

## Original Article

# Newly established regulation in Japan: foods with health claims

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The Japanese government enacted a new regulatory system called 'Foods with health claims' in April 2001, which consists of 'Foods for Specified Health Use' (FOSHU) and 'Foods with Nutrient Function Claims' (FNFC). The FOSHU was set up by the Ministry of Health and Welfare in 1991 to approve descriptions on a label regarding an effect of food on the human body. It was enacted as a part of 'food for specified dietary use' under the Nutrition Improvement Law. There are three important requirements for FOSHU approval. The first is scientific evidence of the efficacy, including clinical testing. The second is safety for consumption. The third is analytical determination of the effective component. At present there are 293 items approved as FOSHU. Most of the descriptions of foods under the FOSHU system are similar to the category of enhanced function claims of Codex. Under FNFC, 12 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. These claims are similar to the nutrient function claims approved by Codex in 1997. It is desirable that the Japanese administration and the food industry cooperate with ASEAN countries to work together in the development and promotion of nutrition and health claims on foods.

**Key words:** food with nutrient function claims, foods with health claims, FOSHU, functional food.

## Introduction

The ratio of people over 65 years is rapidly increasing in Japan compared with other developed countries. This year, the ratio in Japan is around 16%, similar to European countries such as the United Kingdom and France. But after 20 years this ratio is expected to increase to 25%, or one quarter of the total population, and will be much higher than other countries.

Expecting this increase in proportion of senior citizens in the country, the Ministry of Education started Research and Development projects on functionalities of food in 1984. In this project, the term 'functional food' was defined for the first time. Foods have three functions: the primary function is nutrition function; the secondary is sensory function, or sensory satisfaction, such as flavor and texture; and the tertiary function is the physiological function including regulation of biorhythm, neuro-system and immune-system and body defense. The 1984 project defined functional food as a food which has the tertiary function.

## Foods for specified health use

With the rapid increase of elderly people in the country, the health of this group of people has been given a great deal of attention. Several years ago, the Japanese government changed the name of 'elderly people's diseases' to 'lifestyle related diseases' for diseases such as diabetes, cardiovascular disease, hypertension and cancer. This means that these diseases are related not only to age but also lifestyle such as

diet, nutrition and physical exercise. Scientific evidence on the physiological functions of foods is increasing. To provide health information on foods to the people, the Ministry of Health and Welfare established a regulatory system for foods with health claims. Foods for Specified Health Use (FOSHU) was set up by the Ministry of Health and Welfare in 1991 to approve descriptions on a label regarding an effect of food on the human body.

Foods for Specified Health Use was enacted as a part of 'food for specified dietary use' under the Nutrition Improvement Law. Foods for Special Dietary Uses include foods for medical purpose, milk powder for pregnant and lactating women, formulated milk powder for infant and food for elderly person with difficulty in mastication or swallowing. There are three important requirements for FOSHU approval. The first is scientific evidence of the efficacy including clinical testing. The second is safety for consumption. The third is analytical determination of the effective component. At present there are 251 items approved as FOSHU.

## Foods with health claims

The Ministry of Health and Welfare enacted a new regulatory system in April 2001, 'Foods with health claims' (FHC).

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Foods with health claims consists of two categories: (i) FOSHU and (ii) 'Foods with nutrient function claims (FNFC)'. Twelve vitamins (Vitamin A, B<sub>1</sub>, B<sub>2</sub>, B<sub>6</sub>, B<sub>12</sub>, C, E, D, Biotin, Pantothenic acid, Folic acid, and Niacin) and two minerals (calcium and iron) are standardized as FNFC.

Nutrient function claims are as follows:

- Vitamin A ( $\beta$ -carotene) is a nutrient which helps to maintain vision in the dark.
- Vitamin A ( $\beta$ -carotene) is a nutrient which helps to maintain skin and mucosa healthy.
- Vitamin D is a nutrient which promotes the absorption of calcium in the gut intestine and aid in the development of bone.
- Vitamin E is a nutrient which helps to protect fat in the body from being oxidized and maintain the cell healthy.
- Vitamin B<sub>1</sub> is a nutrient which helps to produce energy from carbohydrate and maintain skin and mucosa healthy.
- Vitamin B<sub>2</sub> (niacin, Biotin, Pantothenic acid) is a nutrient which helps to maintain skin and mucosa healthy.
- Vitamin B<sub>6</sub> is a nutrient which helps to produce energy from protein and maintain skin and mucosa healthy.
- Folic acid is a nutrient which aids in the red blood cell formation and which contributes to the normal growth of the fetus.
- Vitamin B<sub>12</sub> is a nutrient which aids in the red blood cell formation.
- Vitamin D is a nutrient which promotes the absorption of calcium in the gut intestine and aids in the development of bone.
- Vitamin C is a nutrient which helps to maintain skin and mucosa healthy and have antioxidizing effect.
- Calcium is a nutrient which is necessary for the development of bone and teeth.
- Iron is a nutrient which is necessary in red blood cell formation.

The required attention and warning labelling are as follows:

- Every nutrient: Excess intake of this product neither cures your disease nor promotes your health. Take only the optimum amount.
- Vitamin A: Women who are pregnant or expecting should be careful of excess intake.
- Folic acid: Folic acid is a nutrient which contributes to the normal growth of the fetus but does not improve the growth of fetus with excessive intake.

The labelling of health claim should be based on scientific evidence bearing in mind harmonization with global standards. Codex proposed health claims consist of three categories: (i) Nutrient Function Claim; (ii) Enhanced Functional Claim; and (iii) Disease Risk Reduction Claim. These are defined by Codex as follows:

Nutrient Function Claim describes the physiological role of the nutrient in growth, development and normal functions of the body. Eg: 'Calcium aids in the development of strong bones and teeth'.

Enhanced Function Claims concern specific beneficial effects of the consumption of foods and their constituents on physiological functions or biological activities. For example, 'certain non-digestible oligosaccharides improve the growth of specific bacterial flora in the gut'.

Reduction of Disease Risk Claims relate the consumption of a food or food constituent to the reduced risk of developing a disease. For example, 'iron can help reduce the risk of anaemia. This food is a high source of iron.'

Most of the descriptions of foods under the Japanese FOSHU system are similar to the category of Enhanced Function Claims. Although these descriptions are permitted to mention an improved effect on a preliminary stage of a disease or a borderline condition due to an unbalanced nutrient state, a description which relates to the disease itself is not permitted. In the United States of America, the 1990 Nutrition Label Education Act (NLEA) approved mention of a specific disease name with FDA approval. Claims regarding reduction of disease risk have been proposed in LSI Europe and the Codex. The main concern with this claim is that it is difficult to differentiate 'reduction of disease risk' with 'prevention of diseases'. Further considerations are necessary before approval of the labelling of FOSHU in relation to specific diseases is permitted.

The newly established 'Food with Nutrient Function Claims' in Japan is similar to the Nutrient Function Claim approved by Codex in 1997.

Since April 2001, the form or shape of FOSHU was deregulated to accept forms such as capsules or tablets. The reason is that FOSHU can be evaluated individually so it is possible to evaluate the form or shape.

The code of practice on Health claims on food in UK proposes the following two types of Health Claims:

- 1 Generic Health Claims: based on well-established, generally accepted knowledge from evidence in the scientific literature and/or to recommendations from national or international public health bodies.
- 2 Innovative Health Claims: other than a generic health claim based on scientific evidence applied to existing or new foods.

The author proposed to the Japanese Health Authorities at the public hearing in 1999 for establishment of the new regulatory system that new categories should be classified as in Table 1. Nutrient Function Claims proposed by Codex are generic claims. Both Enhanced Function Claims and Disease Risk Reduction Claims are innovative claims. These innovative claims should be evaluated individually and approved by an expert committee like FOSHU in Japan. The generic claims could be standardized by the Government like FNFC.

## Conclusion

The labelling of health-related foods should be based on scientific evidence, always bearing in mind harmonization with global international standards. The newly established claims of FNFC in Japan is equivalent to the Nutrient Function Claims approved by Codex in 1997. Most descriptions of Japanese FOSHU are close to the category of the

**Table 1.** Classification of Foods for Specified Health Use (FOSHU) and Foods with Nutrient Function Claims

	Standard regulation type (Generic claims)	Individual evaluation type (Innovative claims)
Nutrient function claim	Codex 1997	FOSHU
Enhanced Function claim	Does not exist currently	FOSHU; Codex 1999
Risk Reduction of Diseases Claim	Does not exist currently	Codex 1999

Structure/Function Claim in America or the Enhanced Function Claims proposed by Codex and the EU project in collaboration with ILSI Europe.

Following the issuance of a federal regulation clarifying Structure and Function Claims in the United States in January 2000, many European countries have established their own standards. Japan has been ahead of the rest of the world in the definition, research and development of food functions and the regulatory system for food function claims. Several ASEAN countries have established nutrient claims

and are setting up nutrition and health claims. It is desirable that the Japanese administration and the food industry cooperate with ASEAN countries to work together in the development and promotion of nutrition and health claims on foods.

In the mean time, ILSI Japan will actively promote the newly proposed system and make further proposals to the authorities from a neutral standpoint for all issues related to health, nutrition and safety of food, based on scientific evidence.