



2018 Vol. 4(3) 1:1-6

Nutritional Function Claims on Japanese Food Labels: “Foods for Specified Health Uses”, “Foods with Nutrient Function Claims” and the Newly Instituted “Foods with Function Claims”

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Citation: FUJITA, A. Nutritional Function Claims on Japanese Food Labels: “Foods for Specified Health Uses”, “Foods with Nutrient Function Claims” and the Newly Instituted “Foods with Function Claims” *JAS 4QoL* **2018**, 4(3) 1:1-6.

Online: <http://as4qol.org/?p=2134#art1>

Received Date: 2019 09 26 Accepted Date: 2019 09 27 Published: 2019 09 30

2018 International Meeting and Cruise

- The 2018 International Meeting on Quality of Life was held recently. Proceedings as well as photos and other information from past conferences can be found at <http://as4qol.org/icqol/2018/>

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Abstract

Before this system was put in place, making nutritional function claims on food labels had only been allowed for government-approved Foods for Specified Health Uses (FOSHU) and for Foods with Nutrient Function Claims (FNFC) that complied with the specifications and standards designated by the government. In addition to these categories, a new type of Foods with Health Claims, called Foods with Function Claims (FFC), was introduced in April 2015 in order to make more products available that were clearly labeled with certain nutritional or health functions and to enable consumers to make more informed choices. These food products are allowed to be labeled with the function the food performs in terms of the specified health effects that it can achieve (i.e., helpful for maintaining and promoting health) such as "Helps maintain good GI condition" or "Slows fat absorption." In this article, we introduce and explain the differences between these categories of labels.

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1. General Information:

The original FOSHU registration was well received by Japanese food manufacturers as the prior lengthy and expensive process had limited the food industry's ability to market the health benefits of specific products, a particularly effective marketing strategy in Japan. In order to increase the number of foods with functional claims and to promote a healthier, longer-living society, on June 14, 2013 the government decided to establish the Food with Functional Claims (FFC) category of health claims labeling.

The establish the FFC category, a fourteen-member committee representing academia, national food and drug laboratories, consumer groups, and

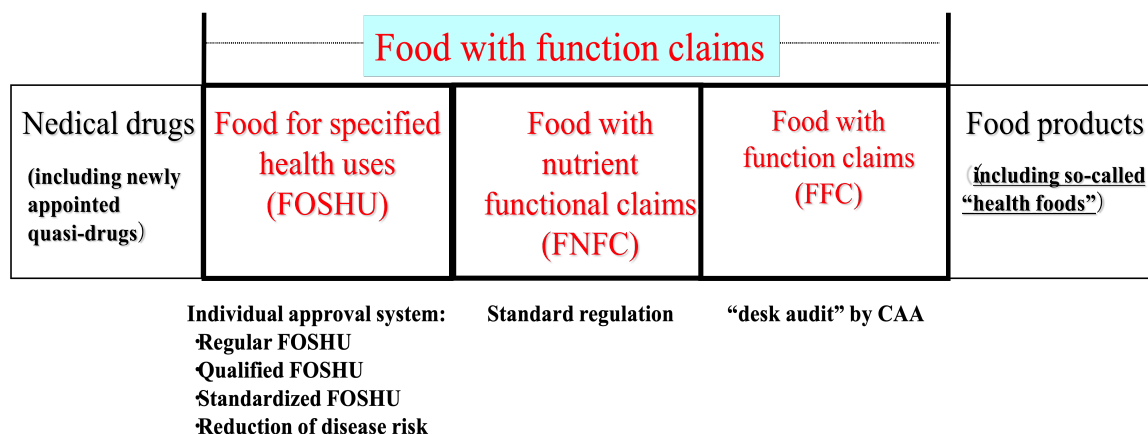


Fig.1 Categories of Food with Health Claims

health food companies, among others, was brought together to develop FFC guidelines in December 2013. In July 2014, the committee released a report on how the FFC system would function in terms of securing food safety, citing scientific evidence for functional claims, avoiding false labeling, and the role of government. Japan's Consumer Affairs Agency (CAA) established the FFC category based largely on that report and included the FFC in the comprehensive Food Labeling Standard that went into effect on April 1, 2015. The official FFC guidelines for the preparation of an FFC-compliant food label also became effective on April 1, 2015. FFC system was based on US "Dietary Supplement Health and Education Act of 1994 (DSHEA)". The difference in these systems include that the DSHE-compliant labels can only be used on tablets and capsules, and the company must notify the FDA within 30 days of putting the product on the market.; on the other hand, the FFC allows labeling not only on tablets and capsules but also conventional foods including farm products. In the FFC system, they do not require approval of CAA, but the CAA checks the applications, e.g. mechanism of function and systematic review of human trials, and sometimes reject the applications. Therefore, even if they notify the CAA 60 days before putting the product on the market, is not always true they capable of being marketed.

2. Overview of the Previous Health Claims System

Prior to the FFC system, there had been two categories of health claims in Japan: Food for Specialized Health Uses (FOSHU) and Food with Nutrient Functional Claims (FNFC). Fig. 1 shows categories of food with health claims. FOSHU was introduced in 1991, and the number of FOSHU products registered as of September 3, 2018 was 1,053. Nonetheless, utilization of FOSHU has remained limited due to the rigorous requirements for eligibility. Clinical trials of a product are required in order to acquire FOSHU, which has proven too great a burden for small- and medium-sized companies in terms of cost and time; some companies have paid more than 100 million yen (about \$ 810 thousand) and had to wait more than three years for approval.

The FNFC system was introduced in 2001. Unlike FOSHU, there is no registration procedure for FNFC. Products containing vitamins and minerals that meet the standards determined by CAA are eligible to be labeled without application, registration or prior notification. Under FNFC, products may use approved standard statements of functionality for a limited number of nutritional ingredients (vitamins, minerals and fatty acids) on product labels.

3. Revision of FNFC

FNFC health claims may be used on food package labels if the functional nutrients in the product conform to CAA-established standards. Manufacturers need not prepare an application or notification to the CAA in order to use FNFC claims on their labels, and they may produce and sell products with FNFC claims, at their own risk. In April 2015, the CAA revised the lower limit of the specified range for approved nutrients based on the nutrient labeling standard values. This move expanded eligibility for FNFC claims to products that previously did not have enough of the specific functional nutrient to qualify for FNFC claims. In addition, the CAA added three new functional nutrients to the approved list (n-3 fatty

acid, vitamin K and potassium) and expanded the range of products eligible for FNFC claims to include fresh foods. The 20 approved functional nutrients (13 vitamins, 6 minerals and one fatty acid) eligible for FNFC health claims labeling are shown in the Table 1.

Table-1. Nutritional Ingredients of FNFC

Nutritional Ingredients	Specified range of nutritional ingredient of the advisable daily intake	Function Claims	Warning Indication
n-3 fatty acid	0.6 g – 2.0 g	Helps to maintain skin	Increased intake of this product will not result in curing diseases or promoting health. Please comply with the advisable daily intake.
Zinc	2.64 mg - 15 mg	Necessary nutrient to maintain normal taste and helps to maintain healthy skin and mucous membranes. Involved in the metabolism of proteins and nucleic acids and helpful in maintaining health.	Increased intake of this product will not cure disease nor promote health. Too much intake of zinc might inhibit absorption of copper. Please comply with the advisable daily intake. Infants and young children should avoid use of this product.
Potassium	840 mg– 2,800 mg	Helps to maintain proper blood pressure.	Increased intake of this product will not cure disease nor promote health. Please comply with the advisable daily intake. Those with loss of hepatic function should avoid use of this product.
Calcium	204 mg - 600 mg	Necessary for the development of bones and teeth.	Increased intake of this product will not cure disease nor promote health. Please comply with the advisable daily intake.
Iron	2.04 mg - 10mg	Necessary for red blood cell formation.	
Copper	0.27 mg – 6.0 mg	Helps in formation of bone and red blood cells, and in the proper functioning of many bodily enzymes.	Increased intake of this product will not cure disease nor promote health. Please comply with the advisable daily intake. Infants and young children should avoid use of this product.
Magnesium	96 mg - 300 mg	Necessary for the development of bones and teeth, maintenance of proper blood circulation, proper function of many bodily enzymes, and the generation of energy.	Increased intake of this product will not cure disease nor promote health. Increased intake may cause diarrhea. Please comply with the advisable daily intake. Infants and young children should avoid use of this product.
Niacin	3.9 mg - 60 mg	Helps to maintain skin and mucosal health.	Increased intake of this product will not cure disease nor promote health. Please comply with the advisable daily intake.
Pantothenic acid	1.44 mg - 30 mg		
Biotin	15 µg - 500 µg		
Vitamin A	231 µg - 600 µg	Helps to maintain vision in the dark, and skin and mucosal health.	Increased intake of this product will not cure disease nor promote health. Please comply with the advisable daily intake. Women within the third month of pregnancy or women considering becoming pregnant should be careful of over consumption.
Vitamin B1	0.36 mg - 25 mg	Helps to produce the energy from carbohydrates and to maintain skin and mucosal health.	Increased intake of this product will not cure disease nor promote health. Please comply with the advisable daily intake.
Vitamin B2	0.42 mg - 12 mg	Helps to maintain skin and mucosa health.	
Vitamin B6	0.39 mg - 10 mg	Helps to produce energy from proteins and to maintain skin and mucosal health.	
Vitamin B12	0.72 µg - 60 µg	Aids in red blood cell formation.	
Vitamin C	30 mg - 1,000 mg	Helps to maintain skin and mucosal health and has an anti-oxidizing effect.	

Table-1. Nutritional Ingredients of FNFC

Nutritional Ingredients	Specified range of nutritional ingredient of the advisable daily intake	Function Claims	Warning Indication
Vitamin D	1.65 µg - 5.0 µg	Promotes absorption of calcium in the gut intestines and aids in the growth of bone.	
Vitamin E	1.98 mg - 150mg	Helps to protect fat in the body from being oxidized and to maintain the cell health.	
Vitamin K	45 µg - 150 µg	Helps to maintain proper blood coagulability.	Increased intake of this product will not cure disease nor promote health. Please comply with the advisable daily intake. Those who take anticoagulants should avoid use of this product.
Folic acid	72 - µg 200 µg	Aids in red blood cell formation, and ontributes to normal growth of the fetus.	Increased intake of this product will not cure disease nor promote health. Please comply with the advisable daily intake. This product helps normal development of fetus, but increased intake of this product will not result in better development of fetus.

4. About FOSHU

FOSHU refers to foods containing ingredients performing functions that improve health and that are officially approved to claim beneficial physiological effects on the human body. FOSHU approved foods are intended to be consumed for the maintenance / promotion of health or for special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol. In order to be sold under FOSHU guidelines, the assessment of the safety of the food and effectiveness of the functions for health is required, and the claim must be approved by the CAA. Table-2 showed the main approved FOSHU products.

4.1 Requirements for FOSHU Approval as follows:

- (1) Effectiveness on the human body is clearly proven
- (2) Absence of any safety issues (animal toxicity tests, confirmation of effects in the cases of excess intake, etc.)
- (3) Use of nutritionally appropriate ingredients (e.g. no excessive use of salt, etc.)
- (4) Guarantee of compatibility with product specifications by the time of consumption
- (5) Established quality control methods, such as specifications of products and ingredients, processes, and methods of analysis

4.2 Types of FOSHU

In addition to "regular" FOSHU, additional types of FOSHU, such as Qualified FOSHU and Standardized FOSHU, were introduced to facilitate applications for FOSHU approval. These are:

- (a) Qualified FOSHU: Food with health functions which are not substantiated by scientific evidence that meets the levels specified in FOSHU, or foods with a certain level of effectiveness but without an established mechanism for the effective element for the function will be approved as qualified FOSHU.
- (b) Standardized FOSHU: Standards and specifications are established for foods with sufficient FOSHU approvals and accumulation of scientific evidence. Standardized FOSHU are approved when it meets the standards and specifications.
- (c) Reduction of disease risk FOSHU: A reduction of disease risk claim is permitted when reduction of disease risk is clinically and nutritionally established fo a given ingredient.

4.3 Approved Reduction of Disease Risk Claim

Approved reduction of disease risk claims are “Calcium and Osteoporosis” and “Folic Acid and Neural Tube Defects”.

- i) Calcium and Osteoporosis:

Specified Health Uses	Principal Ingredients (ingredients exhibiting health functions)
Foods to modify gastrointestinal conditions	Oligosaccharides, lactose, bifidobacteria, lactic acid bacteria, dietary fiber, digestible dextrin, polydextrol, guar gum, psyllium seed coat, etc.)
Foods related to blood cholesterol level	Chitosan, soybean protein, degraded sodium alginate
Foods related to blood sugar levels	Indigestible dextrin, wheat albumin, guava tea polyphenol, L-arabinose, etc.
Foods related to blood pressure	Lactotripeptide, casein dodecanepptide, tochi leaf glycoside (geniposide acid), sardine peptide, etc.
Foods related to dental hygiene	Parathose, maltitose, erythritol, etc.
Cholesterol plus gastrointestinal conditions, triglycerol plus cholesterol	Degraded sodium alginate, dietary fiber from psyllium seed husk, etc.
Foods related to mineral absorption	Calcium citrated malate, casein phosphopeptide, hem iron, fructo-oligosaccharide, etc.
Foods related to osteogenesis	Soybean isoflavone, MBP (Milk basic protein), etc.
Foods related to triglycerol	Middle chain fatty acid, etc.

"Intake of proper amount of calcium contained in healthy meals with appropriate exercise may support healthy bones in young women and reduce the risk of osteoporosis as they grow older."

ii) Folic Acid and Neural Tube Defect:

"Intake of the proper amount of folic acid contained in healthy meals may support pregnant women by reducing the risk of neural tube defects, such as spondyloschisis, during fetal development.

5. What's FFC


Under the FFC category, food manufacturers may label a package with the specific health claims associated with the functional components in a given product as to maintaining and promoting health in those who are not suffering from disease. FFC claims can be made for all foods, including fresh foods, except for foods with FOSHU or FNFC claims or those that lead to excessive intake of fat, cholesterol, sugar, and/or sodium. Following FFC guidelines, food manufacturers must provide CAA with scientific information on the safety and efficacy of their products. The number of FFC products registered as of August 4, 2018 was 1,429.

Food manufacturers must provide all required information to the CAA no less than 60 days prior to the release of FFC-labelled products to market. Following a 'desk audit,' the CAA will issue an acceptance number and add the product and associated FFC health claim information to the CAA website. The CAA may request additional information from a manufacturer before issuing an FFC acceptance number if the FFC information package is incomplete.

5.1 Labeling Contents Required under FFC

FFC labeling must include cross-category quality labeling items as well as the following 16 specific items:

- (1) Indication of FFC.
- (2) The functional components on a scientific basis and the functionality of these components or foods containing these components.
- (3) Adequate daily intake.
- (4) Amount of nutritional components and calories in the adequate daily intake.
- (5) Amount of a functional component contained in the adequate daily intake.
- (6) Acceptance number.
- (7) Phone number as contact information of the manufacturer.
- (8) Notice that functionality and safety are not evaluated by CAA.
- (9) Method of intake.
- (10) Instruction on intake.
- (11) Notice promoting a balanced diet.
- (12) Precautionary statements for products which require special attention when cooked or stored.
- (13) Notice that the product is not intended to diagnose, treat, or prevent disease.

Table-3. Differences of FOSHU and FFC			
	FOSHU		FFC
Labeling	Consumer Affairs Agency Approved food for specified health uses		No trade mark Food with Functional Foods
Inspection	Consumer Affairs Agency (Food Safety Commission)		No inspection ("desk audit")
Effectiveness	Need human trial (RCT) of final product		Systematic review (not necessary RCT trial)
Exhibition of report information	Non-disclosure		Disclosure
Cost	>one hundred million yen		~one million yen
Time for approval	>2 Years		6 months

(14) Notice that it does not target those suffering from disease, minors, pregnant women (including women planning to become pregnant) and nursing women.

(15) Notice recommending that those suffering from disease consult with a physician, and that those taking drugs consult a physician or pharmacist.

(16) Notice that in cases of unusual physical changes, consumers are recommended to stop eating the product immediately and to consult a physician.

5.2 Differences between FOSHU and FFC

Unlike FOSHU, FFC labeling claims do not receive individual approval from the CAA, since the CAA does not review the safety and efficacy of the product. The FFC system places responsibility for the scientific accuracy of the health claims on the manufacturers themselves, requiring that they refer to either a clinical trial or a systematic review of scientific evidence. Manufacturers must follow the guidelines for FFC labeling contents, including the amount of a functional component in the product, a warning label about intake method, and the manufacturers' contact information. Table-3 showed differences

As of July 15, 2015, no FFC health claims have been accepted for fresh foods. Orange (β -cryptoxanthin), Bean sprouts (iso-flavones), Seriola (DHA, EPA), Tamato (GABA) and 30% milled rice (GABA) were approved for FFC by CAA. Industry sources have noted that the FFC process may pose significant challenges for fresh foods, which may not be able to demonstrate a minimum content of a functional component as the quantities of such compounds vary across seasons and growing areas. Further, it is not clear how fresh food producers will be able to prepare labels for individual items at retail stores, establish measures to avoid commingling with similar non-FFC labeled products, and whether producers will be able to recover the investment in establishing such systems through increased prices/sales based on increased consumer valuation of the product as a result of the FFC health claim.

6. Conclusions

The newly introduced FFC health claim system is more effective and less risky than bringing a FOSHU product to market in Japan. In fact, the number of FFC products exceeded 1,000 items only three years after it was introduced in April, 2015; Currently the number has exceeded that allowed for FOSHU approval.

As the number of products able to provide information about nutritional function and efficacy through the FFC system may contribute to increased awareness of health benefits of various foods, and to improved health and reduced health costs for the general public.