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Food with Health Claims : Regulation System and Current Status of Functional Foods and Nutraceuticals in Japan

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Abstract

Labeling of functional food is important for both consumers and manufacturers. On the one hand, consumers are able to understand features, content of functional components, and usage of the foods, through the information on the label. On the other hand, manufacturers can emphasize characteristics of their products and promote sales through the labeling or claims. The health claims on food labels should always be based on scientific evidence. The Japanese Ministry of Health, Labor and Welfare (MHLW) set up "Food for Specified Health Uses (FOSHU)" in 1991 as the regulatory system to approve health claims on labels, regarding the effects of foods on the human body. This system was revised and included in the newly established regulatory system in April 2001. FOSHU is one of the categories of Food with Health Claims (FHC) in the new system. In this paper, the FHC regulatory system and principal procedures for its evaluation and approval are outlined.

Food with Health Claims (Figure 1)

Food with health claims (FHC) refers to all foods that comply with the specifications and standards established by the Japanese Ministry of Health, Labor and Welfare (MHLW), considering necessary requirements such as safety and effectiveness, based on the Enforcement Regulations under the Food Sanitation Law and the Health Promotion Law. These foods are categorized into two classes, according to differences in purpose and function : food for specified health uses (FOSHU) and food with nutrient function claims (FNFC).

	Food with Health Claims (FHC)		
Drug (including quasi-drug)	Food for Specified Health Uses (FOSHU) (individual approval system)	Food with Nutrient Function Claims (FNFC) (standard regulation system)	Other Foods (including a part of so-called health food)
	nutrient contents labeling health claims (nutrition claims) attention and warning statement	nutrient contents labeling nutrition claims attention and warning statement	(nutrient contents labeling)

Figure 1. Classification and Class Name

FOSHU is the only type of food product (not ingredients) that can carry health claims and is composed of functional ingredients that affect the structure/function (physiological functions) of the body. These food products are intended to be consumed for the maintenance/promotion of health or special health uses by people who wish to control specified health conditions, such as gastro-intestinal conditions, blood pressure, and blood cholesterol level. Therefore, FOSHU products target healthy people and/or people in a preliminary stage of a disease or a borderline condition in persons at risk group. When the products are manufactured or distributed, permission or approval from the government is required, after rigorous evaluation of the safety and effectiveness of proposed specified health uses. The functional element of FOSHU must be proven scientifically. This means that carefully planned human clinical trials, along with *in vitro* and *in vivo* animal studies, must be performed and published in a scientific journal. Every FOSHU product is evaluated and approved individually by the government. There is no restriction concerning the type or shape of food.



Figure 2. The FOSHU approval mark

Once the permission for marketing is granted, the food must carry the mark of approval somewhere on the package label (Figure 2). The mark symbolizes "jumping for health". Approvals had been given for 370 FOSHU products by the end of June 2003.

FNFC refers to all foods that are intended for consumption for the purpose of supplying or complementing nutrients that are likely to be deficient in our daily life. These foods may be manufactured without restriction and distributed without any permission from or notification to the government, provided that they meet the established standards and specifications.

Procedure for Approval of FOSHU

Applicants for FOSHU approval must submit the following documentation to MHLW.

- a) A sample of the entire package with label and health claims.
- b) Documentation that demonstrates clinical and nutritional proof of the physiological effectiveness of the product and/or its functional component for the maintenance/promotion of health.
- c) Documentation that demonstrates clinical and nutritional proof of the intake amount of the product and its functional component.
- d) *Documentation concerning the safety of the product and its functional component, including additional eating experience in human.*
- e) Documentation concerning the stability of the product and its functional component.
- f) Documentation of the physicochemical characteristics of the product and the functional component.
- g) Methods of qualitative/quantitative analysis of its functional component, and the analytical result of the component in the product.
- h) A report on the analysis of the designated nutrient constituents and calorie (energy) of the product.
- i) A statement about the method of production, the equipment of the factory, and an explanation of the quality control system.

The above documentation can be summarized into three essential requirements for FOSHU approval. First, effectiveness based on scientific evidence including clinical studies. Second, safety from eating experience and additional safety studies in humans. Third, analytical determination of the specific effective component in the product.

Human studies to show physiological efficacy should be conducted using the food/product for a period of at least two months. To establish the safety and the safe intake of the foodstuff, both in vitro and in vivo studies including human studies should be conducted. The safety margin for

humans must be at least three times the minimum effective dosage. The analytical method is applied for clinical studies, animal studies, in vitro studies and stability tests.

Health Claims for FOSHU

FOSHU products have positive effects on human physiological functions and the existing health claims for FOSHU generally can be grouped into 10 categories as shown below.

Gastrointestinal (GI) conditions. More than one-half the FOSHU products claim improvement of GI conditions. The effective components are carbohydrates and bacteria such as lactic acid bacteria and bifidobacteria. The former can be divided into oligosaccharides, lactulose and dietary fiber. Approved products containing these components can claim that they help increase intestinal bifidobacteria and thus help maintain good GI condition.

Blood pressure. Lactotripeptide from fermented milk, dodecapeptide from casein, a group of peptides from sardine and soy protein, and Tochu leaf glycoside (geniposidic acid) can reduce blood pressure. Approved products containing these components can claim that these products are suitable for people with slightly high blood pressure.

Blood glucose. *Examples of the effective components* are indigestible dextrin, wheat albumin, L-arabinose, and guava tea polyphenol. Approved products containing these components can claim that they are helpful for those who are concerned about their blood glucose level.

Blood cholesterol. The effective components are soybean protein, chitosan, degraded sodium alginate and phytosterol. Approved products containing these components can claim that they help decrease serum (blood) cholesterol level.

Blood neutral fat. Globin digest and diacylglycerol can suppress blood neutral fat elevation after a meal. Approved products containing these components can claim that they help reduce postprandial blood triglyceride (neutral fat) level.

Body fat accumulation. Diacylglycerol, structured triacylglycerols combined with medium-chain fatty acids and tea catechins can suppress body fat accumulation. Approved products containing these components are permitted to claim that they help suppress body fat accumulation.

Absorption of minerals. Fructo-oligosaccharides, casein phosphopeptide and calcium citrate malate can improve calcium absorption from the small intestine. Approved products containing these components can claim that they improve absorption of calcium. Approved products containing heme iron from hemoglobin can claim that they are suitable for people with slight iron-deficient anemia.

Tooth caries. Some sugar alcohols such as xylitol, maltitol, erythritol, and palatinose are less cariogenic and green tea polyphenol is non-cariogenic. Approved products containing these compounds can claim that they are low- or non-cariogenic products.

Healthy teeth. Compounds such as xylitol and CPP-ACP (casein phosphopeptide-amorphous calcium phosphate compound) can make teeth strong and healthy. Approved products containing these components can claim that they make teeth strong and healthy.

Healthy bones. Vitamin K2, soybean isoflavone, MBP (milk basic protein) and fructo-oligopeptides can promote bone calcification. Approved products containing these components can claim such effects.

Health claims for FOSHU must not express medical claims for human diseases and/or must not use words such as "prevent", "cure", "mitigate", "treat", or "diagnose" used for human diseases.

Food with Nutrient Function Claims (FNFC) (Figure 1)

Given that many foods are manufactured and marketed as so called healthy food, it was necessary to establish certain standards and guidelines to protect the health of consumers and to offer appropriate information about this kind of product. Twelve vitamins (Vitamin A, B1, B2, B6, B12, C, E, D, Biotin, Pantothenic acid, Folic acid, and Niacin) and two minerals (calcium and iron) are standardized as FNFC. The work to standardize vitamin K, remaining minerals and other nutrients such as fatty acids and protein is continuing.

Standards for Food with Nutrient Function Claims (FNFC)

The upper and lower levels for the daily intake of 12 vitamins and two minerals have been set as shown in Table 1. A FNFC should contain an amount of a nutrient between the designated upper limit and the lower limit (Table 1). The lower limit was set as one-third of the recommended daily intake for Japanese and the upper limit was referred to the maximum amount of OTC (over the counter) nutrient items.

Table 1. The upper and lower limits of Food with Nutrient Function Claims

<Vitamins>

	Upper limit	Lower limit
Vitamin A (retinol)	2000IU 600ug	600IU 180ug
Vitamin D	200IU 50ug	35IU 0.9ug
Vitamin E	150mg	3mg
Vitamin B ₁	25mg	0.3mg
Vitamin B ₂	12mg	0.4mg
Niacin	15mg	5mg
Vitamin B ₆	10mg	0.5mg
Folic acid	200ug	70ug
Vitamin B ₁₂	60ug	0.8ug
Biotin	500ug	10ug
Pantothenic acid	30mg	2mg
Vitamin C	1000mg	35mg

<Minerals>

	Upper limit	Lower limit
Calcium	600mg	250mg
Iron	10mg	4mg

Nutrient Function Claims

Nutrient function claims are determined according to recommendations of Codex in 1997. These claims have been widely accepted by scientific experts, based on scientific evidence applied to existing foods or supplements internationally, and are readily understood by the general public.

Vitamin A (or β -carotene) helps maintain vision in the dark and maintain skin and mucosa healthy.

Vitamin D promotes absorption of calcium from the intestine and aids in the development of bone.

Vitamin E helps protect body lipids from being oxidized and maintain the cell healthy.

Vitamin B₁ helps produce energy from carbohydrate and maintain skin and mucosa healthy.

Vitamin B₂ helps maintain skin and mucosae healthy.

Vitamin B₆ helps produce energy from protein and maintain skin and mucosae healthy.

Niacin helps maintain skin and mucosae healthy.

Biotin helps maintain skin and mucosae healthy.

Pantothenic acid helps maintain skin and mucosa healthy.

Folic acid aids in red blood cell formation and contributes to the normal growth of the fetus.

Vitamin B₁₂ aids in red blood cell formation.

Vitamin C helps maintain skin and mucosae healthy and has antioxidant effects.

Calcium is necessary in the development of bone and teeth.

Iron is necessary for red blood cell formation.

Attention and Warning Labeling

Every nutrient : Excessive intake of this product neither cures disease nor promotes health.
Take only the recommended amount.

Vitamin A : Women who are pregnant or expect to become pregnant should avoid the excessive intake.

Folic acid : Folic acid contributes to the normal growth of the fetus, but intake above the recommended amount does not improve fetal growth.