



## FFC’s Advancement of the Establishment of Functional Food Science

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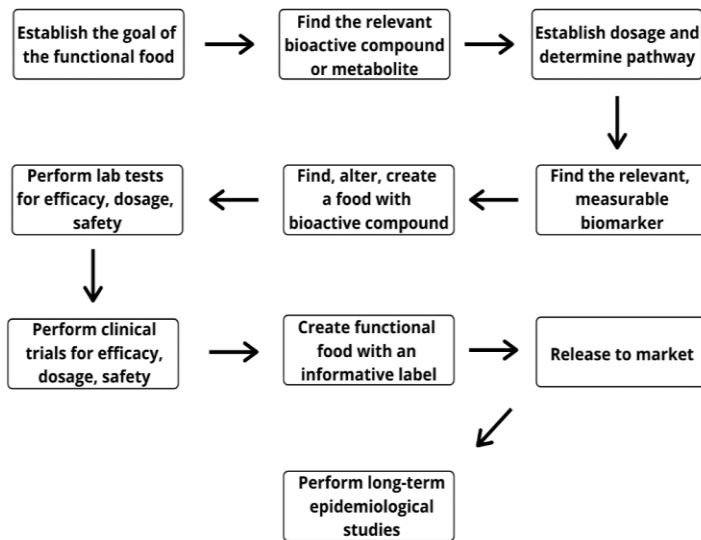
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### ABSTRACT

The Functional Food Center (FFC) has previously defined functional food as foods which have scientifically-proven benefits toward improving general health and ameliorating the effects of chronic diseases. Given this useful working definition of functional food, it’s now imperative to delineate and establish a field of functional food science. Currently, there are no published articles on what functional food science is. Defining functional food science is necessary so that a legitimate field can be established and

### Functional Food Science: Proposed Process Outline



and recognized by the government as well as a global network of researchers and scientists. In this way, appropriate funding and advancements can be made, and functional foods can make their way towards significantly improving the lives of people in the United States and also around the world, as is the goal. As a result of this need, functional food science will be defined as the process of preparing functional foods as well as a field intersecting the realms of health and medical treatment. In this sense, functional food science not only deals with preparing functional foods but also with the efficacy of their health benefits. More specifically, as sciences are often defined by their processes, functional food science can be defined as the comprehensive, aggregate, interdisciplinary, and

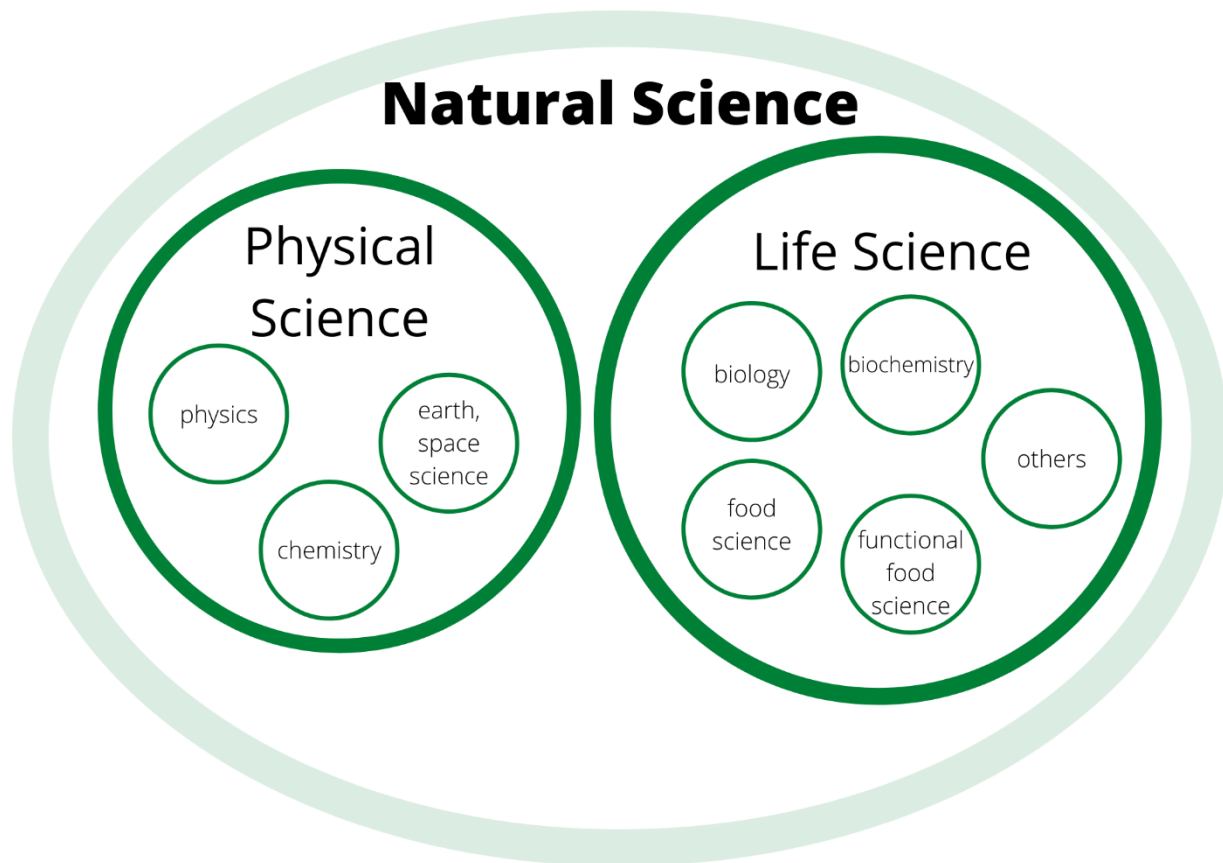
collaborative processes of: establishing a target and finding a bioactive compound that enables that effect, finding the correlated measurable biomarker, running testing to find proper dosage and effectiveness, performing clinical trials to ensure efficacy, creating the functional food with an informative label, releasing to market and running epidemiological studies to verify it. Although this understanding and definition is nascent, this can be a starting ground for the FDA and other governmental bodies, as well as the scientific and functional food community, to develop a robust, extrapolatable, and useful outline of functional food science. With an established field of functional food science, functional foods can be researched, produced, and made official and trustworthy, so that there can be large positive impacts on public health, both in disease prevention and in maintenance of good health.

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## INTRODUCTION

In order to properly address and create a realm of functional food science, it's first necessary to address the definitions and processes of food and food science, such that this new realm of functional food and functional food science has a basis. In affluent societies, food can be defined as "an adequate diet to avoid deficiency" [1]. In this sense, food is a basic component of life and can be correlated with basic sustenance. Food science can be understood as the "study of the physical, microbial, and chemical makeup of food [with] applications... to develop safe, nutritious, and sustainable foods and innovative packaging" [2]. Functional foods, as defined by the FFC, are "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 disease or its symptoms" [3]. In this way, functional food has extra benefits beyond traditional food; besides providing basic sustenance, it would also provide scientifically-researched and clinically-proven health benefits for general health or for the amelioration of diseases and their symptoms.

Functional foods have unique potential applications that make them useful: they can be effective not only in the prevention of the onset of diseases, but also in the treatment of disease or its symptoms. This definition encompasses previous definitions of functional food in a cohesive and useful way, indicating the requirements for a functional food production process—functional food science. The demarcation between food science and functional food science lies in more than the semantics; nutrition, especially in wealthier countries, is now no longer understood as just the basic necessity for life, but rather as the conception of "promoting health as well as reducing the risk of... chronic diseases" [1]. In taking a look at popular nutrition guides, such as ones provided by Harvard Medical School, healthy foods are expected to "prevent nearly every disease and dysfunction... and cancer" [4]. Whereas many or most facets of food science can be focused on packaging, preservation, and taste, functional food science focuses very specifically on working solely on the extra-nutritive side of foods, namely, preparing foods that meet the requirements of basic sustenance while providing and delivering the expectations of food to be fighters of disease and dysfunction and their symptoms. Simply put, functional food science is the



**Figure 1.** A general outline of where a field of functional food science may fit within the realm of natural science: outside of traditional food science, but still very much connected and related to the life sciences as well as food science

research and production of functional foods. Put more rigorously, functional food science can be established as a highly-regimented, highly-focused interdisciplinary science, separate from food science, that is completely focused on discovering and developing foods which have a potentially positive effect on health beyond basic nutrition, along with testing their safety, dosage, and measurable effects in and on the body and mind. Again, the applications and the positive impacts of functional food science extend to both preventing disease onset and ameliorating the effects of viral or chronic diseases. Food science can continue to focus on the non-nutritive side of food: the packaging, the flavor, the color, the processing, the shipping, food security and supply, and other vital sections and operations relating to food. This distinction between functional

food science and traditional food science must be one of the steps in the process to create a field of functional food science as well as the wide-scale production of functional foods. As a food science professor at California Polytechnic Institute once stated, “food science is farm to fork, nutrition is afterward” [5]. This demarcation in the potential role of functional food science is clear, and it’s a role that will only increase in importance as the world looks to foods that will keep them healthy.

There are some nuances and potential disagreements over the definition of functional food, particularly in the United States where the federal Food and Drug Administration (FDA) has not accepted nor issued an official definition of functional food [6]. However, the FFC’s working definition remains comprehensive and in and of itself can serve as a basis

for functional food science. It must be made clear, though, that in order for functional foods to be popularized, trusted by the people, and widely-produced and useful, trusted agencies—not only the FDA but also established and reputable groups such as the National Institutes of Health and the American Academy of Arts and Sciences—must first define functional foods and also functional food science. The potential benefits of functional foods to moderate the effects of disease and improve general health of the entire body [7] can be established, and therefore the positive effects functional foods could have on the quality of life cannot be understated; therefore, it is imperative that a field of functional food science be established and functional foods be systematically researched, designed, and be accessible.

As made clear in the definition set forth by the FFC, functional foods predicate themselves on attributing a health benefit to a compound. The health benefit ranges from support of the immune system to infections, such as the most recent COVID-19, [8] and applications in the improvement of mental health [9] to improvements in general health and the treatment of chronic diseases and their symptoms. With such a wide range of beneficial uses, it's necessary to have a formulated method of creating functional foods, testing their effectiveness, and building public trust and accessibility to them. Some studies indicate that functional foods are part of a market already worth over \$150 billion and growing at 10% per year [10]. These studies may be misleading: are they including functional food ingredients, or established functional foods? Are there even established functional foods if there is no public, federal definition or backing of it? Studies such as these may be taking away from the very real need to establish an official field of functional food science by implying that functional foods are already a large

part of the market. It's important that the development of functional foods—functional food science—has a rigorous, peer-reviewed, and legitimate process that is focused on improving the health of millions, hopefully billions, of people. Only after the system is regulated and established can the broad public trust and have the ability to access a wide range of functional foods for a wide range of health benefits. Alongside the health benefits of functional foods alone—prevention of disease onset and treatment of diseases and their symptoms—the potential combination of functional foods alongside other therapies and treatments may increase the efficacy of all treatments.

#### **Existing Information on a Functional Food Science**

**Process:** There exist several sources that outline a potential functional food science process. In the United States, the Institute of Food Technologists (IFT) seems to provide a relatively thorough outline of a process of producing and releasing functional foods [12]. The American Journal of Clinical Nutrition (AJCN) provides a similar structure as well [13]. In certain developed countries around the world, functional foods and functional food science has already been constituted and established in the government. In Europe, the European Commission Concerted Action on Functional Food Science in Europe (FUFOSE) has outlined concepts, processes, and approaches to functional food science that are backed by the International Life Science Institute (ILSI) [14]. In Japan, the legislation of Food for Specified Health Uses (FOSHU) has established a highly-regulated and comprehensive scaffold for functional food science [15]. These two international bodies, FUFOSE and FOSHU, on functional food science share fundamental ideas in functional food science and are already working to improve the health in the

**Table 1.** A summary of different sources' conclusions on a functional food science process.

Source	Process of Functional Food Science
Functional Food Center, Functional Food Institute (2015) [11]	<ol style="list-style-type: none"> <li>1. Examine the link between a particular food and health benefits.</li> <li>2. Run in vitro and in vivo studies with non-living and animal specimens respectively.</li> <li>3. Run human studies. This involves administering human appropriate dosages of bioactive compounds and testing for adverse side effects.</li> <li>4. Develop an appropriate food vehicle for our bioactive compounds.</li> <li>5. Market to the public and educate them about the health benefits of functional food.</li> <li>6. Create special label for functional food products, establishing dosage and duration of usage of functional food product.</li> <li>7. Run studies on populations (epidemiological studies) in order to test for long term effects and overall product effectiveness.</li> <li>8. Measure public attitudes toward functional food.</li> </ol>
Institute of Food Technologists (IFT) (2004) [12]	<ol style="list-style-type: none"> <li>1. Identify relationship between food component and health benefit.</li> <li>2. Demonstrate efficacy and dosage.</li> <li>3. Demonstrate safety.</li> <li>4. Develop a suitable food vehicle.</li> <li>5. Demonstrate scientific evidence for efficacy.</li> <li>6. Communicate benefits to consumers.</li> <li>7. Conduct in-market confirmation of efficacy and safety.</li> </ol>
American Journal of Clinical Nutrition (AJCN) (2000) [13]	<ol style="list-style-type: none"> <li>1. Establish an understanding of a body function that can be modulated by food components.</li> <li>2. Identify, characterize, and validate relevant markers.</li> <li>3. Run hypothesis-driven human studies.</li> <li>4. Accurately communicate with the public and consumers.</li> </ol>
The European Commission Concerted Action on Functional Food Science in Europe (FUFOSE) (1999) [14]	<ol style="list-style-type: none"> <li>1. Identify interactions between a functional food/component and it's bodily function and verify its mechanism.</li> <li>2. Identify and validate markers to test the effects of modulation.</li> <li>3. Assess safety of food needed for functionality.</li> <li>4. Formulate hypotheses for human intervention trials, using the valid marker, to test functional food efficacy.</li> </ol>
Food for Specified Health Uses (Japan, FOSHU) (1991) [15]	<ol style="list-style-type: none"> <li>1. Submission of functional food to the Ministry of Health, Labour, and Welfare.</li> <li>2. Consultation between the Ministry and a separate Council on Pharmaceutical Affairs and Food Sanitation for tests on effectiveness.</li> <li>3. Consultation between the Ministry and a separate Food Safety Commission for safety.</li> <li>4. Approval as a government-certified functional food.</li> </ol>

communities of Europe and Japan. Because there is not an official recognition and federal approval of functional foods or functional food science in the United States, reports like those from the IFT and AJCN, and especially the governmentally-recognized ones from FOSHU and FULOSE, can begin to serve as bases and starting points for the United States' own official development towards making functional foods accessible and useful to the entire population which could be benefiting for them.

In the US there are existing academic societies such as the Academic Society for Functional Foods and Bioactive Compounds (ASFFBC), and journals on functional food such as *Functional Foods in Health and Disease* (FFHD) and *Bioactive Compounds in Health and Disease* (BCHD). These bodies, along with groups such as the FFC, are actively working towards researching and developing functional foods as well as educating the public and representatives of the government about the incredible benefits of functional foods for public health. Other avenues for educating the public on functional food include adding functional food curriculum to secondary and higher education, so that more people are aware of the opportunities in functional food science as well as the health benefits. In terms of current functional food science curriculum and education, the FFC has published multiple textbooks on functional food science that are being utilized by over 70 universities worldwide. Notably, two universities in the United States – Western Michigan University and Mississippi State University – have begun functional food science courses utilizing FFC textbooks, slideshow presentations, e-books and e-textbooks, and tests with answer keys. The accessibility of these educational materials is notable, and it's clear that progress has been made and can continue on the front of incorporating a functional food science

curriculum into secondary and post-secondary education. The FFC also actively provides certification for Functional Food Scientists and Functional Food Professionals; as a highly-esteemed figure in the world of functional foods, the FFC ensures that individuals with certifications are well-equipped to navigate the world of functional foods. It's clear that groundwork is being done towards a landscape of creating functional foods. It's now necessary for a unification behind a field of functional food science to advance to the next stages of the development of functional foods.

#### **FFC's Proposal on a Functional Food Science Process:**

Establishing a field of functional food science will rely on intensive research and analysis of other nation's determined processes such as FOSHU and FULOSE, but also on the work of groups in the US such as IFT and the FFC. In hopes of providing a basis for governmental agencies in the United States to establish a process of functional food science—and thereby functional foods as well—the FFC proposes the following layout:

1. Find data, new or old, whether through new studies or through historical, archaeological, ethnobotanical, or other means, about a food that may be used for improving health; establish the goal of the functional food (alleviating chronic illness symptoms, treating disease, increasing energy levels, resolving allergic reactions, etc.)
2. Review literature to assess the current research on any bioactive compounds or biochemical pathways or mechanisms, and find the bioactive compound that causes or leads to the goal or desired effect
3. Develop and establish levels and quantities (dosage) of that bioactive compound that

will sufficiently lead to the goal or desired effect and establish the mechanism or pathway of action

4. Find the biomarker that can be tested via that mechanism or pathway, which indicates effectiveness of the bioactive compound
5. Find, alter, or create a food with that bioactive compound
6. Perform in vitro testing or lab animal/rodent testing, utilizing biomarkers, to find the proper dosage of the bioactive compound to ensure efficacy and safety
7. Perform in vivo, clinical human trials with strict compliance standards, utilizing biomarkers, to confirm dosage and efficacy
8. Create the new functional food product and a special label with intake/consumption guidelines/recommendations as well as shelf life for the food product with bioactive compound(s)
9. Release to market
10. Perform long-term epidemiological studies to ensure efficacy, safety, and consistency or predictability

Finding the mechanisms and pathways of action are relevant not only to a specific functional food and testing its efficacy, but understanding a pathway or mechanism could open doors in other fields for further research as well. With sufficient funding and research in all steps, notably in the determination of a biochemical pathway, advancements in the management of other diseases, and other functional foods utilizing the same or a similar pathway, can also be done. If the pathway has already been researched and understood, functional food science can utilize that data and reinforce the findings.

The importance of performing long-term epidemiological studies cannot be overstated. The

effectiveness of a functional food may be much more variable than seen in controlled studies, and therefore it's vital to see how the functional food performs in uncontrolled and varied environments. Through performing studies like these, the true efficacy and safety of functional foods can be shown; not only this, epidemiological studies can provide information on the consistency of a functional food's effects and if its effects are predictable and reliable. This would build trust with the public and help researchers determine intertwining biochemical pathways as well as dosage, demographic, environmental and other confounding concepts and factors related to that functional food. However, it's understood that running long-term epidemiological studies can be extremely resource-intensive, and it may not be possible for certain functional foods depending on their mechanisms of action, dosage, or other contextual factors. Certainly not every step in the proposed layout will be conducted by one team of researchers; there could be groups dedicated to observing the wide-scale epidemiological impacts of functional foods once they're released. With that being said, epidemiological studies would grant immense certification and verification to functional foods and promote the public trust in the functional food science process and its products.

In terms of guaranteeing that each step is verified and complete, FUFOSSE establishes that a panel of professionals review each of six criterion, parallel to the process just outlined, including the totality of data, in order to conclude whether or not a food is able to be deemed functional. FOSHU involves submission to a ministry followed by two separate consultations for effectiveness and safety with two separate organizations, in order to be labeled as a functional food. The US could adopt either of these models, a hybrid, or establish a new way of certifying

each step in the functional food process is valid and complete. The ILSI, in connection with FUFOSSE, established The Process for the Assessment of Scientific Support for Claims on Food (PASSCLAIM) [16]. In the document, a clear process for running clinical trials for testing functional foods is defined.

#### **Methodology to be Used in Functional Food Science:**

In order to establish functional food science as its own field and its own science, it must be necessary to establish the methodology used. Much like how physics utilizes building blocks and methods from mathematics or how biology utilizes building blocks and methods from chemistry, functional food science will utilize many methods from many sciences and some non-sciences as well, such as food-industry-related methods and historical research. As already established, functional food science is necessarily interdisciplinary and will draw from many related scientific fields. The conception of an idea for a new functional food may begin in archaeology, history, and anthropology, which traditionally lies outside of the traditional realm of science. Looking into other cultures or into the past can provide invaluable information about foods or compounds that have been deemed to result in a positive health benefit. Accordingly, fields such as ethnobotany and medicinal botany may provide great insight as to compounds that can be utilized in the production of functional foods. With scientific advancements and physiological mechanisms being discovered, the conception for a functional food may also arise in working backward through a bodily pathway to find a bioactive compound. Of course, discovering bioactive compounds and biomarkers involves understanding the biochemical pathways and human physiological processes, and accordingly biochemical, as well as molecular biology, methods will be used.

Understanding the biochemical pathways is necessary in order to understand the cellular effects of the bioactive compounds in the functional food as well as to understand and quantify the efficacy of the functional food. In understanding the mechanism, a quantifiable and testable biomarker can be determined and the improvement in the pathway due to the functional food can be examined. The next step would work with established methods of toxicology to understand dosage and quantification and verify their effects on the body. Working with methods of food science would then be vital in order to appropriately deliver or design foods as vehicles for the bioactive compounds. For in vitro and laboratory testing trials, as well as for the clinical human trials, although different methods would be required for each kind of trial, the methodology is very well-established; these methods can be found in documents on food testing as in FUFOSSE [14]. Even after releasing to market, long-term epidemiological studies would have to be conducted, with careful accounting of factors such as demographics and epigenetics, especially if the design or intention of the functional foods has had epigenetics or nutrigenomics in mind. Intense collaboration and utilization of methodology between all of these fields will be required in order to design efficacious functional foods that can garner public trust; in many ways, the steps as outlined above are already being conducted and performed by separate institutions and groups in the United States. It's important to note that many steps of this functional food science are already being performed by research groups around the world. Because of the highly intersectional nature of functional food science, it almost necessarily requires multiple groups, and therefore, oversight for the production of a functional food product. With this oversight and development of a functional food



science, it will be of utmost importance to develop a framework such that functional food science can operate amongst all the other sciences it requires. It will also be important to demarcate a boundary between functional food science and other sciences; however, like differentiation between other sciences, this boundary may be hard to establish and stick to. With sufficient oversight and cooperation, as well as official establishment of functional food science, this boundary and the framework for operation may become clearer in practice.

An important step in the methodology of functional food science must be a comprehensive review of all research conducted. Observational studies, while conditionally useful, will not provide the rigor that is needed in order to produce trustworthy functional foods. Clinical trials and epidemiological studies are not only vital to the process of functional food science, they are more robust and conclusive means to establishing functional foods, and they will be able to be reviewed by an overseeing panel: as proposed in FOSHU, a group overseeing the scientific merit of each step—as well as the overall research findings—in the functional food science process is vital to making sure functional foods are being adequately produced [15].

The definition of functional foods as proposed by the FFC lays the groundwork for this kind of verification to take place; again, it's vital for there to be a recognized and unified definition of functional foods and functional food science. The rigor of the current research in food science and nutrition is not to be understated; in this sense, the process of functional food science is already—if only in a less-centralized way—being performed. With an official, outlined process by the FDA or another governmental body, functional food science will be more centralized and will be able to more readily connect the research

being done on functional foods. With that, the research and development of functional foods will be expedited, with quality and rigor maintained, and the public will be able to access functional foods and trust the science behind them.

#### **The Future Possibilities of Functional Food Science:**

The model is based on the outlined processes as in Table 1, other sources not included in the table, and also research done at the FFC. It's understood that this model may not be comprehensive, or unaltering, but that it stands as a basis for further developments to be made. For example, there are already new ideas of what biomarkers could be tested, including microRNAs and the epigenome [17]. As science is ever-changing, the process of functional food science will be as well. The entire process of functional food science is undoubtedly complex and interdisciplinary, with many moving parts requiring immense cooperation to discover the history of use or historically-used functional foods, to understand the bioactive molecules, to test the pathway and the mechanism of action, to run lab experiments and clinical trials, and to conduct epidemiological studies. The path for a functional food to be verified and certified is long, but only in this way can there be scientific backing for the efficacy of a functional food and only in this way can public trust be established in functional foods. It's also understood that not every step in the process already has a process outlined by other countries or organizations. Especially in terms of biomarkers and clinical trials, the quantitative data is extremely vital: dosage, biomarker levels, serving sizes, etc. The process indeed requires much more analysis, development, and establishment; with those efforts and developing a functional food science, though, the immense benefits of functional foods will be accessible and available to the population.

There are other barriers to the development of functional food science outside of the establishment of the scientific process to create and test them. With the current standards of FDA labeling, notably the Dietary Supplement Health and Education Act of 1994 (DSHEA), food manufacturers are able to place “structure/function claims without FDA preapproval” [18]. As a result, because of the ubiquitous nature of perhaps-untrue or non-scientific-backed health claims printed on many foods, consumer trust in health claims such as the ones functional foods are addressing has plummeted. Furthermore, the FDA still has no “regulations on the claims for ordinary foodstuffs” [6], meaning that many functional foods, which are delivered via ordinary food, are not regulated. Without any sort of regulation, coupled with the lack of consumer trust, much rebuilding of labeling fidelity and public trust and new establishment of rigorous, scientific claims must be made. Because of this, the FDA must also address its labeling policies, or create new ones for functional foods. Once a functional food science is made official, granting generally-recognized-as-safe (GRAS) status will have positive impacts on public perception of functional foods. Alongside that, an option is to include one label for functional foods which have been scientifically and clinically backed but have not yet passed through epidemiological studies, and a different label once they have passed through those studies. There may be many real functional foods on the market or in development. However, they can only help the broad population once a process of functional food science is established and implemented.

A method that could serve to increase the numbers of functional foods available is to share research and collaborate with international partners, especially those in Europe and Japan with already-

established functional food programs. Questions of congruence in methods and reproducibility come into play, however, epidemiological studies and other verification methods may be accelerated by the sharing of functional foods internationally. Another partner could be the World Health Organization (WHO); forming a unified global idea of functional foods could have major positive impacts in global health and open avenues for treating and preventing many diseases.

As stated by FUFOSE, “a science-based, ‘function-driven’ approach is preferable, because the functions and their modulation are universal. Functional food science, therefore, refers to the new concepts in the science of nutrition that lead to the stimulation of research and to the development of functional foods” [14]. It’s important to note that only a detailed, science-based outline to functional food, as asserted in not only FUFOSE but also FOSHU, AJCN, and others, will allow the US to develop functional foods in a regulated and useful manner. This process should be defined sooner, rather than later, so that the population can begin to trust, understand, and reap the benefits of functional foods. Functional food science can be effectively utilized—not only in the United States but also worldwide—to treat not only diseases that have existed for long periods of time, but it can also be utilized in safely and efficiently in the treatment of new or emerging diseases, such as the use of functional foods in the recent COVID-19 pandemic [8]. Efficacious functional foods to treat new diseases such as COVID-19 builds trust in the general public regarding functional foods, which is a vital part of encouraging functional food consumption to better general population health.

Again, there are nuances in the definitions of functional food that exist, especially in the United States, where there’s no federally-recognized

definition. With applications for general health as well as chronic diseases and their symptoms, the FFC definition remains comprehensive, working, and useful, and includes the uses of functional foods in mental health, allergy treatments, and non-chronic diseases. Although the definition of functional foods may not be agreed upon, and although there is not an explicit functional food science, research and advancements are already being made.

Besides the establishment of functional food science and a functional food definition, regaining public trust is also imperative to the goal of functional food science. In order for the robust nature and rigor of functional food science to be effectively utilized by the public, food labeling must be made clear and trustworthy. The public value and utility of functional foods is great, for chronic and non-chronic diseases alike, and with an ever-expanding field of usefulness, functional foods should be made efficacious and accessible for the population. Other regions such as Europe and Japan have already developed or implemented outlines for functional food science in their areas, and there are already hundreds of functional foods available to consumers with meaningful and validated health benefits [19].

Looking forward, with a functional food science field established, the future of functional foods is vast. There are already advancements utilizing functional foods in nutrigenomics to tailor diets or foods to an individual's genome in order to minimize their risk of chronic diseases or to address other conditions [20]. Additionally, progress in biotechnological engineering allows for nearly boundless potential and possibilities in the designing of functional foods, which could couple with nutrigenomics to create an extremely vast and useful array of functional foods [21].

## CONCLUSION

Functional foods undoubtedly have the potential to benefit not only the population in America but all around the world. In matters of chronic illness and its symptoms, mental health, non-chronic illness, and with a future in nutrigenomics and bioengineering, functional foods can be a powerful tool for helping all people improve their health. To create a formal functional food science field in the US means to create the official process of producing functional foods as well as creating the formal definition of functional foods. Many groups in the United States are already performing great research in the process of producing functional foods. Creating an official functional food science will elevate all the great work that is already being done, and in doing so, the general population will have access to certified, scientifically-proven, effective functional foods that will improve public health. *The FFC proposes an outline for functional food science that involves: establishing a target and finding a bioactive compound that enables that effect, finding the correlated measurable biomarker, running testing to find proper dosage and effectiveness, determining the biochemical pathway and mechanism of action, performing clinical trials to ensure efficacy, creating the functional food with an informative label, releasing to market and running epidemiological studies to verify.*

Functional food science must certainly be complex, weaving together many specialties and fields of research along with long-term, rigorous clinical trials and epidemiological studies; it's also important to garner and build public trust in functional food science and its products. Together, though, along with the processes outlined and to be regimented and made official, functional foods can be

created efficiently, understood soundly, and consumed happily and healthily.

Outlining a process of functional food science in this paper has the goal of creating a foundation for the ultimate purpose of the United States formulating its own official functional food and functional food science definition such that the general population can have access to the benefits of functional foods. Defining functional food science as a concept as well as a process is difficult; it's understood that this definition, outline, and process of functional food science is dynamic and will change with time. Hopefully, the steps outlined here, along with the implications, background, and resources, provide a good foundation for that purpose.

**List of Abbreviations:** FFC, Functional Food Center; FDA, United States Food and Drug Administration; COVID-19, coronavirus disease 2019; IFT, Institute of Food Technologists; AJCN, American Journal of Clinical Nutrition; FUFOSSE, European Commission Concert Action on Functional Food Science in Europe; ILSI, International Life Science Institute; FOSHU, Food for Specific Health Uses; US/USA, United States of America; ASFFBC, Academic Society for Functional Foods and Bioactive Compounds; FFHD, Functional Foods in Health and Disease; BCHD, Bioactive Compounds in Health and Disease; PASSCLAIM, Process for the Assessment of Scientific Support for Claims on Food; DSHEA, Dietary Supplement Health and Education Act of 1994; GRAS, Generally Recognized as Safe; WHO, World Health Organization.

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