

Regulatory Framework on Nutrition Labelling and Health Claims in Japan – An Update

International Symposium on Health/Function Claims in Foods
with Focus on Nutrient Function Claims

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FOODs and PHARMACEUTICALs in JAPAN

FOODs 食品

Foods in General
一般食品

Foods with Health Claims
保健機能食品

Foods for Special Dietary
Uses 特別用途食品 1952

Foods for Specified
Health Uses
特定保健用食品 1991

Foods with Nutrient
Function Claims
栄養機能食品 2001

Foods with
Function Claims
機能性表示食品 2015

PHARMACEUTICALs 医薬品

Pharmaceuticals including OTC
and Quasi-pharmaceutical
products 含OTC及び医薬部外品

Progress in Regulatory Framework on Food Labelling and Nutrition/Health Claims in Japan

- 1947 : Food Sanitation Act (FSA) 食品衛生法** (Labelling Provisions)
- 1952 : Nutrition Improvement Act 栄養改善法**
: Foods for Special Dietary Uses (FOSDU) 特別用途食品
- 1984-86 : Studies on Functional Foods in Japan
– State of Art (Systematic Reviews)
- 1991 : Foods for Specified Health Uses (FOSHU) 特定保健用食品
- 1996 : Amendment of FSA to introduce Nutrition Labelling Standards 栄養表示基準**
- 2001 : Foods with Nutrient Function Claims (FNFC) 栄養機能食品
- 2002 : Health Promotion Act 健康増進法** (Labelling Provisions)
- 2004 : Amendment of FNFC
- 2005 : Amendment of FOSHU (Standardized, QHC & Disease Risk Reduction Claims)
- 2009 : Establishment of Consumer Affairs Agency (CAA) 消費者庁**
- 2011-12 : Roundtable Discussions for Unification of Food Labelling Provisions
- 2013 : Food Labelling Act 食品表示法**
- **2013 : The Council of Regulatory Reform 規制改革会議**
 - 2014 : Dietary Reference Intakes (DRIs) for Japanese 2015
: Research Project for Revision of DRIs/NRV and for further Amendment of FNFC
- 2015 : Food Labelling Standards 食品表示基準**
: Foods with Function Claims (FFC) 機能性表示食品
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Today's Topics (1)

- **Provisions on Food Labelling**
- **New Food Labelling Act 2013**
 - ✓ **A newly promulgated Act on Food Labelling**
 - ✓ **Introduction of Mandatory Nutrition Labelling**
- **Perspective of new Function Claims System**
 - ✓ Revision of Current FOSHU Procedures
 - ✓ Amendment of Nutrient Function Claims
 - ✓ Introduction of Self-determined Function Claims

FOODs and PHARMACEUTICALs in JAPAN

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Foods in General
一般食品

Incl. Nutr.
Content &
Comparati
ve Claims

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Towards New Food Labelling Act

Issues to be addressed:

1. **Different definitions among Acts (Food Sanitation, JAS and Health Promotion)**
2. Many/various notifications under the Acts
3. Voluntary nutrition labelling

One-year Roundtable Discussions on
“Unification of Food Labelling Provisions”
(From Sept. 2011 to Aug. 2012)

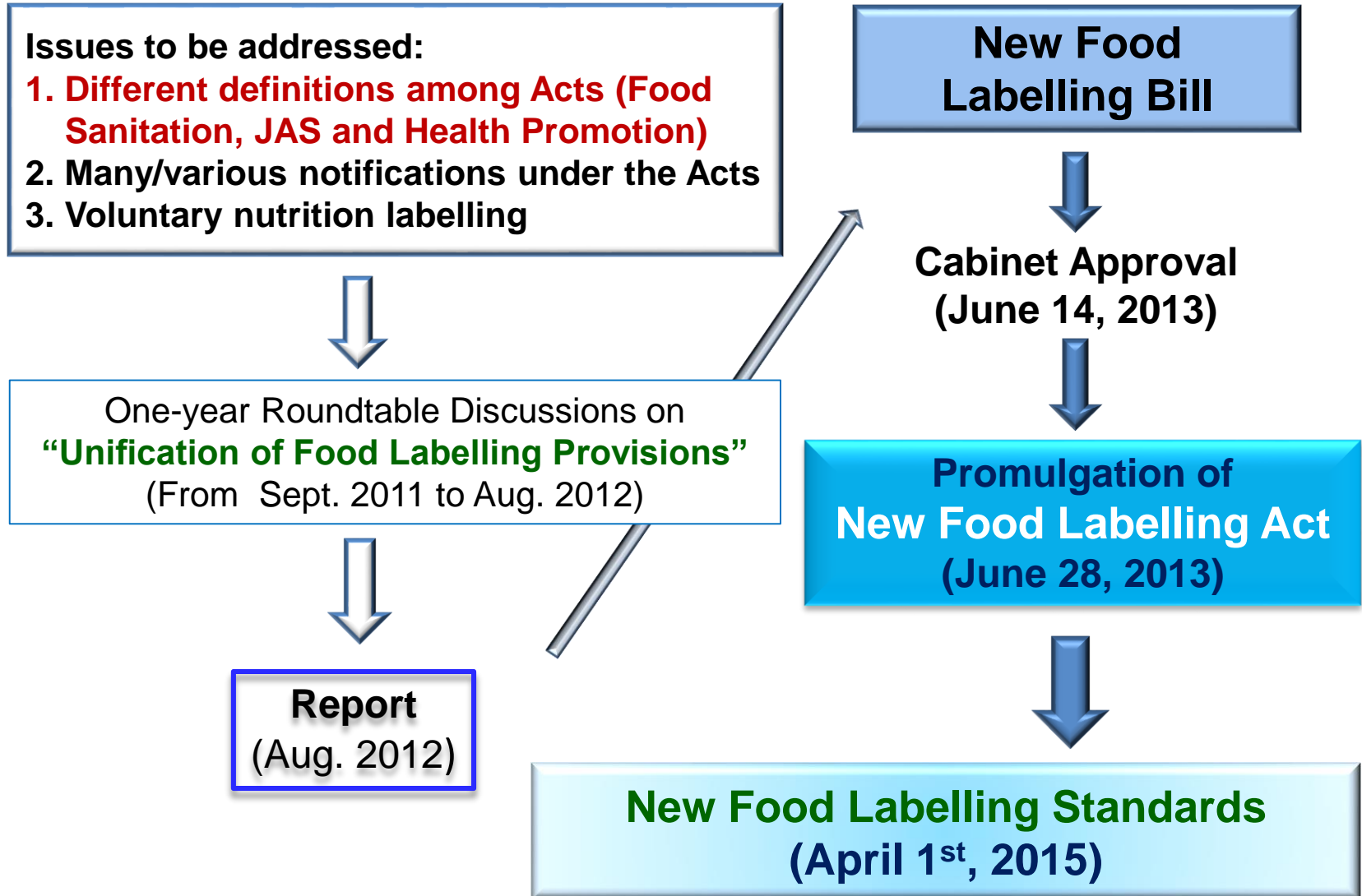
Report
(Aug. 2012)

**New Food
Labelling Bill**

Cabinet Approval
(June 14, 2013)

**Promulgation of
New Food Labelling Act**
(June 28, 2013)

New Food Labelling Standards
(April 1st, 2015)



Nutrition Labelling Formats

Mandatory:

Energy (kcal)
Protein (g)
Fat (g)
Carbohydrate (g)
Salt equivalent (g)

OR

Energy (kcal)
Protein (g)
Fat (g)

- Saturated fatty acids (g)
- n-3/n-6 fatty acids (g)
- Trans fatty acids (g)
- Cholesterol (mg)

Carbohydrate (g)

- Available carbohydrates (g)
- + Dietary fiber (g)
- Sugars (g)

Salt equivalent (g)
(Sodium mg)

3. NUTRIENT DECLARATION

(Guidelines on Nutrition Labelling: CAC/GL 2-1985)

3.1 Application of nutrient declaration

3.1.1 Nutrient declaration should be mandatory for all prepackaged foods for which nutrition or health claims, as defined in the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997), are made.

← 2012

3.1.2 Nutrient declaration should be mandatory for all other prepackaged foods except where national circumstances would not support such declarations. Certain foods may be exempted for example, on the basis of nutritional or dietary insignificance or small packaging.

3.2 Listing of nutrients

3.2.1 Where nutrient declaration is applied, the declaration of the following should be mandatory:

3.2.1.1 Energy value; and

3.2.1.2 The amounts of protein, available carbohydrate (i.e. dietary carbohydrate excluding dietary fibre), fat, saturated fat, sodium⁵ and total sugars; and

← 2011

3.2.1.3 The amount of any other nutrient for which a nutrition or health claim is made; and

3.2.1.4 The amount of any other nutrient considered to be relevant for maintaining a good nutritional status, as required by national legislation or national dietary guidelines⁶.

¹ See also the Annex for the General Principles for the Establishment of Nutrient Reference Values.

² When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds associated with polysaccharides in the plant cell walls. These compounds also may be measured by certain analytical method(s) for dietary fibre. However, such compounds are not included in the definition of dietary fibre if extracted and re-introduced into a food.

³ Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.

⁴ Codex Members may, for the purposes of nutrition labelling, review the inclusion of specific trans fatty acids (TFAs) in the definition of TFAs if new scientific data become available.

⁵ National authorities may decide to express the total amount of sodium in salt equivalents as "salt".

⁶ Countries where the level of intake of trans-fatty acids is a public health concern should consider the declaration of trans-fatty acids in nutrition labelling.

Nutrition Labelling in Japan: Summary

- **Legal Framework:**
 - Food Labelling Act (2013)**
 - Food Labelling Standards (2015)**
- **Application of Nutrient Declaration:**
 - Nutrient declaration became mandatory for all prepackaged foods as from April 1st, 2015 (5 years transitional periods).**
- **Listing of Nutrients:**
 - Energy values, Protein, Fat, Carbohydrate (or Available carbohydrate and Dietary fiber), Salt equivalent (Sodium) and amount of any other nutrients**
- **Comparative & Non-Addition Claims:**
 - Revised and newly adopted according to Codex Guidelines (CAC/GL 2-1985), amended in 2012/2013**
- **Specific Features of Presentation**
 - Tabular Format for Nutrient Content**
 - No Specific Nutrient Profiling or FOP Labelling applied**
- **Any food even such labelled as a nutritional / health supplement or a nutrient controlling food falls under this category, and those foods can make nutrition labelling and claims including nutrient content and comparative claims, but, cannot make any health claims.**

6. COMPARATIVE CLAIMS

(CAC/GL 2-1985)

Comparative claims should be permitted subject to the following conditions and based on the food as sold, taking into account further preparation required for consumption according to the instructions for use on the label:

- 6.1 The foods being compared should be different versions of the same food or similar foods. The foods being compared should be clearly identified.
- 6.2 A statement of the amount of difference in the energy value or nutrient content should be given. The following information should appear in close proximity to the comparative claim:
 - 6.2.1 The amount of difference related to the same quantity, expressed as a percentage, fraction, or an absolute amount. Full details of the comparison should be given.
 - 6.2.2 The identity of the food(s) to which the food is being compared. The food(s) should be described in such a manner that it (they) can be readily identified by consumers.
- 6.3.1 For comparative claims about energy or macronutrients and sodium, the comparison should be based on a relative difference of at least 25% in the energy value or the nutrient content respectively between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as “low” or as a “source” in the Table to these Guidelines.
- 6.3.2 For comparative claims about micronutrients other than sodium the comparison should be based on a difference of at least 10% of the NRV between the compared foods.
- 6.4 In addition to the conditions set out in Section 6.3, the content of trans fatty acids should not increase for foods carrying a comparison claim for decreased saturated fatty acids content.
- 6.5 The use of the word “light” or a synonymous claim should follow the criteria listed in Section 6.3 of these Guidelines and include an indication of the characteristics which make the food “light”.

2013

7. NON-ADDITION CLAIMS

(CAC/GL 2-1985)

7.1 Non-Addition of Sugars

2012

Claims regarding the non-addition of sugars to a food may be made provided the following conditions are met.

- (a) No sugars of any type have been added to the food (Examples: sucrose, glucose, honey, molasses, corn syrup, etc.);
- (b) The food contains no ingredients that contain sugars as an ingredient (Examples: jams, jellies, sweetened chocolate, sweetened fruit pieces, etc.);
- (c) The food contains no ingredients containing sugars that substitute for added sugars (Examples: non-reconstituted concentrated fruit juice, dried fruit paste, etc.); and
- (d) The sugars content of the food itself has not been increased above the amount contributed by the ingredients by some other means (Example: the use of enzymes to hydrolyse starches to release sugars).

7.2 Non-Addition of Sodium Salts

2013

Claims regarding the non-addition of sodium salts to a food, including “no added salt”, may be made provided the following conditions are met⁵.

- (a) The food contains no added sodium salts, including but not limited to sodium chloride, sodium tripolyphosphate;
- (b) The food contains no ingredients that contain added sodium salts, including but not limited to Worcestershire sauce, pickles, pepperoni, soya sauce, salted fish, fish sauce; and
- (c) The food contains no ingredients that contain sodium salts that are used to substitute for added salt, including but not limited to seaweed.

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Health Claims in Japan-1: Foods for Specified Health Uses (FOSHU)

Definition: Foods that contain constituents that have science based specific health benefits on physiological functions or biological activities of the body, and to contribute to preserving or improving health or to other specified health uses (1991).

➤ **Legal framework:**

Food Sanitation Act (1947)

Health Promotion Act (2002)

Food Labelling Act (2013)

Food Labelling Standards (2015)

➤ **Product-specific Claims**

➤ **Pre-marketing permission required for Claims based on Scientific Substantiation**

➤ **Applicable Food Type: Ordinary Prepackaged Foods and Tablet/Capsule Type Foods**



Documentation Required for FOSHU Application

1. Sample of the package labelling, including a claim on the label for which permission or approval is sought
2. Explanation of how the food contributes to the improvement of one's diet and the maintenance or enhancement of one's health
3. Recommended daily intake of the food and conditions for consumption (caution statement, in case of excessive consumption)
4. Clinical and nutritional documentation demonstrating the specified health uses and showing determination of the recommended daily intake for the food and its constituents concerned. Results should be statistically significant
5. Documentation demonstrating the safety of the food and its constituents concerned
6. Documentation on the stability of the food and its constituents concerned
7. Documentation of the physicochemical properties of the food's constituents concerned, and description of the analytic methods used
8. Results of qualitative and quantitative determination of the food's constituents concerned, and description of the analytic methods used
9. Results of tests determining the constituents concerned and nutrients, and energy value of the food
10. Description of the quality control system explaining the facilities, equipment, production methods used in manufacturing the food

Foods for Specified Health Uses (FOSHU)

1,210 Food Products Approved as of Dec. 31, 2015

Health Claims (Examples)	Functional Ingredients	No. of FOSHU	Share %
“Helps maintain good gastrointestinal condition”	Oligosaccharides, Dietary Fiber, Lactobacillus, Bifidobacterium	408	33.7
“Good for those who have high serum cholesterol / are concerned about serum triglycerides ”	Soy Protein, Peptides, MCTs, Dietary Fiber, Plant Sterol / Stanol (Esters), Coffee Polyphenols	301	24.9
“Good for those who have high blood glucose levels”	Dietary Fiber, Albumin, Polyphenols, L-Arabinose	210	17.4
“Good for those who have high blood pressure”	Peptides, Glucosides, Amino Acids	126	10.4
“Helps maintain dental health ”	Xylitol, Polyols, Tea Polyphenols, CPP-ACP	102	8.4
“Helps improve absorption of calcium minerals” “Good for those who have bones health”	CPP, CCM, Oligosaccharides, Heme Iron, MBP, vitamin k2 Soy Isoflavonoids	63	5.2

FOSHU Amended 2005, last amended 2015

1. **Standardized FOSHU:**

Standardized Claims for 3 Dietary Fibers and 6 Oligosaccharides for maintaining GI conditions and 1 Dietary Fiber for attenuation of post prandial Blood Glucose level.

No clinical efficacy study, but safety study on excessive consumption is still required on a product basis

2. **Qualified Health Claims for FOSHU:**

Evidence (supporting data) is suggestive, but not conclusive (not reaching the established standards for FOSHU approval)

3. **Reduction of Disease Risk Claims for FOSHU:**

Calcium and osteoporosis, Folic acid and Neural tube defects;

No clinical efficacy study, but safety study on excessive consumption is still required on a product basis

Foods for Specified Health Uses (FOSHU)

1,210 Food Products Approved as of Dec.31, 2015

Type of Approval	No. of Products	Share %
(Ordinary) FOSHU	1,059	87.5
Qualified Health Claims FOSHU	-	-
Standardized FOSHU	135	11.2
Reduction of Disease Risk Claims FOSHU	16	1.3
Total	1,210	100.0

Foods for Specified Health Uses (FOSHU) Current Procedures

Applicant

Efficacy Review

Consumer Affairs Agency: CAA

Safety Review

Consumer Commission: CC

Comprehensive
Review of
Efficacy and
Safety

Food Safety Commission: FSC

Consumer Commission: CC

**Ministry of Health, Labour
and Welfare: MHLW**

Check whether the
labelling / claim violates
Pharmaceuticals and
Devices Act

Report

**National Institute of Health
and Nutrition: NIHN**

Analysis of
Constituents
Concerned

Consumer Affairs Agency: CAA Approval

“The Council of Regulatory Reform”

formed under Cabinet Office (Jan.-Jun., 2013)

<Background>

- To respond to the public need to reduce noncommunicable disease burdens and promote health so as to live longer
- To lead the world as the longest longevity society



- **Revision of FOSHU Procedures**
- Amendment of Nutrient Function Claims
- Introduction of Self-determined Function Claims



Cabinet Approval: June 14, 2013

Foods for Specified Health Uses (FOSHU)

Revision of the Procedures

- **Claims are evaluated/approved individually by Consumer Affairs Agency**
- **Structure/function claims and reduction of disease risk claims are allowed**
- **Required scientific substantiation from human (intervention) studies, which may generally require large amounts of time and costs, to evaluate its safety and effectiveness for approval**
 - ⇒ **High burden especially for small and medium-sized industries**
- ⇒ **Revision of the Procedures – UNDERWAY –**

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Health Claims in Japan-2 : Nutrient Function Claims (FNFC)

Definition: Foods that are intended to provide or supplement necessary nutrients and to describe the physiological role of the nutrients in normal growth and development or preserving health of the body (2001).

- **Legal framework:**
 - Food Sanitation Act (1947)**
 - Health Promotion Act (2002)**
 - Food Labelling Act (2013)**
 - Food Labelling Standards (2015)**
- **MHLW Pre-authorized Nutrient Function Claims**
- **Min. & max. daily dose levels for each nutrient specified**
- **No pre-marketing permission nor notification required**

Authorized Nutrient Function Claims (1)

NUTRIENTS	Min./Max. per Day	NUTRIENT FUNCTION CLAIMS
Vitamin A	231/600 (µg)	A nutrient which helps maintain vision at night A nutrient which helps maintain healthy skin and mucosa
Vitamin D	1.60/5.0 (µg)	A nutrient which promotes absorption of calcium and aids in the development of bone
Vitamin E	1.89/150 (mg)	A nutrient which helps protect fat in the body from being oxidized and helps maintain healthy cells
Vitamin B1	0.36/25 (mg)	A nutrient which helps produce energy from carbohydrate and helps maintain healthy skin and mucosa
Vitamin B2	0.42/12 (mg)	
Niacin	3.9/60 (µg)	

Authorized Nutrient Function Claims (2)

NUTRIENTS	Min./Max. per Day	NUTRIENT FUNCTION CLAIMS
Biotin	15/500 (µg)	A nutrient which helps produce energy from carbohydrate and helps maintain healthy skin and mucosa
Pantothenic acid	1.44/30 (mg)	
Vitamin B6	0.39/10 (mg)	A nutrient which helps produce energy from protein and helps maintain healthy skin and mucosa
Folic acid	72/200 (µg)	A nutrient which aids in red blood cell formation A nutrient which contributes to the normal growth of a fetus
Vitamin B12	0.72/60 (µg)	A nutrient which aids in red blood cell formation
Vitamin C	30/1,000 (mg)	A nutrient which helps to maintain healthy skin and mucosa, and has anti-oxidizing effect

Authorized Nutrient Function Claims (3)

NUTRIENTS	Min./Max. per Day	NUTRIENT FUNCTION CLAIMS
Calcium	204/600 (mg)	A nutrient which is necessary in the development of bone and teeth
Iron	2.04/10 (mg)	A nutrient which is necessary for red blood cell formation
Zinc	2.64/15 (mg)	<p>A nutrient which is necessary to maintain the normal function of the sense of taste</p> <p>A nutrient which helps maintain healthy skin and mucosa</p> <p>A nutrient which is involved in the metabolism of protein and nucleic acid, and helps maintain good health</p>
Copper	0.27/6.0 (mg)	<p>A nutrient which helps red blood cell formation</p> <p>A nutrient which helps normal function of various enzymes in the body and development of bone</p>
Magnesium	96/300 (mg)	<p>A nutrient which is necessary in the development of bone and teeth</p> <p>A nutrient which helps normal function of various enzymes, helps generate energy, and is necessary to maintain normal blood circulation</p>

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- Revision of FOSHU Procedures
- **Amendment of Nutrient Function Claims**
- Introduction of Self-determined Function Claims



Cabinet Approval: June 14, 2013

Criteria for Consideration for Expansion of Foods with Nutrient Function Claims

Criteria for Consideration for Expansion of Foods with Nutrient Function Claims	Not Applicable	YES, Applicable
<p>1. Those which have physiological role in growth, development and normal functions of the body and a deficit of which will cause characteristic bio-chemical or physiological effects to the public health</p>	<p>Cholesterol, Sugars, Sodium, Manganese, Selenium, Chromium, Molybdenum, Phosphorous</p>	
<p>2. Those for which DRIs (NRVs) have been established and the average intake levels of which for Japanese have been surveyed</p>		
<p>3. Those for which there is no concern in excessive amounts of intake that may increase the risk of adverse health-related effect</p>	<p>Iodine, n-6 Fatty Acids Dietary Fiber</p>	<p>Vitamin K, Potassium n-3 Fatty Acids</p>
<p>4. Those which may help maintain good health, by supplementation to the daily diet</p>		

Newly Authorized Nutrient Function Claims (as of 2015.04.01)

NUTRIENTS	Min./Max. per Day	NUTRIENT FUNCTION CLAIMS
Vitamin K	45/150 (μ g)	A nutrient which helps maintain normal coagulation of blood
Potassium	840/2,800 (mg)	A nutrient which is necessary to maintain normal blood pressure (Tablet or capsule types of foods are not applicable)
n-3 Fatty acids	0.6/2.0 (g)	Nutrients which help maintain healthy skin

Amendment of Foods with Nutrient Function Claims

- Pre-authorized claims
- Self-determined according to the pre-set standards
- No pre-marketing authorization nor notification required
- Limited to claims only for 12 vitamins (A, D, E, B1, B2, Niacin, Biotin, Pantothenic acid, B6, Folic acid, B12, C) and 5 minerals (Ca, Fe, Zn, Cu, Mg)
 - ⇒ Vitamin K, Potassium and n-3 Fatty acids are added (2015.04.01)
 - ⇒ Applicable Food Type: Ordinary Prepackaged, Tablet/Capsule Type Foods and Fresh Produce

8. HEALTH CLAIMS (Guidelines for Use of Nutrition and Health Claims : CAC/GL 23-1997)

8.1 Health claims should be permitted provided that all of the following conditions are met:

8.1.1 Health claims must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health as recognized by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available.⁶ The health claim must consist of two parts:

- 1) Information on the physiological role of the nutrient or on an accepted diet-health relationship; followed by
- 2) Information on the composition of the product relevant to the physiological role of the nutrient or the accepted diet-health relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food.

8.1.2 Any health claim must be accepted by or be acceptable to the competent authorities of the country where the product is sold.

8.1.3 The claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituent in the context of a healthy diet.

8.1.4 If the claimed benefit is attributed to a constituent in the food, for which a Nutrient Reference value is established, the food in question should be:

- (i) a source of or high in the constituent in the case where increased consumption is recommended; or,
- (ii) low in, reduced in, or free of the constituent in the case where reduced consumption is recommended.

Where applicable, the conditions for nutrient content claims and comparative claims will be used to determine the levels for "high", "low", "reduced", and "free".

8.1.5 Only those essential nutrients for which a Nutrient Reference Value (NRV) has been established in the *Codex Guidelines on Nutrition Labelling* or those nutrients which are mentioned in officially recognized dietary guidelines of the national authority having jurisdiction, should be the subject of a nutrient function claim.

8.2 Health claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health-related condition. The health claim should not be made if it encourages or condones excessive consumption of any food or disparages good dietary practice.

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Cabinet Approval: June 14, 2013

**Proposals from “The Council of Regulatory Reform”:
June 5, 2013**

Cabinet Approval: June 14, 2013



- **A new system** under which **Processed Foods and Fresh Produce in addition to Supplement type of products** can make function claims should be developed.
- **Food Business Operators are responsible for safety assessment and scientific substantiation of the function claims**
- **Food Labelling Act (Food Labelling Standards)** came into effective on **April 1st, 2015.**

Health Claims in Japan-3 : Foods with Function Claims (FFC)

- ◆ **Food business operators, on their own responsibility, are required to evaluate the safety and effectiveness in accordance with rules prescribed by the Guidelines.**
(Guidelines on Notification of Food with Function Claims, 2016.03.31rev.)
- ◆ **They must then submit the information to the Consumer Affairs Agency (CAA) 60 days prior to marketing the product.** *(Notification number provided from CAA)*
- ◆ **Submitted documents are disclosed on the CAA website**
(<https://www.fld.caa.go.jp/caaks/cssc01/>)
- ◆ **Consumers can check the product information on how the safety and effectiveness of the product is ensured before the product is placed on market** *(CAA website above).*
- ◆ **Applicable Food Type: Ordinary Prepackaged Foods, Tablet/Capsule Type Foods and Fresh Produce**

Process for Submission and Marketing the Product

Food Business Operator : Submission

CAA review the submitted documents.

In cases where deficiencies are identified, a notification and related documents are returned

CAA : Issue of Notification Number

Related information is disclosed on the CAA website.

Marketing the Product with Function Claims with a Notification Number

- ✓ 60 days prior to the targeted launch date, a completed notification and related documents must be submitted to CAA
- ✓ Following documents must be submitted to CAA:
 1. Details of the product labelling
 2. Basic information, such as name of the Food Business Operator
 3. Scientific evidence for Safety and Effectiveness
 4. Information for Production and QC
 5. System to collect adverse health events
 6. Other required information
- ✓ Putting the product on the market is not the end of the process. Information about adverse health events must be collected continuously after introduction of the product on the market

3.1. Process for the substantiation of health claims

The systematic review of the scientific evidence for health claims by competent national authorities takes into account the general principles for substantiation. Such a process typically includes the following steps:

- (a) Identify the proposed relationship between the food or food constituent and the health effect;
- (b) Identify appropriate valid measurements for the food or food constituent and for the health effect;
- (c) Identify and categorise all the relevant scientific data;
- (d) Assess the quality of and interpret each relevant scientific study;
- (e) Evaluate the totality of the available relevant scientific data, weigh the evidence across studies and determine if, and under what circumstances, a claimed relationship is substantiated.

3.2. Criteria for the substantiation of health claims

3.2.1 The following criteria are applicable to the three types of health claims as defined in section 2.2 of the Guidelines for use of nutrition and health claims:

- (a) Health claims should primarily be based on evidence provided by well-designed human intervention studies. Human observational studies are not generally sufficient *per se* to substantiate a health claim but where relevant they may contribute to the totality of evidence. Animal model studies, *ex vivo* or *in vitro* data may be provided as supporting knowledge base for the relationship between the food or food constituent and the health effect but cannot be considered as sufficient *per se* to substantiate any type of health claim.
- (b) The totality of the evidence, including unpublished data where appropriate, should be identified and reviewed, including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear.
- (c) Evidence based on human studies should demonstrate a consistent association between the food or food constituent and the health effect, with little or no evidence to the contrary.

Foods with Function Claims Notified

(Notification number issued, 2015/04/13–2016/05/02, as of 2016/06/30)

Food Category	Number of Products	Share %
Dietary Supplement Types (Capsules, Tablets, etc.)	153	47
Ordinary Prepackaged Foods	168	52
Fresh Produce (Agricultural, Fishery Products)	3	1
TOTAL	324	100

消費者の
皆様へ

For
Consumers

What are "Foods with Function Claims"?

The new system of Foods with Function Claims has been launched. This is different from Foods for Specified Health Uses and Foods with Nutrient Function Claims.



http://www.caa.go.jp/foods/pdf/151224_1.pdf
http://www.caa.go.jp/foods/pgf/151224_2.pdf

食品関連
事業者の
方へ

Guidance
for
Industry

The system of "Foods with Function Claims" has been launched!

Before considering
development and sale of products



FOODs and PHARMACEUTICALs in JAPAN

FOODs 食品

Foods in General
一般食品

Foods with Health Claims
保健機能食品

Foods for Special Dietary
Uses 特別用途食品

Foods for Specified
Health Uses
特定保健用食品

Foods with Nutrient
Function Claims
栄養機能食品

Foods with
Function Claims
機能性表示食品

PHARMACEUTICALs 医薬品

Pharmaceuticals including OTC
and Quasi-pharmaceutical
products 含OTC及び医薬部外品

Foods for Special Dietary Uses (FOSDU)

(64 products as of 2016.03.24)

(Regulated under the Health Promotion Act (2002), renamed from the Nutrition Improvement Act (1952), Last amended 2016)

➤ Medical Uses for the Diseased (37)

- Low protein, Allergy-free,
Lactose-free and
Comprehensive Food
Products

- For those with certain illness

➤ Formulas for Pregnant and Lactating Women (1)

➤ Infant Formulas (14)

➤ Foods for those with Difficulty in Swallowing (12)

● Health Promotion
Act 2002, Last
amended 2016

● Standardized
Formula and
Claims

● Product-specific
Approval



FOODs and PHARMACEUTICALs in JAPAN

FOODs 食品

Foods in General
一般食品

Foods with Health Claims
保健機能食品

Foods for Special Dietary Uses 特別用途食品
Medicinal Claims

Foods for Specified Health Uses
Other Function & Reduction of Disease Risk Claims

Foods with Nutrient Function Claims
Nutrient Function Claims

Foods with Function Claims
Other Function Claims

PHARMACEUTICALs 医薬品

Pharmaceuticals including OTC and Quasi-pharmaceutical products 含OTC及び医薬部外品

2. Definitions: 2.2 Health Claim (adopted in 2004)

(CAC/GL 23-1997)

2.2.1 Nutrient function claims – a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.

Example:

“Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A.”

2.2.2 Other function claims – These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

Examples:

“Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A.”

2.2.3 Reduction of disease risk claims – Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

Examples:

“A healthful diet low in nutrient or substance A may reduce the risk of disease D.
Food X is low in nutrient or substance A.”

“A healthful diet rich in nutrient or substance A may reduce the risk of disease D.
Food X is high in nutrient or substance A.”

**Thank you very much
for your attention !**