# Review

# Foods with Health Claims in Japan

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The Japanese Ministry of Health, Labour and Welfare (MHLW) established the "Foods for Specified Health Uses (FOSHU)" designation in 1991 as a regulatory system for the approval of health claims on labels that refer to the physiological effects of foods or food components on the human body. This labeling system has been revised twice, most recently in 2005. Thus, "Food with Health Claims" (FHC) in Japan consists of two categories. One is "Foods with Nutrient Function Claims" (FNFC), for which health claims on labels can be freely used if the product satisfies the standard for the minimum and maximum levels per daily portion of consumption; the other is FOSHU. FOSHU are foods that contain beneficial dietary ingredients that maintain or promote human health, or that improve risk factors for lifestyle-related diseases. In the present system, FOSHU health claims are individually reviewed and approved on the basis of scientific evidence. In addition to the existing FOSHU, three new types of classifications were established in February 2005: the new regulatory standards of "Standardized FOSHU" and "Qualified FOSHU" and the new health claim "Reduction of disease risk".

Keywords: health claim, FOSHU, FNFC, Japan

## Introduction

Since the early 1980s, functionalities of food or food components has become an active area of research and development in Japan, and support for many of these investigations is provided the Japanese Ministry of Education, Culture, Sports, Science and Technology (MEXT). The Japanese scientific academy defined functional food as a food which has a tertiary or physiologically active function. The tertiary function of food is a physiological function, such as the regulation of a physical condition or the prevention of certain kinds of diseases. Thus, functional foods are assessed as foods with tertiary function. Research supported by MEXT has provided evidence of a number of physiological functions of foods or food components (Arai, 1996).

Consumption of functional foods has also increased rapidly in recent years due to increased public interest in the prevention of lifestyle-related diseases and improvement of general health against the background of a rapidly aging society. Increasing numbers of consumers now consider health

\*To whom correspondence should be addressed. Email: jnagata@nih.go.jp issues to be the primary factor in their purchasing decisions, and manufactures emphasize the health-related characteristics of their products using labels in order to enhance their sales. Therefore, an appropriate regulatory system of labeling for functional foods is important for both consumers and producers. Since consumers can acquire various information such as the content of functional components and usage of foods from labels, it is imperative that the health claims on food labels are based on scientific evidence.

Food labels with health claims should generally meet the following conditions: 1) be compliant with the national nutritional goal and public health policy, 2) be based on the proven usefulness of the food in supplying nutrition or in a specified health effect, 3) be based on acceptable scientific data and use simple and intelligible expressions, 4) offer appropriate information to the consumer, 5) contain any relevant warnings or cautions, including appropriate intake, to prevent adverse effects on health due to overdoses, 6) comply with the Food Sanitation Law, Health Promotion Law, and other related laws, and 7) avoid confusion with drugs and the implication of prevention, treatment and diagnosis of human disease.

	Food with Health Claims $\longrightarrow$ (FHC)					
Drug (Including quasi-drug)	Food with Nutrient Function Claim (FNFC) 12 Vitamins and 5 Minerals	Food for Specified Health Uses (FOSHU) Individual approval system			Other Foods (Including so-	
	Standard regulation system	Ordinary FOSHU	Standardized	Reduction of disease risk	Qualified	-

Fig. 1. Classification and class name of Food with Health Claims.

Labeling of nutrient function should be based on internationally recognized findings, i.e., examples of nutrient function claims should include a reference to the Codex Alimentarius and be easy to understand. Food labels with health claims also require attention notices and warnings for intake ranges consistent with safe consumption.

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In Japan, the regulatory system to approve health claims on labels was established by the Japanese Ministry of Health, Labour and Welfare (MHLW) in 1991 (Shimizu, 2003; Tanaka, 2004; Ohama, 2006). The current system for regulation of health foods is called "Food with Health Claims" (FHC), the enforcement regulations for which are based on the Food Sanitation Law and the Health Promotion Law (Shokuanhatsu Notification No. 0201002, 2005).

In this paper, we introduce the FHC regulatory system and the principal procedures for its approval in Japan.

Food with Health Claims (FHC) The FHC system, originally established in 2001, was revised on the basis of the "Foods for Specified Health Uses" (FOSHU) system established in 1991; the present regulatory system was finalized in 2005. FHC classifications and class names are illustrated in Figure 1. FHC are defined as foods located between drugs and common foods, including so-called health foods, and are categorized into two classes based on differences in purpose and function: "Foods with Nutrient Function Claims" (FNFC) and FOSHU, in which heath claims are limited to benefits for maintaining or improving health and physical condition. FNFC is the standard regulation system, consisting of 12 vitamins and 5 minerals, while FOSHU is an individual approval system. In the 2005 revisions to FOSHU, three new categories were added: "Standardized FOSHU", "Health Claim for the Reduction of Disease Risk", and "Qualified FOSHU". Once the permission for marketing is granted, the food must carry the logo of approval on the package label (Figure 2). Both labels symbolize "jumping for health".



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Fig. 2. FOSHU logo of approval, symbolizing "jumping for health".

Application document and procedure for FOSHU approval Applicants for FOSHU approval must submit their documentation to MHLW as listed in Table 1. FOSHU documentation must meet three essential requirements for approval. First, the effectiveness of the functional component should be based on scientific evidence, including human studies. Second, its safety as assessed from historical consumption pattern data, and additional safety studies are required in humans. Third, analytical determination of the functional component responsible for the beneficial physiological function is needed.

The document on the physiological effects on human health should be prepared based on scientific evidence related to not only the effects of the functional component on the physiological functions of humans and animals but also its mechanism of action. In addition, these data should be statistically significant. In order to conduct a proper evaluation, the study must be well designed, that is, utilizing the appropriate biological indices and a sufficient number of subjects to be statistically evaluable.

With respect to the document of safety, both in vivo and in vitro studies should be carried out to assess the safety of intake in humans. Even if the functional component has been

- 1. Sample of the entire package with labels and health claims.
- 2. Proof of the clinical and nutritional function of the product and/or its functional component for the maintenance of health.
- 3. Clinical and nutritional proof of the intake amount of the product and/or its functional component.
- 4. Documentation concerning the safety of the product and its functional component, including additional human studies and <u>eating experience</u>.
- 5. Documentation concerning the stability of the product and its functional component.
- 6. Documentation of the physical and biological characteristics of the product and its functional component.
- 7. Methods of qualitative/quantitative analytical determination of the functional component, and analytical results on the amount of component in the product.
- 8. Report on the analysis of the designated nutrient constituents and calorie content of the product.
- Statement of the production method and equipment of the factory and explanation of the quality control system.

consumed by a number of people for many years, safety data regarding human consumption has to be provided using at least three times the amount of the minimum effective dosage.

The documentation of the methods for the functional components analysis is also required, and must include both qualitative and quantitative analysis.

In addition, a document on the stability of products and functional components should be provided.

It is important that to specify that FOSHU products are designed for healthy individuals and individuals in a preliminary stage or marginal zone between the health and disease stages. Therefore, the physiological effects of FOSHU may be mild compared to medicine for patients (Yamada, 2008).

The Scheme of FOSHU approval is illustrated in Figure 3. The Office of Health Policy on Newly Developed Foods of MHLW initiates the application process for FOSHU in accordance with the receipt of all documents described above. An Expert Committee then evaluates the validity of a FOSHU in either of two sub-committees. One sub-committee assesses products related to lipid metabolism such as cholesterol and neutral fats, obesity, blood pressure, and blood glucose. The other sub-committee evaluates products related to gut condition, mineral absorption, and dental health, among others. After the completion of the evaluation by the Expert Committee, the Pharmaceutical Affairs and Food Sanitation Council and the Food Safety Commission review the applied dossier. When the Council determines the application to be appropriate, the MHLW notifies the applicant and requests that the applicant send samples of the product, along with documentation of the analytical method, to the National Institute of Health and Nutrition. The Institute then validates the method and determines the amount of the effective component. After validation and determination of the product has been completed, MHLW makes the decision to grant approval for the product under FOSHU. The applicant is permitted to use the approved health claim on the label with the FOSHU logo.

*Health claims for FOSHU* FOSHU products have some benefit to human health and physiological functions. As of April 2008, 779 items had been granted FOSHU status, consisting of approximately 70 kinds of effective components. Although it is difficult to classify accurately, the existing health claims for FOSHU generally can be classified as shown below (Saito, 2005; Saito, 2007, Yamada, 2008).

(1) Gastrointestinal (GI) conditions: About half of all FOSHU products have health claims relating to the improvement of GI condition. The effective components are carbohydrates, which can be divided oligosaccharides, dietary fiber and chitosan, and bacteria such as lactic acid bacteria and bifidobacteria. Approved products containing these components can claim that they help increase intestinal bifidobacteria and thus maintain good GI condition.



Fig. 3. Scheme of the FOSHU approval.

(2) Blood pressure: Lactotripeptide from fermented milk, dodecapeptide from casein, a group of peptides derived from sardine, dry bonito, soybean protein and salmon, and gamma-aminobutyric acid (GABA), as well as Tochu leaf glycoside (geniposidic acid), are proposed to reduce blood pressure. Approved products containing these components can claim beneficial effects for people with moderately high blood pressure.

(3) Blood glucose: Effective components include indigestible dextrin, wheat albumin, L-arabinose, and guava tea polyphenol. Approved products containing these components can claim that these materials are helpful for those who are concerned about their blood glucose level.

(4) 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.

(5) Blood neutral fat: Globin digest and diacylglycerol (DAG) can suppress the elevation of blood neutral fat level after a meal. Therefore, approved products containing these components can claim that they help to reduce postprandial blood triglyceride (neutral fat) levels. In addition, a mixture of eicosapentaenoic acid and docosahexaenoic acid is also believed to decrease blood neutral fat level. This product can claim that beneficial effects for people with moderately high blood triglyceride level.

(6) Body fat accumulation: DAG, structured triacylglycerol combined with medium-chain fatty acids and tea

Vitamins	Upper limit	Lower limit		
Vitamin A (retinol)	600 µg (2000 IU)	135 µg (600 IU)		
Vitamin D	5 µg (200 IU)	1.5 µg (60 IU)		
Vitamin E	50 mg	2.4 mg		
Thiamin	25 mg	0.3 mg		
Riboflavin	12 mg	0.33 mg		
Niacin	60 mg	3.3 mg		
Vitamin B6	10 mg	0.3 mg		
Folic acid	200 µg	60 µg		
Vitamin B12	60 µg	0.6 µg		
Biotin	500 µg	14 µg		
Pantothenic acid	30 mg	1.65 mg		
Vitamin C	1000 mg	24 mg		
Minerals				
Calcium (Ca)	600 mg	210 mg		
Iron (Fe)	10 mg	2.25 mg		
Zinc (Zn)	15 mg	2.1 mg		
Copper (Cu)	6 mg	0.18 mg		
Magnesium (Mg)	300 mg	75 mg		

 Table 2. Upper and lower limits of food with nutrient function claims.

catechins can suppress body fat accumulation. Approved products containing these components are permitted to claim that they help suppress body fat accumulation.

(7) Absorption of minerals: Fructo-oligosaccharide, calcium citrate malate and casein phosphopeptide can improve calcium absorption from intestine. Approved products containing these components can claim such effects.

(8) Dental health: Dental health has two categories of

health claims. One is anti-cariogenesis, in which some sugar alcohols such as xylitol, maltitol, erythritol, and palatinose are considered to be hypo-cariogenic, while green tea polyphenol is regarded as non-cariogenic. Approved products containing these sugar alcohols can claim that these products are low or non-cariogenic. The other category is tooth health. Compounds such as xylitol and CPP-ACP (casein phosphopeptide-amorphous calcium phosphate compound) can make

Table 3. Nutrient Function Claims for FNFC in Japan.

Nutrient	t Nutrition functional claims		
Vitamins			
Vitamin A	Vitamin A is a nutrient that helps to maintain vision in the dark.		
(β-carotene)	Vitamin A is a nutrient that helps maintain skin and mucosa in a healthy state.		
Vitamin D	Vitamin D is a nutrient that promotes calcium absorption in the gut intestine and aids in the development bone.		
Vitamin E	Vitamin E is a nutrient that prevents lipid in the body from oxidizing through its antioxidant effect and helps maintenance of healthy cells.		
Thiamin	Thiamin is a nutrient that helps energy production from carbohydrate and maintain skin and mucosa in a healthy state.		
Riboflavin	Riboflavin is a nutrient that helps maintain skin and mucosa in a healthy state.		
Niacin	Niacin is a nutrient that helps maintain skin and mucosa in a healthy state.		
Vitamin B6	Vitamin B6 is a nutrient that helps energy production from protein and helps maintain skin and mucosa in a healthy state.		
Folic Acid	Folic acid is a nutrient that helps red cell formation.		
	Folic acid is a nutrient that contributes the normal growth of the fetus.		
Vitamin B12	Vitamin B12 is a nutrient that helps red cell formation.		
Biotin	Biotin is a nutrient that helps maintain skin and mucosa in a healthy state.		
Pantothenic acid	Pantothenic acid is a nutrient that helps maintain skin and mucosa in a healthy state.		
Vitamin C	Vitamin C is a nutrient that helps maintain skin and mucosa in a healthy state, and has an antioxidant effect.		
Minerals			
Calcium (Ca)	Calcium is a nutrient, which is necessary in the development of bone and teeth.		
Iron (Fe)	Iron is a nutrient, which is necessary in red blood cell formation.		
Zinc (Zn)	Zinc is a nutrient required to maintain healthy sense of taste.		
	Zinc is a nutrient that helps maintain skin and mucosa in a healthy state.		
	Zinc is a nutrient that is involved in protein and nucleic acid metabolism and helps heath maintenance.		
Copper (Cu)	Copper is a nutrient that helps red cell formation.		
	Copper is a nutrient that helps normal functions of enzymes in the body and bone formation.		
Magnesium (Mg)	Magnesium is a nutrient required for bone and tooth formation. Magnesium		
	is a nutrient that helps normal functions of enzymes in the body and energy production and that is required to maintain normal blood.		

teeth strong and healthy. Approved products containing these components can claim such effects.

(9) Bone health: Vitamin K2, soy isoflavone, milk basic protein and fructo-oligopeptides are regarded as promoters of bone calcification. Approved products containing these components can claim such effects.

The health claims on FOSHU must not express, specify or validate any medical terminology used for human health such as "prevent", "cure", "treat", or "diagnose".

Foods with Nutrient Function Claims (FNFC) MHLW enacted a new regulation system of "Food with Health Claims (FHC)" in 2001. FHC consists of two categories, FOSHU and FNFC. Twelve vitamins including vitamins A, B1, B2, B6, B12, C, E, D, biotin, pantothenic acid, folic acid and niacin, as well as calcium and iron, have been standardized as FNFC. In 2003, three minerals, zinc, magnesium and copper, were added to FNCN. The upper and lower levels for the daily intake of 12 vitamins and 5 minerals have been set as shown in Table 2. The minimum daily level per portion for consumption of the products is 30% of the standard values for the nutrition labeling as per the 2005 edition of the Japanese dietary reference intakes (DRIs) (MHLW, 2005). The maximum level is set as the maximum amount of nutrient items in quasi drugs.

*Nutrition Function Claims* Nutrient function claims are approved according to the guidelines of the 1997 Codex Alimentarius. These claims have been widely accepted by scientific experts, are based on scientific evidence, are applied to existing foods or supplements internationally, and are readily understood by the general public (Table 3).

Attentions and warnings should be also provided on labels for every nutrient, including information concerning excess intake of the product. The recommended consumption should also be provided.

### Conclusion

The current Japanese system for regulation of "health foods", called "Food with Health Claims" (FHC) consists of two categories: "Foods with Nutrient Function Claims" (FNFC) and "Foods for Specified Health Uses" (FOSHU). The FNFC label can be freely used if a product satisfies the standard for the minimum and maximum levels per daily consumption. FOSHU products contain specified dietary ingredients that have physiologically beneficial effects for human health, that maintain and promote health, or that improve healthrelated conditions. In terms of approval, the Food Safety Commission examines the safety of the product and the Pharmaceutical Affairs and Food Sanitation Council evaluates its effectiveness. Subsequently, the MHLW approves individual claims, which allow the manufacturer to officially display the health claims and the FOSHU logo on their products.

In order to maintain and improve human health and to prevent lifestyle related diseases, Japanese authorities recommend the intake of a well-balanced diet. Healthy individuals should obtain all necessary energy, nutrients and nonnutritious components from regular meals.

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