



## Medical Foods: Beyond the Functional Food Claim

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### Food of specified health use

Japan has a long history of using foods with health benefits, and Japanese people are well-known for their longevity. In 1991, the Ministry of Health, Labor and Welfare introduced a functional food regulation called “foods for specified health uses” (FOSHU) [1,2]. After presenting the available food system, many clinically proven FOSHU products with health benefits have been developed and launched. As a result, the net sales of FOSHU products reached 6.2 billion dollars in 2007 [3]. Most of the health claims relate to improving gastrointestinal health using probiotics. Hypertriglyceridemia, hyperglycemia, high blood pressure, and high LDL-cholesterol are mainly associated with the related health claims. After 2007, the market for FOSHU products was almost saturated because of the expensive cost of RCT and poor performance.

Prime Minister Abe established a novel system in 2015 to overcome the shrinking market for functional foods based upon the Dietary Supplement Health and Education Act (DSHEA) system already installed in the USA. The DSHEA was introduced in the USA as a regulatory system for supplements with health benefits in 1994. The new system called “Foods with function claims” was established in 2015 based on the idea of the DSHEA.

Under Abe’s “Japan Revitalization Strategy,” the Cabinet approved the lifting ban on functional claims displayed on foods, including so-called health foods, food/beverage products, and agricultural foods, on June 14<sup>th</sup>, 2013, to build a society of good health and longevity.

Major health claims in the new regulation system are associated with fatigue, eyes, memory, stress, sleep, joints, blood flow, body temperature, muscles, and Body Mass Index. After introducing the new system, the total sales for functional foods, including FOSHU products, reached 8 billion dollars in 2018. The latest available regulatory system is more flexible regarding health claims, the protocol for clinical studies, and the required results. Therefore, the market for new regulatory products is still growing, and the number of foods in May 2023 reached 7000.

The new system is regulated under revised Food Labeling Standards. It will categorize food with health claims, foods with

specified health uses (FOSHU), and foods with nutritional function claims (FNFC) [4].

### Foods with functional claim

Under the new system, companies are responsible for verifying safety and interactions with pharmaceuticals as the Consumer Affairs Agency requires. They can label its functionality if they are confident that the product is effective and safe. The government does not examine the contents of the labeling system but only checks the procedures and assigns an acceptance number to the labeling system.

Until the establishment of this system, the only foods in Japan that could be labeled as functional were foods with nutrient function claims, such as vitamins and minerals, foods for specified health uses (FOSHU), and foods for particular uses (for vulnerable persons). Under these circumstances, a world of healthy food combines gems and stones. The typical problems can be summarized as follows.

In Japan, no statements can be allowed regarding the functionality of foods other than health foods (food with functional claims, food with nutrient function claims, food for specified health uses) and foods for particular uses. It is impossible to say that they are effective in preventing or treating diseases, except for a risk reduction. It comes from a population-based epidemiological term and does not fit the individual response.

### The evidence of efficacy needs to be clarified.

Most products are based mainly on animal experiments, and personal experiences exaggerate the effects.

### Poor consideration of safety.

There is a widespread belief that because a product is a natural food, it is safe.

It is no exaggeration to say that foods do not show immediate effects like ward medicines, but the consequences of long-term ingestion as a supplement are entirely unknown.

### Quality control could be more lax

In the U.S., only health foods manufactured in the most recent Current GMP (cGMP)- plants issued by the FDA are allowed to sell.

### Interactions with pharmaceuticals and other drugs are ambiguous.

It has been pointed out that products such as chlorella and green juice with high vitamin K content may strongly attenuate the effects of warfarin.

### Labeling regulations need to be clarified.

Since health foods are not legally defined, legal regulations regarding their labeling are mainly governed by the Pharmaceutical Affairs Law, the Food Sanitation Law, and the Act Against Unjustifiable Premiums and Misleading Representations. As a result, the health functions of health food products are expressed in a nuanced manner [5].

The new system, in a roundabout way, gave a definition of “food with functional claims,” imposed specific rules on the efficacy, safety, interaction with drugs, labeling methods, and damage information collection system for such foods, and prohibited the registration of products that did not meet these rules.

One year later, 94 items were supplements, 80 were processed, and 2 were fresh foods. In addition, more than 140 items rely on systematic literature reviews as the scientific basis for their functional claims, and less than 30 items rely on actual clinical trials. The functionality claims for these products include several items not found in FOSHU. Specifically, the following items are indicated as samples of labels.

- This food is suitable for people who are aware of physical fatigue
- It can help retain moisture in the skin and relieve dryness
- Has the ability to relieve mental stress
- Helps relieve discomfort in the eyes and nose caused by dust and house dust
- Improves intestinal health
- Helps improve high BMI
- Supports eye focus regulation and function
- Supports healthy sleep
- Knee joint movement
- Has the ability to reduce tension
- Improvement of liver function
- Improvement of cognitive function

### The consumer group raised the following doubts.

The sales performance of the supplement shape is based on something other than food experience.

It is difficult for consumers to understand, and there needs to be more evidence of functionality. There is misleading labeling. The

paper on which it was based needs to be peer-reviewed. Is it OK even if FOSHU does not approve the product? Is it OK if the product is not supported in foreign countries? The adverse health effects of the above doubts are unknown.

Many subjective complaints are covered, and the number of functional ingredients was over 280 in May 2023. Popular items are GABA, dextrin, lactobacillus, lutein, DHA/EPA, methoxyflavon, Xanthin, etc. Consumers need help to select the most effective supplement.

### Dietary guidelines in Asia

Dietary guidelines are now widely used worldwide to provide information about the public’s practically healthy diet and lifestyle habits and provide nutritional health information to avoid under-nutrition and over-abundance of nutrients. Provide information on food safety and other health-related foods. Provide food information and agro-products at various individual, family, and societal levels. Nutrition societies in Southeast Asia have played a significant role in helping governments solve prosperity problems.

To share information among regional nutrition societies, Tee E. Siong [6] created SEAPHN with this goal in mind. The guidelines will focus on nutrition and health issues based on scientific findings without bringing in cultural or religious conflicts. Some countries already have guidelines, but even in these countries, there is a double burden of under- and over-nutrition and food safety issues.

Enjoying food and having a variety of foods is common in all countries. In addition to nutrients, Indonesia and Singapore mentioned spices and other healthy foods. Indonesia, Malaysia, Thailand, and Singapore also listed rice as the primary cereal, while Malaysia and Singapore listed whole grains and brown rice. Cereals and grains are also good sources of dietary fiber. Comparing the inertia reports from the participating countries, T.E. Siong divided the 17 topics into eating various foods, special foods, breastfeeding, food labeling, and food safety.

Standardization of food function is done primarily through CODEX.

The meal-based guidelines are helpful in addressing nutritional problems in each country. The problem of the nourishment understood that there was a common point in ASEAN nations. An agreement is provided, even if uneven in scientific validity, by putting a scientific thing in the basics of this trial. It is helpful in a cost-effective intervention program in the future. In addition, as for promoting the understanding of meal guidelines with the food, which is helpful to a country referring to other developing countries and Food Based Dietary Guideline, it must be thought of as a thing that seriously opens knowledge of nourishment to the nation. It is the next problem of this project.

Only a few countries have a system of functional food claims, but many still need a registration system.

Both WHO and FAO have advocated food-based guidelines for diet, and pairing individual functional ingredients with their specific actions in applicable nutrient claims is undesirable. The data on which the vendors base their claims is often literature-based, and some may need to be more familiar to consumers.

### Medical food

I have studied the health benefits of brown rice for many years [7,8]. It is a multifactorial, complex system, with starch as an energy source, plus about 8% protein, several percent fat, abundant vitamins and minerals, dietary fiber to stabilize intestinal bacteria, and gamma oryzanol to lose weight and even control addiction [9,10]. It is a multifactorial and complex system.

In addition, low-protein processed brown rice, which is low in potassium and phosphorus, is used to control uremic dysbiosis of intestinal bacteria and leaky gut caused by toxins and to suppress urinary protein excretion, thereby slowing down the progression of CKD [11]. Foods that have a beneficial effect on health because they reduce a particular substance are not considered to be functional foods. Furthermore, since this dietary therapy is effective for a wide range of illnesses, from the pre-symptomatic state in which proteinuria is observed to diabetic nephropathy in which proteinuria is evident, it is easier to understand if such foods are integrated into a new medical food category.

First, the line of when a chronic disease begins to be a disease is unclear. While sick people with obvious illnesses may be considered for medical treatment, those who are not yet ill are often left unchecked. The term “pre-symptomatic” refers to people with abnormal test results but no subjective symptoms, such as hyperglycemia before diabetes, hypertension before hypertension, or metabolic syndrome, as well as people who are consciously very sick due to lack of sleep or depression but whose test results are expected.

In Western medicine, all pre-symptomatic illnesses are considered to progress into diseases, and early diagnosis and early treatment with drugs lead to fixed symptoms and go to actual diseases. Instead, we should restore people to health through diet, exercise, and hot spring therapy, as in the Chinese approach to curing pre-symptomatic diseases.

If such a person with pre-symptomatic disease tries to solve the problem with functional food supplements in the form of pills or drinks, they will end up buying ten different kinds of supplements. Selecting and eating several kinds of appropriate medical foods would be more effective. China and Japan have a long history of dietary therapy.

There is a history of medicinal herbs in China and Japan, and there may be many candidates for medical food in those countries.

### Definition and evidence for medical foods

The following six definitions of “medical food” are appropriate.

- Long eating experience without toxicity.
- Any health benefit by eating.
- Explainable mechanism (Rationale).
- Pre-Post intervention study.
- Post-marketing surveillance.
- Add to medical food

1 and 2 are empirical evidence, 3 and 4 are epidemiological evidence, and 5 and 6 are social evidence.

At the current evidence level, RCTs are the most important. It is difficult for a food company to conduct an RCT as long as a drug, which would take several months and cost tens of millions of yen [12]. For this reason most supplement advertisements are based primarily on NARRATIVE REVIEWS, leading consumers astray. Many results deemed good in short-term dietary RCTs have been overturned in long-term re-reviews. For example, one egg was once limited to one egg per day because cholesterol was thought to be a risk factor for cardiovascular disease. Still, after 30 years of analysis, it was found to be ineffective, and it was decided that any number of eggs could be eaten [13]. An intervention study to reduce salt intake to 3 g was also found to be ineffective [14]. Many studies could not have had better results even when conducted with a rigorous RCT design, such as the MDRD study and the Doit3 study [15,16].

Pharmaceutical companies can recoup the cost of expensive drugs if RCTs are successful, but it is difficult for food companies with weak financial resources to conduct RCTs. In some cases, such as the high cholesterol drug statin, the results were valid when the RCT involved a pharmaceutical company. Still, the results were invalid when the study strictly excluded interested parties [17]. In the JPHC cohort study we established at the National Cancer Center, we created a cohort of 140,000 participants in 11 health centers nationwide from a cross-sectional study of 4 regions and were able to publish over 300 papers in a nested study within the cohort over a 30-year period [18,19]. The JPHC cohort can be used for multifactorial studies, integrating diet, exercise, personal preferences, and social background. It can be used not only for guidelines but also to engage people in proactive ways of life [20].

### Pre-and post-assessment design for cost-effective Intervention Study

Among many clinical intervention designs, pretest-posttest designs are the preferred method to compare participant groups and measure the degree of change occurring due to treatments or interventions. Cost, easiness of practice, and comprehensiveness are other benefits of pre-post tests for most practitioners [21].

So, we recommend a pre-and post-assessment design for a

more straightforward and practical method under the solution-oriented strategy. Well-designed case studies such as observational epidemiology are often helpful in judging the effects of treatment by the bird's eye.

Historical evidence has an essential role in evaluating the effect of diet and health. Several foods have been continuously consumed over several centuries. A population-based cross-sectional study confirms the insight and further confirmation is possible by a nested case-control study. Then, candidate food is used in the intervention study, and if the results are good, it applies to a prospective cohort study. An intervention study may need months to years, and a prospective cohort study needs 3 to 10 years to conclude. Then we can adapt it to medical foods.

It is an ideal integrative evidence network to evaluate medical food.

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