Regulatory Systems of Health Claims in Japan

June, 2011
Consumer Affairs Agency
Food Labelling Division
Article 2 of the Consumer Basic Act sets out the state’s role to protect consumer’s right and support consumer’s independence in the society where the consumer takes a lead for life with safety and security. The mission of the CAA is:

- to protect and promote consumer’s interest and benefit
- to ensure the voluntary and rational choice of goods and services
- to ensure fair labelling of the goods which is closely related with life of consumers.
<I. Planning and Coordination>
Policy planning and coordination function for the resolution of consumer-related troubles.

<II. Enforcement>
Administrative work to enforce CAA's duties/jurisdictions
Relationships among Japanese Agricultural Standards Law (JAS), Food Sanitation Act, and Health Promotion Act

**JAS:**
Law Concerning Standardization and Proper Labelling of Agricultural and Forestry Products
- To help consumers for better food choice
  - Ingredient lists
  - Origin of foods

**Food Sanitation Act**
For safety and security of food
- Statement of identity
- Expiration date
- Storage condition
- Genetically modified foods
- Manufacturer’s name and address
- Food allergens
- Food additives

**Health Promotion Act** (Nutrition Labelling and Health Claims System)
For improvement of nutritional status and promotion of health
So-called "Health Foods"
- Dietary supplements
- Other health related products etc
- Prohibited to indicate Health Claims or Function Claims

Food With Nutrient Function Claims
- Vitamins & Minerals
- Allowed to indicate Claims for Nutrient Function

Food for Specified Health Uses (FOSHU)
- Dietary fibers
- Oligosaccharides
- Isoflavones etc
- Allowed to indicate Claims for Specified Dietary Uses

Food for Special Dietary Uses (FOSDU)
- Low protein food
- Lactose-free food
- Infant formula etc
- Allowed to indicate Claims for Special Dietary Uses

For patients
For pregnant and lactating women
For infants
For dysphagia patients

Pharmaceuticals
- Prescribed drugs
- Over-the-Counter drugs

Health Foods

Foods
Food With Nutrient Function Claims

12 Vitamins: Niacin, Pantothenic acid, Biotin, Vitamin A, Vitamin B₁, Vitamin B₂, Vitamin B₆, Vitamin B₁₂, Vitamin C, Vitamin D, Vitamin E, and Folic acid

5 Minerals: Zinc, Calcium, Iron, Copper, and Magnesium

Vitamin B₁
Vitamin B₁ is a nutritional element that assists in the production of energy from carbohydrates and in maintaining the health of the skin and mucous membranes.

Vitamin E
Vitamin E is a nutritional element that has antioxidant effects that prevent oxidation of lipids in the body and helps maintain cellular health.

Calcium
Calcium is a nutritional element necessary for bone and tooth formation.

Iron
Iron is a nutritional element necessary for red blood cell formation.
Food for Special Dietary Uses (FOSDU)

- approved to label that the food is appropriate for uses to maintain health and/or recover from diseases, particularly in infants, young children, pregnant and lactating women, and patients.

- Categories
  1. Medical uses for the diseased
  2. Formulas for pregnant and lactating women
  3. Infant formulas
  4. Foods for the elderly with difficulty in masticating or swallowing
  5. Foods for Specified Health Uses

- Requires approval from CAA in order to sell a food with FOSDU labelling

- Reviews
  • Standard approval process: checks with the established standards for approval
  • Individual approval process: reviews individually in cases of no established standards
Market share of Health Foods

«Market Growth of Food for Specified Health Uses (FOSHU) Products»

(Billion Yen)

1997 1999 2001 2003 2005 2007 2009
131 227 412 567 630 680 549

«Market Growth of other Health Foods (excluding FOSHU)»

(Billion Yen)

320 370 420 580 650 690 810 1,030 1,210 1,230 1,135 1,180
Procedure Flow for Food for Specified Health Uses (FOSHU)

Applicant

Consumer Affairs Agency Food Labelling Division

Consumer Commission
Assessment and Evaluation Group for Novel Food

Reviews efficacy

Food Safety Commission
Expert Assessment Group for Novel Food

Reviews safety

Consumer Commission
Assessment Committee for Novel Food

Reviews efficacy and safety comprehensively

Ministry of Health, Labour and Welfare

Checks whether the labelling violates Pharmaceutical Affairs Act

Consumer Affairs Agency Approval
Categories of Food for Specified Health Uses (FOSHU)

**FOSHU**
- Requires detailed review process with scientific evidence for each application.

**Standardized FOSHU**
- No requirement of detailed review process for food products meeting the established standards and specifications.
- Must be accompanied by sufficient accumulation of scientific evidence.
- For efficiency: short cut process for products whose safety of use already approved.

**Reduction of disease risk FOSHU**
- Requires detailed review process with scientific evidence for each application.
- Permitted for products whose ingredients clinically and nutritionally established to reduce a risk of certain disease (i.e., Calcium for Osteoporosis and Folic acid for neural tube defects).

**Qualified FOSHU**
- Requires detailed review process with scientific evidence for each application.
- Permitted for products with ingredients showing certain health effects but not reaching the established standards for FOSHU approval.
- Labelled as “Qualified Food for Specified Health Uses.”
Required conditions for approval

1. Improvement of dietary habits and contribution to health maintenance and enhancement can be expected by consuming the product.
2. Scientific evidence for the claimed health benefit is available.
3. Clinical and nutritional intake level of the product and/or its functional component is established.
4. The product and/or its functional component is safe for human consumption.
5. Following items regarding functional component are defined:
   a) Physical, chemical, and biological characterization and its methods
   b) Methods of qualitative and quantitative analytical determination
6. Nutrient constituent of same type of the food is not significantly changed
7. The food is intended to be consumed on a daily basis and not on rare occasions
8. The product or its functional component is not included in the medical drug list

Notification Shokuanhatsu 0201002, 2007 February 1
Food for Specified Health Uses (FOSHU)

- FOSHU refers to any food containing functional component which can provide positive effects on health condition or function and which is approved to make specific health claim on the food label.
- Currently, 955 foods are approved for FOSHU.

(※) e.g., lowers glucose level / support good bowel movement

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2011, April 1st

Trends of approved FOSHU

- Annual approval
- Total approval
## Approved Health Claims on FOSHU

<table>
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<tr>
<th>Health uses</th>
<th>Food category</th>
<th>Ingredients (Example)</th>
<th>Model Claim, statements</th>
<th>Number approved (As of 2011/04/01)</th>
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</table>
| GI function          | Table sugar   | Oligosaccharides                                     | ● Helps maintain good GI condition.  
                                                                 ● Helps improve bowel movement. | 350                               |
| Cholesterol level    | Powdered soft drink | Chitosan                      | ● Helps lower cholesterol level.                  | 142                               |
| Triacylglycerol      | Refined oil   | Medium-chain fatty acids                            | ● Helps resist body fat gain.                     | 70                                |
| Body fat             | Oolong tea    | Polyphenol                                         | ● For those concerned about body fat.             |                                    |
| Blood pressure       | Instant powder soup, candy | Peptides                                    | ● For those with high blood pressure.            | 120                               |
| Bone                 | Soft drink    | Soy isoflavone                                     | ● Promotes calcium absorption.  
                                                                 ● Supports bone health.           | 53                                |
| Teeth                | Chewing gum   | Mixture of Xylitol, Calcium Monohydrogen Phosphate and Fukuronori extract | ● Helps maintain strong and healthy teeth         | 79                                |
| Blood glucose level  | Soft drink, Instant miso soup | Indigestible dextrin | ● For those concerned about blood glucose level. | 141                               |
Consumer’s health, dietary habits, and food labelling

Patients (Diet-related diseases)
- Treatment

Border area
- Health maintenance and promotion
- Healthy people

Food for Specified Health Uses
- Food with Nutrient Function Claims
- Food with Health Claims

Dietary Reference intakes for Japanese
- Nutrition Labelling Standards

Participation
- Coordination

CODEX Alimentarius
- CODEX Committee on Food Labelling
- CODEX Committee on Nutrition and Foods for Special Dietary Uses

WHO Global Strategy on Diet, Physical Activity, and Health

Shows intakes of energy and core nutrients for the aim of health maintenance and promotion and diet-related disease prevention. (Ministry of Health, Labour and Welfare)
Prohibition of False and Misleading Labelling with respect to Health maintenance and Promotional effects

(Under Health Promotion Act, Articles 32-2 and 32-3)

No person shall sell or advertise any prepackaged product containing a label in a manner that
(1) substantially differs from the declared content or
(2) likely fall into confusion with respect to health maintenance or promotional effects

Advisory
Issued when the labelling may cause a significant negative impact on health maintenance and promotion of the public and/or on delivery of accurate information to the public.

Order
Issued upon failure to comply with Advisory.

Enforcement action (Penalty, inspection, administrative detention, imprisonment, etc) imposed upon failure to comply with Order.
Roundtable on Health Claims

**Time period:** From November 2009 to July 2010

**Areas of Discussion**
- Review current systems of Health Foods and identify areas in need of improvement
- Labelling systems of Food for Specified Health Uses (FOSHU) and other foods under Health Promotion Act
- Enforcement for appropriate labelling of Health Foods

**Final report released on August 27th, 2010**
- **FOSHU Approval**
  - Improve approval process (e.g., speed, clarity, and transparency)
  - Improve labelling presentation of information (e.g., clear, accurate, and understandable)
- **Regulation of so-called “Health Foods”**
  - Develop Guidelines for tightening regulatory control on False and misleading labelling
  - Collect scientific evidence on targeted nutritional components for further discussion about authorization
- **Further issues**
  - Transfer some responsibilities of Consumer Affairs Agency to Consumer Commission (e.g., Discussion on standards of suspension and expansion of regulation)
  - Start functional assessment of nutritional components found in foods