Example of health claims on food labels

(ตัวอย่าง การกล่าวอ้างทางสุขภาพบนผลิตภัณฑ์อาหาร)

Country	Regulatory body
➢ USA	FDA (U.S. Food and Drug Administration)
➢ EU	EFSA (European Food Safety Authority) and the European Commission (EC) in conjunction with the Member States
➢ Japan	Ministry of Health Labour and Welfare (MHLW) and the Consumer Affairs Agency (CAA)
➢ Taiwan	Taiwan Food and Drug Administration (FDA), Ministry of Health and Welfare

USA- Health Claims

HOW DIETARY SUPPLEMENTS ARE REGULATED

Dietary Supplements must be manufactured under the current Good Manufacturing Practices *(DSHEA Sec. 9)*.

Labeling must bear a Supplement Facts table, including the name and quantity of each dietary ingredient *(DSHEA Sec. 7)*.

Labeling may bear statements of nutritional support. Such statements must be adequately substantiated and may not claim to diagnose, mitigate, treat, cure, or prevent any disease. The manufacturer should notify the FDA of any such statements within 30 days of first marketing *(DSHEA Sec. 6)*.

False or misleading claims are prohibited *(FFDCA Sec. 403)*.

Health claims must be pre-approved by FDA *(NLEA)*.

Disclosure of key allergens is required *(Food Allergen Labeling Act)*.

Dietary Supplements may only be intended for oral ingestion. They may not be represented for use as a conventional food and may not contain any drug substances *(DSHEA Sec. 3)*.

Safety data regarding "new dietary ingredients" not previously present in the food supply must be submitted to FDA at least 75 days prior to marketing *(DSHEA Sec. 8)*.

All ingredients must be safe for consumption *(DSHEA Sec. 4 and Food Additive Regulations)*.

Accurate disclosure of contents is required *(Fair Packaging & Labeling Act)*.

The label must state that the product is a "Dietary Supplement" *(DSHEA Sec. 7 (a))*.

Supplement manufacturers must register each facility with FDA *(Bioterrorism Act)*.

Labeling must bear a phone number or address through which consumers can report serious adverse events *(Dietary Supplement and Nonprescription Drug Consumer Protection Act)*.

Lot number control is required to enable product traceability *(Dietary Supplements Good Manufacturing Practices)*.

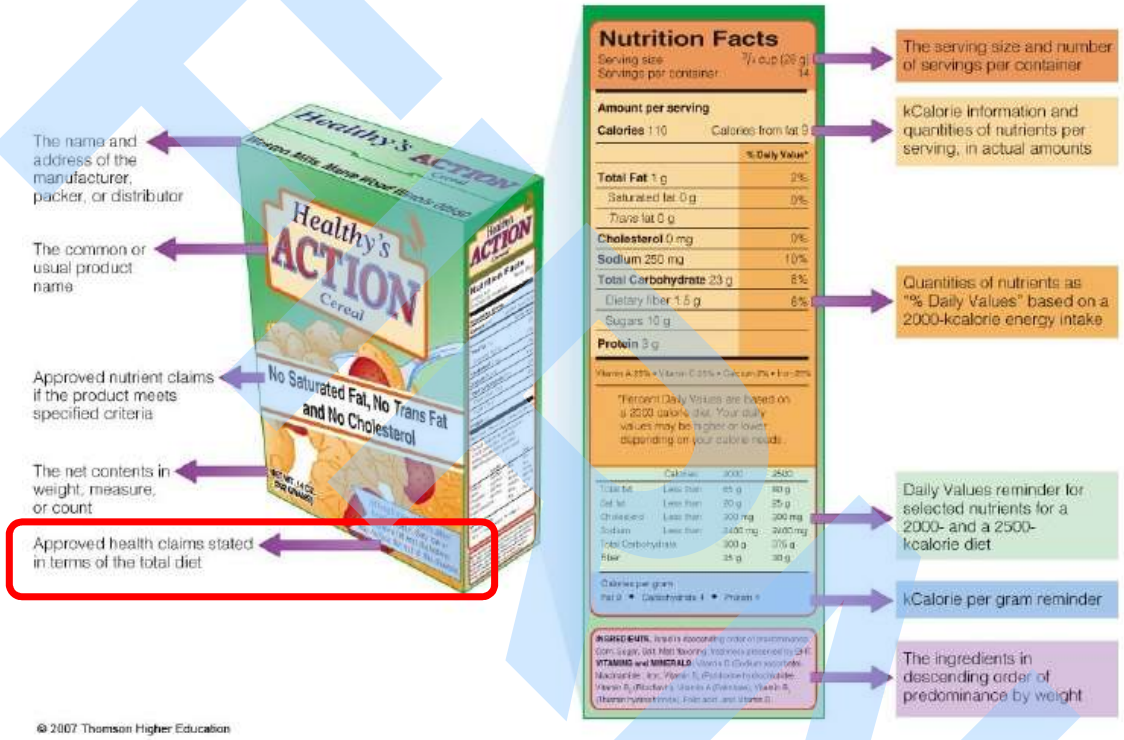
Labels bearing statements of nutritional support must prominently display a prescribed advisory statement *(DSHEA Sec. 6)*.

LAWS THAT DIRECTLY IMPACT DIETARY SUPPLEMENTS

- DSHEA: Dietary Supplement Health and Education Act
- NLEA: Nutrition Labeling and Education Act
- FFDCA: Federal Food, Drug, and Cosmetic Act
- Fair Packaging and Labeling Act
- Bioterrorism Act
- Food Allergen Labeling Act
- Dietary Supplement and Nonprescription Drug Consumer Protection Act

The United States Pharmacopeia (USP) sets official standards for dietary supplements. For products carrying the USP mark, USP has tested and verified ingredients, potency, and manufacturing processes. A supplement must conform to the specifications of an official compendium, if so represented. Otherwise, a supplement must meet the identity, strength, purity and composition as represented *(DSHEA Sec. 7(a))*.

http://www.naturemade.com/about-nature-made/accountability/how-supplements-are-regulated#xMFKHH8rEVMvBI1M.97



Food Labels Ingredient list Serving sizes Nutrition facts –Daily Values Copyright 2005 Wadsworth Group, a division of Thomson Learning

Health Claims

1) **NLEA Authorized Health Claims.** The Nutrition Labeling and Education Act of 1990 (NLEA) provides for the use in food labeling of health claims that characterize a relationship between a food, a food component, or dietary ingredient and risk of a disease (for example, "adequate calcium throughout life may reduce the risk of osteoporosis"), provided the claims meet certain criteria and are authorized by an FDA regulation. FDA authorizes these types of health claims based on an extensive review of the scientific literature, generally as a result of the submission of a health claim petition, using the significant scientific agreement standard to determine whether the substance/disease relationship is well established.

2) **Health Claims Based on Authoritative Statements.** The Food and Drug Administration Modernization Act of 1997 (FDAMA) provides a second way for the use of a health claim in food labeling to be authorized. Under FDAMA, a new health claim can be authorized by submitting a notification to FDA of a claim based on an "authoritative statement" from certain scientific bodies of the U.S. Government or the National Academy of Sciences. FDA has issued guidance on how a firm can submit such a notification and make use of authoritative statement-based health claims. This guidance can be found at: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body. FDAMA does not include dietary supplements in the provisions for health claims based on authoritative statements. Consequently, this method of oversight for health claims cannot be used for dietary supplements at this time. Examples of health claims based on authoritative statements may also be found at: A Food Labeling Guide - Appendix C: Health Claims.

3) **Qualified Health Claims.** FDA's Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements describes the agency's process for considering petitions for the use of a qualified health claim in food labeling. When there is emerging evidence for a relationship between a food substance (a food, food component, or dietary ingredient) and reduced risk of a disease or health-related condition, but the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation, the qualified health claim petition process provides a mechanism to request that FDA review the scientific evidence and exercise enforcement discretion to permit the use of the qualified claim in food labeling. If, after evaluating the quality and strength of the totality of the scientific evidence, FDA finds that credible evidence supports the claim, the agency issues a letter outlining the circumstances under which it intends to consider the exercise of enforcement discretion for use of the claim in food labeling. Qualifying language is included as part of the claim to indicate that the evidence supporting the claim is limited. Although FDA's letters of enforcement discretion are issued to the petitioner requesting the qualified health claim, the qualified claims are available for use on any food or dietary supplement product meeting the enforcement discretion conditions specified in the letter. FDA has issued guidance on interim procedures for qualified health claims (see Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements) and on the scientific criteria the agency uses in conducting health claim evaluations (see Evidence-Based Review System for the Scientific Evaluation of Health Claims). Qualified health claim petitions that are submitted to FDA will be available for public review and comment. A listing of petitions open for public comment is at the FDA Dockets Management website. A summary of the qualified health claims authorized by FDA may be found at: Qualified Health Claims Subject to Enforcement Discretion. For more information see Qualified Health Claims.

1.) NLEA Authorized Health Claims

21 CFR Part 101, Subpart E - Specific Requirements for Health Claims

1) § 101.72 Health claims: calcium, vitamin D, and osteoporosis.
2) § 101.73 Health claims: dietary lipids and cancer.
3) § 101.74 Health claims: sodium and hypertension.
4) § 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.
5) § 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer.
6) § 101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.
7) § 101.78 Health claims: fruits and vegetables and cancer.
8) § 101.79 Health claims: Folate and neural tube defects.
9) § 101.80 Health claims: dietary noncariogenic carbohydrate sweeteners and dental caries.
10) § 101.81 Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD).
11) § 101.82 Health claims: Soy protein and risk of coronary heart disease (CHD).
12) § 101.83 Health claims: plant sterol/stanol esters and risk of coronary heart disease (CHD).

§ 101.81 Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD).

Approved health claim statements

"3 grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the risk of heart disease"

§ 101.82 Health claims: Soy protein and risk of coronary heart disease (CHD).

Approved health claim statements

"Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease"

§ 101.79 Health claims: Folate and neural tube defects.

Approved health claim statements

"Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect"

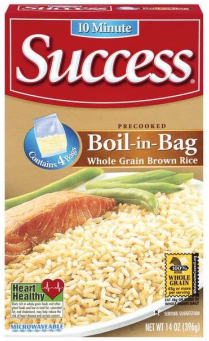
Approved health claim statements

"Women who consume healthful diets with adequate folate may reduce their risk of having a child with birth defects of the brain or spinal cord. Folate intake should not exceed 250% of the DV (1,000 mcg)"

2.) **FDA Modernization Act (FDAMA) Claims**

- Whole Grain Foods and the Risk of Heart Disease and Certain Cancers
  (Docket ID FDA-2008Q-0270)
- Potassium and the Risk of High Blood Pressure and Stroke
  (Docket No. 2000Q-1582)
- Fluoridated Water and Reduced Risk of Dental Carries
  (Docket No. 2006Q-0418)
- Saturated Fat, Cholesterol, and Trans Fat, and the Risk of Heart Disease
  (Docket No. 2006Q-0458)
- Substitution of Saturated Fat with Unsaturated Fatty Acids and Risk of Heart Disease
  (Docket No. 2007Q-0192)

FDAMA approved statements—Whole grains



Approved health claim statements

"Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and certain cancers"

FDAMA approved statements—Potassium

Approved health claim statements

"Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke."

3.) **Qualified Health Claims**

Qualified Health Claims About Atopic Dermatitis Risk

- 100% Whey-Protein Partially Hydrolyzed Infant Formula and Reduced Risk of Atopic Dermatitis

Qualified Claims About Cancer Risk

- Tomatoes and/or Tomato Sauce & Prostate, Ovarian, Gastric, and Pancreatic Cancers
- Calcium and Colon/Rectal Cancer & Calcium and Recurrent Colon/Rectal Polyps
- Green Tea & Cancer
- Selenium & Cancer
- Antioxidant Vitamins & Cancer

Qualified Claims About Cardiovascular Disease Risk

- Nuts & Heart Disease
- Walnuts & Heart Disease
- Omega-3 Fatty Acids & Coronary Heart Disease
- B Vitamins & Vascular Disease
- Monounsaturated Fatty Acids From Olive Oil and Coronary Heart Disease
- Unsaturated Fatty Acids from Canola Oil & Coronary Heart Disease
- Corn Oil & Heart Disease

Qualified Claims About Cognitive Function

- Phosphatidylserine & Cognitive Dysfunction and Dementia

Qualified Claims About Diabetes

- Psyllium Husk & Diabetes NEW
- Chromium Picolinate & Diabetes

Qualified Claims About Hypertension

- Calcium & Hypertension, Pregnancy-Induced Hypertension, and Preeclampsia

Qualified Claims About Neural Tube Birth Defects

- 0.8 mg Folic Acid & Neural Tube Birth Defects

Nuts & Heart Disease

Approved health claim statements

"Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts [such as name of specific nut] as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. [See nutrition information for fat content.]"

Types of nuts eligible for this claim are restricted to almonds, hazelnuts, peanuts, pecans, some pine nuts, pistachio nuts, and walnuts. Types of nuts on which the health claim may be based is restricted to those nuts that were specifically included in the health claim petition, but that do not exceed 4 g saturated fat per 50 g of nuts.

Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease

Approved health claim statements

"Limited and not conclusive scientific evidence suggests that eating about 1 ½ tablespoons (19 grams) of canola oil daily may reduce the risk of coronary heart disease due to the unsaturated fat content in canola oil. To achieve this possible benefit, canola oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day"

Corn Oil and Reduced Risk of Heart Disease

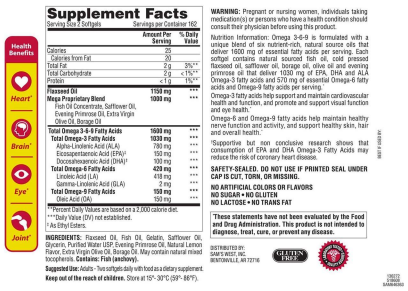
Approved health claim statements

"Very limited and preliminary scientific evidence suggests that eating about 1 tablespoon (16 grams) of corn oil daily may reduce the risk of heart disease due to the unsaturated fat content in corn oil. FDA concludes that there is little scientific evidence supporting this claim. To achieve this possible benefit, corn oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of corn oil"

Omega-3 Fatty Acids & Coronary Heart Disease

Approved health claim statements

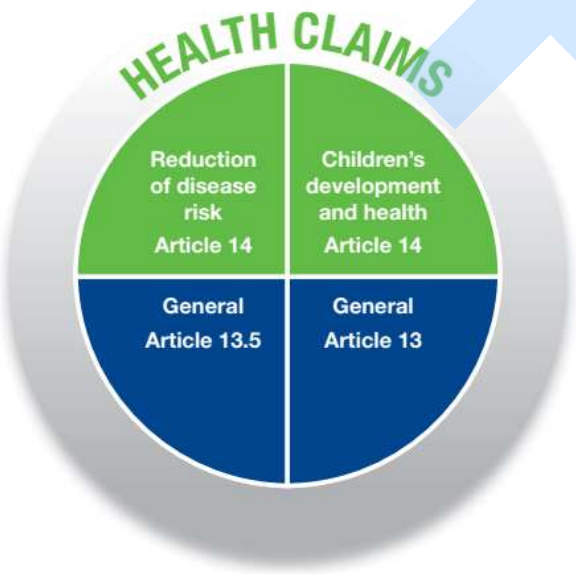
"Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]"



Conventional foods and dietary supplements that contain EPA and DHA omega-3 fatty acids.

EU- Health Claims

Health Claims



Claim	Type of Claim
Article 14 health claims	Reduction of disease risk claims and **<Article 14.1 (a)>**
	Claims referring to children's development and health. **<Article 14.1 (b)>**
Article 13(5) health claims	Health claims other than disease risk reduction and children's development and health. These claims are based on newly developed scientific evidence and may include a request for the protection of proprietary data.
Article 13 health claims	Health claims other than disease risk reduction and children's development and health. Also known as 'General health claims', these claims relate to the effect of a substance on a body function.

Information on Nutrition and Health Claims (April 2016)

European Commission

TABLE 1. Examples of European Union health claims under Regulation (EC) No 1924/2006

Article	Claim
Article 13.1	Beta-glucans contribute to the maintenance of normal blood cholesterol levels.
Article 13.5 (proprietary)	Water-Soluble Tomato Concentrate (WSTC) I and II helps maintain normal platelet aggregation, which contributes to healthy blood flow[a]
Article 14.1a (disease risk factor reduction)	Barley beta-glucans have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease[b]
Article 14.1b (children)	Docosahexaenoic acid (DHA) maternal intake contributes to the normal brain development of the fetus and breastfed infants.

[a] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:336:0055:0057:EN:PDF.
[b] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:310:0038:0040:EN:PDF.

Baldwin and Poon (2014)

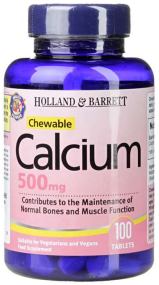
Article 13.1 - Function claims : Based on generally accepted scientific evidence

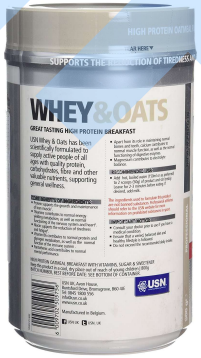
Authorized health claim statements

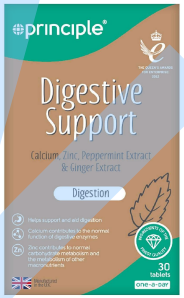
"**Calcium** is needed for the maintenance of normal bones"

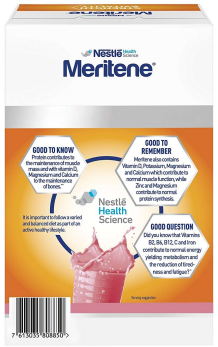
"**Calcium** contributes to normal muscle function"

"**Calcium** contributes to the normal function of digestive enzymes"









Article 13.1 - Function claims : Based on generally accepted scientific evidence

Authorized health claim statements

“Biotin contributes to the maintenance of normal hair”

“Biotin contributes to the maintenance of normal skin”

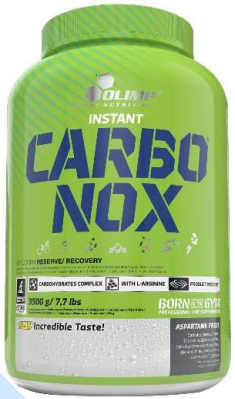
“Biotin contributes to normal energy-yielding metabolism”

“Biotin contributes to normal functioning of the nervous system”

Article 13.5 - Function claims : Based on newly developed scientific data

Authorized health claim statements

“Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle”



Authorized health claim statements

“Consumption of foods/drinks containing <name of all used **non-digestible carbohydrates**> instead of sugars induces a lower blood glucose rise after their consumption compared to sugar-containing foods/drinks”

Authorized health claim statements

“**Sugar beet fibre** contributes to an increase in faecal bulk”

Article 14.1(a) - Reduction of disease risk claims

Authorized health claim statements

"**Oat beta-glucan** has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"

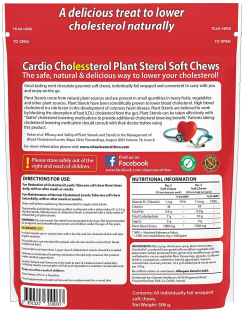
Article 14.1(a) - Reduction of disease risk claims

Authorized health claim statements

"**Plant stanol esters** have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"

"**Plant sterols and plant stanol esters** have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"

Plant stanol ester – Approved health claim in EU
Based on a scientific evaluation by the European Food Safety Authority EFSA, the European Commission has authorized an Article 14 health claim (Disease risk reduction health claim) for Plant stanol ester. Article 14 health claims are the strongest possible health claims for foods.

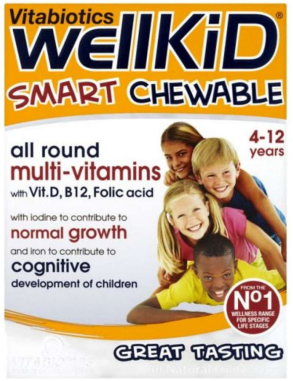


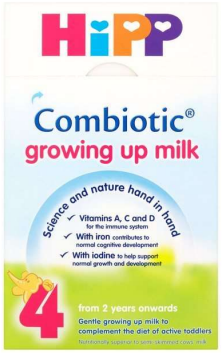
Article 14.1(b) - Claims on growth and development of children

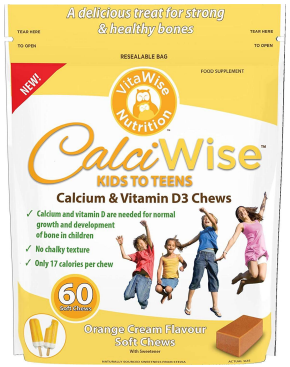
Authorized health claim statements

"**Iodine** contributes to the normal growth of children"

"**Iron** contributes to normal cognitive development of children"







"**Calcium and vitamin D** are needed for normal growth and development of bone in children"

Japan- Health Claims

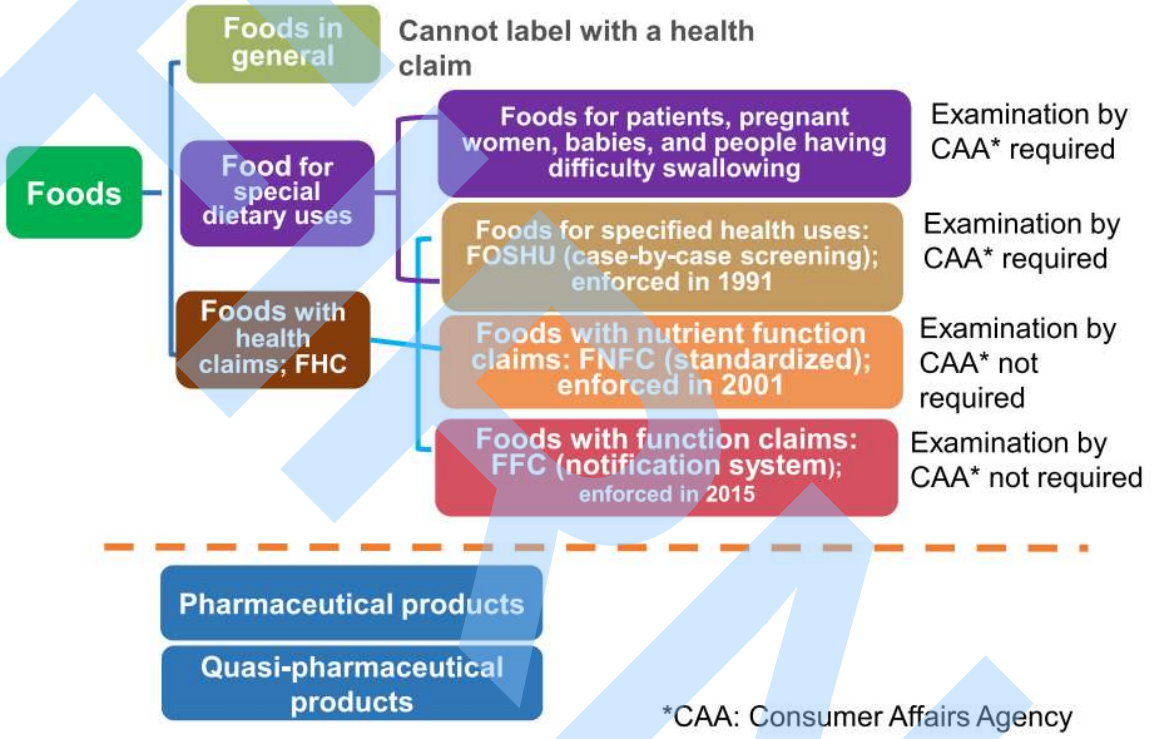


Figure 1. Classification of orally ingested products in Japan.

Maeda-Yamamoto & Ohtani (2018)

Categories of FOSHU

(1) Ordinary FOSHU

Requires detailed review process with scientific evidence for each application

(2) Standardized FOSHU:

(a) No detailed review process for food products meeting established standards and specifications,

(b) Must be accompanied by sufficient accumulation of scientific evidence

(c) Fast-track approval for products with previously approved safety

(3) Reduction of disease risk FOSHU:

(a) Detailed review process requiring scientific evidence

(b) Products with clinically and nutritionally established ingredients that reduce the risk of certain diseases (i.e. calcium for osteoporosis and folic acid for neural tube defects)

(4) Qualified FOSHU:

(a) Detailed review process requiring scientific evidence

(b) Products containing ingredients with demonstrated health effects that do not reach established standards for FOSHU approval

(c) Labeled as “Qualified Food for Specified Health Uses”

**such as “the evidence is not established, but this product may be suitable for a person with slightly elevated blood neutral fat.” (Bagchi *et al.*, 2014)

Maeda-Yamamoto & Ohtani (2018)

Examples of approved “foods with specified uses” products are as follows (1099 items as of July 29, 2017):

Special health uses of foods	Principle ingredients
1.) For modifying gastrointestinal conditions	oligosaccharides, lactose, bifidobacteria, lactic acid bacteria, and dietary fiber (ingestible dextrin, polydextrose, guar gum, and psyllium seed coat)
2.) For acting on blood cholesterol levels	chitosan, soybean protein, and degraded sodium alginate
3.) For acting on blood glucose levels	indigestible dextrin, wheat albumin, guava tea polyphenol, and L-arabinose
4.) For acting on blood pressure	lactotripeptide, casein dodecapeptide, tochu leaf glycoside (geniposidic acid), and sardine peptide
5.) For promoting dental hygiene	palatinose, maltitol, and erythritol
6.) For lowering cholesterol and improve gastrointestinal conditions	degraded sodium alginate, and dietary fiber from psyllium seed husk
7.) For affecting mineral absorption	calcium citrate malate, casein phosphopeptide, heme iron, and fructooligosaccharide
8.) For promoting osteogenesis	soybean isoflavone and milk basic protein
9.) For mitigating triacylglycerol and body fat	Medium chain fatty acids, tea catechin, chlorogenic acid, EPA, DHA, quercetin glycoside, apple procyanidin, mannooligosaccharide, oolong tea polyphenol
10.) For reducing the risk of specific diseases: osteoporosis	calcium
11.) For preventing neural tube defects (spondyloschisis)	folic acid

Maeda-Yamamoto & Ohtani (2018)

1.) For modifying gastrointestinal conditions

Example of the claim

“This helps increase intestinal bifidobacteria and thus helps maintain a good GI condition”
“This product helps to improve bowel movements.”

Prebiotics

Product: クルルのおいしいオリゴ糖 (Sweetener)
Key component: Fructo-oligosaccharide

Product: 毎朝爽快 (Refreshing drink)
Key component: Lactulose

Product: 天寿りんご黒酢 (Seasoned vinegar (soft drink))
Key component: Galacto-oligosaccharide

Product: オリゴタイム（シロップ） (Syrup)
Key component: Isomalto-oligosaccharides

Probiotics

Product: タカナシドリンクヨーグルト　おなかへGG! (Fermented milk)
Key component: *Lactobacillus rhamnosus* GG, ATCC 53103 (Lactobacillus GG)

Product: ピルクル (Dairy products Lactobacillus drinks)
Key component: *Lactobacillus Casei* (NY 1301)

Product: ソフール　プレーン、LT、ストロベリー (Yogurt)
Key component: *Lactobacillus casei* YIT 9029 (Shirota strain)

Dietary fibers

Product: 蒟蒻畑ララクラッシュ
ぶどう味、オレンジ味、マスカット味 (Sweets)
Key component: Resistant indigestible dextrin

Product: 充実センイココアビスケット (Biscuits)
Key component: Indigestible dextrin (as dietary fiber)

Product: ファイブミニ (Carbonated drink)
Key component: Polydextrose

Product: ぱぱ寒天ゼリー (Powdered jelly)
Key component: Dietary fiber (Agar)

2.) For acting on blood cholesterol levels

Product: 緑でサラナ (Vegetable / Fruit Mixed Beverage)
Key component: S-methyl cysteine sulfoxide (SMCS) - (natural amino acid) derived from broccoli and cabbage

Product: キトサン明日葉青汁 (Green Juice)
Key component: Chitosan

Product: ハイ！調製豆乳 (Soymilk)
Key component: Soybean protein

Product: 特濃調製豆乳 (Soymilk)
Key component: Soybean protein

Example of the claim

“This helps people decrease serum cholesterol levels.”

Product: ヘルシーコレステ (Cooking oil)
Key component: Plant sterol

Product: ピュアセレクトサラリア (Salad Dressing)
Key component: Plant sterol ester

Product: ラーマ　プロ･アクティブ (Margarine)
Key component: Plant sterol ester

3.) For acting on blood glucose levels

Product: サラシア100 (Food supplement)
Key component: Neocotalanol

Product: 健やか豆腐 (Tofu)
Key component:(Indigestible dextrin (as dietary fiber))

Product: 健茶王　黒豆黒茶 (Refreshing drink)
Key component: Resistant dextrin (as dietary fiber))

Product: ヤクルト蕃爽麗茶（ばんそうれいちゃ）
Key component: Refreshing drink
(Guava leaf polyphenol)

Product: グルコケア　粉末スティック　濃い茶 (Powdered soft drink)
Key component: Indigestible dextrin (as dietary fiber)

Product: グルコデザイン (Powdered soup)
Key component: Wheat albumin

Product: 血糖の気になりはじめた人の フィットライフコーヒー (Powdered soft drink)
Key component: Resistant to dextrin (as dietary fiber)

Example of the claim

“This is helpful for those who are concerned about their blood glucose levels.”

Product: 松谷のおみそ汁　合わせ、赤だし、白みそ (Instant miso soup)
Key component: Resistant indigestible dextrin (as dietary fiber))

Taiwan- Health Claims

Types of registration for health foods

- **Type 1** (Individual case review)

Suppliers must provide testing results and proof of food safety and healthcare functions. The approval permit number shall be Wei Bu Chien Shi Kui Tzu No. Axxxxx

- **Type 2** (Standard specification review)

Product must comply with specifications and standards stipulated by the Ministry of Health and Welfare (MOHW). The approval permit number shall be Wei Bu Chien Shi Kui Tzu No. xxxxxx

***Now, red mold rice (*Monascus purpureus*) and fish oil are the two health food specification standards (Wu, 2015)

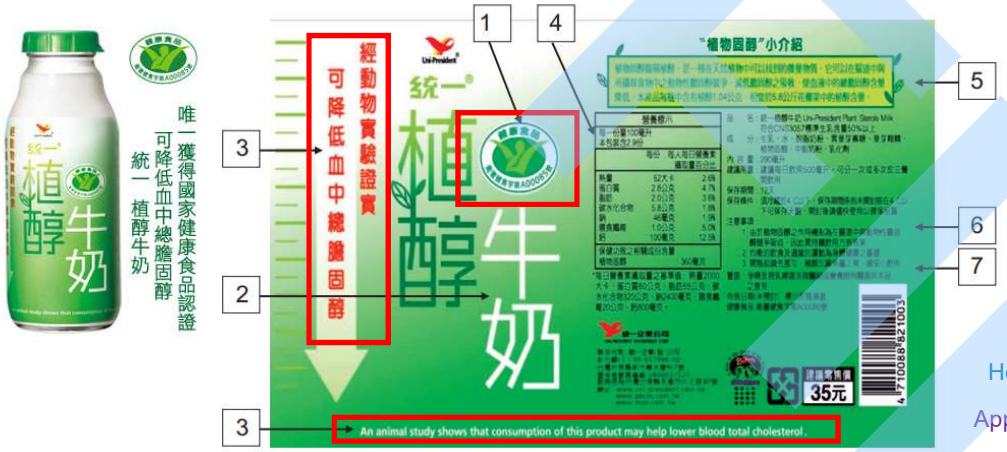
FDA 食品藥物管理署 Food and Drug Administration

(As of December 2016, 376 permits were issued for health foods, including 312 permits for Type 1 approvals and 64 permits for Type 2 approvals. 37 of the permits were voided (include termination as a result of permit expiration, revocation of the permit, or permit merging). As of end of 2016 the number of approved permits issued is 339)

“Health care effects” of the permitted health foods (Wu, 2015)

1.) Modulating blood lipids
2.) Improving gastrointestinal functions
3.) Regulating immune system
4.) Adjuvant modulating allergic constitution
5.) Protecting bone health
6.) Maintaining dental health
7.) Modulating blood sugar
8.) Protecting liver functions (chemically induced liver damage)
9.) Reducing body fat formation
10.) Anti-weariness
11.) Postponing aging
12.) Adjuvant modulating blood pressure
13.) Promoting iron absorption

Example of health claim label on food product



A label of Taiwanese health (functional) food product; sterols containing milk drink for the risk reduction of coronary heart disease. (Bagchi, 2008)

1. Logo for "health food" with the reference number of the permit. (Wei Bu Chien Shi Kui Tzu No. A00085)
2. Name of product "Plant sterols milk."
3. Approved health claim: "An animal study shows that consumption of this product may help lower blood total cholesterol" in Chinese and English.
4. Nutritional information.
5. Information on plant sterols.
6. Instruction of use.
7. Warning "pregnant and breast feeding women should consult their doctor before drinking this product."

1.) Modulating blood lipids

No. A00181
Product: Uni-President No Sugar added & Hi-fiber SoyMilk
Key component: Soy protein; Chicory fiber (Inulin)
Approved health claim:
(1)有助於降低血中總膽固醇。
(2)有助於增加血中高密度脂蛋白膽固醇。
(3)有助於減少發生心血管疾病的危險因子。」 本產品之功效宣稱乃依統一陽光低糖高纖豆漿產品之實驗結果作為依據。
(1) Helps to lower total blood cholesterol.
(2) Helps increase blood high-density lipoprotein cholesterol.
(3) It helps to reduce the risk factors for cardiovascular disease. The effectiveness of this product is claimed to be based on the experimental results of a unified low-sugar and high-fiber soybean milk product.

No. A00230
Product: Cranberry Vinegar(Reduced Sugar)
Key component: Chlorogenic acid
Approved health claim: 有助於降低血中總膽固醇
(Helps lower total cholesterol in the blood)

No. A00092
Product: Natto Extract Capsule
Key component: HMG-COA reductase inhibitor-Monacolin K; the content of each soft capsule was greater than 0.15 mg.
Approved health claim:
(1) 有助於降低血中總膽固醇。
(2) 有助於降低血中低密度脂蛋白膽固醇。
(3) 有助於減少發生心血管疾病的危險因子。
(1) Helps to lower total blood cholesterol.
(2) Helps lower blood LDL cholesterol.
(3) It helps to reduce the risk factors for cardiovascular disease.

No. 000044
Product: 歐米茄3深海魚油軟膠囊 (Capsule)
Key component: Omega-3 acids
Approved health claim: 本產品可能有助於降低血中三酸甘油脂；其功效乃由學理得知，非由實驗確認。
(This product may help reduce triglyceride in blood; its efficacy is known by science and is not confirmed by experimentation.)

No. 000024
Product: 紅麴養生膠囊 (Capsule)
Key component: Monacolin K
Approved health claim: 本產品可能有助於降低血中總膽固醇；其功效由學 理得知，非由實驗確認。
(This product may help reduce total cholesterol in the blood; its efficacy is known by academics and is not confirmed by experimentation.)

No. A00240
Product: Uni-biotech Imperial Natto Red Mold Rice Capsule
Key component: Monacolin K
Approved health claim:
(1) 有助於降低血中總膽固醇；
(2) 有助於降低血中低密度脂蛋白膽固醇。
(1) Helps lower total blood cholesterol;
(2) Helps lower blood LDL cholesterol.

2.) Improving gastrointestinal functions

No. A00012
Product: 奧利多mini-Oligo (Carbonated drinks)
Key component: Oligosaccharides (containing isomalt oligosaccharides and galactooligosaccharides)
Approved health claim: 有助於改善腸內細菌菌相，增加腸Bifidus菌菌數。
(Helps to improve the intestinal bacterial flora and increase the number of intestinal Bifidus bacteria.)

No. A00030
Product: 高鈣脫脂奶粉 (Skim milk powder)
Key component: Total lactic acid bacteria (including *Lactobacillus acidophilus* and *Lactobacillus casei*), *Bifidobacterium lactis*, and calcium
Approved health claim: 有助於
1.增加腸內益菌。
2.減少腸內害菌（*Clostridium perfringens*）。
3.改善腸內細菌菌相。
經動物實驗證實:
1.可降低血中三酸甘油酯。
2.可降低血中低密度脂蛋白膽固醇。
3.可增加血中高密度脂蛋白膽固醇。

1) Increase intestinal bacteria.
2) Reduce the intestinal bacteria (*Clostridium perfringens*).
3) Improve intestinal bacterial flora

No. A00070
Product: ProBioPCC (Dietary supplement) (Capsule)
Key component: *Lactobacillus fermentum*
Approved health claim:
(1) 可通過胃酸和膽鹽之考驗。
(2) 增加腸內益生菌。
(3) 減少腸內有害菌 （*Clostridium perfringens*）。
(4) 改善腸內細菌菌相。

No. A00324
Product: Burner -倍熱®食事纖纖粉 (Dietary fiber powder)
Key component: Total dietary fiber
Approved health claim:
(a)調節血脂 「經動物實驗證實：
1. 有助於降低血中總膽固醇。
2. 有助於降低血中三酸甘油酯。
3. 有助於降低血中低密度脂蛋白膽固醇(LDL-C)。」
(b)胃腸功能改善 「經動物實驗證實：有助於增加腸內益生菌。」

Improvement of Gastrointestinal Function "Confirmed by animal experiments: It helps to increase intestinal probiotics."

No. A00113
Product: AGV Oligo Tomato Drink (Beverage)
Key component: Isomalto-oligosaccharides
Approved health claim:
(1) 有助於增加腸內益生菌
(2) 有助於改善腸內細菌菌相

1) Helps increase intestinal probiotics
2) Helps to improve intestinal bacterial flora

No. A00215
Product: 龍泉金鑽健康麥汁(黑麥風味) Healthy malt beverage Dark malt flavor (Beverage)
Key component: Isomaltose, Panose
Approved health claim: 經動物實驗證實：
(1) 有助於增加腸內益生菌。
(2) 有助於減少腸內有害菌(*Clostridium perfringens*)。

The animal experiments confirmed:
(1) It helps to increase intestinal probiotics.
(2) It helps to reduce the harmful bacteria (*Clostridium perfringens*).

No. A00247
Product: Fiber Cup Soup Healthy Fiber Potato Soup
Key component: Total dietary fiber (including indigestible maltodextrin)
Approved health claim: 經動物實驗證實：有助於促進胃腸運動。
("It has been confirmed by animal experiments that it helps to promote gastrointestinal motility.")

6.) Maintaining dental health

No. A00058
Product: 益齒達®無糖口香糖-薄荷 (Sugar-free Gum)
Key component: Xylitol
Approved health claim:
(1.)可減少口腔內的牙菌斑。
(2.)可減少牙菌斑內突變形鏈球菌數量(*Streptococcus mutans*)。
(3.)有助於降低蛀牙的發生率。

1) Can reduce dental plaque in the mouth.
2) It can reduce the number of *Streptococcus mutans* in dental plaque.
3) Helps reduce the incidence of tooth decay.

No. A00135
Product: Dental-Lac Troches (Tablet)
Key component: *Lactobacillus paracasei*
Approved health claim:
有助於減少牙菌斑內突變型鏈球菌數量 (*Streptococcus mutans*)。
(Helps reduce the number of *Streptococcus mutans* in dental plaque.)

11.) Postponing aging

No. A00238
Product: 極品綠寶藻精王®滋補飲 (Healthy Drink)
Key component: Total polyphenols (based on Gallic acid)
Approved health claim: 經易老化動物實驗結果顯示，有助於延緩老化。

No. A00194
Product: 頂級玫瑰四物飲 (Healthy Drink)
Key component: Total polyphenol (Ferulic acid)
Approved health claim:
(1.) 有助於增加血漿中總抗氧化能力。
(2.) 經易老化老鼠動物實驗結果顯示，有助於延緩老 化。

"1. It helps to increase the total antioxidant capacity in plasma.
2. It has been shown by the results of animal experiments on aging rats to help delay aging."

No. A00345
Product: Memoregain Capsules
Key component: Phenylethanoid glycosides from *Cistanche tubulosa* (based on Acteoside, Isoacteoside, Echinacoside, 2'-Acetyl echinacoside)
Approved health claim: 經誘導型老化動物實驗模式結果顯示，本產品有助於延緩衰老之功效。
(The experimental results of inducible aging animals show that this product helps to delay aging.)