Njwen Anyangwe, Ph.D.
Curriculum Vitae
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Njwen Anyangwe, Ph.D.

Executive Summary

- Regulatory Toxicologist with many years of experience at the U.S. Food and Drug Administration (FDA), evaluating toxicology and safety data in regulatory submissions (food additives, color additives, GRAS substances and new dietary ingredients) to the FDA and providing guidance in toxicology subject matters to industry in pre-submission meetings.

- Review and evaluate toxicity data relating to food additives, color additives, GRAS substances and hazards associated with contaminants and/or natural toxicants present in these food ingredients.

- Constantly attending continuous education courses, webinars and symposia to keep abreast of the relevant scientific literature, as well as current toxicological methods and principles.

- CFSAN Liaison to the International Life Sciences Institute Low Calorie Sweetener Committee, a committee which seeks to improve and communicate the physiological, metabolic and cognitive/behavioral science of low-calorie sweeteners and the general understanding of their role in dietary management, as well as evaluate how the consumption of LCS can contribute to overall health and wellness.

- Co-authored several research publications in toxicology, DNA repair, and cancer research. Currently have a manuscript under review for publication regarding the use of the acceptable daily intake by nutrition and health care professionals.

- Previously, Toxicology and Food Safety Consultant (Senior Scientist) at Exponent Engineering and Scientific Consulting Firm (Washington DC), assisting industry obtain approvals and acknowledgements from the U.S. FDA for their food and dietary ingredients, through providing regulatory support and technical expertise in the areas of toxicology, food safety, contaminants in food, nutrition, and bioinformatics.

- Previously, Oak Ridge Institute of Science and Education (ORISE) fellow (Toxicology Reviewer) at the U.S. FDA, evaluating the safety of new dietary ingredients in dietary supplements and providing guidance in toxicology subject matters to industry in pre-notification meetings.

- Conducted hazard evaluations for dietary ingredients for use in dietary supplements.

- Multidisciplinary scientist with education, experience and training in Biochemistry, Cancer Biology, Molecular Biology, Nutrition and Regulatory Toxicology.

- Over 20 years of experience, teaching Biochemistry, Biology, Food Science, Nutrition and Health, and Organic Chemistry courses at several universities including Howard University, Wayne State University, and Madonna University.

ACADEMIC CREDENTIALS

- Ph.D., Nutrition and Food Science (Major), Cancer Biology (Minor), Wayne State University, Detroit, MI, USA, 2005.
- M.S., Medical Biochemistry, University of Port Harcourt, Nigeria, 1995.
- B.S., Biochemistry (First Class Honors), University of Port Harcourt, Nigeria, 1991.

PROFESSIONAL EXPERIENCE

A. REGULATORY TOXICOLOGY EXPERIENCE

September 2015-Present: **Toxicology Reviewer, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (CFSAN), US FDA.**

- Evaluate experimental toxicology data as well as human data, to permit toxicologically-based decisions directed towards the protection of health, to ensure the safety of food additives and color additives.

- Ensure that any contaminants present in these food ingredients and color additives do not pose any safety concerns at the levels present.

- Review the safety of Generally Recognized As Safe (GRAS) food ingredients.

- Provide toxicology recommendations to industry during pre-submission consultations for their intended food ingredient.

- Member of several internal working groups at the FDA.

- FDA/ CFSAN Liaison to the International Life Sciences Institute (ILSI) North America, Committee on Low Calorie Sweeteners.

2013- September 2015: **Toxicology Consultant (Senior Scientist), Exponent's Health Sciences Center for Chemical Regulation and Food Safety, NW, Washington DC.**

- Provided regulatory and technical support to clients including: strategy; advice; toxicology guidance; reviewed study protocols; evaluated toxicology data packages, identified data

gaps, and made recommendations; bioinformatics analysis; allergenicity assessment; and product characterization.

- Conducted scientific literature search and evaluated preclinical pharmacology and toxicology data and human data in the safety assessments of food and dietary ingredients including Food Contact Substances (FCS), GRAS ingredients, and New Dietary Ingredients (NDI).

- Performed risk assessments for a variety of food ingredients based on a combination of pharmacology / toxicology / human data and the utilization of surrogate approach.

- Developed comprehensive toxicology profiles for FCS and comprehensive safety profiles for GRAS ingredients and NDI.

- Prepared reports and submissions to the US FDA - GRAS dossiers, Food Contact Substance Notifications (FCN) and NDI Notifications.

- Assessed the toxicological potential of new manufacturing processes or changes in current manufacturing processes used for food ingredients and food contact substances.

- Provided technical review of waivers for inerts and pesticides.

January 2008-2013: **ORISE Fellow (Toxicology Reviewer), US FDA, CFSAN, Division of Dietary Supplements Program, Office of Nutrition, Labeling and Dietary Supplements**

- Reviewed over 150 NDI notifications to ensure the safety of new dietary ingredients.
- Prepared comprehensive reports on the experimental methods, results and conclusions of preclinical studies on food and dietary ingredients.
- Prepared toxicology review memorandum that discussed findings from the evaluation of the data and submitted substantive recommendations regarding the safety of the dietary ingredients.
- Reviewed labeling of the dietary supplement to ensure that the conditions of use of the dietary supplement are supported by the preclinical and clinical data and are consistent with the regulations.
- Prepared health hazard evaluations (HHEs) and talking points for dietary ingredients of public health concern and provided expert guidance and consultation to management within the agency on the public health impacts of these exposures.
- Coordinated with other scientists within a multidisciplinary environment (toxicologists, medical officers, chemists, botanist, compliance officers, and nurses) to resolve scientific regulatory conflicts to avoid delays in achieving goals.
- Met with industry representatives to exchange information and to provide advice and guidance regarding toxicology subject matter related to their new dietary ingredient.
- Routinely acted as project manager for ingredient submissions and prepared response letters and related correspondence to stakeholders.
- Served on several working groups and technical expert panels at the FDA.

- Developed and maintained expertise in the field of toxicology and risk assessment.
- Provided scientific support in enforcement and compliance cases.
- Provided scientific support in the development of the "Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredients Notifications and Related Issues.

B. TEACHING EXPERIENCE

2016-Present ***Adjunct Assistant Professor*** Department of Nutritional Sciences, College of Nursing and Allied Health Sciences, Howard University, Washington DC Graduate Courses taught: Carbohydrate and Energy Metabolism; Vitamin Metabolism; and Mineral Metabolism.

2013 ***Adjunct Faculty*** College of Health Studies, Prince Georges Community College, Largo, MD. Course taught: Introduction to Nutrition

2005 -2007 ***Adjunct Assistant Professor,*** College of Mathematics and Science, Madonna University, Livonia, MI. Courses taught: Introduction to Life Chemistry; The living World

2006 ***Adjunct Faculty,*** Department of Nutrition and Food Science, Wayne State University, Detroit, MI. Course taught: Nutrition and Health.

2002-2005 ***Graduate Teaching Assistant,*** Department of Nutrition and Food Science, Wayne State University, Detroit**.** Courses taught: Nutrition and Health; Laboratory Techniques; Introductory Food Science; Nutritional Biochemistry.

Summer 2002/2003 ***Research Assistant,*** **Department of Nutrition and Food Science, Wayne State University, Detroit.**

- Conducted research on folate deficiency and susceptibility to cancer.
- Supervised and trained new graduate students in the laboratory.
- Assumed responsibility for day-to-day management of research laboratory (maintain inventory of laboratory equipment, reagents and supplies; performed purchase orders; performed wipe tests).

1995- 1999 ***Assistant Lecturer,*** **Department of Life Sciences (Biochemistry unit), University of Buea, Cameroon.**

Team-taught courses: Structural Biochemistry; Metabolic Pathways I and II; Analytical Biochemistry; Molecular Biology and Biophysical Chemistry**.**

University of Buea, Cameroon / University of Manchester, UK workshop on Staff development for university administrators and lecturers, University of Buea. September 9th, 1997.

C. RESEARCH EXPERIENCE

Doctoral and post-doctoral research studies focused on cancer and molecular biology. Experienced in animal experimentation, cell culture techniques, and molecular biology techniques including BLAST, Western blot, polymerase chain reaction, gel electrophoresis, DNA damage / repair assays, and siRNA technology.

- Post-doctoral fellowship: studied the effect of pressure and strain on colon cancer cell adhesion, migration, and proliferation with the goal to identify potential therapeutic targets for colorectal cancer.

- Ph.D. dissertation examined the role of the tumor suppressor gene p53 in DNA polymerase β-dependent base excision repair pathway.

- M.S. dissertation examined the efficacy of antidiabetic herbs *Scoparia dulcis* and *Catharanthus roseus* in the management of diabetes mellitus.

- B.S. dissertation examined the efficacy of different brands of chloroquine in the treatment of malaria.

AWARDS

- FDA Group Recognition Award: Synthetic Flavors Petition Review Team, September 2019
- Several CFSAN Incentive Awards: December 2017, May 2018, December 2019, March 2020.
- FDA CFSAN Team Spirit Award: Caffeine Working Group, 2015.
- FDA CFSAN Team Spirit Award: Hydroxycut Recall and Reformulation Review Team, 2010.
- Poster of Distinction, Digestive Disease Week 2008, San Diego, CA, 2008.
- Biotechnology Institute Fellow, 2007.
- National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK) Minority RO1 Supplement, 2006-2007.
- Graduate Student Professional Travel Award, Wayne State University, 2005.
- Summer Dissertation Fellowship, Graduate School, Wayne State University, 2004.
- Arthur J. Walker Memorial Annual Scholarship, Wayne State University, 2003.
- Parent Family Endowed Scholarship, Department of Nutrition and Food Science, Wayne State University, 2002.
- Nomination into Wayne State University's Epsilon Beta Chapter of Phi Beta Delta Honor Society for International Scholars, 2002.
- Thomas Rumble Fellowship, Wayne State University, 2001.
- Best Graduating Female Student; Best Graduating Faculty of Science Student; Best Biochemistry Student; Dr. Omogbai's Memorial Prize for Best Biochemistry Student; University of Port Harcourt Women's Prize for Best Graduating Female student, University of Port Harcourt, 1991.

SELECTED TRAININGS IN NON-CLINICAL DRUG DEVELOPMENT AND OTHER RELEVANT EXPERIENCE

- American College of Toxicology Advanced Toxicology Course, August 5-9, 2019
- Systematic Review Workshop,
- MID-AMERICA Toxicology Course, Kansas City, MO. April 28- May 3, 2019.
- PBPK Modeling Workshop, Michigan State University, Lansing Michigan, May 15-17, 2018.
- University of Maryland / FDA Joint Institute of Food Safety and Applied Nutrition (JIFSAN) Risk Analysis Training (Overview, Risk Management, Risk Communication, Qualitative Risk Assessment, Quantitative Risk Assessment, June 2017.
- Epidemiology Course, CFSAN Staff College, 2017.
- IEEE 'Getting project Management Basic Right' Course, completed September 2014.
- 'Introduction to Risk Sciences and Public Policy' Course (4 credits), Johns Hopkins Bloomberg School of Public Health, Baltimore MD, Third Term Winter January - April 2013 (Completed- 'A' grade).
- Completed many Continuing Education Courses / training in Toxicology and Drug Development from the Society of Toxicology (SOT) and the American College of Toxicology (ACT).
  - The what, when, and How of Using data from Alternative testing methods in Chemical Safety Assessments, March 11, 2018, SOT 2018, 4 hours.
  - Current principles for Nonclinical Chronic Toxicity / Carcinogenicity Testing of Environmental Chemicals, March 12, 2017, SOT 2017, 4 hours.
  - Detecting Cancer Risks in drugs: Design, Conduct and Interpretation of Carcinogenicity studies for Regulatory Approvals, March 12, 2017, SOT 2017, 4 hours.
  - Adverse Outcome Pathway (AOP) Development and Evaluation, SOT 2016, 4 hours.
  - Human Health Risk Assessment: A Case Study Application of Principles, SOT 2016, 4 hours.
  - PBPK Modeling to support Modernized Chemical Safety Assessment, March 11, 2018, SOT 2018, 4 hours.
  - Preclinical Drug Development from Small Molecules to Biologics, March 11, 2012, SOT 2012, 4 hours.
  - Basic Embryology and Developmental Toxicity Testing, March 11, 2012, SOT 2012, 4 hours.
  - Drug Development 101, November 7, 2010, ACT 2010, 4 hours.
  - Toxicology for Industrial and Regulatory Scientists, April 26-30, 2010, ACT, 40 hours.
  - New Technologies and Approaches in Genetic Toxicology and their expanding role in Genetic Toxicology and Safety Assessment, March 6, 2011, SOT 2011, 4 hours
  - ICH Initiatives for Conducting Pharmaceutical Preclinical Safety Studies: new and revised Guidelines and Challenges, March 7, 2010, SOT 2010, 4 hours.
  - Translation of Safety Biomarkers in Drug Discovery and Development, March 15, 2009, SOT 2009, 4 hours.
  - Introduction: Epidemiology for Toxicologist, March 16, 2008, Sot 2008, 4 hours. Mini-pigs as an alternative Non-Rodent Species in Toxicology and Safety Studies, March 16, 2008, SOT 2008, 4 hours.

- Technical Writing Course for Reviewers, FDA White Oak Campus, May 10-14, 2012.
- Use of plain language to write documents for the FDA, May 5, 2009
- The Federal Register: What it is and How to use it. September 29, 2009.
- Genotoxicity and Carcinogenicity Workshop, BioReliance, MD, April 23-24, 2009
- Developmental Toxicology Workshop: New Directions workshop by HESI,
- Washington DC, April 29-30, 2009
- Basic Food and Drug Laws Certificate, 2008, 2010.
- Nanotechnology in Medicine, The Foundation for Advanced Education in theSciences Inc., NIH, July 2008.
- Certificate in 'College Teaching': Professional development, Office of Teaching and Learning, Wayne State University, Detroit. February 18th, 2005.

INVITED SPEAKER / GUEST LECTURER

Invited Keynote Speaker, 10th West African Society of Toxicology (WASOT) Annual Meeting, February 10-12, 2021.

Invited Speaker, Saudi Food and Drug Authority (SFDA), 1st Annual Food Conference, November 7-9, 2017; 2nd Annual Food Conference, September 24-27, 2018, , Riyadh, Saudi Arabia.

Invited Speaker: ILSI North America / Diabetes Canada Webinar on "Tools and Tactics for Reducing Added Sugars Intake, September 18, 2019.

Invited Speaker: ILSI North America / American Association of Clinical Endocrinologists webinar on "Tools and Tactics for Reducing Added Sugars Intake: Guidance for Practitioners with a Focus on Low-Calorie Sweetener Safety and Appropriate Use, October 18, 2019.

Career Panelist, Exploring Careers in Toxicology Roundtable, Society of Toxicology (SOT) Undergraduate Diversity Initiative Career Opportunities Session, March 11, 2018; March 10, 2019.

Career Panelist, The 8th Frontiers in Chemistry and Biology Interface Symposium (FCBIS), University of Maryland Baltimore Campus (UMBC), May 16, 2015.

Guest Lecturer (Topic-Food Toxicology), Foundations of Environmental Health (MIEH 600), Graduate Course, University of Maryland Institute of Environmental Health, University of Maryland School of Public Health, College Park, March 3, 2017.

Invited Speaker, 14th International Symposium on Recent Advances in Environmental Health Research, Jackson State University, Mississippi, September 13, 2017.

Keynote Speaker, Marqueta C. Huyck Lecture Series, Department of Nutrition and Food Science, Wayne State University, Detroit, Michigan. October 11, 2013.

PUBLICATIONS, PUBLISHED ABSTRACTS, AND PRESENTATIONS

Seneca E. Fitch, Lauren E. Payne, Jennifer L.G. van de Ligt, Candace Doepker, Deepa Handu, Samuel M. Cohen, **Njwen Anyangwe**, Daniele Wikoff. Use of acceptable daily intake (ADI) as a health-based benchmark in nutrition research studies that consider the safety of low-calorie sweeteners (LCS): A systematic map. Submitted 02.02.2021 to BMC Public Health.

Anyangwe, Njwen; Fitzpatrick, Suzanne; Flannery, Brenna; Mattia, Antonia; Schaefer, Heather; Tyler, Tina; and Whiteside, Catherine. Use of Dog Studies in FDA's Safety Assessments for Food Additives and Color Additives, ACT 2019, November 17-20, 2019.

Anyangwe, Njwen; Fitzpatrick, Suzanne; Flannery, Brenna; Mattia, Antonia; Schaefer, Heather; Tyler, Tina; and Whiteside, Catherine. Use of Dog Studies in FDA's Safety Assessments for Food Additives and Color Additives. Accepted Abstract # 2781, SOT 2019, March 13.

Njwen Anyangwe, Tyler Tina, Catherine Whiteside. Utility of Dog Studies in FDA's Decision-Making on the Safety of Food Ingredients. OFAS Toxicology Meeting. November 19, 2018. (Oral presentation).

Anyangwe, N. Fungwe T. Premarket Evaluation of Food and Color Additives. 14th International Symposium on Environmental Human Research, Jackson State University, Jackson, MS, September 11, 2017 (Oral presentation).

Njwen Anyangwe. Regulation and Safety Assessment of Dietary Supplements containing new dietary ingredients. OFAS Toxicology Monthly Discussion, November 15, 2016 (Oral presentation).

Heilman J, **Anyangwe N**, Tran N, Edwards J, Beilstein P, López J. Toxicological evaluation of an olive extract, H35: Subchronic toxicity in the rat. Food Chem Toxicol. 2015 Oct;84:18-28.

Anyangwe-Ngute N, Orisakwe OE. Regulation of dietary supplements by the U.S. Food and Drug Administration. Presentation, 2nd West African Society of Toxicology Conference, University of Port Harcourt, Port Harcourt, Nigeria, February 21, 2013.

Anyangwe N, Levy D, Gudi R, Abdel-Rahman A, Enongene E, Fabricant D. Genetic toxicology data play an integral role in the safety assessment of dietary supplements containing new dietary ingredient (s). Poster presentation, Abstract #272, Society of Toxicology 51st Annual Meeting, San Francisco, CA, March 11–15, 2012.

Abdel-Rahman A, **Anyangwe N**, Carlacci L, Casper S, Danam RP, Enongene E, Erives G, Fabricant D, Gudi R, Hilmas CJ, Hines F, Howard P, Levy D, Lin Y, Pfeiler E, Thurmond TS, Turujman S, Walker NJ. The safety and regulation of natural products used as foods and food ingredients. Toxicology Sciences 2011; 123(2):333–348.

Carlacci L, Abdel-Rahman A, **Anyangwe N**, Casper S, Enongene E, Gudi R, Hilmas C, Hines F, Levy DD, Lin Y, Turujman S. Regulatory review of botanical ingredients submitted to FDA in new dietary ingredient notifications. Poster Presentation, AOAC International Meeting, New Orleans, LA, September 18–21, 2011.

Anyangwe N, Gudi R, Fabricant D, Abdel-Rahman A, Enongene E, Levy D. Role of genetic toxicology data in the safety assessment of dietary supplements containing new dietary ingredient (s). Poster presentation, Abstract #29, Genetic Toxicology Association Annual Meeting, September 14, 2011.

Anyangwe N. Assessment of the genetic toxicity potential of new dietary ingredients: Enzymes. Oral presentation, Office of Food Additive Safety and Division of Dietary Supplements Program Enzyme Symposium, January 20, 2011.

Unnikrishnan A, Raffoul JJ, Patel HV, Prychitko TM, **Anyangwe N**, Meira LB, Friedberg EC, Cabelof DC, Heydari AR. Oxidative stress alters base excision repair pathway and increases apoptotic response in apurinic/apyrimidinic endonuclease 1/redox factor-1 haploinsufficient mice. Free Radical Biology and Medicine 2009 Jun 1; 46(11):1488–1499.

Anyangwe N, Van der Voort Van Zyp J, Craig DH, Bassoon MD. Src kinase inhibition may inhibit experimental cancer metastasis (poster of distinction). Digestive Disease Week 2008, San Diego, CA, May 17–22, 2008.

Cabelof DC, Ikeno Y, Nyska A, Busuttil RA, **Anyangwe N**, Vijg J, Matherly LH, Tucker JD, Wilson SH, Richardson A, Heydari AR. Haploinsufficiency in DNA polymerase beta increases cancer risk with age and alters mortality rate. Cancer Research 2006 Aug 1; 66(15):7460–7465.

Anyangwe N, Cabelof DC, Lucente LV, Raffoul JJ, Heydari AR. Role of the tumor suppressor gene p53 in DNA polymerase β-dependent base excision repair pathway: regulation of β-pol

expression (poster presentation). *Midwest DNA Repair Symposium 2006*, Indianapolis, IN. *May 20-21, 2006*.

Anyangwe N, Cabelof DC, Van Remmen H, Raffoul JJ, Heydari AR. p53 loss results in accumulation of abasic sites and deregulation of base excision repair in vivo. FASEB 2005; Abstract A1506, 855.5.

Anyangwe N, Cabelof DC, Van Remmen H, Lucente LV, Raffoul JJ, Heydari AR. p53 deficiency results in abasic site accumulation and down regulation of base excision repair in vivo (oral presentation). *Midwest DNA Repair Symposium 2005*, Detroit, MI. *May 21-22, 2005*.

OTHER ACTIVITIES

- Member of the Mentoring Committee, Toxicologists of African Origin (TAO), Society of Toxicologist (SOT), 2018 - present.
- SOT-TAO Newsletter Editor, 2019 to present.
- Keynote speaker, moderator, panelist at various career, health-related and alumni conferences.

PROFESSIONAL AFFILIATIONS

- African Society for Toxicological Sciences (Member, Newsletter Editor, Mentoring Committee)
- American Cancer Society (Certified Health Promotion Instructor)
- American Society for Nutrition (Member)
- Association for Women in Science (Member)
- Food and Drug Law Institute (Member)
- Genetic Toxicology Association (Member)
- Society of Toxicology (Member)