



## Functional foods regulation system: Proposed regulatory paradigm by Functional Food Center

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### ABSTRACT

In response to the rising demand for functional foods driven by health-conscious consumers, a robust regulatory framework is imperative. The absence of specific guidelines creates uncertainties for both manufacturers and consumers. In response to the rising demand for functional foods driven by health-conscious consumers, a robust regulatory framework is imperative. The absence of specific guidelines creates uncertainties for both manufacturers and consumers. This article discusses the Functional Food Center's pioneering 17-step approval process for functional foods, emphasizing scientific validation and transparent communication. However, challenges persist within the FDA approval system, including a protracted timeline and the lack of a dedicated category for functional foods. Drawing inspiration from the efficient kosher labeling system, the Functional Food Center could serve as a certification agency. Certified functional foods could display a designated symbol, ensuring credibility and trustworthiness. This approach streamlines the approval process, fostering innovation, ensuring consumer safety, and meeting the evolving health needs of consumers in a transparent, credible, and regulated functional food market.

**Key Words:** Functional Food Classification, Functional Food Regulation, Functional Food Products, Bioactive Compounds, Functional Food Safety, Kosher Labeling Model, Regulatory Paradigm.

## Approval Process for Functional Food Products

1. Applicants send in their application to the Functional Food Center
2. The Functional Food Center sends application documents to be reviewed by Certified Functional Food Scientists from the Academic Society of Functional Foods and Bioactive Compounds (ASFFBC)
3. *If necessary*, clinical studies are repeated at an ideal Functional Food Clinical Study Center
4. The application is either approved by the Functional Food Center, or denied and sent back to applicant
5. Government agencies are informed *after* approval is granted by the Functional Food Center

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### INTRODUCTION

In response to the escalating demand for functional foods, driven by a burgeoning health-conscious consumer base and a preference for nutritionally enriched products, regulatory bodies face a pressing challenge. The absence of a specific regulatory framework for these foods creates uncertainties for both manufacturers and consumers, necessitating immediate attention to ensure consumer safety and public health. Functional foods are defined as 'natural or processed foods that contain biologically active compounds, which, in defined, effective, non-toxic amounts, provide a clinically proven and documented health benefit utilizing

specific biomarkers, for improving general health, for the prevention, management, or treatment of chronic and viral diseases or their symptoms,' by the Functional Food Center, have become central to this discourse [1].

In response to the industry's challenges related to defining and classifying functional foods, the Functional Food Center has meticulously developed a 17-step process for defining functional foods. The proposed classification system (A, B, or C) integrates rigorous post-market research, epidemiological studies, and follows clinical trials. Classification A signifies functional food products (FFPs) that have undergone exhaustive aftermarket research and clinical trials, demonstrating

their efficacy and safety. Reapplication is required for approval at this level, indicating a continual commitment to high standards. Classification B acknowledges FFPs supported by robust epidemiological studies and clinical trials, validating their functional status. Reapplication at this level signifies an ongoing dedication to scientific validation. Classification C recognizes products that have achieved functional status through after-market research and clinical trials, requiring reapplication for continual assessment at level A [2].

In tandem with these classifications, the mandatory publication of peer-reviewed articles for each functional food product ensures enhanced accessibility and trustworthiness of functional claims. This comprehensive strategy, encompassing detailed definition, creation methodology, and a structured classification system, establishes the foundation for a transparent, credible, and regulated functional food market.

Through this editorial, we hope to expand on these regulations to streamline the process of regulation of functional foods, which won't require FDA approval. Recognizing the need for an updated regulatory paradigm, akin to the efficient kosher labeling system and the Japanese Foods for Specified Health Uses model, the updated regulation aims to facilitate the approval process for functional foods. Drawing inspiration from the kosher labeling model, which relies on established religious guidelines without direct FDA oversight, the new approach seeks to implement a set of standardized rules developed by the Functional Food Center [3]. These rules, informed by scientific research and industry expertise, will facilitate expedited approval for functional foods meeting specific criteria, ensuring consumer safety while promoting innovation within the industry. The protracted timeline associated with the FDA approval process, which can span a minimum of 6 to 10 months for functional foods, underscores a significant challenge in

the industry [4]. This extended waiting period not only imposes a considerable burden on manufacturers but also hampers timely innovation and market responsiveness. The prolonged duration of 6 to 10 months for FDA approval is particularly concerning given the absence of a dedicated regulatory category for functional foods within the FDA framework [5]. In the dynamic landscape of nutritional science and consumer preferences, swift approval mechanisms are imperative to facilitate the timely introduction of functional foods that cater to the evolving health needs of the population. Moreover, health claims play a crucial role in enhancing transparency and fostering trust within the food industry, as they promote information based on solid evidence [6]. Shortening this approval timeframe is crucial to fostering a more agile and innovative functional food industry, ensuring that cutting-edge products can reach consumers efficiently, benefiting both public health and the industry's growth.

**Functional Foods Regulation System:** In this section, we explore the Functional Food Center's groundbreaking 17-step regulation process for functional foods. Delving into each level, we highlight the specific criteria for approval, emphasizing the critical role of scientific validation. The detailed breakdown of the 17 individual steps is as follows [7]:

1. Establishes a goal of the functional food product,
2. Determines relevant bioactive compound(s),
3. Establishes the appropriate dosage of bioactive compound(s),
4. Establishes the appropriate time of consumption of bioactive compound(s)
5. Determines the specific pathway and mechanism of action,
6. Establishes relevant biomarker(s),

7. Chooses an appropriate food vehicle for bioactive compound(s),
8. Provides preclinical studies on efficacy and safety,
9. Provides clinical trials for dosage, efficacy, and safety,
10. Creates a special label that informs the consumers of the most effective way to consume the product,
11. Publications are necessary in open-access, peer-reviewed journals,
12. Educates the market,
13. Sends information to credible third parties and/or governmental agencies for approval,
14. Official establishment of the accredited functional food product,
15. Release the functional food product to the market. (Receive the basic category (level C)),
16. Provides epidemiological studies. (Reapply for the approval for a new category (level B)),
17. Provides after-market research. (Reapply for the approval for a new category (level A)).

In step 8 of the functional food approval process, preclinical studies are conducted to assess efficacy and safety after meeting initial requirements. These studies, involving in vitro and in vivo experiments with animals, help establish effective dosages without adverse effects before human trials. Passing this checkpoint is crucial; without approval at this stage, functional foods cannot proceed further [8]. This step is consistent with previous iterations and ensures the safety and effectiveness of functional foods in subsequent clinical trials, benefiting future consumers.

In the ninth step, human clinical trials refine dosages and assess efficacy and safety [7]. Adverse effects are closely monitored; if significant issues arise, the compound's application may be halted. The trials,

adhering to standardized regulations, ensure consistency and prevent biased judgments. This stage highlights the need for an ideal Functional Food Clinical Study Center, ensuring rigorous evaluation and reducing the risk of faulty products entering the market, thus avoiding potential liabilities for regulatory bodies. In theory, the establishment of an ideal Functional Food Clinical Study Center would transform the evaluation process for functional foods. Equipped with advanced technology and expert researchers, this facility would conduct meticulous assessments adhering to rigorous scientific protocols. Operating independently and free from commercial influence, the center's focus on objective evaluation and consumer safety would be paramount. By monitoring adverse effects and halting applications in case of significant issues, the center prioritizes public well-being. Additionally, as a collaborative hub, it would expedite the regulatory approval process by fostering cooperation between researchers, clinicians, and regulatory authorities. In tandem with this, it's important to note that the evaluation process is contingent upon the successful completion of trials by the applicant. In the event of necessary trials to verify results on our end, we maintain a vigilant approach to ensure the reliability and safety of functional foods in compliance with standardized regulations.

In the tenth step of the approval process, a label is created for functional food products (FFPs) once human clinical trials confirm their effectiveness [7]. This label provides essential information to consumers, including intake levels, ingestion instructions, observed health benefits, recommended usage, identification of bioactive substances, consumption methods, and precautions. This

labeling approach, inspired by the established FOSHU system in Japan, ensures accurate information about the content and function of FFPs. The label distinguishes FFPs based on categories such as regular, standardized, risk-reduction, reauthorized, and qualified, each representing different stages of evaluation and certification. Unlike previous outlines, this step emphasizes the development of a consumer-friendly label, enhancing communication of FFP benefits. The design of the label is crucial, with a focus on easy readability and specific health benefits [9]. Modeled after the simplicity of the FOSHU label, the Functional Food Center's labels aim to facilitate consumer understanding and informed decision-making regarding the effects of functional foods.

The eleventh step recommends publishing research findings in peer-reviewed journals focused on bioactive molecules and food science [7]. Open access publication enhances accessibility and transparency, allowing public scrutiny and fostering trust. While not mandatory, this

step is crucial for expanding knowledge, legitimizing bioactive compounds, and educating the market. Accessible research supports consumer confidence and acceptance, emphasizing the importance of credible publications within specialized journals [10].

In the thirteenth step, gathered data is submitted to third parties and governmental agencies, primarily the FDA, for approval [7]. The FFC acts as a mediator, providing recommendations based on analyses in the updated 17-step process. This step is vital for building public trust as it validates the food product and its benefits. Transparent scientific communication with official bodies enhances consumer confidence, ensuring acceptance by both agencies and the public [11]. This step is under review in this editorial, proposing a label provided by the FFC for certified functional foods, like kosher labeling, aiming for transparent and scientifically backed procedures to gain public trust.

## Release the functional food product to the market. (Receive the basic category (level C))



- *With items already in the market* - a release would act as categorization and documentation of values observed.
- *With items that not seen in the market yet* - requires a proper release.
- At this point, the grade associated with the product will be the basic 'C', as it has yet to be studied in uncontrolled environments on a large scale.



Logo for the certification of a Category C functional food product.

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**Figure 1.** Certification of Functional Food Product with category "C".

**Provides epidemiological studies. (Reapply for the approval for a new category (level B))**

- A better analysis for its efficacy can be made as well as establishing a line of trust with the public.
- The dosage, efficacy, and safety will be analyzed even more in a non-laboratory setting.
- Any negative outcomes that could not previously be observed due to study design limitations may become apparent in this step.
- It was determined that a randomized controlled trial design is the most applicable to the revitalized 16 step process.
- Once this stage is completed, the FFP may reapply for the approval of category 'B'.



Logo for the certification of a Category B functional food product.

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**Figure 2.** Certification of Functional Food Product with category “B”.

**Provides after market research. (Reapply for the approval for a new category (level A))**

- This is the most refined release when compared to the earlier epidemiological studies since the dosage and use should be more optimal when compared to previous sausages.
- Analyzes a much wider population as there is little to no control besides legal regulations.
- Will monitor the potential gap between the controlled studies and how the product actually affects an individual’s health .
- Should discrepancies arise in efficacy or safety, the product will be re-evaluated.
- Upon completion, the product can now be subject to reapplication for the approval of being classified under category ‘A’.



Logo for the certification of a Category A functional food product.

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**Figure 3.** Certification of Functional Food Product with category “A”.

The FFC introduced the classification of functional food products into categories A, B, and C [7]. In the culmination of the regulatory process, step 15 involves releasing the functional food product to the market, thereby receiving the basic category designation at level

C (Figure 1). This signifies the product's compliance with established standards and its readiness for consumer access. Subsequently, in step 16, the process entails providing epidemiological studies, a crucial step prompting a reapplication for approval to attain a new

category at level B (Figure 2) . This phase underscores the commitment to ongoing scientific scrutiny and adaptation to evolving knowledge. Finally, at step 17, the regulatory journey involves supplying after-market research, and initiating another reapplication for approval, this time aspiring for a new category at level A (Figure 3). This iterative approach reflects a dynamic commitment to research, development, and regulatory alignment throughout the lifecycle of the functional food product.

**Challenges with FDA Approval System:** In examining the challenges within the FDA approval system for functional foods, a significant concern arises due to the extensive timeline of 6 to 10 months required for approval. This lengthy process poses substantial hurdles for manufacturers and researchers alike, delaying the introduction of beneficial functional foods to the market. Furthermore, the absence of a dedicated FDA category for functional foods underscores a critical gap in the regulatory framework. The process of obtaining FDA approval for health claims can be challenging. Studies focusing on risk reduction are prevalent, but the FDA requires robust evidence, especially for claims related to diagnosed conditions [12]. This scrutiny emphasizes the rigorous standards functional foods must meet to substantiate their health benefits and provide accurate information to consumers. The lack of specific guidelines tailored to the unique nature of functional foods complicates the approval process and raises the necessity for a distinct regulatory framework. Addressing these challenges is pivotal in fostering innovation, ensuring consumer safety, and facilitating the timely availability of functional foods that can significantly impact public health.

GRAS, an acronym for Generally Recognized As Safe, holds significant relevance in the context of the Functional Food Center's regulatory paradigm. Within the intricate regulatory framework of functional foods,

GRAS assumes paramount significance as it serves as a pivotal determinant for premarket review and FDA approval, offering manufacturers a pathway to ensure the safety and efficacy of their products in compliance with stringent regulatory standards. As outlined in sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance intentionally added to food is subject to premarket review and FDA approval unless it is generally recognized as safe by qualified experts [13]. The GRAS status can be achieved through either scientific procedures or, for substances used in food before 1958, through experience based on common use. Scientific procedures necessitate the same rigorous scientific evidence required for FDA approval of a food additive. This involves the application of generally available and accepted scientific data, methods, and principles, published or unpublished. On the other hand, GRAS status through experience relies on a substantial history of consumption of food use by a significant number of consumers. Understanding and navigating the GRAS framework is integral for manufacturers seeking approval for functional foods, aligning with the overarching goal of ensuring safety and efficacy in the evolving landscape of the functional food industry.

**Proposed Regulatory Paradigm:** Building upon our analysis of the FOSHU system and the FDA health claim approval system in previous articles, we aim to explore how drawing inspiration from the kosher labeling model could significantly benefit our approach to certifying functional foods [14]. This innovative approach seeks to streamline the approval process for functional foods, ensuring both efficiency and adherence to stringent standards. Certification of kosher products is typically granted by reputable kosher certification agencies or authorities. These organizations are responsible for ensuring that products meet the standards and requirements of Jewish dietary laws [15]. Each certification agency may put a kosher label on it, which is displayed on the packaging of certified products [16].

Consumers recognize these symbols as indicators of a product's kosher status, and they trust the certification granted by these established authorities. Companies seeking kosher certification usually work closely with one of these agencies to obtain the necessary approval for their products.

Like how kosher certification agencies ensure products meet specific standards of Jewish dietary laws, the Functional Food Center could serve as a certification agency for functional foods. Once applications for functional food certification are submitted, the Functional Food Center would be responsible for evaluating these products to ensure they adhere to stringent standards and requirements related to health benefits and safety [7]. Upon approval, certified functional foods could display a designated symbol or label on their packaging, indicating their status as approved by the Functional Food Center. Much like consumers trust kosher symbols as indicators of a

product's adherence to dietary laws, they could rely on the certification granted by the Functional Food Center, establishing credibility and trustworthiness in the realm of functional foods. Companies seeking functional food certification would collaborate closely with the Functional Food Center to obtain the necessary approval for their products, ensuring consumers have access to reliable and beneficial functional food options. To enhance transparency and maintain a high standard of quality, these certified products would be submitted to government agencies such as the FDA, NIH, and USDA. This proactive step ensures that these regulatory bodies are informed about the approved functional foods, aligning with our commitment to public health and safety. By establishing a streamlined and efficient certification process akin to the kosher labeling model, we aim to empower consumers with reliable and beneficial functional food options while promoting innovation and trust within the industry.

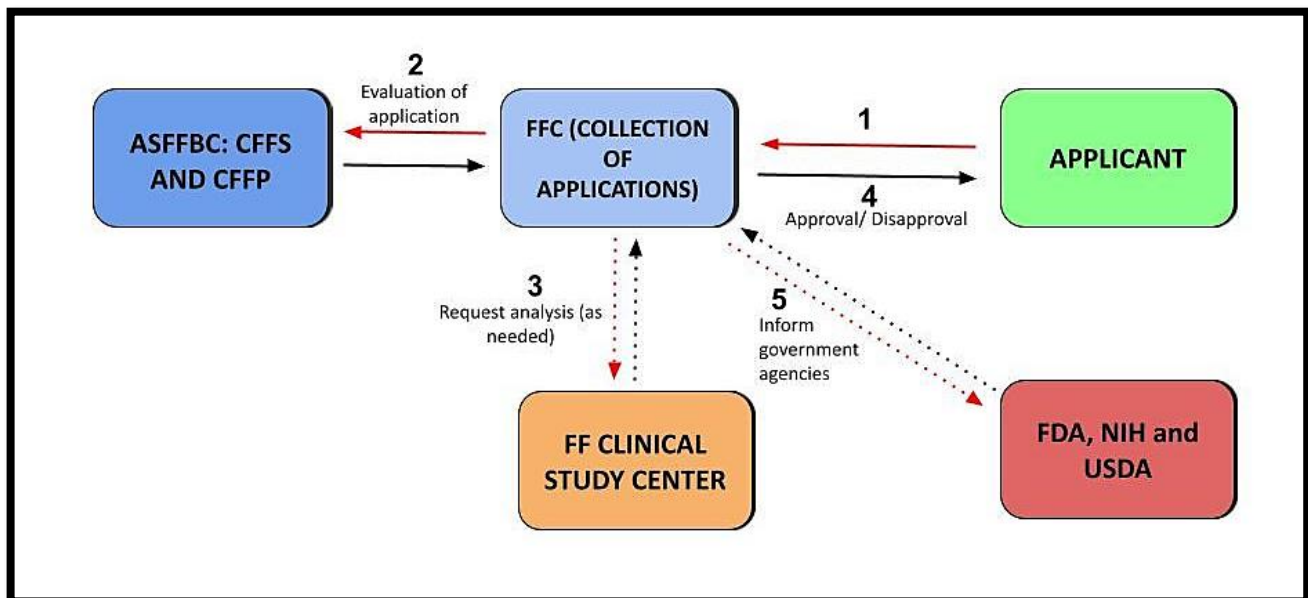


Figure 4. Proposed process for approval of Functional Food Products

The new proposed process for approval/recommendation is outlined in Figure 4 above. It's important to note that this proposal is dynamic and open

to future modifications. The first step entails applicants submitting comprehensive documentation as part of their application to the Functional Food Center. The FFC



then engages functional food scientists from ASFFBC to assess specific cases involving potential certified functional foods (CFFs) and certified functional food products (CFFP). Upon verification and approval of the submitted documents, along with relevant functional food science publications, the FFC provides recommendations regarding the case's continuation. This preliminary screening process enhances applicant efficiency, allowing them to develop a Functional Food Product before submitting data to any agencies. The FFC must explicitly state that, as part of the approval process, the applicant bears responsibility for ensuring the safety and functionality of the product, and approval is granted contingent upon the adequacy of the submitted documents.

In the subsequent step of the certification process, an essential milestone is reached as the functional food product undergoes comprehensive analysis at an ideal Functional Food Clinical Study Center (FFCSC). This critical phase, building upon the foundation of previous preclinical studies and human clinical trials, marks a pivotal moment in ensuring the safety, efficacy, and reliability of the functional food in question. Rigorous evaluations are conducted, adhering to standardized protocols and meticulous scientific methodologies. This center serves as a beacon of objective evaluation, prioritizing consumer safety above all else. By closely monitoring adverse effects and promptly halting applications in the event of significant issues, the FFCSC plays a vital role in safeguarding public well-being. Furthermore, as a collaborative hub, it fosters cooperation between multidisciplinary teams of researchers, clinicians, and regulatory authorities, expediting the regulatory approval process and ensuring that only the most reliable and beneficial functional foods reach the market. It is important to note that this step is optional and conducted only if needed, ensuring a streamlined yet thorough certification process.

Following the meticulous analysis conducted by the Functional Food Center, the functional food product undergoes a decisive evaluation. Based on the comprehensive findings, the product is either approved or disapproved for certification. This step serves as the final checkpoint, ensuring that only functional foods meeting the highest standards of safety and efficacy are granted approval. Only after a product receives official approval is it communicated to relevant government agencies such as the FDA, NIH, and USDA. In cases of disapproval, contact with government agencies may not be necessary, while if approval is warranted, government agencies may be notified for public safety. This stringent process guarantees that certified functional foods entering the market have undergone rigorous scrutiny, providing consumers with the utmost confidence in the products they choose for their health and well-being.

**Bridging FOSHU, FFC, and EFSA Guidelines:** The comparison between the Ideal Process and Development of Functional Food Products (FFP) by FOSHU, FFC, and additional insights into EFSA regulations reveals intriguing distinctions and implications for the international scenario. FOSHU and FFC, while sharing commonalities in emphasizing scientific evidence, transparency, and consumer education, diverge in their specific approaches to health conditions and risk reduction. This nuanced variation caters to regional nuances, ensuring relevance in diverse markets.

Conversely, the European Commission's (EC) regulatory framework, facilitated by the European Food Safety Authority (EFSA), adopts a less restrictive stance on health claims. The absence of explicit restrictions on claims related to disease treatment, mitigation, diagnosis, or cure distinguishes the EC's approach from that of the FDA and FFC [17]. Instead, the EC focuses on claims based on scientific evidence that can be easily understood by consumers. This contrast reflects a more

permissive environment in the European Union, where there is no legislative prohibition against claims promoting disease prevention or treatment.

The lack of stringent restrictions in EFSA regulations could result in a landscape where consumers are less skeptical of food claims. However, this also introduces challenges, such as the absence of a clear distinction for functional foods and a potential lack of awareness in the European population regarding the intricacies of health claims. The FFC's proposed paradigm, with its emphasis on a comprehensive and transparent certification process, could offer valuable insights to address these challenges.

In navigating the intricate landscape of international functional food regulations, the role of the FDA stands out as a crucial benchmark. In contrast to the European Commission's less restrictive stance, the FDA, guided by the GRAS framework, plays a pivotal role in scrutinizing health claims associated with functional foods. This rigorous approach not only ensures consumer safety but also sets a precedent for transparent and evidence-based certification processes, addressing potential challenges in the absence of stringent restrictions.

FOSHU's meticulous approach sets a benchmark in establishing causal compounds with proven mechanisms, characteristics, and stability. The imperative identification and measurement of bioactive compounds, along with the definition of functional foods, positions FOSHU within a robust regulatory framework. Notably, FOSHU's emphasis on addressing special health conditions, maintaining general health, and reducing the risk of viral diseases tailors its focus to Japan's unique health landscape. The comprehensive evaluation process, including testing the effectiveness on the final product basis, underlines FOSHU's commitment to ensuring the safety and efficacy of functional foods [18]. The specified 12 weeks of randomized controlled trials and the requirement for specialized labels, intake

guidelines, and shelf-life recommendations contribute to a thorough and transparent certification process.

FOSHU's distinct approach to epidemiological studies further sets it apart, highlighting a dedication to confirming effects in real-world scenarios. The government's approval, granted by the CAA after a meticulous evaluation, positions FOSHU as a hallmark of regulatory excellence in Japan. The beneficiaries, including manufacturers, government entities, and consumers, all play pivotal roles in the FOSHU functional food ecosystem [18].

Considering the FFC's proposed paradigm, inspired by the kosher labeling model, FOSHU's stringent standards and regulatory processes offer valuable insights for a comprehensive and transparent certification framework. The FFC, in urging the creation of a distinct category for functional foods, can draw inspiration from FOSHU's approach. Moreover, the call for rigorous scientific testing followed by third-party evaluation, a cornerstone in FOSHU's approval system, resonates with the global vision of building functional foods trusted by the public.

In synthesizing FOSHU's meticulous processes, the FFC's proposed paradigm, and insights into EFSA and FDA regulations, the manuscript is poised to contribute significantly to the discourse on international functional food regulations. The integration of diverse regulatory approaches, drawing inspiration from FOSHU's specificity, FFC's transparency, and EFSA's permissiveness, positions the manuscript within a dynamic global landscape, offering a potential blueprint for harmonized regulations and collaborative efforts among regulatory bodies worldwide.

**Why the Functional Food Center?** The Functional Food Center (FFC) stands as a pioneering institution in the realm of functional food research and development. Established in 1998, the FFC embarked on a mission to revolutionize the functional food industry by fostering

collaboration among professionals worldwide. Over the years, the FFC has successfully connected a global network of experts, facilitating groundbreaking research, development, and commercialization of functional food innovations. What sets the FFC apart is not only its extensive network but also its substantial contributions to the field. The center has meticulously crafted a comprehensive and practical definition of functional food, serving as a guiding light for researchers and industry practitioners. Additionally, the FFC has made a significant impact through its publications, having authored, and published over 40 books and 11 textbooks, along with maintaining many active, peer-reviewed, open-access scientific journals dedicated to functional food advancements [19]. Furthermore, the FFC's influence extends beyond the written word; as of now, FFC has organized 31 international conferences, attracting leaders in the field of functional food from diverse corners of the world. With a readership surpassing a million, including medical doctors, researchers, and governmental agency representatives, the Functional Food Center stands as an indisputable authority, well-qualified to drive the future of functional food research and innovation.

The Functional Food Center also has the Academic Society for Functional Foods and Bioactive Compounds (ASFFBC) which plays a vital role in advancing global awareness of functional and medical foods, championing health and wellness worldwide. Established in response to the growing field, ASFFBC unites scientists, medical doctors, dietitians, nutritionists, students, and industry professionals [20]. With roots in the esteemed Functional Food Center Inc., ASFFBC benefits from years of experience in research and development, marked by influential publications like the journal *Functional Foods in Health and Disease*, *Functional Food Science*, *Bioactive Compounds in Health and Disease*, and many other FFC's

functional foods related journals. Society's diverse community includes experts from prestigious governing agencies, ensuring a wealth of expertise. ASFFBC's dedicated focus on researching functional and medical foods, bioactive compounds, nutraceuticals, and innovative scientific techniques makes it a driving force in this critical field, promoting collaboration and progress in the pursuit of healthier lives worldwide.

**Novelty of this work:** This comprehensive study stands at the forefront of the evolving functional food landscape, presenting a groundbreaking regulatory paradigm inspired by the efficient kosher labeling system. The innovation lies in the integration of the Functional Food Center's meticulous 17-step regulation process for functional foods, emphasizing rigorous scientific validation and transparent communication. By proposing the Functional Food Center as a certification agency akin to established kosher certification bodies, this work pioneers a streamlined and efficient approval process, ensuring both adherence to stringent standards and credibility in the realm of functional foods. This approach bridges the gap between consumer demand and regulatory challenges, fostering innovation, enhancing consumer safety, and meeting the dynamic health needs of today's discerning consumers.

This study not only incorporates insights from FDA, EFSA, and FOSHU but also draws inspiration from the efficient kosher labeling system. By combining knowledge from these diverse regulatory frameworks, alongside implementing FFC's 17-step process, it proposes a novel and advanced paradigm for functional foods. The approach aligns with the transparent evaluation emphasized by the FDA and FOSHU, considering EFSA's permissive stance on health claims. Integration of FFC's functional food classification and certified scientists from ASFFBC contributes to a

comprehensive framework, streamlining approval with credibility and adherence to standards while fostering innovation for today's consumers.

## CONCLUSION

In conclusion, the demand for functional foods, driven by health-conscious consumers, necessitates an updated regulatory paradigm to ensure safety and efficacy. The absence of specific guidelines poses challenges for both manufacturers and consumers. The Functional Food Center's proposed 17-step regulation process provides a structured approach, emphasizing scientific validation and transparent communication. However, the lengthy FDA approval timeline and the lack of a dedicated category for functional foods underscore significant hurdles in the industry. Drawing inspiration from the efficient kosher labeling system, the Functional Food Center jointly with the Academic Society of Functional Foods and Bioactive Compounds could serve as a certification agency for functional foods. By evaluating products and granting approval, the Functional Food Center would establish credibility, similar to consumers' trust in kosher symbols. This approach not only streamlines the approval process but also ensures the availability of reliable functional foods, benefiting both public health and industry innovation. Through these efforts, a transparent, credible, and regulated functional food market can be achieved, meeting the evolving health needs of consumers.

In addressing the thorny issue of protecting patenting for manufacturers and researchers, it is crucial to underscore the role of intellectual property rights in fostering innovation. As functional foods gain prominence, researchers should actively pursue patent applications to secure exclusive rights, providing a foundation for collaboration with manufacturers. This strategic approach not only protects the intellectual property of innovators but also enhances fundraising potential by showcasing the uniqueness and market

potential of patented products. As a further research suggestion, a comprehensive examination of patent strategies within the evolving landscape of functional foods can be conducted. By aligning regulatory initiatives with robust patent protection, we can create a harmonious environment that not only meets the health needs of consumers but also fuels the growth and sustainability of the functional food industry.

**Abbreviations:** FDA: Food and Drug Administration, GRAS: Generally Recognized as Safe, FFC: Functional Food Center, FFP: Functional Food Product, EC: European Commission, EFSA: European Food Safety Authority, CAA: Consumer Affairs Agency, FOSHU: Foods for Specified Health Uses, ASFFBC: Academic society for Functional Foods and Bioactive Compounds

**Competing Interests:** The authors declare no competing interests.

**Author Contributions:** DM brought the idea of Functional Foods Regulation System: Proposed Regulatory Paradigm by FFC and discussed details with AA. Both authors are involved in researching information, writing, and editing processes.

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