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Professional Profile

Dr. Keefe has 30+ years working in FDA on food additive regulatory issues and 15+ years working on the development of international standards for food additives in the Codex Alimentarius. From 2011-2022 he was the Director of the FDA's Office of Food Additive Safety (OFAS). OFAS is responsible for the premarket review of food additives, color additives, and food contact substances. It also manages FDA's voluntary programs for Generally Recognized as Safe (GRAS) substances and Foods Derived from New Plant Varieties (Biotechnology Notifications – BNFs), the use of Recycled Plastics in Food Packaging and foods derived from cultured animal cells. Dr. Keefe was integral to the significant accomplishments of the Office during this period. These accomplishments include, folic acid fortification of corn masa flour, removal of partially hydrogenated oils (PHOs) from foods, sodium reduction guidance, negotiation of the voluntary removal of certain PFAS from use in food packaging, revoking previous approvals of the use of phthalates based on abandonment, approval of the use of soy leghemoglobin, and delisting of lead acetate's use in hair coloring. From the mid-1990's until 2011, Dr. Keefe led the Codex Alimentarius effort to develop the Codex General Standard for Food Additives.

Academic Credentials & Professional Honors

Ph.D., Molecular Genetics and Cell Biology, University of Chicago, 1987

M.S., Biology, University of Chicago, 1983

B.S., Biology, Saint John's University, 1979

FDA Outstanding Service Award For superior communication surrounding FDA's draft guidance to the food industry for the voluntary reduction of sodium in processed and commercially prepared foods. (2017)

FDA Leveraging and Collaboration Award for successful implementation of a comprehensive, proactive stakeholder engagement strategy that leverages coalitions to achieve food safety and nutrition goals. (2017)

FDA Group Recognition Award for superior communication surrounding the FDA's final determination that partially hydrogenated oils are not "generally recognized as safe" for use in human food. (2016)

FAO/WHO Certificate of Appreciation for significant contributions while serving as Chair of the GSFA Working Group of the Codex Committee on Food Additives. (2013)

CFSAN Exceptional Achievement Award as a member of the Melamine Infant Formula and Dairy Product Investigation Team for high quality performance to ensure the safety of infant formula and dairy containing foods and responding to consumer concerns. (2009)

CFSAN Exceptional Achievement Award as a member of the OFAS Enforcement Activities Team for superior performance in providing support to the Center's enforcement actions related to food ingredients and food contact substances. (2008)

FDA Award of Merit for sustained superior performance and achievement as CFSAN's senior representative to Codex Alimentarius on food additive issues. (2007)

USDA's International Honor Award for exemplary commitment to reduce trade barriers for U.S. food exports in the area of food additives. (2003)

Publications

Keefe, D., P. Kuznesof, S. Carberry, and A. Rulis (2000) The Codex General Standard for Food Additives - A Work in Progress. In International Standards for Food Safety, N. Rees and D. Watson ed. Aspen Publication, Gaithersburg, MD

Keefe, D. and B. Fabech (1998) Food Additive Legislation - Development of an International Standard. European Food Law Review.

Keefe, D., P. Kuznesof, T. Troxell, and A. Rulis (1998) CCFAC Develops General Standards for Food Additives and Contaminants. Inside Laboratory Management AOAC International April 1998.

Presentations

Food and Drug Law Institute: Panel on the use of bioactive substances in food and dietary supplements (2023)

Grocery Manufacturers Association Science Forum: State of the Food Additives Program (2016)

Asian Pacific Economic Cooperation (APEC) Case Study of the Codex Committee on Food Additives Related to Wine Trade (2011)

Asian Pacific Economic Cooperation (APEC) Role of Risk Analysis and International Standard-Setting (2008)

Institute of Food Technologists, International Division 2010 Distinguished Lecturer.

Keefe, D. (2004) "The Codex General Standard for Food Additives: Principles, Development and Issues" Grocery Manufacturers of America's conference entitled: "Scientific & Regulatory Policy Conference: Consumer Trust in an International Food Supply

Keefe, D. (2003) "The Codex General Standard for Food Additives" and "U.S. Food Regulatory System: Food Ingredients." Invited presentations given during the U.S. Codex Office Technical Workshop on Codex Alimentarius for India.

Keefe, D. (2002) "The Codex General Standard for Food Additives and Science-Based Risk Analysis." Invited presentation given during the U.S. Codex Office Technical Workshop on Codex Alimentarius for South East Asia.

Keefe, D. (2001) "Codex Alimentarius: Working Principles for the Risk Analysis of Food Additives and Contaminants" Invited presentation given during the U.S. Codex Office Technical Workshop on Codex Alimentarius for Latin America and the Caribbean.

FDA's Food Additive Premarket Approval Process. Presented during FDA's Seminar for the International Community, May 14 - 15, 1996.

Project Experience

Led FDA’s food additive rulemaking to allow the use of folic acid in standardized and non-standardized foods.

Led U.S. Delegations to the Codex Committees on Food Additives, Fats and Oils, and Sugars and participated as a technical expert on food additives to the Codex Committees on Milk and Milk Products and Chocolate and Chocolate Products.

Managed FDA’s review of multiple Biotech consultations.

Led the 2017 reorganization of the Office of Food Additive Safety.

Director, Office of Food Additive Safety (OFAS), 2011-2022

FDA’s OFAS is responsible for the premarket review of industry submissions for food additives, color additives, food contact substances, generally recognized as safe (GRAS) substances and foods derived from new varieties of plants. The program strives to provide predictable, science-based safety decisions on food ingredients prior to market entry. In a typical year the program will make decisions on 150-200 industry submissions. In addition, it develops guidance to industry to improve the premarket review program and processes.

Prior to the US FDA, Dr. Keefe worked as a staff scientist at Argonne National Laboratories, Argonne Illinois (1991) where he conducted research on the "docking” of proteins to the electron donor site of the bacterial photosynthetic reaction center through the use of molecular cloning techniques to develop novel mutants; and as a research fellow at the Friedrich Miescher Institute, Basel Switzerland (1987-1990), where he examined the subcellular localization and the effects of hormone treatment on cell specific expression of ß-1,3-glucanase and chitinase in wild type and transgenic Nicotiana tabacum plants.