defects Res Part A, 70(5):42.

Grasty RC, Grey BE, Lau CS, Rogers JM. 2003. Window of susceptibility to perfluorooctane sulfonate (PFOS)-induced neonatal mortality in the rat. Birth Defects Res Part B, 68(3):5.

Grasty RC, Grey BE, Thibodeaux J, Lau C, Rogers JM. 2002. Critical period for increased neonatal mortality induced by perfluorooctane sulfonate (PFOS) in the rat. The Toxicologist 66(1-S):118.