

Scientific Substantiation of Functional Food Health Claims in China^{1–3}

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Abstract

This article provides an overview of the procedures involved in scientific substantiation of functional food health claims in China. The definition of a functional food is discussed, in addition to the factors that led to its modification in 2005. The framework of administration includes the regulation of functional foods, steps involved in submission of dossiers, the safety control system for raw materials and products, and technical procedures for testing and evaluation. Scientific evidence required for a claim includes evidence from product tests in addition to evidence resulting from complete scientific literature searches relative to the food material or component in question. Currently, the 4 main rules for functional food assessment in China include 1) functional assessment procedures; 2) standard toxicological assessment; 3) regulations on nutrient supplements; and 4) standard analytical methods for functional components. The current situation for functional foods in China is analyzed, including a discussion of the distribution of the 27 currently allowed functional food health claims. The effectiveness of functional foods and health claims for improving health relies largely on the motivation and education of the public to be able to make good choices. *J. Nutr.* 138: 1199S–1205S, 2008.

Introduction

Over the past decade in China, functional foods, also called healthy foods, have become increasingly important with positive impact on both world health and international trade. At the same time, economic benefits of functional foods are growing in both developing and industrialized countries.

China is the home of traditional Chinese medicine. There is an ancient saying that food and medicine are from the same

source, which is also the foundation of functional foods today. Presently, China is one of the world's most important and developed markets for functional foods, which are based on traditional dietary culture and the rapid economic development among individuals and communities (1). The development of functional foods is also profiting from some national or governmental programs, which are improving access to quality health care, strengthening public health services, and improving the availability and dissemination of health-related information (2).

In this article, the current regulations and status of functional foods in China are discussed, and the scientific substantiation of health claims is also examined.

Definition of functional food in China

According to “The provision for functional foods administration,” which was promulgated by the Ministry of Health (MOH)⁴ in March 1996 (3), a functional food is defined as a food that has special health functions. It is suitable for consumption by special groups of people and has the function of regulating human body functions but is not used for therapeutic purposes.

In July 2005, “The guideline of registration for functional foods” was promulgated by the State Food and Drugs Administration (SFDA), and the definition of a functional food was extended as the following: “Health (functional) food means that a food has special health functions or is able to supply vitamins or minerals. It is suitable for consumption by special groups of people and has the function of regulating human body functions

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⁴ Abbreviations used: EBM, evidence-based medicine; EJC, Experts Judgmental Committee for Functional Food; EWG, Experts Work Group; MOH, Ministry of Health; SFDA, State Food and Drugs Administration.

but is not used for therapeutic purposes. And it will not cause any harm whether acute or subacute or chronic” (4).

According to the new definition, food with function claims and nutrient supplements are both included in the system of classification. Here, nutrient supplements are products intended to supply vitamins or minerals, but not energy, to replenish dietary insufficiency, defend against nutrition deficiency, and reduce the risk of chronic degenerative diseases. Single nutrient supplements and complex nutrient supplements are both included within the definition.

Framework for administration and regulation of functional foods

The SFDA has been authorized to direct and conduct all affairs relating to functional foods since 2003. For each functional food, many tests should be done before application, including security toxicity tests, functional tests (except for nutritional supplements), stability tests, hygiene tests, identifying tests for functional ingredients, etc. All the tests should be done following the standard procedures by specialized agencies or laboratories qualified by the MOH and SFDA. The approval flow chart for functional foods in China is illustrated in Figure 1.

Dossier list for the preparation of an application for a health food. The following information must be provided in the application dossier, and the structure should follow a common format (4). Dossiers provided in the application should be organized into 5 parts: 1) information on the enterprise and product for the administrative data; 2) information specific to the food and its characteristics; 3) laboratory testing data for the product; 4) information for the consumer; and 5) evidence from scientific literature. More details are provided in Table 1.

For an imported product, the following additional materials are needed: 1) a certificate conforming to relevant local production quality control standards issued by the originating country; 2) a certificate for products having been sold for >1 y in the producing country by the certifying agency of the originating country and the Chinese embassy in the originating country; 3) label and directions for use in the originating country; 4) relevant product standards of the producing country or international organizations. All the documents should be in Chinese, and the content should be consistent with the original language version.

Guidelines for administration and regulation of functional foods. “The guideline of registration for functional foods” is the main directive document in China for functional foods. This document is comprised of 9 chapters and 105 articles, including the general principles; application; examination and approval; raw materials and supplementary materials; labels and specifications; and testing, reregistration, and reexamination, i.e., testing, legal liabilities, and supplementary provisions. Within these regulations, there are guidelines that stipulate the requirements for testing archives and the main materials for health food registration documents (4,5).

Other important rules include the “General hygiene regulations for functional foods,” which prescribe hygiene requirements for functional foods, such as the requirement for raw material and the limit for heavy metals and microbes.

The “Good manufacture practice of functional foods” prescribes the conditions for manufacturing and processing the health food, design and instruments, raw materials, manufacturer procedures, storage, transportation, management, etc.

FIGURE 1 Examination and approval flow chart for functional foods in China.

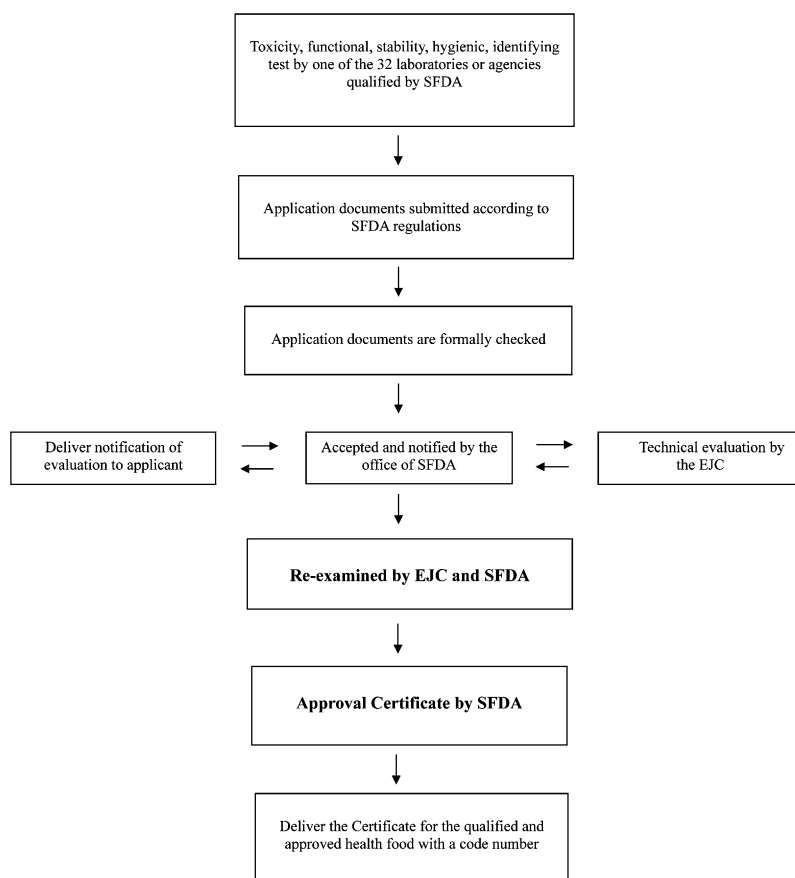


TABLE 1 Dossier components for preparation of functional food applications in China

Information on enterprise and product for administrative data
Health food registration application form
A copy of legal registration certificate of enterprise or applicant
Testimony that the name of the product is unique and different from any authorized registration products of food or drug
A guarantee document provided by applicants that there is no infringement on other patents
A copy of a brand registration certificate
Information specific to the food and its characteristics
A report on product research and development
A description of the product's formulation or ingredients
The analytical methods for functional or representative components
The manufacturing process description in brief and its flow chart
The specifications or standard of product and raw materials
The quality standards and selective basis of packing materials
Testing laboratory data for the product
Test reports of the product and other relevant materials issued by testing agencies, as follows:
Test application form
The requisition to applicant by testing agencies
The toxicology test report
The functional test report
Test reports on dope, illegal drugs, etc. (for special functions only, including alleviation of physical fatigue, loss of weight, and improvement of growth functions)
The test report for functional component and composition
The stability test report
The hygiene test report
Other test reports to help application (such as an identification test for raw material or virulence of bacterial categories)
Information to consumer
The label and directions for use of the product
3 product samples to be provided in the application
The evidence from scientific literature
A summary and a literature review
Published original data in scientific literature
Any document from other countries' governments (that is helpful for the approval of products)

Raw material control. A “functional food” may consist of a nutrient or other substance or a combination of nutrients or substances or a food or herb. Thus, it is important to control all raw materials and ingredients. There are >15 regulations, rules, and criteria that can be used in making a judgment or decision if a food is not in the Chinese Food Composition tables. The 4 main rules include 1) “The rule of application on wild source of animal and plant”; 2) “Food items that can be used in functional food”; 3) “Herb items that can be used in functional food and drug”; and 4) “Restrictive herbs list that can not be used in functional food.” Some raw herbs or substances such as plants (Table 2) and probiotics (Table 3) have been specifically outlined on lists that show if they are permitted to be included in functional foods.

Applicants must provide additional scientific evidence regarding safety, composition, function, and metabolism for any food, herb, or other compounds that are not on the specifically outlined lists mentioned above for labeling as functional food. Dose-response studies and toxicological studies are also required (6,7).

Other rules such as “Guideline for ingredients combining about herbs and other,” and “The extracts from edible foods,”

TABLE 2 Authorized and unauthorized herbs for use in functional foods in China

PinYin name	Pharmaceutical name	English name
Authorized herbs in functional foods		
Renshen	<i>Radix ginseng</i>	Ginseng
Renshenye	<i>Folium ginseng</i>	Ginseng leaf
Renshenguo	<i>Potentilla anserina L.</i>	Silverweed cinquefoil
Sanqi	<i>Radix notoginseng</i>	Sanchi
Tufuling	<i>Rhizoma smilacis glabrae</i>	Glabrous greenbrier rhizome
Daji	<i>Herba seu radix Cirsii japonici</i>	Japanese thistle herb or root
Nuzhenzi	<i>Fructus ligustri lucidi</i>	Glossy privet fruit
Shanzhuyu	<i>Fructus corni</i>	Common macrocarpum fruit
Chuanniuxi	<i>Radix cyathulae</i>	Medicinal cyathula root
Chuanbeimu	<i>Bulbus fritillariae unibracteatae</i>	Unibract fritillary bulb
Chuanxiong	<i>Rhizoma chuanxiong</i>	Szechuan lovage rhizome
Danshen	<i>Radix salviae miltiorrhizae</i>	Danshen root
Wujiapi	<i>Cortex acanthopanacis</i>	Slenderstyle acanthopanax bark
Wuweizi	<i>Fructus schisandrae</i>	Chinese magnoliavine fruit
Shengma	<i>Rhizoma cimicifugae</i>	Large-trifolious bugbane rhizome
Tianmendong	<i>Radix asparagi</i>	Cochinchinese asparagus root
Tianma	<i>Rhizoma gastrodiae</i>	Tall gastrodia tuber
Unauthorized herbs in functional food		
Bajiaolian	<i>Rhizoma et radix dysosmatis</i>	Common dysosmatis rhizome and root/sixangular dysosmatis rhizome and root
Shanlangdang	<i>Radix anisodi tangutici</i>	Tangut anisodus radix
Ma sang ye	<i>Coriariae sinicae folium</i>	Tutu leaf
Maqianzi	<i>Semen strychni</i>	<i>Nux vomica</i>
Tianxianzi	<i>Semen hyoscyami</i>	Henbane seed
Badou	<i>Semen crotonis</i>	Croton seed
Changchunhua	<i>Herba catharanthi rosei</i>	Madagascar periwinkle herb
Aheng bai fu zi	<i>Typhonii rhizoma crudum</i>	Raw aconite/typhonium
Shisuan	<i>Bulbus lycoridis radiatae</i>	Shorttube lycoris bulb
Guanmutong	<i>Caulis aristolochiae manshuriensis</i>	Manshurian dutchmanspipe stem
Nongjili	<i>Herba crotalariae</i>	Purpleflower crotalaria herb
Jiazhutaoye	<i>Folium nerii</i>	Sweet-scented oleander leaf
Zhusha	<i>Cinnabaris</i>	Cinnabar
Hong sheng dan	<i>Hydrargyri oxydum rubrum</i>	Red powder
Hong dou shan	<i>Taxus chinensis(piger)rehd</i>	

provide rules on the permitted minimum and maximum doses of nutrient supplements and extracts.

Technical assessment procedures and methods. For quality and safety control, >100 technical methods and assessment, function, and safety methods were established by the MOH and SFDA. The National Institute of Nutrition and Food Safety, China Centre for Disease Control, is in charge of drafting technical methods and assessment procedures. An Experts Work Group (EWG) was established for these procedures on evaluation and assessment of functional foods in China. The most important rules for functional food assessment are in Table 4.

Other regulations such as technical and assessment procedures as well as methods on epiphytes, probiotics, wild animals and plants, and nucleic acid and amino acid chelates are also issued by the SFDA.

Labeling and advertisement regulations for functional foods. The “Regulation on the labeling of functional foods” was

TABLE 3 Probiotics approved for use in functional and novel foods in China

Approved for use in functional food
<i>Bifidobacterium bifidum</i>
<i>Bifidobacterium infantis</i>
<i>Bifidobacterium longum</i>
<i>Bifidobacterium breve</i>
<i>Bifidobacterium adolescentis</i>
<i>Lactobacillus delbrueckii</i> subsp. <i>Bulgaricus</i>
<i>Lactobacillus acidophilus</i>
<i>Lactobacillus casei</i> subsp. <i>Casei</i>
<i>Lactobacillus reuteri</i>
<i>Streptococcus thermophilus</i>
Approved for use in novel food ¹
<i>Bifidobacterium lactis</i> HN-019
<i>Bifidobacterium lactis</i> Bi-07
<i>Bifidobacterium animalis</i> Bb12
<i>Lactobacillus rhamnosus</i> GG
<i>Lactobacillus rhamnosus</i> HN-001
<i>Lactobacillus acidophilus</i> NCFM

¹ Authorized novel foods can be used in functional foods.

issued by the MOH in 1996 and later revised. In this regulation, the labeling content on the package of functional foods is prescribed to include the name, the symbol/logo and code number, the net weight, ingredients, functional components, health functions to be claimed, target population, use or consumption method, and the name and address of the manufacturer (8).

A symbol is used to identify functional foods, which is presented as a logo on the label of a functional food along with a code number. The characters mean “functional food” under a blue cap, which represents “to give expression protecting human health of functional food.”

The “Regulation on the advertisement of functional foods,” which was issued by the SFDA in 2005, stipulates what is allowed in terms of advertising functional foods to consumers (4).

Scientific substantiation and qualification approval of health claims

Permitted health claims and acceptable evidence in China. When health claims were first introduced in China, 12 functional claims were developed, which were chosen because of their value in regulating physiological functioning or reducing disease risk. Gradually, more claims were proposed by the industry or members of the EWG, which are discussed and confirmed by the EWG and passed through legislation when appropriate. Currently, in China, there are 27 categories of product specific

TABLE 4 Main rules for functional food assessment in China

Regulation	Description of regulation
“The standard functional assessment procedures and methods of health foods”	Describes the basic requirement for the test samples, details individual function standard procedures of assessment among 27 functions including animal and human tests; the biomarkers, determinants and judgment indicators in each method are included.
“The standard toxicological assessment procedures and methods of health foods”	Describes the basic requirements for the test samples and details standard procedures of safety assessment such as acute toxicity tests, Ames tests, 30- or 90-d feeding tests, etc.
“Regulation on nutrient supplements”	Describes the definition of nutrient supplements, the amount and compounds of vitamins and minerals that can be used in nutrient supplements.
“The standard analytic methods for functional components”	Describes the basic requirements and components of herb, food, or extracts that must be tested if the substance is used in the product, and the analytical methods involving 100 plant substances.

health claims, which are function related or refer to reduction of disease risk (Table 5). A claim for a functional food means any representation that states, suggests, or implies that a food or food component has particular characteristics relating to its origin, nutritional properties, healthy function, or any other quality. Such claims relate to a positive contribution to health or to the improvement of a function or health modification.

Applicants should select from the 27 permitted claims for their product and provide a dossier (as per Table 1) as an application to the Experts Judgmental Committee (EJC) for evaluation. Most importantly, 2 types of evidence are required: 1) evidence from testing of the product itself, as performed by special testing agencies qualified by the SFDA; the reports must have positive results that assess and examine functional effectiveness in addition to toxicity and quality control testing, showing the absolute safety of the products; and 2) evidence from literature; i.e., the claim must be based on generally accepted knowledge from a textbook or a recommendation from national or international bodies, or evidence from human testing emphasized in the scientific literature.

Substantiation based on product testing. Product testing is the most important substantiation for a functional food in China. Substantiation of a claim should be based on functional tests of the product, both animal and human data, toxicity tests, as well as stability and hygiene tests. For food or component characteristic data, the report should describe the final product’s composition, including characterization of the food matrix, physicochemical characterization and structure of the main component, other relevant properties of stability information, and analytical procedure and methods (9,10). Some ingredients need to undergo identification tests and special examinations, such as testing for hormones and excitability chemicals, i.e., amphetamine, fenfluramine, and caffeine, and a bacterium identification test for raw materials. A standard and substantive procedure for each claim has been put into practice by the special testing agencies qualified by the SFDA. All final test results are reviewed by the EJC, and whether the product will be validated depends on all the test data and ingredient evidence. The EJC will judge which is acceptable and which may be a misinterpretation or falsification of data, and finally, a conclusion is guided by a vote of the EJC.

Substantiation based on scientific literature. In addition to product-testing results, evidence based on scientific literature also needs to be provided to the EJC. The evidence from literature includes human and animal data, both for safety and function, and food or component characteristic data. If a novel

TABLE 5 Permitted health claims in China

Claims	
Function	
1) Enhance immunity	13) Increase bone density
2) Antioxidative	14) Improve nutritional anemia
3) Assist in memory improvement	15) Assist in protecting against chemical injury to the liver
4) Alleviate eye fatigue	16) Eliminate acne
5) Facilitate lead excretion	17) Eliminate skin chloasma
6) Moisten and clean throat	18) Improve skin water content
7) Improve sleep	19) Improve skin oil content
8) Facilitate milk secretion	20) Regulate gastrointestinal tract flora
9) Alleviate physical fatigue	21) Facilitate digestion
10) Enhance anoxia endurance	22) Facilitate feces excretion
11) Assist in irradiation hazard protection	23) Assist in protecting against gastric mucosa damage
12) Improve child growth and development	
Reduction of disease risk	
24) Weight loss	26) Assist in blood sugar reduction
25) Assist in blood lipids reduction	27) Assist in blood pressure reduction

food or herb is used, historical and traditional use as well as present-day use should be provided (4,5).

Human data such as intervention trials, safety studies, and epidemiology or observation data, randomized control tests, consumption data, and edible history should be provided. If available, relevant data and/or a supporting rationale that the food seeking the health claim is in a form that is available to be used by the human body, e.g., dose-response, absorption ratio, or metabolism studies, should be identified. Any factors that could impair the absorption or utilization of the food in the body should be provided.

Animal or model systems studies may be included only as supporting evidence; e.g., in vitro studies and cell model studies may help to explain the mechanism underlying the health effect of the food or provide supporting evidence on safety.

Food or component characteristic data including structure, physical chemistry properties, and edible use history should be provided, especially for a new, novel food or food component to be used for the first time in a functional food.

Finally, a comprehensive review of the data from literature studies pertaining to the specific food-health relation is required. This review, and the identification of data considered pertinent to the claim, should be performed in a systematic and transparent manner to demonstrate that the application adequately reflects the balance of all the evidence available.

In cases where any of the required data do not apply for a particular application, reasons or justifications must be given for the absence of such data in the application.

There is no specification in the regulation reflecting the relative strength of evidence that may be obtained from different types of studies, such as intervention studies and observational studies in humans, according to a hierarchy of study designs. There is also no discussion within the regulations about the quality of data from individual studies, to highlight the relevant aspects related to the design, outcome, and quantity of the studies. However, during evaluation, the EJC takes into consideration that the application has distinguished the differences among studies. Further consideration is given to the extent to which 1) the claimed beneficial effect of the food or food component is relevant for long-term human health and the evidence obtained from the specific study groups can be generalized

to the target population for which the claim is intended; 2) a cause-and-effect relation is established between the consumption of the food and the health outcome in humans, including the strength, consistency, specificity, dose-response, and biological plausibility of the relation; 3) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect could be reasonably achieved as part of a balanced diet.

The current situation of functional foods in China

Recently, functional foods in China have played an important role in the health of Chinese people and have also brought great economic benefits to the society. According to preliminary data, ~30–40 billion Chinese yuan are generated every year, which is equal to US\$4–5 billion.

From 1996 to 2005, 7557 products were approved by the MOH and SFDA in China (11), and as of May 2007, almost 8200 functional food products were approved. Recent data have shown that only 27–33% of all submitted products were authorized by the SFDA each year from 2003 to 2007 (data from SFDA office statistics). Of the approved products, only ~30% of them are currently on the market (12). The reason for this is very complex. Some manufacturers are waiting for an appropriate time to market the product. Some of the products may be made by small factories, which are waiting to follow bigger companies with a similar product to avoid excess expenditure on advertising. In some other cases, the manufacturer may not pass all regulations, such as good manufacturing practice.

The category distribution of functional foods in China.

Currently, functional foods can be found in 11 different formats including capsule, tablet, powder and granule, liquid, and food forms. Functional foods in the conventional food form contribute to <1% of all functional foods.

The function distribution of functional foods in China.

For all 27 health claims among 7457 products currently approved by the MOH and SFDA, approximately one-third of them had a health claim for enhancement of immune function; the second and third categories with the most claims are for alleviating physical fatigue and assisting in blood lipid reduction, which account for 15.28% and 8.84% of all health claims, respectively.

Future prospect of functional foods in China

With the rapid development of food science and technology in China, in addition to the large aging population and rapid increase in health care costs, an increasing proportion of the population is becoming interested in achieving and maintaining well-being and a high quality of life. Thus the demand and market value for health-promoting foods and food components are expected to grow rapidly (13).

A decade's experience of functional foods in China has shown that rigorous standards of performance are most important for functional food production. Scientific substantiation from literature based on human testing is helpful in forming a conclusion on health claims. Undoubtedly, the future of functional foods in China will involve a continued debate regarding the scientific substantiation of health claims. For future research on functional foods, it would be of interest to focus on the mechanisms by which various food components, such as phytochemicals found in fruits, vegetables, whole grains, and herbs, positively affect health and whether these components work independently or synergistically. Further research on specific food ingredients, when added, removed, increased, or decreased, may also be of

interest in functional foods of the future, such as soy products, oats, flaxseed, herbs, broccoli and other cruciferous vegetables, and eggs enhanced with (n-3) fatty acids (14).

Some suggestions for a way forward in future work on functional food health claims include 1) scientific review based on evidence-based medicine (EBM), 2) modifications for the procedures used in function claim testing, and 3) better differentiation between drugs and functional foods.

Scientific evidence based on EBM. The development of EBM has played an important role in the diagnosis and treatment of diseases. The definition and principles that guide the scientific assessment of EBM may be a way to help scientific substantiation of health-related claims in functional foods. Currently, the project “Process for the Assessment of Scientific Support for Claims on Foods” (15,16), which originated in Europe, offers a practical scientific framework to prepare scientific dossiers supporting claims and will improve the efficiency of the regulatory review process. The Process for the Assessment of Scientific Support for Claims on Foods project is an excellent reference for functional food evaluation in China. The year 2006 was the first period of China’s 11th Five-Year Scientific and Technical Plan that included a functional food program, “The evaluation procedure and techniques on functional food.” The program will develop a means to classify the grades and qualifying strength of scientific evidence for foods or food components and develop the databases for functional components. Additionally, complete test procedures and revised biomarkers will be further elaborated. In September 2007, members from both the EJC and EWG discussed the issues of scientific substantiation of health claims. However, the actual process and standard of substantiation remain complex issues. Four steps are considered in the substantiation process: 1) the types of scientific studies involved; 2) ways to qualify and select studies from literature; 3) the number of studies that are enough; and 4) the authorization process.

“The administering provision of nutrition labeling on packaging food,” will take effect in May 2008, as issued by the MOH. This provision freely allows nutrition and function claim labeling on all packaged food, where the nutrition and function claims must be based on scientific substantiation as per Codex guidelines. The implementation of the provision ought to relax the examination and steps to approval for some function claims, and will most probably contribute to the progress in the classification of functional food health claims.

Modification for the procedure of function claim testing.

With the development of food science and technology research, some assessment methods need to be reevaluated and modified. Are middle and endpoint biomarkers still appropriate for the health function to be claimed? Are there any better methodological and biological characteristics or biomarkers for certain diseases? All these matters should be further studied in coming years.

The currently approved listing of 27 health functions in China cannot meet the various demands of new components, food or herbs, so the extension of the function test methods should be enhanced by both the government and scientists, especially for herbs with both traditional experience and modern science evidence.

On other hand, there is still controversy around the matter of the validity of a food with a function claim that has not undergone product testing in China because the component, food or herb, is generally accepted on the basis of knowledge and evidence in the scientific literature or recommendation from international bodies.

Differentiating functional foods and drugs. Functional food products in the form of conventional foods comprise just 0.8% of all functional foods, whereas >60% of functional foods are in the form of tablets or capsules. Thus, there is confusion on where the division lies between functional foods and drugs. Many consumers would prefer to take foods rather than pills every day to keep healthy; accordingly, functional foods in conventional food forms should be more widely permitted, and without any limitations, i.e., milk products, beverages, grains, canned foods. Additionally, to help resolve the confusion between foods and drugs, the wording of health claims on labels should be easily understood to assist consumers in making informed choices. Health claims are also intended to help consumers identify particular foods and food components and may encourage greater consumption (17). It may therefore be advisable to revise the wording of some of the 27 claims, such as “Assisting protection against chemical injury of liver function” or “Assisting protection against gastric mucosa damage function,” as the wording of these claims may be difficult to understand; furthermore, a claim such as “Improving child growth and development function” may be misleading for consumers.

In summary, as shown in this review, functional foods are very important in Chinese society in terms of public health and economic benefits. Currently, there are 27 product specific claims in China, 4 of which are reduction of disease risk claims. During the past decade, functional food regulations have been successfully enforced to control and promote quality of products and protect consumer health. As functional foods become more popular, health claims will continue to be a much debated topic for consumers and manufacturers. Major food companies are eager to expand into the market for health-promoting foods, but regulators will need to ensure that purported health effects are based on solid research so that products can be marketed successfully on the basis of truly novel claims.

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Other articles in this supplement include references (18–27).

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