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Bioactive Compounds in Health and Disease

Advancing functional food regulation

Danik Martirosyan[1,2], Sarah Stratton[1,3]

[1]Functional Food Center Inc., Dallas, TX, USA; [2]Functional Food Institute, San Diego, CA, USA; [3]Virginia Commonwealth University, Richmond, Virginia, USA

Corresponding Author: Danik Martirosyan, PhD, Functional Food Institute, 4659 Texas St, San Diego, CA, 92116, USA

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ABSTRACT

The increasing demand for functional foods, stemming from the growing health consciousness among consumers and their preference for products that provide more than just basic nutrition, presents both opportunities and challenges for regulatory agencies, notably the U.S. Food and Drug Administration (FDA). Functional foods lack a specific regulatory category, leading to uncertainties for manufacturers and consumers. Collaboration between the FDA and the Functional Food Center (FFC) is proposed as a solution to enhance functional food regulation. The FFC's expertise in biomedical sciences and its 17-step process for defining functional foods can contribute valuable scientific research and aid the FDA's evaluation process. By fostering collaboration, both organizations can ensure consumer protection and promote public health while meeting the growing demand for functional foods.

Keywords: Functional foods, health claims, regulation, functional food definition, consumer demand, collaboration

INTRODUCTION

The U.S. Food and Drug Administration (FDA) health claims play a vital role in the regulation of food, dietary supplements, and medical foods. These health claims aim to provide consumers with accurate and scientifically supported information about the potential health benefits of these products [1]. The process of establishing FDA health claims involves a rigorous evaluation of

scientific evidence submitted by manufacturers or distributors. The agency carefully assesses the quality and strength of the evidence to ensure that the claims are valid and reliable. This evaluation process includes a comprehensive review of clinical trials, epidemiological studies, and other relevant scientific data that support the claimed health benefits [2-3].

The FDA has faced challenges in establishing a comprehensive functional food recognition, definition, and evaluation system. While the FDA has regulatory frameworks in place for conventional foods, dietary supplements, and medical foods, there is no specific regulatory category for functional foods [1, 3-4]. The Functional Food Center (FFC) offers a definitive description of functional foods (FFs) as "natural or processed foods that contain bioactive compounds, which, in defined, effective, non-toxic amounts, provide a clinically proven and documented health benefit utilizing specific biomarkers, to promote optimal health and reduce the risk of chronic/viral diseases and manage their symptoms" [6]. To establish a precise classification of functional foods, the FFC advocates a comprehensive 17-step process. This process encompasses several crucial stages, including identifying the food item, evaluating its intended health benefits and active compounds, scientific reviews, safety assessment, setting appropriate dosage guidelines, conducting biomarker assessments and clinical trials, and considering cost-effectiveness and regulatory compliance. The FFC underscores the significance of post-market monitoring, data collection, stakeholder engagement, and educational programs to foster the establishment of global standards for functional foods [5-7].

The absence of a comprehensive system for functional food recognition, definition, and evaluation within the U.S. Food and Drug Administration (FDA) poses significant challenges to both consumers and manufacturers [8,9]. As functional foods offer potential health benefits beyond basic nutrition, it is crucial to establish clear regulatory guidelines to ensure accurate labeling and credible health claims [5]. Currently, the FDA lacks a specific category for functional foods, leading to uncertainties for manufacturers regarding appropriate marketing strategies and potential health claims [10].

The rising demand for functional food: In recent years, there has been a remarkable surge in the demand for functional foods, driven by the growing health consciousness among consumers and their desire for food products that offer more than just basic nutrition [4,11]. Functional foods have gained popularity due to the scientific evidence supporting their potential health benefits [12]. For instance, research has shown that antioxidants found in certain functional foods can neutralize free radicals, reducing oxidative stress and inflammation in the body, which are risk factors for chronic diseases like cardiovascular disease and cancer [13-14]. The prevalence of chronic diseases, such as obesity, diabetes, and hypertension, has also fueled the demand for functional foods [6, 15-16]. Consumers are increasingly seeking dietary solutions to manage and prevent these conditions, realizing that a well-balanced diet, supplemented with functional foods, can contribute significantly to their overall health and quality of life [17]. In response to this surging demand, the food industry has been quick to capitalize on the functional food trend. Manufacturers are now incorporating various bioactive compounds into a wide range of products, including beverages, dairy products, cereals, and snacks, to meet consumer preferences [18-19]. However, this rapid growth has also brought challenges related to the authenticity of health claims and the need for proper regulation and oversight.

Regulatory challenges in functional foods: One significant aspect of FDA regulation is that functional foods are generally recognized and classified as conventional foods rather than drugs [20]. This categorization means that manufacturers do not need to undergo the rigorous drug approval process, which can be time-consuming and costly. Instead, manufacturers could market functional foods without obtaining pre-market approval from the FDA, if the ingredients used in the products are generally recognized as safe (GRAS) [21] or meet other food product use criteria [8-9]. The FDA primarily oversees functional foods' safety and labeling under the existing framework for conventional foods. Manufacturers are responsible for ensuring that the ingredients used in functional foods are safe for consumption, and the FDA may act against products that are found to be unsafe or misbranded [22]. This lack of pre-market approval for functional food has led to concerns about misleading marketing and unsupported health claims associated with some functional foods. Critics argue that consumers may be exposed to products with questionable health benefits or potential risks without more stringent regulations [23]. The evolving nature of functional foods and the growing body of scientific research on bioactive compounds and their health effects pose challenges to regulatory agencies like the FDA [8, 20, 25]. Adapting regulatory frameworks to address these complexities and ensure consumer protection remains an ongoing process.

Enhancing functional food regulation: The FFC can play a crucial role in assisting the FDA with the regulation of functional foods by providing valuable scientific research and expertise [25]. At the heart of the FFC's contributions to functional food regulation lies its cutting-edge expertise in the biomedical sciences. Through extensive research, the FFC explores the bioactive compounds present in functional foods, investigating their potential health benefits and safety profiles [25-26]. The scientific knowledge generated by the FFC serves as a valuable resource for the FDA, enabling a more informed and evidence-based evaluation of functional food ingredients and their effects on human health.

A collaborative approach between FFC and FDA: Collaboration between the FFC and the FDA would have significant beneficial implications for regulating, recognizing, defining, and evaluating functional foods. The FFC is a leading organization in classifying and defining functional foods through its well-established functional food evaluation framework and 17-step process in defining a functional food [5, 28]. The FFC's unique ability to connect a diverse network of professionals in the functional food industry is a key factor in collaboration with the FDA’s regulatory efforts [24]. By fostering an environment of collaboration, the FFC facilitates innovative research endeavors that span multiple disciplines, driving progress in functional food science [27]. The multidisciplinary approach encourages a comprehensive assessment of functional foods, considering nutritional, health, and safety aspects. Consequently, this facilitates the FDA's ability to make well-informed regulatory decisions, benefiting public health. Beyond research, the FFC's practical business experience plays a pivotal role in furthering the development and commercialization of functional food products [16]. As the FFC bridges the gap between academia and industry, it assists in bringing functional food innovations to both domestic and international markets [29].

CONCLUSION

The growing demand for functional foods and the increasing body of scientific evidence supporting their

potential health benefits present both opportunities and challenges for regulatory agencies like the U.S. Food and Drug Administration (FDA) [4, 11-12]. As functional foods become more popular among health-conscious consumers seeking dietary solutions to manage and prevent chronic diseases, clear regulatory guidelines and credible health claims are paramount [6, 15-17].

The absence of a specific regulatory category for functional foods within the FDA has resulted in uncertainties for manufacturers and consumers alike [8,10]. While the current categorization of conventional foods allows for faster market entry, it raises concerns about misleading marketing and unsupported health claims [23]. Striking the right balance between streamlining the approval process and ensuring consumer protection remains a delicate task [20-22].

To address these challenges and foster a more effective regulatory framework, a collaboration between the FDA and the Functional Food Center (FFC) holds great promise [25]. The FFC's expertise in biomedical sciences and its comprehensive 17-step process for defining functional foods can significantly contribute to the FDA's evaluation of functional food ingredients and their potential effects on human health [5, 25-26]. The FDA can make well-informed regulatory decisions that benefit public health by tapping into the FFC's research and extensive professional network [27].

The multidisciplinary approach fostered by the FFC encourages a comprehensive assessment of functional foods, considering their nutritional and health aspects and their safety profiles [8,20]. This approach is essential in navigating the evolving nature of functional foods and the ongoing scientific research surrounding their bioactive compounds [25].

A collaborative approach between the FFC and the FDA has the potential to establish clear regulatory guidelines, ensure accurate labeling, and strengthen credibility in health claims related to functional foods [5]. By working together, these organizations can better meet the surging demand for functional foods while safeguarding consumer interests and promoting overall public health [4, 11-12]. As functional foods continue to shape the food industry and consumer choices, the collaboration between the FFC and the FDA becomes ever more crucial in paving the way for a healthier and more informed future [6, 15-17].

Abbreviations: FFC: Functional Food Center; FDA: U.S. Food and Drug Administration; FF: Functional foods; GRAS: Generally recognized as safe.

Conflicts of Interest: No conflicts of interest are associated with this study.

Authors' Contribution: The original idea (FDA's Integral Role in Advancing Functional Foods: Collaborative Efforts with the Functional Food Center) was conceived by DM and was discussed with SS. SS collected data and wrote the manuscript. DM advised and participated in writing and editing the manuscript.

REFERENCES

1. U.S. Food and Drug Administration. (1994). Food labeling: Health claims; nutrient content claims; definition of terms. Federal Register, 59(234), 61434-61472.
2. Food and Drug Administration. (2016). Food Labeling: Revision of the Nutrition and Supplement Facts Labels. Federal Register, 81 FR 33741, 33741-33999.
3. U.S. Food and Drug Administration. (2009, January). Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims. Office of Nutrition, Labeling and Dietary Supplements, Division of Nutrition Programs and Labeling,

HFS-830, Center for Food Safety and Applied Nutrition.

4. Hasler C. M.. Functional foods: benefits, concerns and challenges-a position paper from the american council on science and health. The Journal of nutrition, 2002, 132(12), 3772–3781. DOI: https://doi.org/10.1093/jn/132.12.3772
5. Martirosyan D.M., Lampert T., Ekblad M. Classification and regulation of functional food proposed by the functional food center. *Functional Food Science* 2022; 2(2): 25-46. DOI: https://www.doi.org/10.31989/ffs.v2i2.890
6. Martirosyan D., Kanya H., Nadalet C. Can functional foods reduce the risk of disease? Advancement of functional food definition and steps to create functional food products. Functional Food in Health and Disease 2021. 11(5): 213-221. DOI: https://www.doi.org/10.31989/ffhd.v11i5.788
7. Martirosyan D., von Brugger J., Bialow S. Functional food science: Differences and similarities with food science. Functional Foods in Health and Disease 2021. 11(9): 408-430. DOI: https://www.doi.org/10.31989/ffhd.v11i9.831
8. Hasler, C. M. Functional foods: the western perspective. Nutrition Reviews, 1996, 54(11), S6.
9. Ross, S. Functional foods: the Food and Drug Administration perspective. The American journal of clinical nutrition, 2000, 71(6), 1735S-1738S.
10. Milner, J. A. Functional foods and health: a US perspective. British Journal of Nutrition, 2002, 88(S2), S152-S158.
11. Bigliardi, B., and Galati, F. Innovation trends in the food industry: The case of functional foods. Trends in Food Science and Technology, 2013, 31(2), 118-129.
12. John, R., and Singla, A. Functional Foods: Components, health benefits, challenges, and major projects. DRC Sustainable Future, 2021, 2(1), 61-72.
13. Sobenin, I. A., Pryanishnikov, V. V., Kunnova, L. M., Rabinovich, Y. A., Martirosyan, D. M., and Orekhov, AN(2010). The effects of time-released garlic powder tablets on multifunctional cardiovascular risk in patients with coronary artery disease. Lipids in health and disease, 9(1), 1-6. DOI: https://doi.org/10.1186/1476-511X-9-119
14. Nikolaevsky, V.A., Martirosyan, D.M., Muzalevskaya, E.N., Miroshnichenko, L.A., Zoloedov, V.I. Hepatotropic, antioxidant and antitoxic action of amaranth oil. Functional Foods in Health and Disease, 2014, 4(5), 159–171. DOI: https://doi.org/10.31989/ffhd.v4i5.18
15. Coats, R., and Martirosyan, D.. The effects of bioactive compounds on biomarkers of obesity. Functional Foods in Health and Disease, 2015, 5(11), 365-380. DOI: https://doi.org/10.31989/ffhd.v5i11.219
16. Martirosyan, D. M. (2006). Functional Foods for Chronic Diseases. D&A Inc., Dallas, USA
17. Castillo, M., Iriondo-DeHond, A., and Martirosyan, D. M.. Are functional foods essential for sustainable health? Ann Nutr Food Sci. 2018; 2(1): 1-4
18. Valero-Cases, E., Cerdá-Bernad, D., Pastor, J. J., and Frutos, M. J.. Non-Dairy Fermented Beverages as Potential Carriers to Ensure Probiotics, Prebiotics, and Bioactive Compounds Arrival to the Gut and Their Health Benefits.Nutrients, 2020, 12(6), 1666. DOI: https://doi.org/10.3390/nu12061666
19. Abdi, R., & Joye, I. J.. Prebiotic Potential of Cereal Components. Foods (Basel, Switzerland), 2021, 10(10), 2338. DOI: https://doi.org/10.3390/foods10102338
20. Mcnamara, S. H. (n.d.). Food and Drug Administration Regulation of Dietary Supplements. Regulation of Functional Foods and Nutraceuticals, 2005, 89–100. DOI: https://doi.org/10.1002/9780470277676.ch6
21. Burdock, G. A., Carabin, I. G., and Griffiths, J. C.. The importance of GRAS to the functional food and nutraceutical industries. Toxicology, 2006, 221(1), 17–27. DOI: https://doi.org/10.1016/j.tox.2006.01.012
22. Heller, I. R. (n.d.). Functional Foods: Regulatory and Marketing Developments in the United States. Regulation of Functional Foods and Nutraceuticals, 2005, 169–199. DOI: https://doi.org/10.1002/9780470277676.ch11
23. Wong, A. Y.-T., Lai, J. M. C., and Chan, A. W.-K. (2015). Regulations and protection for functional food products in the United States. Journal of Functional Foods, 17, 540–551. DOI: https://doi.org/10.1016/j.jff.2015.05.038
24. Martirosyan, D. M., Singh, J.. A new definition of functional food by FFC: what makes a new definition unique? Functional Foods

in Health and Disease, 2015; 5(6):209-223DOI: https://doi.org/10.31989/ffhd.v5i6.183

25. Martirosyan D., Miller E., Bioactive Compounds: The Key to Functional Foods. Bioactive Compounds in Health and Disease 2018; 1(3): 36-39. DOI: https://doi.org/10.31989/bchd.v1i3.539
26. Martirosyan D.M., Lampert T., Lee M. A comprehensive review on the role of food bioactive compounds in functional food science. Functional Food Science 2022; 3(2): 64-79. DOI: https://www.doi.org/10.31989/ffs.v2i3.906
27. Bornkessel, S. and Bröring, Stefanie and Omta, Onno. Cross-industry Collaborations in the Convergence Area of Functional Foods. The International Food and Agribusiness Management Review. 2016, 19)(2); 75-98
28. Gur, J., Mawuntu, M., and Martirosyan, D. FFC's Advancement of Functional Food Definition. Functional Foods in Health and Disease, 2018. 8(7), 385-397. DOI: https://doi.org/10.31989/ffhd.v8i7.531