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# Craig Llewellyn, Ph.D.

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## Professional Profile

Craig Llewellyn, Ph.D., has more than 25 years of experience in toxicology, analytical food chemistry, scientific and regulatory affairs, designing and conducting scientific research, and product development from positions in academia; food, pharmaceutical, and coatings corporations; and state government. He provides scientific and regulatory evaluations and support in various areas including direct and indirect food additives, flavorings, food allergens, ingredients, and precursors used by food and beverage, cosmetic ingredients, dietary supplements, consumer products, specialty chemicals, and pharmaceutical industries. Dr. Llewellyn has a background in immunotoxicology, toxicology, and pharmacology from graduate studies at Medical College of Virginia, Virginia Commonwealth University and post-doctoral training with Eli Lilly and Co. He also has held positions with ingredient and product safety and global scientific and regulatory affairs responsibilities for SafeBridge Regulatory and Life Sciences Group, Kraft Foods, The William Wrigley Jr. Company, and The Coca-Cola Company. Dr. Llewellyn has participated in and held leadership positions in numerous trade and scientific organizations and coauthored or sponsored more than 100 peer-reviewed publications and reports.

## Academic Credentials & Professional Honors

Ph.D., Pharmacology and Toxicology, Virginia Commonwealth University, 1998

B.S., Biology, Virginia Commonwealth University, 1993

## Prior Experience

Principal Toxicologist and Scientific Director, SafeBridge Regulatory and Life Sciences Group, Trinity Consultants, Inc., 2020 to 202

Principal Toxicologist, SafeBridge Regulatory and Life Sciences Group, Trinity Consultants, Inc., 2018 to 2020

Director, Global Regulatory, The Coca-Cola Company, 2016 to 2018

Director, Ingredient Safety, The Coca-Cola Company, 2011 to 2016

Research Principal, Global Toxicology; Kraft Foods Global, Inc., 2008 to 2011

Principal Scientist, Global Scientific and Regulatory Affairs, The William Wrigley Jr. Company, 2006 to 2008

Assistant Principal Scientist, Scientific Affairs; Kraft Foods Global, Inc., 2000 to 2006

 

Postdoctoral Fellow, Investigative Toxicology, Eli Lilly and Company, 1998 to 2000

Analytical Chemist, Food Chemistry Laboratory, Division of Consolidated Laboratory Services, Commonwealth of Virginia, 1988 to 1994

Laboratory Technician, Research and Development Laboratory, Sampson Coatings, 1986 to 1988

## Professional Affiliations

Institute of Food Technologists

International Association for Food Protection

Society of Toxicology

The Toxicology Forum

## Publications

Llewellyn, G.C., Rihner, M., Hanlon, P. (2021). An evolution of risk assessment for potential carcinogens in food: Scientific session proceedings. Regulatory Toxicology and Pharmacology.126:104047.

Felter, S., Llewellyn C., Navarro, L., and Zhang, X. (2020). How a 62-year old Delaney Clause continues to thwart science: Case study of the flavor substance β-myrcene. Regulatory Toxicology and Pharmacology. 115:104708.

Llewellyn, G,C., Penberthy, J.K., and Parker, J.M. (2020). Food Color Additives in the US Food Supply: Review of Neurobehavioral Safety. Journal of Pediatric Neurology and Neuroscience. 4(1): 55-72.

Brusick, D., Aardema, M., Allaben, W., Kirkland, D., Williams, G., Llewellyn, G., Parker, J., and Rihner, M. (2020). A weight of evidence assessment of the genotoxic potential of 4-methylimidazole as a possible mode of action for the formation of lung tumors in exposed mice. Food and Chemical Toxicology.145:111652.

Bastaki, M., Aubanel, M., Bauter, M., Cachet, T., Demyttenaere, J., Diop, M., Harman, C., Hayashi, S., Krammer, G., Li, X., Llewellyn, C., Mendes, O., Renskers, K., Schnabel, J., Smith, B., and Taylor, S. (2018). Absence of renal adverse effects from β-myrcene dietary administration in OECD guideline-compliant subchronic toxicity study. Food and Chemical Toxicology.120:222-229.

Bastaki, M., Aubanel, M., Bauter, M., Cachet, T., Demyttenaere, J., Diop, M., Harman, C., Hayashi, S., Krammer, G., Li, X., Llewellyn, C., Mendes, O., Renskers, K., Schnabel, J., Smith, B., and Taylor, S. (2018) Absence of adverse effects following the gavage administration of methyl propyl trisulfide to Sprague-Dawley rats for 90 days. Food and Chemical Toxicology.120:544-551.

Bastaki, M., Aubanel, M., Bauter, M., Cachet, T., Demyttenaere, J., Diop, M., Harman, C., Hayashi, S., Krammer, G., Li, X., Llewellyn, C., Mendes, O., Renskers, K., Schnabel, J., Smith, B., and Taylor, S. (2018) Absence of adverse effects following administration of piperine in the diet of Sprague-Dawley rats for 90 days. Food and Chemical Toxicology.120:213-221.

Bialk, H., Llewellyn, C., Kretser, A., Canady, R., Lane, R., and Barach, J. (2013). Insights and perspectives on emerging inputs to weight of evidence determinations for food safety: Workshop proceedings. International Journal of Toxicology. 32:405-413.

Canady, R., Lane, R., Paoli, G., Wilson, M., Bialk, H., Hermansky, S., Kobielush, B., Lee, J., Llewellyn,

C., and Scimeca, J. (2013). Determining the applicability of threshold of toxicological concern approaches to substances found in food. Critical Reviews in Food Science and Nutrition. 53(12):1239-1249.

Felter, S.P., Connolly, R.B., Bercu, J.P., Bolger, P.M., Boobis, A.R., Bos, P.M.J, Carthew, P., Doerrer, N.G., Goodman, J.I., Harrouk, W.A., Kirkland, D.J., Llewellyn, G.C., Preston, R.J., Schoeny, R., Schnatter, A.R., Tritscher, A., van Velsen, F., and Williams, G.M. (2011). A proposed framework for assessing risk from less-than-lifetime exposures to carcinogens. Critical Reviews in Toxicology. 41(6):507-544.

Felter, S., Lane, R.W., Latulippe, M.E., Llewellyn, G.C., Olin, S.O., Scimeca, J.A., and Trautman, T.D. (2009). Refining the threshold of toxicological concern for risk prioritization of trace chemicals in food. Food and Chemical Toxicology. 47(9):2236-45.

Doull, J., Borzelleca, J., Becker, R., Daston, G., DeSesso, J., Fan, A., Fenner-Crisp, P., Hoslapple, M., Holson, J., Llewellyn, G.C., MacGregor, J., Seed, J., Walls, I., Woo, Y., and Olin, S., (2007). Framework for use of screening tools for potentially toxic chemicals in context-based decision-making. A report from the ILSI Risk Science Institute Expert Panel on evaluating the utility and application of screening tools. Food and Chemical Toxicology. 45:759-796.

Llewellyn, G.C., McCay, J.A., Brown, R.D., Musgrove, D.L., Butterworth, L.F., Munson, A.E., and White Jr., K.L. (1999). Immunologic evaluation of the Mycotoxin Patulin in female B6C3F1 mice. Food and Chemical Toxicology. 36:1107-1115.

Gagliardi, S., Mooney, R.L., Cheatle, T.F., Llewellyn, G.C., O'Rear, C.E. and Llewellyn, G.C. (1991). The occurrence of Aflatoxin peanut butter from 1982-1989. Journal of Food Protection. 54:627-631.

Mooney, R.L., O'Rear, C.E., Llewellyn, G.C., and Llewellyn G.C. (1990). Aflatoxin Occurrence in Virginia Price Support-Corn: 1986 Crop-Year. In: Llewellyn, G.C., O'Rear C.E. (eds) Biodeterioration Research. Biodeterioration Research, Vol 3. Springer, Boston, MA, pp 207-227.Mooney, R.L., Llewellyn, G.C., O'Rear C.E., and Llewellyn, G.C. (1990) Aflatoxin Occurrence in Samples of Commercial Corn Meal Sold in Virginia: 1983–1986. In: Llewellyn G.C., and O'Rear C.E. (eds) Biodeterioration Research. Biodeterioration Research, vol 3. Springer, Boston, MA, pp 235-243.Llewellyn, G.C., and Llewellyn G.C. (1990). The Effects of Patulin on the Development of Oncopeltus fasciatus. In: Llewellyn G.C., and O'Rear C.E. (eds) Biodeterioration Research. Biodeterioration Research, Vol 3. Springer, Boston, MA, pp 261-268.

**Presentations**

Llewellyn, C. Optimization in the Production of Caramel Colors. 254th American Chemical Society National Meeting and Exposition. 2017.

Rodriguez, C., Llewellyn, C., Parker, A., and Dourson, M. Benchmark Dose Modeling for 5-Hydroxymethylfurfural: A Comparison of Models for Superior Fit. Toxicological Sciences Supplement, Society of Toxicology Meeting. 2016.

Llewellyn, C. Case Studies Demonstrating the Utility of the Metal Dietary Exposure Screening Tool. Toxicological Sciences Supplement, Society of Toxicology Meeting. 2016.

Rodriguez, C., and Llewellyn, C. Benzoate Preservatives: An Evaluation of the Safety Database. Toxicological Sciences Supplement, Society of Toxicology Annual Meeting. 2015.

Llewellyn, C., and Rodriguez, C. Caffeine Intake: A Comparison of Consumption Data and Marketing Data. Toxicological Sciences Supplement, Society of Toxicology Annual Meeting. 2015.

Llewellyn, C. Food Allergen Management. A Linked Chain. Food Safety Summit. 2014.

Llewellyn, C. Thresholds: A Practical Approach to Food Allergen Control and Labeling. A Food Industry Perspective. Cereal Foods World. 57(4S, A7). American Association of Cereal Chemists International Annual Meeting. 2012.

Doull, J., Borzelleca, J., Becker, R., Daston, G., DeSesso, J., Fan, A., Fenner-Crisp, P., Hoslapple, M., Holson, J., Llewellyn, G.C., MacGregor, J., Seed, J., Walls, I., Woo, Y., and Olin, S. Framework for Use of Screening Tools for Potentially Toxic Chemicals in Context-Based Decision-Making. A Report from the ILSI Risk Science Institute Expert Panel on Evaluating the Utility and Application of Screening Tools. Toxicological Sciences Supplement, Society of Toxicology Annual Meeting. 2005.

Llewellyn, G.C., Lockwood, J.F., and Wierda, D. Utility of the Local Lymph Node Assay for the Identification of Immunosuppressive Drugs. Toxicological Sciences Supplement, Society of Toxicology Annual Meeting. 2000.

Llewellyn, G.C., and Wierda, D. Characterization of the NZB/NZWF1 Mouse Model for Identification of Drug Induced Autoimmune Disease. Toxicological Sciences Supplement, Society of Toxicology Annual Meeting. 2000.

Ritter, J.K., Grove, A.D., Llewellyn, G.C., White Jr, K.L., Crespi, C.L., and Kessler, F.K. Differential Protection by Rat UDP-Glucuronosyl Transferase UGT1A7 Against Benzo(a)pyrene-3,6-quinone Versus Benzo(a)pyrene- Induced Cytotoxic Effects in Human Lymphoblastoid Cells. Toxicological Sciences Supplement, Society of Toxicology Annual Meeting. 2000.

Booker, C.D., Llewellyn, G.C., Parrett, J.W., and White Jr, K.L. Evaluation of Benzo(a)pyrene in the NZBWF1 Mouse Model of Autoimmunity. Toxicological Sciences Supplement, Society of Toxicology Annual Meeting. 1999.

Llewellyn, G.C., Lockwood, J.F., and Wierda, D. Evaluation of Transdermally-Delivered Drugs Using the Local Lymph Node Assay. Toxicological Sciences Supplement, Society of Toxicology Annual Meeting. 1999.

Grove, A.D., Llewellyn, G.C., White Jr, K.L., Crespi, C.L., and Ritter, J.K. Studies on the Protective Role of Rat UDP-Glucuronosyltransferase 1A7 (UGT1A7) Towards Benzo(a)pyrene. Toxicological Sciences Supplement, Society of Toxicology Annual Meeting. 1998.

Llewellyn, G.C., and White Jr, K.L. Benzo(a)pyrene Induced Suppression of the Memory Humoral Immune Response in Female B6C3F1 Mice. Toxicological Sciences Supplement, Society of Toxicology Annual Meeting. 1998.

Llewellyn, G.C., McCay, J.A., Brown, R.D., Musgrove, D.L., Butterworth, L.F., Munson, A.E., and White, K.L. The Effects of the Mycotoxin Patulin on the Immune System in Female Fischer 344 Rats. American College of Toxicology Annual Meeting. 1997.

Llewellyn, G.C., and White Jr, K.L. Benzo(a)pyrene Induced Suppression of the Secondary Humoral Immune Response in Female B6C3F1 Mice. Eastern Symposium on Mechanisms of Immunotoxicity, Foundation for Immunotoxicology. 1997.

Llewellyn, G.C. and White Jr, K.L. Benzo(a)pyrene Induced Suppression of the Secondary Humoral Immune Response. Journal of Science, Virginia Academy of Science. 1997.

Harper, N., Llewellyn, C., Ritter, J., and White Jr, K.L. The Alteration of IgM and IgG Titers in B6C3F1 Mice Exposed Dermally to a Complex Mixture of Polycyclic Aromatic Hydrocarbons (PAHs). Society of Toxicology Annual Meeting. 1997.

Llewellyn, G.C., McCay, J.A., Brown, R.D., Musgrove, D.L., Munson, A.E., and White Jr, K.L. Evaluation of the Effects of Patulin on Immune Function in Female B6C3F1 Mice. Society of Toxicology Annual

Meeting. 1997.

Llewellyn, G.C., and White Jr, K.L. Evaluation of Selected Anti-carcinogenic Phytocompounds Effects on and the Ability of Compounds to Protect from Benzo(a)pyrene Suppression of the Humoral Immune Response. American College of Toxicology Annual Meeting. 1996.

Llewellyn, G.C., and White Jr, K.L. The Effects of Ellagic Acid, a Dietary Phytochemical, on Dermal Benzo(a)pyrene Induced Immune Suppression. Eastern Symposium on Mechanisms of Immunotoxicity, Foundation for Immunotoxicology. 1996.

Llewellyn, G.C., and White Jr, K.L. Ellagic Acid a Dietary Anticarcinogenic Phytochemical Does Not Protect Against Dermal Benzo(a)pyrene Induced Humoral Immune Suppression. Journal of Science, Virginia Academy of Science. 1996.

Llewellyn, G.C., Metz, R.P., Kessler, F.K., Ritter, J.K., and White Jr, K.L. Oltipraz Reverses Benzo(a)pyrene Suppressed Secondary Humoral Immune Response and Enhances Selected Liver Enzymes in Female B6C3F1 Mice. Society of Toxicology Annual Meeting. 1996.

Llewellyn, G.C., Metz, R.P., Grove, A.D., Kessler, F.K., Ritter, J.K., and White, K.L. Immunosuppressive and Liver Enzyme Enhancing Effects of Oltipraz (4-methyl-5-(2-pyrazinyl)-1,2-dithiole-3-thione) on Female B6C3F1 Mice. Eastern Symposium on Mechanisms of Immunotoxicity, Foundation for Immunotoxicology. 1995.

Llewellyn, G.C., and White Jr, K.L. Immunotoxic Effects of Cobra Venom Factor (Naja haja) on C3 and Isotype Switching as Evaluated by ELISA. Journal of Science, Virginia Academy of Science. 1995.

## Project Experience

Led regulatory clearance for food ingredient for use in the US, Canada, EU, UK, and Australia. Developed strategic approach and engaged with regulatory officials.

Led nonclinical safety testing for food ingredient. Reviewed study protocols, liaised with CRO, addressed interim findings, interpreted results, reviewed study report, and authored manuscript.

Developed novel approach to support R&D flavoring work with pharmaceuticals. Designed tool to assist in R&D daily work priorities for testing flavorings in pharmaceutical products.

Led development and submission of dossiers for food contact materials/substances in the US and EU. Developed strategic approach and engaged with regulatory officials.

Provided safety and regulatory support for food production incident. Conducted human health risk assessment for manufacturing event.

Performed safety and regulatory reviews for ingredients of interest. Supported novel technologies for food and ingredient production.

Assessed safety and global acceptance for dietary supplement ingredient. Provided expert technical service to the development of safety and regulatory filings for dietary supplement ingredient in US, EU, and Australia.

Supported safety and regulatory clearance for alcoholic beverage ingredient. Developed strategic approach and engaged with regulatory officials.

Developed novel approach to assess products for potential for Proposition 65 lawsuits. Designed multifactorial tool to assist in risk ranking products for likelihood of Proposition 65 lawsuits.

Designed novel approaches to addressing regulatory questions. Combined existing and novel data to address regulatory concerns associated with changing food ingredient consumption patterns.

Led expert panel to evaluate safety dataset for food ingredient constituent. Provided guidance and leadership for an expert panel assessment of genotoxicity evidence and publishing of a manuscript.

Led expert review of food ingredients and associations with human behavioral changes. Reviewed literature, identified co-author and published manuscript.

Led safety and regulatory review for cosmetic ingredient. Provided technical leadership and support for clearance of a cosmetic ingredient produced using new technology.