New Zealand Food Safety
Haumaru Kai Aotearoa

Global Regulatory Environment of Health Claims in Foods

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Publications Logistics Officer
Ministry for Primary Industries
PO Box 2526
WELLINGTON 6140

Email: brand@mpi.govt.nz
Telephone: 0800 00 83 33
Facsimile: 04-894 0300

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1 Purpose of this document

This document summarises the regulations for making health claims on foods in different countries/jurisdictions. For each country/jurisdiction covered, there is information detailing;

- the government agencies responsible for the regulation of health claims; and
- the legal regulatory framework for making health claims (where applicable).

The regulation of health claims is a constantly evolving area and this is a living document. This document may be useful for food businesses wanting to find out more about health claims in specific countries as a way of exploring potential export opportunities for their food products. This document outlines:

- the types of health claims that are permitted;
- the way health claims are regulated; and
- the process of applying for permission to use a new health claim.

While the exact process for applying to use a new health claim differs from country-to-country, in most cases the applicant must provide evidence from scientific studies (usually in the form of clinical trials) to support the health effect of the food. For some countries, the safety of the food will also need to be demonstrated. For the majority of countries/jurisdictions, imported products must comply with the labelling requirements of the country/jurisdiction the food is being imported to.

This document could also be useful for those wanting to better understand the regulatory framework in countries that New Zealand may look towards:

- developing cooperative agreements for health claims on foods exported from New Zealand; and
- developing a recognition of equivalence in the process of scientific substantiation for health claims on foods.

The information presented here is intended as a guide. The government agencies responsible for regulating and enforcing health claims on foods regulatory documents, should be consulted for the most accurate and up-to-date information.

2 Definition of the different types of health claims in each country/jurisdiction

In Table 1, health claims have been categorised into two main groups and the following definitions apply (taken from Codex Alimentarius 'Guidelines for Use of Nutrition and Health Claims' (CAC/GL 23-1997):

Nutrient function and other function claims

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

Reduction of disease risk claims

Reduction of disease risk 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.

Each country/jurisdiction uses slightly different terminology when referring to these two main types of health claims. It is important to note these differences in definitions, as it could mean that they are not interchangeable between countries/jurisdictions. In this document, the different types of health claims are referred to by the name that is given to them in each country/jurisdiction.

Table 1. Definition of the different types of health claims by country/jurisdiction

Country	Definition of a nutrient and other function claim	Definition of a reduction of disease risk claim
Australia and New Zealand	A nutrient function claim is called a general level health claim which refers to a nutrient or substance in a food and its effect on a health function. General level health claims must not refer to a serious disease or to a biomarker of a serious disease.	A reduction of disease risk claim is referred to as a high level health claim which is defined as a nutrient or substance in a food and its relationship to a serious disease or to a biomarker of a serious disease.
Canada	Nutrient function claims are a type of function claim. They describe the well-established roles of energy or known nutrients that are essential for the maintenance of good health or for normal growth and development. Function claims refer to statements about the specific, beneficial effects of a food or a food constituent on the normal functions or biological activities of the body.	Disease risk reduction claims are statements that link a food to a reduced risk of developing a diet-related disease, condition, or risk factor in the context of the total diet. Claims about the reduction of certain disease risk factors recognised as part of dietary management (e.g. blood cholesterol lowering) are also referred to as therapeutic claims.
China	A nutrient function claims means a claim that describes the role of a nutrient component in normal growth, development and normal physiological function of the body.	A health food in the "Provisions for Health Food Registration (Trial)" refers to food with claims that state certain health functions; or for the purpose of supplementing vitamins and minerals, which is suitable for specific groups of people, and able to affect body functions. Health foods must not be for the purpose of curing diseases and must not cause any acute, sub-acute or chronic effect to humans.

Country	Definition of a nutrient and other function claim	Definition of a reduction of disease risk claim
European Union (EU)	General function health claims under Article 13.1 of the EU Regulation (function claims) are health claims describing or referring to: the role of a nutrient or other substance in growth, development and the functions of the body; or psychological and behavioural functions; or without prejudice to Directive 96/8/EC, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet. New function health claims under Article 13.5 are for claims which are based on newly developed scientific evidence and/or for which protection of proprietary data is requested. A nutrition claim is any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: • Energy (calorific value) it (a) provides, (b) provides at a reduced or increased rate or, (c) does not provide, e.g. 'low energy'; or • Nutrients or other substances it (a) contains, (b) contains in reduced or increased proportions or, (c) does not contain, e.g. 'reduced sugar', 'high fibre'	A reduction of disease risk claim means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease. For reduction of disease risk claims, the beneficial physiological effect (which Regulation (EC) No 1924/2006 requires to be shown for the claim to be permitted) is the reduction (or beneficial alteration) of a risk factor for the development of a human disease (not reduction of the risk of disease). The wording of the claim should refer to the specific risk factor for the disease, for example, 'Plant sterols/stanols have been shown to reduce blood cholesterol levels. High cholesterol levels are a risk factor in the development of coronary heart disease.
Hong Kong	A nutrient function claim means a nutrition claim that describes the physiological role of a nutrient in growth, development and normal functions of the body.	There are no statutory requirements for reduction of disease risk claims, as long as they are accurate and not used for medicinal purposes. These claims are not subject to approval by the Centre for Food Safety.
India	A health claim is one that describes the physiological role of the nutrient or substance or an accepted diet-health relationship; and contains information on the composition of the product relevant to the physiological role of the nutrient or substance or an 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. Nutrition function claims and other function claims are based on current relevant scientific substantiation and provide sufficient evidence on the type of claimed effect and the relationship to health.	All reduction of disease risk claims must be made in accordance with the conditions specified in Schedule III of the Gazette Notification of the Food Safety and Standards (Advertising and Claims) Regulation, 2018
Indonesia	Nutrient function claims are those that describe the physiological role of nutrients for growth, development and normal functioning of the body. Other function claims are those claims that relate to 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.	Reduction of disease risk claims link the consumption of food or food component in the total diet with a reduced risk of developing a particular disease or health condition.

Country	Definition of a nutrient and other function claim	Definition of a reduction of disease risk claim
Japan	Nutrient function claims are referred to as Food with Nutrient Function Claims (FNFC). FNFC refers to all food labelled with the nutrient function claims specified by the Ministry of Health, Labour and Welfare. The standards and specifications for indication of nutritional function have been established for 17 ingredients (12 vitamins and 5 minerals). Function Claims are referred to as Foods with Function Claims (FFC). FFC refers to all food labelled with function claims based on scientific evidence.	Foods for specified health use (FOSHU) refers to foods containing ingredients with a health function/effect and the claimed physiological effect on the human body has been officially approved. FOSHU includes both nutrient function and reduction of disease risk claims. FOSHU 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.
Malaysia	A nutrient function claim is one that describes the physiological role of the nutrient in growth, development and normal functions of the body. Other function claims refer to substances that are not considered nutrients and that provide a positive contribution to health or to the improvement of a function or to modifying or preserving health by other food component.	Reduction of disease risk claims relate the consumption of a food or food component to the reduced risk of developing a disease or health-related condition. Reduction of disease risk claims are prohibited.
Philippines	A nutrient function claim describes the physiological role of the nutrient in growth, development and normal functions of the body. Nutrient function claims can only be made about nutrients that have an established nutrient reference value (NRV) and the food which has the claim must be considered a source of that nutrient.	These are 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. Reduction of disease risk claims are prohibited.
Singapore	Nutrient function claims refer to physiological role of the nutrient in growth, development and normal functions of the body. Other function claims refer to claims concerning 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, and relating to a positive contribution to health or to the improvement of a function. There is also a list of acceptable nutrient function claims for infant foods and foods for children younger than six years in the guide. There is also a claim for foods containing plant sterols/stanols.	Reduction of disease risk claims are referred to as nutrient specific diet-related health claims in Singapore. These are 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.
South Korea	Nutrient function claims relate to the modification of any physiological parameters associated with consumption of nutrients such as growth, development and normal functions of the human body. Other function claims relate to any positive contribution to health to the improvement of a function, or to modifying or preserving health in the context of the total diet. Biologically active function claim relates to any positive contribution to health to the improvement of a function, or to modifying or preserving health in the context of the total diet.	Disease risk claim relate to the reduced risk of developing a disease or health-related conditions in the context of the total diet.

Country	Definition of a nutrient and other function claim	Definition of a reduction of disease risk claim
Switzerland	No definitions given.	N/A
Taiwan	N/A	A health food is defined as a food with specific nutrient or health maintenance effects which is especially labelled or advertised and are not aimed at treating or remedying human diseases.
Thailand	Nutrition function claims are any claims that describe the physiological role of the nutrient in growth, development and normal functions of the body. Other function claims are any claims that describe 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.	Reduction of disease risk claims mean benefits relating the consumption of a food or food constituents, in the context of the total diet, to the risk reduction of developing a disease or health-related condition.
USA	Nutrient function claims are referred to as structure/function claims which describe the effect that a substance has on the structure or function of the body and do not make reference to a disease. Structure/function claims must be truthful and not misleading and are not pre-reviewed or authorised by FDA. The focus for structure/function claims on conventional foods is on the effects taken from the nutritive value.	Any claim made on the label or in labelling of a food that expressly or by implication characterises the relationship of any substance (e.g. a specific food or component of food) to a disease or health-related condition is referred to as a health claim. Health claims in the US are limited to claims about reduction of disease risk.
Vietnam	Functional foodstuffs are foods that are used to support human's organ functions, have nutrient effects, put the body at ease, increase resistance and reduce pathogenic dangers.	N/A

3 Overview of requirements for making food health claims by country/jurisdiction

Note: certain countries/jurisdictions refer to the different types of health claims (nutrient function and reduction of disease risk) using different terminology (see Table 1).

Table 2. Summary of requirements for making health claims on foods by country/jurisdiction

Country	Regulatory body	Can you make a health claim?	Is there a list of pre-approved health claims?	Can you apply to have a new health claim approved for use?	Requirements for health claims on imported foods	Regulatory document(s)
Australia and New Zealand	Food Standards Australia New Zealand (FSANZ) develops the Food Standards Code which is enforced by the Australian states and territories and New Zealand agencies	Regulated health claims are permitted.	• ~200 nutrient function claims; and • 13 reduction of disease risk claims listed in Standard 1.2.7	New reduction of disease claims are subject to approval by FSANZ. Details of this process can be found in the FSANZ Act 1991. For new nutrient function claims, there is an option to self-substantiate by conducting a systematic review with a focus on human (intervention) studies. Guidance for self-substantiation can be found on the FSANZ website.	All foods imported into Australia and NZ must comply with labelling and composition standards in the Food Standards Code.	Standard 1.2.7 Nutrition, Health and Related Claims which should be used in conjunction with other relevant standards of the Food Standards Code.
Canada	Health Canada develops standards and policies which are enforced by the Canadian Food Inspection Agency (CFIA)	Health claims are permitted. Claims about diseases or health conditions listed in Schedule A are permitted only when listed in the Food and Drug Regulations. Claims about other diseases or health outcomes are covered by a general law that requires claims to be truthful and not misleading.	• Three function claims • ~65 nutrient function claims • Four pre-approved non-strain specific health claims that can be made on probiotics. • 11 eligible bacterial species • Five disease risk reduction claims in the Food and Drug Regulations • Seven disease risk reduction claims have been accepted and are available on the Health Canada website.	Premarket approval by Health Canada is required for new claims about the diseases or health conditions listed in Schedule A of the Food and Drugs Act. Manufacturers who wish to seek approval for such claims should contact the Food Directorate of Health Canada before submitting a health claim application using Health Canada's Guidance Documents for Preparing Health Claim Submissions. Claims about the diseases or health outcomes not in Schedule A are subject to the same general law as function claims, which requires claims to be truthful and not misleading. See Guidance Documents for Preparing Health Claim Submissions for more details.	All foods packaged for consumer use and imported into Canada must comply with the food labelling requirements.	Food and Drugs Act Food and Drug Regulations

Country	Regulatory body	Can you make a health claim?	Is there a list of pre-approved health claims?	Can you apply to have a new health claim approved for use?	Requirements for health claims on imported foods	Regulatory document(s)
China	State Food and Drug Administration (SFDA)	Regulated health claims are permitted.	• ~65 nutrient function claims listed in the Standard for Nutrition Labelling of Pre-packaged Foods. • ~27 health functions that have been approved for use for health foods.	All health (functional) foods (i.e. foods with health claims) must be reviewed and approved by the SFDA. Applications for the registration of a health food are product specific. A full list of the requirements for an application to register a health food is listed in the Provisions for Health Food Registration.	For an imported health food, the food must have been produced and marketed outside of China for more than one year.	National Food Safety Standard: Standard for Nutrition Labelling of Pre-packaged Foods and the Provisions for Health Food Registration (Trial)
European Union	European Food Safety Authority (EFSA) and the European Commission (EC) in conjunction with the Member States	Regulated health claims are permitted.	• More than 200 authorised health claims (include both nutrient function and reduction of disease risk claims)	Proposals for health claims are submitted to a National Competent Authority of the Member States who then make the application available to EFSA. Guidance can be found here.	Imported foods can use the list of pre-approved health claims but will have to make an application for the scientific evaluation and authorisation of any new health claim.	REGULATION (EC) No 1924/2006 on Nutrition and Health Claims Made on Foods
Hong Kong	Centre for Food Safety (CFS)	Regulated nutrient function claims are permitted. There are no regulations for reduction of disease risk claims, but these are not prohibited.	• 26 nutrient function claims that are listed as examples.	Nutrient function claims are allowed as long as they meet certain requirements. New claims do not appear to be subject to approval by the CFS.	The Centre for Food Safety encourages food importers to avoid using health claims.	Food and Drugs (Composition and Labelling) (Amendment: Requirements for Nutritional Labelling and Nutrition Claim) Regulation 2008
India	Food Safety and Standards Authority of India (FSSAI)	Regulated nutrition function claims are permitted.	• ~ 9 nutrient function claims have been approved for use. • 6 Reduction of disease risk claims are also permitted.	An application of the nutrient function claims and other function claims are submitted to the FSSAI for approval.	All food products imported into India shall comply with the labelling requirements as specified in the regulations.	Food Safety and Standards (Advertising and Claims) Regulations, 2018 Food Safety and Standards (Functional Food and Novel Food)
Indonesia	National Agency of Drug and Food Control	Regulated health claims are permitted.	• ~11 nutrient function claims • ~11 reduction of disease risk claims • in the 'Control of Claims on Processed Food Labels and Advertising'	An application for approval of a new nutrient function or a reduction of disease risk claim must be made to the Head of the National Agency of Drug and Food Control.	All food products imported into Indonesia must comply with the labelling requirements.	'Control of Claims on Processed Food Labels and Advertising'

Country	Regulatory body	Can you make a health claim?	Is there a list of pre-approved health claims?	Can you apply to have a new health claim approved for use?	Requirements for health claims on imported foods	Regulatory document(s)
Japan	Ministry of Health Labour and Welfare (MHLW) and the Consumer Affairs Agency (CAA)	Regulated health claims are permitted.	• ~17 nutrient function claims listed on the MHLW website (English). • Foods for Specified Health Use (FOSHU) claims are product specific. • 8 FOSHU Health claims have been approved.	FOSHU claims are product specific. The safety of the food and effectiveness of the functions for health must be assessed, and the claim approved by the MHLW and CAA. More information about FOSHU can be found on the MHLW website. In a recent review of the Food Labelling Act a new system will be established to allow health claims on fresh and processed foods if the food meets certain requirements. Health claims will be allowed without government approval if industry holds a certain amount of scientific evidence on the safety and effectiveness of the food.	Given there is a specific regulatory system set up for FOSHU and food with functional claims, all claims made on imported food products must comply. The scientific requirements are very similar to those required for self-substantiated general level health claims in New Zealand.	'Food Labelling Standard' and 'Foods for Specific Health Use (FOSHU) regulations' 'Foods for Functional Claims (FFU) regulations'
Malaysia	Food Safety and Quality Division, Malaysian Ministry of Health (MoH)	Regulated nutrient function claims are permitted. Reduction of disease risk claims are prohibited.	• ~50 nutrient function claims listed in the 'Guide to Nutrition Labelling and Claims' • 29 other function claims for bioactive ingredients have been approved	The process for applying to the MoH for approval of a new nutrient function claim is outlined in Appendix 6 of the 'Key Message 14 of the Malaysian Dietary Guidelines'. The application must contain sound scientific evidence for the claim based on data from human intervention trials.	All food products imported into Malaysia must comply with the labelling regulations.	Malaysia's Food Act 1983 and Food Regulations 1985 are found here.
Philippines	Philippines Food and Drug Administration (FDA) which is part of the Department of Health.	Regulated health claims are permitted.	• There is no list of pre-approved health claims.	In the Philippines, all food products must be registered with the FDA. Nutrition and health claims will be evaluated by the FDA's Product Services Division based on compliance with the Codex Guidelines.	All food products imported into the Philippines must be registered with the FDA.	The Philippines has adopted Codex Alimentarius 'Guidelines for Use of Nutrition and Health Claims' (CAC/GL 23-1997).

Country	Regulatory body	Can you make a health claim?	Is there a list of pre-approved health claims?	Can you apply to have a new health claim approved for use?	Requirements for health claims on imported foods	Regulatory document(s)
Singapore	Agri-Food and Veterinary Authority (AVA) and Health Promotion Board (HPB) of Singapore	Regulated health claims are permitted.	• ~121 nutrient function claims • 7 nutrient function claims (infant formula and food, and food for children) • 17 other function claims • 6 reduction of disease risk claims	New nutrient-function claims (not reduction of disease risk claims) are subject to approval by the AVA. Details on the application can be found on the AVA website. To use the reduction of disease risk claims, first the food must have the 'Healthier Choice Symbol' which is subject to approval by the HPB. Food manufacturers then apply to the AVA to use the claim.	All imported foods must be registered with the Director-General of the AVA. The Food Regulations require all pre-packed food products for sale in Singapore to be labelled according to the requirements specified.	'Food Regulations' Health claims are listed in 'A Guide to Food Labelling and Advertisements'.
South Korea	Ministry of Food and Drug Safety	Regulated health claims are permitted.	• List of over 100 pre-approved nutrient function and reduction of disease risk claims	New nutrient function claims are subject to approval for use as a product specific health official food or a new ingredient.	All imported foods must comply with the requirements of the Ministry of Food and Drug Safety guidelines.	'Health Functional Foods Act' and 'Health Functional Food Code'
Switzerland	Federal Food Safety and Veterinary Office FSVO	Regulated health claims are permitted.	• List of over 200 pre-approved nutrient function and reduction of disease risk claims	New nutrient function and reduction of disease risk claims not on the list of pre-approved claims are subject to approval by the FSVO. Information on this process including the application form can be found here	All imported foods must comply with the provisions in the Ordinance on Information on Foodstuffs (FoodIO)	The Ordinance on Information on Foodstuffs (FoodIO)
Taiwan	Taiwan Food and Drug Administration (FDA), Ministry of Health and Welfare	Regulated health claims are permitted.	• ~70 nutrient function claims • ~20 broad claims/slogans that are permissible • 13 health effects (some are reduction of disease risk) that have been approved for use on health food products.	All health food products must be approved by the FDA; once they have been approved and registered, they receive a green TFDA 'Health Food' mark which is valid for five years.	Health claims that are not reduction of disease risk claims (nutrient function claims) can be made on foods as long as they are truthful and not misleading. If a nutrient function claim has been approved in another country, it is likely to be allowed. For a new reduction of disease risk claims an application would have to be made to the FDA for scientific evaluation and approval.	Health Food Control Act of Taiwan (Mandarin); Schedule of Vitamin or Mineral Statements (Mandarin), an (unofficial) English version is available in Appendix 1.
Thailand	Thailand Food and Drug Administration (FDA)	Regulated health claims are permitted	• 29 pre-approved' nutrient function claims	Domestic producers and importers of food can make an application to the Thai FDA (part of the Ministry of Health) to have a new nutrient function or a reduction of disease risk claim approved. In the Thai Nutrition Labelling document, it states that nutrient function claims must be based upon reliable scientific evidence.	All imported foods must apply to the Thai FDA for approval of health claims.	The (unofficial) Notification of the Ministry of Public Health (No. 182) B.E. 2541 (1998)

Country	Regulatory body	Can you make a health claim?	Is there a list of pre-approved health claims?	Can you apply to have a new health claim approved for use?	Requirements for health claims on imported foods	Regulatory document(s)
UK	UK Nutrition and Health Claims Committee (UKNHCC)	Regulated Health Claims are permitted.	• More than 200 authorised health claims (include both nutrient function and reduction of disease risk claims)	From 1 January 2021, proposals for health claims are submitted to UKNHCC who complete the assessment. Guidance can be found here.	Imported foods can use the list of pre- approved health claims but will have to make an application for the scientific evaluation and authorisation of any new health claim.	REGULATION (EC) No 1924/2006 on Nutrition and Health Claims Made on Foods
USA	Food and Drug Administration (FDA)	Regulated health claims (reduction of disease risk) are permitted. Nutrient-function claims are permitted but are not regulated.	• There are no 'pre-approved' nutrient function claims but they must be truthful and not misleading and are not pre-reviewed or authorised by the FDA • 12 authorised reduction of disease risk claims in the Federal Regulations for Food and Drugs	New reduction of disease risk claims are subject to approval if the food business can submit a petition to the FDA in which the evidence for the effect of the nutrient on the disease must meet a high standard of 'significant scientific agreement' (SSA). Details for making a petition for health claims can be found on under 'Petitions for health claims' of the Federal Regulations for Food and Drugs. The FDA has some guidance for the scientific evaluation of health claims on their website. If a health claim is reviewed under the SSA standard but does not meet the level for significant scientific agreement, the FDA can consider the health claim as a qualified health claim.	Health claims that are not reduction of disease risk claims (nutrient function claims) can be made on foods as long as they are truthful and not misleading. If a nutrient function claim has been approved in another country, it is likely to be allowed. For a new reduction of disease risk claims an application would have to be made to the FDA for scientific evaluation and approval.	Nutritional Labelling and Education Act (NLEA) Requirements (8/94 – 2/95)
Vietnam	Vietnam Ministry of Health	There are regulations for functional foodstuffs that contains information on making nutrient function claims.	No	An application for a functional foodstuff should be submitted to the Ministry of Health (Department of Food Safety) and include evidence of the effectiveness on human health. The clinical trials (if conducted outside of Vietnam) must be conducted at accredited medical institutions or be published in scientific journals. The functional foodstuff must also comply with the appropriate Vietnamese Food Safety Provisions.	N/A	Circular No.08/2004/TT-BYT 'Guiding the management of functional foodstuff products' (current) Circular No. 43/2014 'Rules of management for functional foods' which is effective 15 May 2015 (Vietnamese)

4 Detailed requirements for making food health claims by country/jurisdiction

4.1 AUSTRALIA AND NEW ZEALAND

4.1.1 Regulatory authority and documents

Food Standards Australia New Zealand (FSANZ) develops the Food Standards Code which is enforced by the Australian states and territories and New Zealand agencies.

Standard 1.2.7 Nutrition, Health and Related Claims which should be applied in conjunction with other relevant standards of the Food Standards Code (links to all the food standards are found on the FSANZ website).

4.1.2 Pre-approved health claims

There is a list of approximately 200 pre-approved food-health relationships for making general level health claims, and 13 pre-approved food-health relationships for making high level health claims in Standard 1.2.7. Health claims can only be made on foods that meet the Nutrition Profiling Scoring Criteria (NPSC). This means that foods making health claims cannot be high in saturated fat, sugar or salt and there are different cut-offs for NPSC depending on the food.

The food producer constructs the health claim based on the approved food-health relationship; the wording is not prescribed but the wording cannot alter or contradict the food-health relationship.

4.1.3 Process for making new general level health claims

A food business can self-substantiate a food-health relationship that underpins a new general level health claim. This requires that the business undertakes a systematic review in accordance with the requirements outlined in Schedule 6 of Standard 1.2.7. The Standard requires the review to provide evidence of a causal relationship between the food, or the property of the food, and the effect on health. The business would then notify FSANZ of the food-health relationship. FSANZ maintains a list of the notified food-health relationships but publication by FSANZ of a notification does not indicate acceptance or validation of the stated relationship.

There is no approval process for self-substantiated food-health relationships underpinning general level health claims *per se* but a relevant authority for the jurisdiction where the health claim was made (i.e. in New Zealand, the relevant authority is MPI) can ask the food business for their systematic review to ascertain whether it meets the requirements of Schedule 6 in Standard 1.2.7 and that the notified relationship is a reasonable conclusion of the evidence presented in the systematic review. For a self-substantiated general level health claim, only the food business that has the systematic review to support the food-health relationship is permitted to make the general level health claim and the self-substantiated food-health relationship for the general level health claim is not added to Standard 1.2.7.

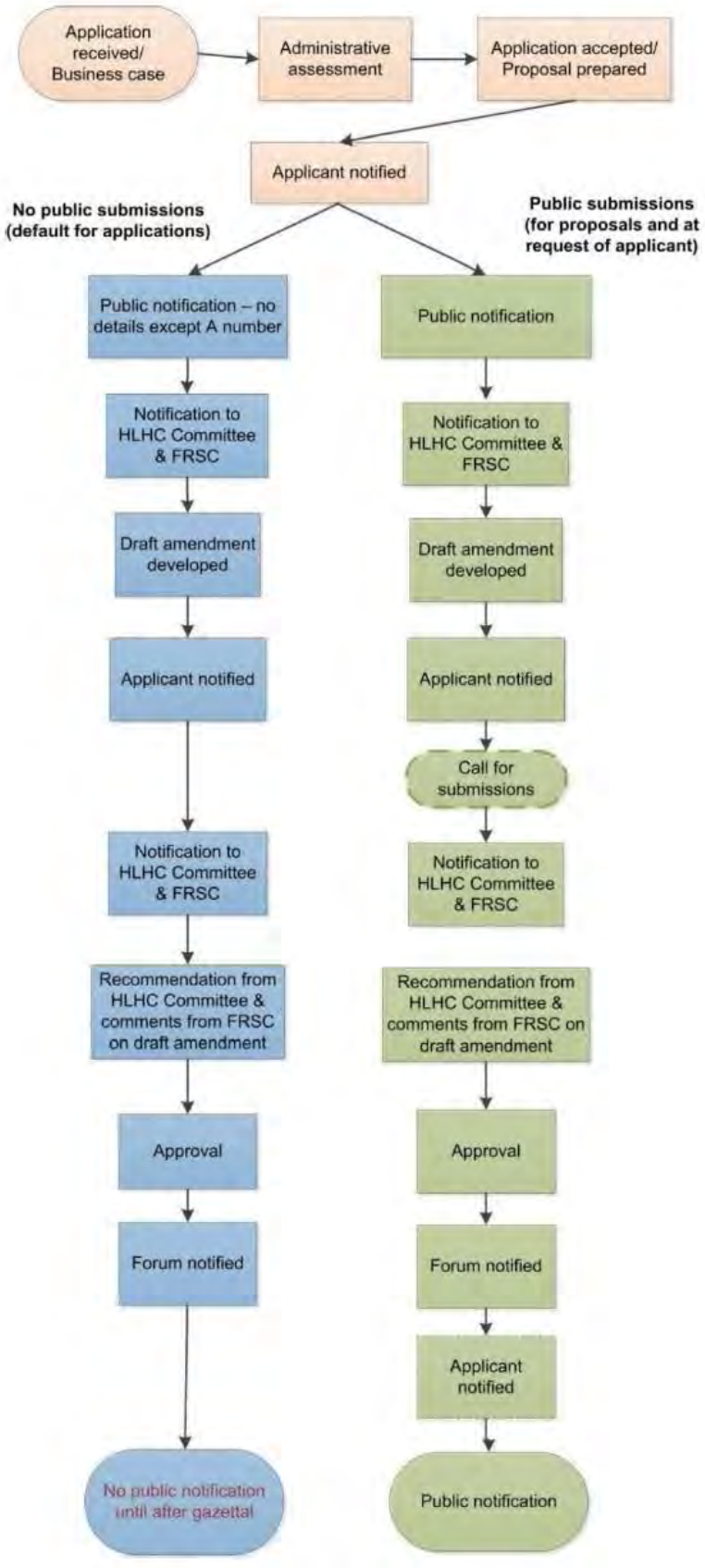
Another option is that the food business provides evidence in support of the proposed food-health relationship and makes an application to FSANZ who will consider the evidence and whether there is a causal relation between the food, or the property of the food, and the health

effect. In this case, an application to have a new general level health claim added to a list of pre-approved health claims in Standard 1.2.7 would be considered as a high level health claims variation and follows the same process for applying to add a new high level health claim to Standard 1.2.7 (see Figure 1 for more detail). The FSANZ High Level Health Claims Committee would also have to consider the evidence and provide a recommendation for approval. This may then go out for public consultation before the food-health relationship underpinning a new general level health claim is added to the standard (see Figure 1 for more details).

4.1.4 Process for making new high-level health claims

In order to make a new high-level health claim is for a food business to make an application to FSANZ where they would provide evidence in support of the proposed food-health relationship. FSANZ will consider the evidence and whether there is a causal relation between the food, or the property of the food and the health effect. The FSANZ High Level Health Claims Committee would also have to consider the evidence and provide a recommendation for approval. This may then go out for public consultation before the food-health relationship underpinning a new general level health claim is added to the standard (see Figure 1 for more details).

Figure 1. Flowchart of the process of applying to FSANZ for approval of a new high level health claim in Australia and New Zealand.



Abbreviations: FRSC, Food Regulation Standing Committee; HLHC, High Level Health Claims *(from Food Standards Australia New Zealand Application Handbook, 2016)*

4.1.5 Health claims on imported foods

Any new health claim that is to be added to Standard 1.2.7 must be approved by FSANZ, regardless of whether it has been accepted for use in another country.

All foods packaged for consumer use and imported into Australia and New Zealand must comply with the food labelling requirements.

4.1.6 Exporting requirements for health claims on foods (New Zealand only)

Any animal product intended for export from New Zealand that does not meet the requirements of the Australia New Zealand Food Standards Code must have a 60b exemption. For products manufactured under the Food Act 2014, exemptions can be issued under section 347. Any product manufactured or labelled under a 60b exemption is only eligible for that market and cannot be sold on the domestic market. For labelling exemptions, the product would need to be re-labelled to meet New Zealand or other market requirements.

All exemption requests are to be made to food.assurance@mpi.govt.nz

More information on 60b exemptions including application forms can be found here.

Last updated 12 September 2020

4.2 CANADA

4.2.1 Regulatory authority and documents

Health Canada in collaboration with the Canadian Food Inspection Agency (CFIA) is responsible for enforcing the food requirements of the Food and Drugs Act and Regulations for health claims.

Food and Drugs Act
Food and Drug Regulations

4.2.2 Pre-approved health claims

Three accepted function claims are listed on the CFIA website. Approximately 65 accepted nutrient function claims are also listed on the CFIA website and there are 11 eligible bacterial species and 4 non-strain specific health claims that can be made on probiotics available on the CFIA website.

General function claims for energy and known nutrients are also accepted. They can be made to the effect that energy or a nutrient is a factor in the maintenance of good health or that energy or a nutrient is a factor in normal growth and development.

There are five disease risk reduction claims in the Food and Drugs Regulations that can be used to make health claims if certain conditions are met.

There are additional disease risk reduction claims that have been accepted and are available on the Health Canada website.

Foods can make these claims as long as they meet the conditions and the compositional criteria for the claim.

4.2.3 Process for getting new nutrient-function claims approved

Function claims are subject to a general law that requires claims to be truthful and not misleading[1]. To be considered truthful and not misleading, function claims (other than nutrient function claims) must meet the standards of evidence described in Health Canada's Guidance Documents for Preparing Health Claim Submissions.

Nutrient function claims must meet the acceptability criteria described on the CFIA website. Manufacturers are advised to contact the Food Directorate of Health Canada before using a new claim to ensure that it is truthful and not misleading. Information required from manufacturers before making a new nutrient function claim include the name of the authorative body; the exact wording of the statement; a copy of the source document in which the statement is published; a description of the review process undertaken by the authorative body to develop the statement; and an indication that there is no conflicting authorative statement.

Claims about well-established function claims of known nutrients approved in other countries should meet the acceptability criteria referred to in the paragraph "How are new function claims approved?" and documented accordingly.

[1] Subsection 5(1) of the *Food and Drugs Act* states "No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."

4.2.4 Process for getting new reduction of disease risk claims approved

Pre-market approval by Health Canada is required for new claims about the diseases or health conditions listed in Schedule A of the Food and Drugs Act. Manufacturers who wish to seek approval for such claims must submit a health claim application using Health Canada's Guidance Documents for Preparing Health Claim Submissions. If the claim is approved, it would be added to the list of pre-approved health claims in the Food and Drugs Regulations.

Claims about the diseases or health outcomes not in Schedule A are subject to the same general law as function claims, which requires claims to be truthful and not misleading. To be considered truthful and not misleading, disease risk reduction claims must meet the standards of evidence described in Health Canada's Guidance Documents for Preparing Health Claim Submissions.

The process of providing evidence to substantiate a new health claim in Canada is similar to that of a systematic review. There is a focus on the following elements being incorporated into the submission:

- Systematic approach
- Transparency
- Comprehensiveness
- Human evidence
- High level of certainty
- Demonstration of causality
- Biological relevance of the claimed effect
- Feasibility of consumption of effective dose

In some cases, an existing systematic review can be used to demonstrate that a proposed health claim is valid. In order to be accepted as the scientific basis for a new health claim, an existing systematic review must have been prepared according to the guidelines of a regulatory or scientific organisation with standards of evidence that are similar to those of Health Canada. Guidance for using an existing systematic review to substantiate a new claim is available in Health Canada's Guidance Document for Preparing a Submission for Food Health Claims Using an Existing Systematic Review.

4.2.5 Health claims on imported foods

All health claims must be approved for use in Canada regardless of whether it has been accepted for use in another country. However, the process that is required to submit an application for a new health claim in Canada follows a similar process to conducting a systematic review.

All foods packaged for consumer use and imported into Canada must comply with the food labelling requirements.

All health claims are subject to General Principles for Labelling and Advertising

Last updated 31st October 2019

4.3 CHINA

4.3.1 Regulatory authority and documents

China State Food and Drug Administration (SFDA)

National Food Safety Standard: Standard for nutrition labelling of pre-packaged foods is available in English.

Measures for the Registration and Filing of Health Food is available in English.

4.3.2 Pre-approved nutrient function claims

In the Standard for nutrition labelling of pre-packaged foods, there is a table of requirements and conditions for making energy and nutrition content claims. There is also an appendix that lists 65 energy and nutrient function claims along with the conditions for making the claim.

4.3.3 Foods and approved health effects for health foods

Any substance which is able to affect/regulate human body functions by initiating enzyme activities or by other means. The following substances are included:

- Polysaccharide such as dietary fibre and lentinan (isolated from the fruit body of shiitake);
- Functional sweeteners such as mono-saccharides, oligose and polyglycitol;
- Functional fatty acids such as polyunsaturated fatty acids, phospholipids and choline;
- Functional antioxidants such as superoxide dismutase and glutathione peroxidase;
- Vitamins such as vitamin A, E and C;
- Peptides and proteins such as glutathione and immunoglobulin;
- Active bacteria such as Lactobacillus and Bifidobacterium;
- Trace-elements such as selenium and zinc; and
- Others such as octacosyl alcohol, phytosterol and saponin.

There is a list of 27 health functions that are approved for use (including cholesterol and blood pressure reduction) for health claims on health foods. There is also a list of authorised and unauthorised herbs for use in health foods. In order to provide evidence for the health effect, the SFDA authority has published procedures and methods for assessing the function that the health food provides. Some health functions require evidence from animal studies only e.g. enhancing immune systems, some require evidence from human studies only e.g. eliminating acne, and others require evidence from both animal and human studies e.g. assisting blood pressure reduction. No health food product is allowed to make any disease prevention or treatment claim.

Health food products sold in China through cross-border e-commerce (CBEC) platforms are not subject to the same degree of scientific evaluation and regulatory compliance as those sold through traditional retail outlets, such as supermarkets, convenience stores and drug stores however there are calls by non-governmental organisations to revisit and revise the e-commerce law.

Table 3. Main requirements for health food assessment in China

Regulation	Description of regulation
``The standard functional assessment procedures and methods of health foods''	Describes the basic requirement for the test samples, details individual function standard procedures of assessment among 27 functions including animal and human tests; the biomarkers, determinants and judgment indicators in each method are included.
``The standard toxicological assessment procedures and methods of health foods''	Describes the basic requirements for the test samples and details standard procedures of safety assessment such as acute toxicity tests, Ames tests, 30- or 90-d feeding tests, etc.
``Regulation on nutrient supplements''	Describes the definition of nutrient supplements, the amount and compounds of vitamins and minerals that can be used in nutrient supplements.
``The standard analytic methods for functional components''	Describes the basic requirements and components of herb, food, or extracts that must be tested if the substance is used in the product, and the analytical methods involving 100 plant substances.

From Yang, 2008.

Table 4. Health functions approved for use in China

	Claims	Animal Test	Human Test
1	Enhancing Immunity	+	-
2	Assisting Blood Lipids Reduction	+	+
3	Assisting Blood Sugar Reduction	+	+
4	Anti oxidative	+	+
5	Memory Improvement	+	+
6	Alleviating Eye Fatigue	-	+
7	Enhancing Lead Excretion	+	+
8	Clearing Throat	+	+
9	Assisting Blood Pressure Reduction	+	+
10	Sleep Improvement	+	-
11	Facilitating Milk Secretion	+	+
12	Alleviating Physical Fatigue	+	-
13	Enhancing Anoxia Endurance	+	-
14	Assisting Irradiation Hazard Protection	+	-
15	Weight Control	+	+
16	Promoting Child Growth	+	+
17	Increasing Bone Density	+	-
18	Alleviating Nutritional Anemia	+	+
19	Protecting Liver Against Chemical Injury	+	-
20	Eliminating Acne	-	+
21	Eliminating Skin Chloasma	-	+
22	Improving Skin Water Content	-	+
23	Improving Skin Oil Content	-	+
24	Regulating Gastrointestinal Tract Flora	+	+
25	Facilitating Digestion	+	+
26	Facilitating Defecation	+	+
27	Assisting the Protection of Gastric Mucosa	+	+

From "Regulatory Procedures for Gaining Approvals for Health Foods in China" – Vitafoods, 2013.

4.3.4 Process of getting health claims on health foods approved

If the raw materials used in the health food are not listed in the Health Food Raw Material List, then an application for health food registration must be made. If it is the first time that a health food is being imported from another country, then an application for health food registration must also be made. For the preparation of an application for a health food the following is required:

- Copy of the business licence of the applicant;
- Research and development report of the product, which includes the researchers, research process and health function;
- Information specific to the food (name, dosage, manufacturing technology etc.) and its characteristics;
- Product safety and health function evaluation information, which includes safety, health function evaluation;
- Type, name and related standards of the package materials that directly touch the food;
- Sample labels.

A full list of the requirements for an application to register a health food is listed in the Measures for the Registration and Filing of Health Food.

For an imported health food, the food must have been produced and marketed outside of China for more than one year and is to be marketed within the territory of China. The applicant must conduct relevant research before applying for health food registration. After the research is completed, the applicant shall provide samples and test-related data to the testing institution designated by the SFDA for relevant testing and examination.

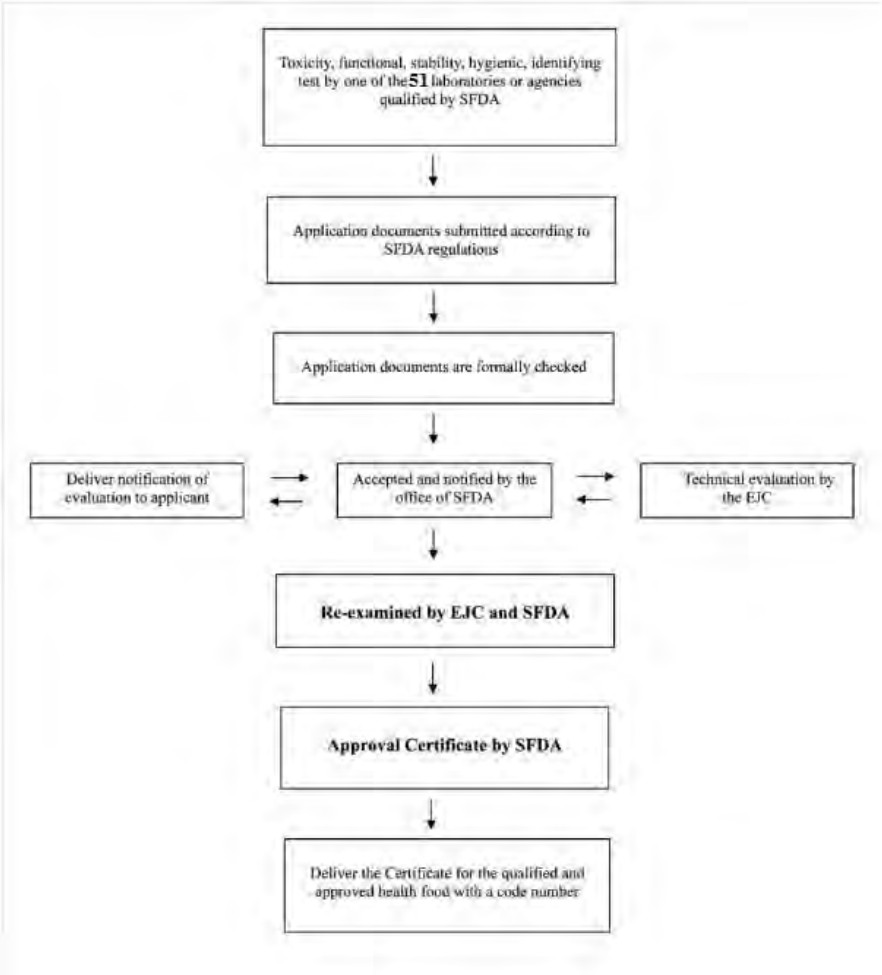
Where a health care function is within the scope published by the SFDA, the applicant shall provide a product research and development report to the designated testing institution; where an application for registration of a health care function is not within the published scope, the applicant shall conduct the relevant animal and human tests and send a function research and development report to the designated testing institution.

The product research and development report shall include information on the ideas for research and development, the screening process of the health functions and the expected effects. The function research and development report shall include the name(s) of function(s), reason for application, function test and evaluation methods and test results. Where it is not possible to conduct experiments in animals and humans, the applicant shall provide reasons and provide relevant information in the research and development report.

After samples and relevant materials provided in an application for a health product are received, the testing institution will conduct toxicology tests of safety, function tests, functional ingredient or major ingredient tests, hygiene tests and stability tests. Where an application for a function is not within the scope published by the SFDA, the testing institution shall also verify its function tests and evaluation methods as well as test results and issue a test report.

The SFDA will organise specialists in food, nutrition, medicine and pharmacy and other technical experts to perform the scientific evaluation and administrative examination on the application and test results and make a decision. Where the registration is approved, an *Import Health Food Approval Certificate* shall be issued to the applicant. This certificate is valid for 5 years and must be re-registered 6 months before the expiration date. The health food must bear the health food label specified by the SFDA.

Figure 2. Flowchart of the examination and approval process for health foods in China.



Abbreviations: EJC, Experts Judgemental Committee for Health Food; SFDA, State Food and Drug Administration
From Yang, 2008.

4.3.5 Health claims on imported foods

All health foods that are to be imported into China for the first time must apply for health food registration. The product must comply with the home country legal requirements. There are certain documents from the originating country that are required for the application of an imported health food:

- certificate of confirmation of local production quality control standards (issued in originating country);
- certificate showing product has been sold in originating country for at least one year;
- label and directions for use in the originating country; and
- relevant product standards from originating country/international organisation.

Last updated 3rd February, 2020

4.4 EUROPEAN UNION (EU)

4.4.1 Regulatory authority and documents

- The European Food Safety Authority (EFSA) – responsible for evaluating the scientific evidence base for health claims.
- The European Commission (EC) in conjunction with the Member States then decides whether to authorise the health claim including their conditions and/or restrictions of use, and final wording of the health claim.
- The Member States of the EU are responsible for enforcing the nutrition and health claims made on food in their countries.

Regulation (EC) No 1924/2006 on Nutrition and Health Claims Made on Foods: Pre-approved health claims

Food businesses can use the list of pre-approved health claims but will have to apply for approval for any new health claim that has not been authorised. The list of authorised (and non-authorised) health claims is available on the European Commission website.

4.4.2 Process of approval of health claims under Articles 13(5), 14, and 19

Proposals for health claims (i.e. applications) are submitted to a National Competent Authority of the Member States who then make the application available to EFSA. The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) provides a scientific evaluation of the application and considers whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence which takes into account the totality of the available scientific data and by weighing the evidence. Human data are central for the substantiation of a claim.

EFSA's opinion is referred to the European Commission for authorisation decision in conjunction with Member States.

The applications for health claim authorisation, i.e. the format and content, should follow the EFSA Scientific and technical guidance for the preparation and presentation of an application for authorization of a health claim (revision 2), which formed the basis of Commission Regulation (EC) No 353/2008 establishing rules for applications for authorisation of health claims.

To assist applicants for submitting health claim applications, EFSA has published:

- general guidance document for stakeholders; and also
- guidance on the substantiation of health claims in specific areas

In deciding whether a health claim has been substantiated, the NDA panel evaluates the evidence provided in the application for the health claim. First, they make an assessment as to whether the food or the component in the food has been defined and sufficiently characterised, to establish that the studies provided for substantiation of the claim were performed with the food/constituent for which the claim is proposed, and they consider whether the information provided includes those characteristics considered pertinent to the claimed effect.

The second aspect of the application that the NDA panel considers is whether the claimed health effect is defined and whether the health effect is a beneficial physiological effect for the target population, particularly if the claimed effect refers to a specific function of the body and can be measured *in vivo* in humans by generally accepted methods. For example, if the health effect was functioning of the gastrointestinal tract (which is too general and is unclear what outcome measure can be used), the specific effect must be stated – e.g. increased absorption

of certain essential nutrients. This health effect would be considered as a beneficial physiological effect. An aspect of the functioning of the gastrointestinal tract that would not be considered a beneficial physiological effect on its own would be change to the gut microbiota as this effect would have to be accompanied by a clinical outcome or specific beneficial health effect.

The third aspect that the panel considers is deciding whether there is a causal relationship between the consumption of the food or the constituent in the food and the claimed effect on health (i.e. for the target group under the proposed conditions of use). In doing so, the NDA Panel evaluates all of the studies included in the dossier to decide whether they were designed and conducted in a way that would allow the effect of the food or the property of the food to be established. For example, if the food or the property of the food was a single microorganism but one of the studies they provided examined the effect of a combination of microorganisms or a different health effect from that claimed, then that study would not provide information that could be used to substantiate the health claim. Relevant and applicable human studies are an absolute requirement for the scientific substantiation of the claimed effect on health and the efficacy of the studies are at the top of the hierarchy that informs decisions on substantiation. The Panel will consider aspects of the way the studies are conducted (quality) when deciding whether a study can provide evidence for an effect of the food on health. The Panel then weighs the evidence from the studies they have considered are relevant to the health claim, with respect to its overall strength, consistency and biological plausibility, taking into account the quality of individual studies and with particular regard to the population group for which the claim is intended, and to the conditions of use proposed for the claimed effect, giving the greatest weighting to well-designed human intervention studies. Animal, *in vitro* and mechanistic studies will provide supporting evidence, especially for the biological plausibility of the health claim which is an important part of considering whether there is a causal relationship.

For Article 13.5 and 14 health claims, it is important that the applicant provides all the available relevant scientific literature in the application, paying particular attention to ensuring that this represents the totality of the pertinent evidence. There are no specific requirements for ensuring that all of the evidence has been collated in the dossier. EFSA makes the summary of the application public as stated in the regulation, excluding the information considered as confidential.

4.4.3 Health claims on imported foods

The health claims must be approved for use in the EU regardless of whether it has been accepted for use in another country.

Last updated 31 January 2017

4.5 HONG KONG

4.5.1 Regulatory authority and documents

The Centre for Food Safety (CFS) is responsible for enforcing food nutrition labelling regulations in Hong Kong.

Food and Drugs (Composition and Labelling) (Amendment: Requirements for Nutritional Labelling and Nutrition Claim) Regulation 2008

4.5.2 Pre-approved nutrient function claims

There is a list of ~26 nutrient function claims that are listed as examples of claims that can be made under the Nutrition Labelling Scheme in Hong Kong available here (note that the list is not exhaustive).

A food can make a nutrient function claim as long as the nutrient has a nutrient reference value (NRV) or is listed in column 2 of Schedule 8 of the Food and Drugs (Composition and Labelling) Amendment. This would include approximately 38 nutrients (including energy). A nutrient function claim must be based on scientific substantiation and scientific consensus and contain information on the physiological role of the nutrient concerned. In order to make a nutrient function claim, the conditions for making a nutrient "source" claim apply (where relevant).

There is currently no specific regulation on reduction of disease risk claims and other function claims on general prepackaged foods.

4.5.3 Health claims on imported foods

The CFS would still need to check the level and quality of the scientific evidence that supports the nutrient function claim which has been approved in another country/jurisdiction. It is also important to note that the CFS encourages food importers to avoid using health claims (including those endorsed by a national agency).

4.5.4 Additional/supplementary information

Proposed regulatory framework for nutrition and health claims for formula and foods for infants and children younger than 36 months.

The proposed regulatory framework for nutrition and health claims for formula and foods for infants and children younger than 36 months lists five 'overarching principles', with the government seeking views on in particular on whether to follow an 'inclusive' approach and allow product-claim combinations that are not already prescribed under these principles, or a more 'restrictive' approach under which these claims would not be allowed.

- Principle 1 – Nutrition claims (i.e. nutrient content claims and nutrient comparative claims) should be prohibited in infant formula.
- Principle 2 – Reduction of disease risk claims should be prohibited in formula products (i.e. infant formula and follow-up formula) and pre-packaged foods for infants and young children.
- Principle 3 – Nutrition claims (i.e. nutrient content claims and nutrient comparative claims)

and nutrient function claims should be permitted in pre-packaged foods for infants and young children.

- Principle 4 – Nutrients or constituents permitted to be subjects of claims should be of high importance to the health of infants and young children.
- Principle 5 – Nutrition and health claims should meet specific content conditions and health claims must be scientifically substantiated and have undergone credible evaluation process.

Part of the consultation for this regulatory framework would be deciding whether Hong Kong should take an inclusive or a restrictive approach on the use of nutrient function and other function claims on formula (infant and follow-up) and for other function claims on pre-packaged foods for infants and young children (see Table 4 for more information). In the proposed regulatory framework for nutrition and health claims for formula and foods for children younger than 36 months, reduction of disease risk claims would be prohibited.

Under the proposed regulatory framework for nutrition and health claims for formula and foods for children younger than 36 months, health claims already approved by national authorities in other jurisdictions will be able to take advantage of a 'fast track' approval mechanism.

Table 5. Inclusive and restrictive approach to regulating nutrition and health claims on formula and foods for infants and young children.

Category of claim	Type of claim	Inclusive approach	Restrictive approach
Infant formula			
Nutrition claim	Nutrient content claim [a]	Not allowed *(Principle 1)*	
	Nutrient comparative claim [b]		
Health claim	Nutrient function claim [c]	Allowed [f]	Not allowed [f]
	Other function claim [d]	Allowed [h]	Not allowed [h]
	Reduction of disease risk claim [e]	Not allowed *(Principle 2)*	
Follow-up formula			
Nutrition claim	Nutrient content claim	Allowed [g]	Not allowed [g]
	Nutrient comparative claim	Allowed [g]	Not allowed [g]
Health claim	Nutrient function claim	Allowed [g]	Not allowed [g]
	Other function claim	Allowed [h]	Not allowed [h]
	Reduction of disease risk claim	Not allowed *(Principle 2)*	
IYC foods			
Nutrition claim	Nutrient content claim	Allowed *(Principle 3)*	
	Nutrient comparative claim		
Health claim	Nutrient function claim		
	Other function claim	Allowed [h]	Not allowed [h]
	Reduction of disease risk claim	Not allowed *(Principle 2)*	

[a] E.g. "*contains choline (144mg / 100g)*".
[b] E.g. "*increased DHA level by 3 times (compared to its original formula)*".
[c] E.g. "*phospholipids (PhD) are essential for the function of brain cells*".
[d] E.g. "*probiotics (益生菌) helps to maintain a healthy digestive system*".
[e] E.g. "*fortified with an appropriate level of iron to reduce the risk of anaemia (貧血)*".
[f] Arguments for and against such claims are set out in paragraphs 4.20 to 4.21 below.
[g] Arguments for and against such claims are set out in paragraphs 4.22 to 4.25 below.
[h] Arguments for and against such claims are set out in paragraphs 4.26 to 4.28 below.

Taken from proposed regulatory framework for nutrition and health claims for formula and foods for infants and children younger than 36 months, 2015.

Last updated 1st July, 2015

4.6 INDIA

4.6.1 Regulatory authority and documents

Food Safety and Standards Authority of India (FSSAI)

- The FSSAI was established under the Food Safety and Standards Act 2006, which is a consolidating statute related to food safety and regulation in India.
- FSSAI is responsible for protecting and promoting public health through the regulation and supervision of food safety.

4.6.2 Pre-approved Nutrition Function Claims

There is a list of ~ 9 nutrient function claims that are listed as examples that can be made under (Advertising and Claims) Regulation in India available here.

Nutrition function claims are made if the food satisfies these requirements:

i. Contains information on the physiological role of the nutrient or the substance or an accepted diet-health relationship
ii. The claimed benefit is attributed to a constituent of the food
iii. Provides a statement on the quantity of a nutrient or a substance that is subject to the claim
iv. Target group is mentioned (where applicable)
v. Directions for use of the food to obtain the claimed benefit in the context of the diet
vi. Maximum safe intake of the food or the constituent (where applicable).

Nutrition function claims and other function claims are made based on current relevant scientific substantiation and sufficient evidence on the claimed effect and the relationship to health. This is reviewed and updated by food business operators as new knowledge becomes available.

In a circumstance where a claimed health benefit is attributed directly to a product, the final outcome of the assessment shall be based on statistically significant results from well-structured human intervention studies conducted under the guidance of established research institutions and in line with the principles of Good Clinical Practice (GCP).

Foods that have a claim must meet the requirements of intake per serving as outlined in Schedule 1 of the Food Safety and Standards (Advertising and Claims) Regulations, 2018.

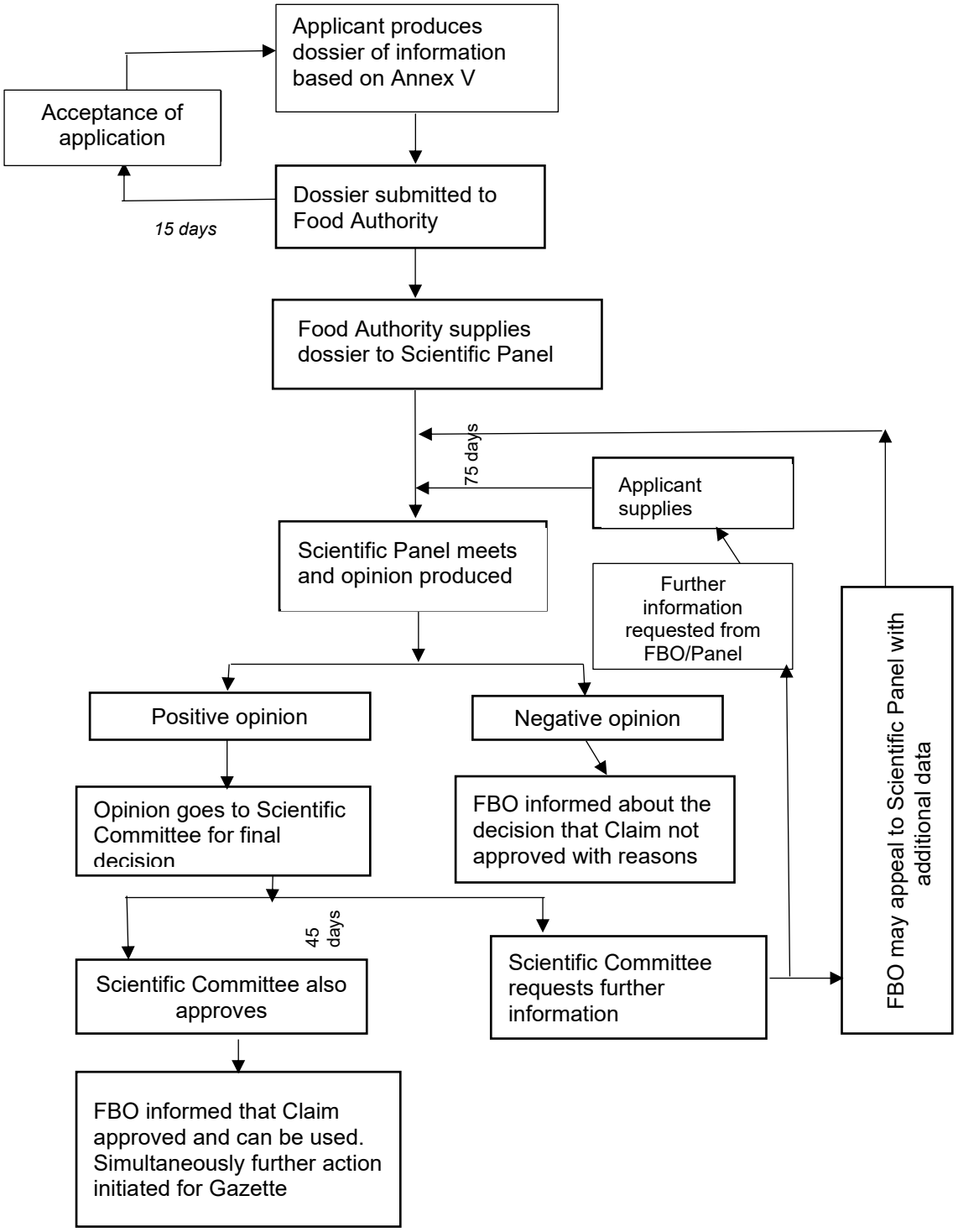
4.6.3 Procedure for approval of claims

An application for the claim shall be submitted by the food business operator along with an application fee consisting of information on the claim to be made; name of the ingredients/nutrient/substance based on the claim to be made; certified method of analysis of ingredient/substance for the claim to be made; well-designed human intervention studies used to substantiate the claims; and scientific/cultural information about the claim. A preliminary review of the application is carried out and if there are any incomplete submissions the food business will be notified within ninety days from the date of receipt of application and the applicant shall provide the information required within thirty days of the receipt of the communication or the application will be rejected without any further reference. More information can be obtained here.

4.6.4 Health claims on imported foods

There are currently no recognition processes in place with any country for the regulation of health claims in India. However, in due course, the FSSAI would be open to having discussion on mutual recognition of health claims from New Zealand.

Figure 3. Flowchart showing process of authorisation of health claims in India. Abbreviations: FBO, Food Business Operator (culled from the Food Safety and Standards 'Advertising and Claims')



4.7 INDONESIA

4.7.1 Regulatory authority and documents

National Agency of Drug and Food Control

HK.03.1.23.11.11.09909 (2011). 'Control of claims on processed food labels and advertising' (in Indonesian).

4.7.2 Pre-approved health claims

There are 11 pre-approved nutrient function claims with their conditions of use listed in the 'Control of claims in processed food labels and advertising'.

There are 11 pre-approved reduction of disease risk claims and these are listed, along with their conditions of use, in the 'Control of claims in processed food labels and advertising'.

Foods that have a claim must meet the requirements of intake per serving of no more than:

- 13 g total fat;
- 4 g saturated fat;
- 60 mg cholesterol; and
- 480 mg of sodium.

4.7.3 Process for getting new health claims approved

An application for approval of a new nutrient function or a reduction of disease risk claim should be made to the Head of the National Agency of Drug and Food Control. A decision on whether to accept or reject the health claim will be made within approximately 6 months. The requirements of the new claim should be the following:

a) In line with national health and nutrition policies;
b) Not associated with the treatment and prevention of disease in individuals;
c) Not encourage an unhealthy eating pattern;
d) Be based and made in the context of the total diet; and
e) Be true and not misleading.

Research is required to process the submission for new components and/or new health claims. The research should be conducted on the food product in a form that is ready to be consumed and if the component in the food is new then the following must be demonstrated:

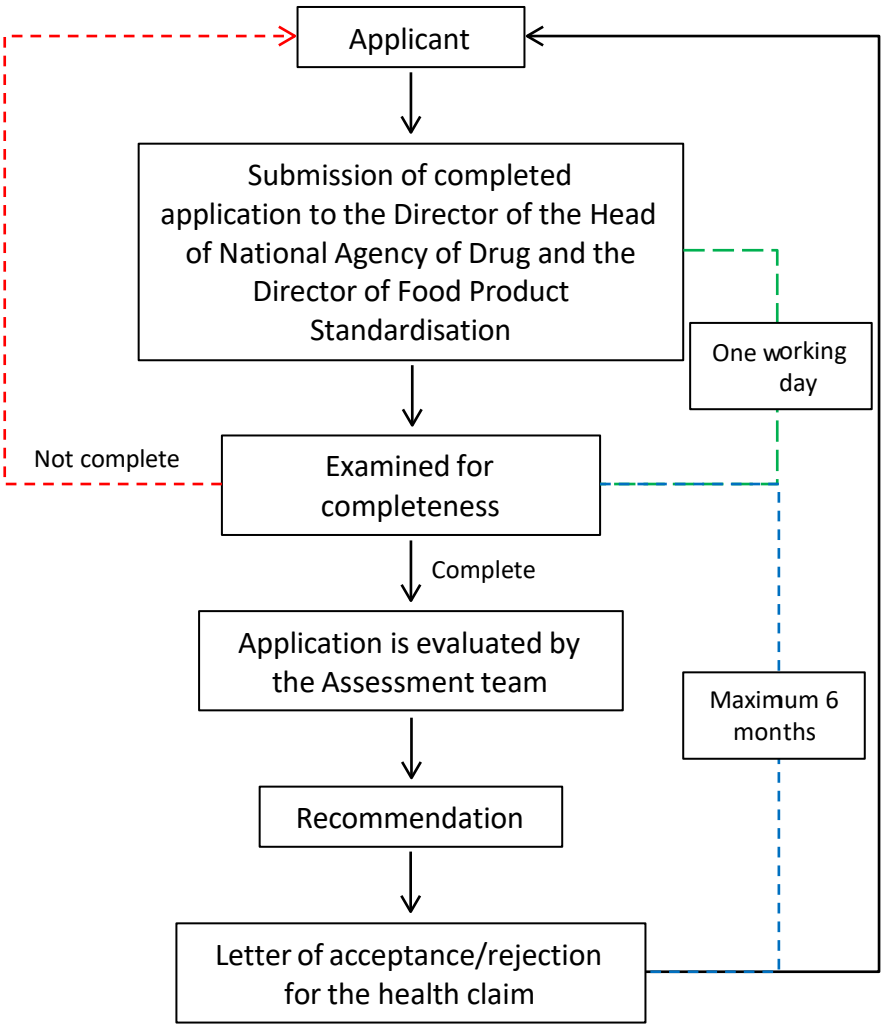
1. The history of use as a food;
2. Physical and chemical properties of the food;
3. The potential to cause allergies;
4. Metabolism of the food;
5. Sub-chronic toxicity studies in animals;
6. The study of human tolerance;
7. If a component in the form of extracts of plant or animal then must be accompanied by information about the methods of extraction and the composition of the extract; and
8. Report of the safety assessment by international agencies or other government agencies.

Scientific evidence to support new nutrient function claims and reduction of disease risk claims should be based on human research that meets the scientific principles that apply (experimental study randomised controlled trials (RCT) or observational if experimental research is not available/not possible to conduct). *In vitro* and animal research data can be submitted to support the application.

Factors that should be considered in experimental research in humans:

a) The purpose of research should be in accordance with the claims filed.
b) Groups of subjects including the control group who are studied should be relevant to the claims submitted and in accordance with the target population. Under certain conditions the research needs be conducted in Indonesia.
c) Statistical power to test the hypothesis and clinical significance should be considered.
d) The number of subjects studied, duration of the intervention and number of outcomes (where applicable) should be sufficient to show the expected health effect.
e) Adherence to the consumption of the foods that contain components of interest must be monitored.
f) Intake of nutrients and tested components will need to be monitored with appropriate validated methods as part of the experimental research.
g) Food consumption patterns used in the study do not exceed the usual patterns of consumption. For product innovation, the food is adjusted to the level of acceptability (based on acceptance test results).
h) Need to consider the nature of the food, how the food is prepared and consumed in relation to the benefit on health.
i) The research included in the application must have received ethical approval by a recognised ethics committee.
j) The research results should represent the totality of the evidence. When the application is being evaluated by the Assessment team, both positive and negative findings will be taken into account.
k) The results of the study should have been published in scientific journals.
l) Research should preferentially be conducted by independent researchers or institutions.
m) The results of the studies should indicate that use of the food product shows a statistically significant effect and clinically appropriate claims using the amount of the recommended intake.

Figure 4. Flowchart showing the process of applying for a new health claim in Indonesia.



From "Control of claims on processed food labels and advertising", 2011.

It is important to note that the results of the test food products cannot be extrapolated to other products, even if they are similar.

Nutrient function claims can only be used on the food that meet the criteria as a "source" of that nutrient, and (other than those listed in Annex 3 of the Regulation) shall meet the following requirements:

a. Function of the nutrient has been recognized internationally; and
b. There is relevance of these nutrients in Indonesian society based on problems and needs in Indonesia which is evidenced by valid scientific methods.

Nutrient function claims, other function claims and disease reduction claims are prohibited from being made on processed foods intended for babies and children aged one to three years old. Health claims that will include a statement that consumption of the food meet the needs of all essential nutrients, encourages excessive consumption of any food or disparages good dietary practice and illustrates that a nutrients or other component can prevent/treat/cure disease are not allowed.

4.7.4 End points and biomarkers

a. The benefits that are claimed should be measured directly as the end point. An intermediate biomarker end point can be used when the functional benefits cannot be measured directly.

b. Biomarkers are chosen to be an indicator of biological, physical, clinical or epidemiological outcome and must be recognised internationally, and can be affected by the consumption of a food, a food component or food ingredient under investigation. The WHO Technical Report Series 916 can be used as a guideline.

c. Variations in individual responses/between population groups should be considered when evaluating studies using biomarkers.

d. The method used to measure the biomarker should be one that is normally used by the international scientific community.

4.1.5 Re-evaluation

Re-evaluation is conducted periodically especially when there are new findings.

4.1.6 Health claims on imported foods

Given the high level of detail put into the requirements for getting new health claims approved in Indonesia, it is unlikely that health claims from other countries would be recognised in Indonesia and an application for approval of a new health claim would have to be made to the National Agency of Drug and Food Control.

Last updated August, 2015

4.8 JAPAN

4.8.1 Regulatory authority and documents

Ministry of Health Labour and Welfare (MHLW) Japan
Regulatory settings of foods with health claims are managed by the Consumer Affairs Agency (CAA)

Nutrition labelling standards under the Health Promotion Act Food Labelling Act (2013).

Information in English on Food with Nutrient Function Claims and Foods for Specific Health Use can be found on the MHLW website. Information in English on Foods with Function Claims from the CAA can be found here .

4.8.2 Pre-approved foods with nutrient function claims

Foods with Nutrient Function Claims (FNFC) are those that are widely accepted by scientific experts, based on scientific evidence, and applied to existing foods or supplements internationally. Foods (including fresh foods) may be labelled with these claims, without food manufacturers having to notify the national government, as long as they meet the standards and specifications. The standards and specifications state that the amount of the nutritional ingredient that is provided in the recommended daily intake of the product must be within the range provided. All of these types of claims must be accompanied by a cautionary statement.

The standards and specifications for indication of nutritional function have been established for 17 nutrients.

4.8.3 Process for getting new foods for specified health use (FOSHU) approved

In order to sell a food as FOSHU, the safety of the food and effectiveness of the functions for health must be assessed, and the claim approved by the MHLW and the CAA. FOSHU reduction of disease risk claims are only allowed for calcium and reduction in the risk of osteoporosis, and folic acid and reduced risk of neural tube defects. Proposals for FOSHU approval include effectiveness in humans is clearly proven (data from human intervention, animal and *in vivo* studies); safety of food product (humans); use of nutritionally appropriate ingredients (e.g. no excessive use of salt, etc.); guarantee of compatibility with product specifications by the time of consumption; quality assurance and control methods. Where there are a number of products that contain ingredients with FOSHU claims, new products containing these ingredients seeking to make these claims will have a shorter process to achieve approval.

4.8.4 Requirements for FOSHU approval

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

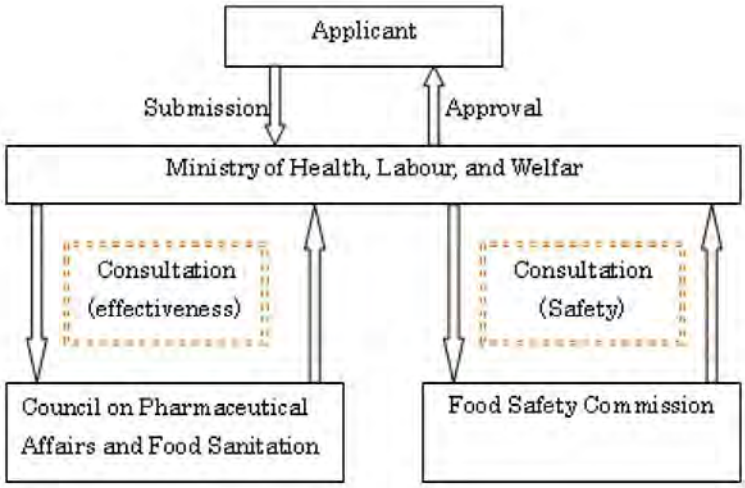
Qualified FOSHU are FOSHU for which there is no conclusive scientific evidence, or if the food has a certain effectiveness but no established mechanism. These are usually accompanied by "grounds for this effectiveness have not necessarily been established".

Standardised FOSHU are FOSHU for which the standards and specifications are established for foods that have had a sufficient number of FOSHU approvals and accumulation of scientific evidence. Standardised FOSHU are approved when they meet the standards and specifications.

Reduction of disease FOSHU are FOSHU for which the claim is permitted when the reduction of disease risk is clinically and nutritionally established for an ingredient.

There are eight approved FOSHU Health function claims for which business operators can apply. These health function claims are related to gastrointestinal conditions, blood cholesterol level, blood sugar levels, blood pressure, dental hygiene, mineral absorption, osteogenesis, and triacylglycerol levels.

Figure 5. Flowchart of the process of applying for Foods for Specific Health Use in Japan.



Taken from the Ministry for Health Labour and Welfare website.

4.8.5 New system for regulation of Foods with Function Claims

A new system was established in April 2015 called Foods with Function Claims regulations to allow health claims on foods (including fresh produce) that do not bear FOSHU or a nutrient function claim. In order to make a function claim under this new system, the food business must submit premarket notification of the function claim to the Secretary-General of the CAA sixty days prior to the targeted launch date. This must include scientific evidence of the safety and the effectiveness of the health claim. The government does not evaluate the science behind the function claim (and the food business is required to include this fact on their food label).

The safety of the food that the function claim applies to, must be evaluated and established by a method set by the CAA. Furthermore, the food business must also investigate whether there is any interaction between the functional component of the food with any drug or other substance found within the food. The scientific evidence for the function claim must be in the form of clinical trials with the finished food product or by the process of a systematic review on the finished food product or the functional component of the food product. The function claims usually relate to the maintenance or the promotion of health and can include a number of different health effects such as blood pressure, blood cholesterol, eye health, intestinal health, sleep and allergies.

In making function claims, the following are not allowed:

i. Claims that state intentional enhancements such as body-building, hair-growth treatment etc.

ii. Claims that appeal to certain vulnerable populations such as minors, pregnant women and lactating women.
iii. Claims that imply the effectiveness of treatment or prevention of disease.

4.8.6 Health claims on imported foods

a) Importers of foods can make health claims under the new Foods with Function Claims as long as they have made premarket notification of the function claim and submitted the necessary evidence for the safety and effectiveness of the food product to the CAA. Variations in individual responses/between population groups should be considered when evaluating studies using biomarkers.
b) The method used to measure the biomarker should be one that is normally used by the international scientific community.

4.8.7 Re-evaluation

Re-evaluation is conducted periodically especially when there are new findings.

4.8.8 Health claims on imported foods

Given the high level of detail put into the requirements for getting new health claims approved in Japan, it is unlikely that health claims from other countries would be recognised in Indonesia and an application for approval of a new health claim would have to be made to the National Agency of Drug and Food Control.

Given there is a specific regulatory system set up for FOSHU and each product receives a seal of approval for FOSHU, these specific type of health claims must go through the FOSHU approval process.

Last updated 27th August, 2019

4.9 MALAYSIA

4.9.1 Regulatory authority and documents

Food Safety and Quality Division, Malaysian Ministry of Health

Malaysia's Food Act 1983 and Food Regulations 1985.

4.9.2 Pre-approved nutrient function claims

There are approximately 50 nutrient function claims listed in the 'Guide to nutrition labelling and claims'.

A few of the nutrient function claims refer to a biomarker for a serious disease e.g. "soy protein helps to reduce cholesterol".

In order to make a nutrient function claim, the conditions for making a "source" claim must be met (where applicable). Additional conditions for making nutrient function claims are listed in Appendix 6 of the "Key Message 14 of the Malaysian Dietary Guidelines".

4.9.3 Process for getting new nutrient function claims approved

There is a system in place to consider applications to the Ministry of Health Malaysia from industry for new nutrient function claims. New claims must be supported by comprehensive evidence from all relevant studies regardless of the results. Data from human intervention trials are preferred and epidemiological and experimental studies and review articles may be included as supportive evidence. Studies should include those conducted by different organisations or institutions and the studies should be published in peer-reviewed journals.

For a nutrient function claim to be permitted on a label, the food must contain a specified minimum quantity of the nutrient that is the subject of the claim and the amount of the four core nutrients (such as energy, protein, carbohydrate and fat) of the food.

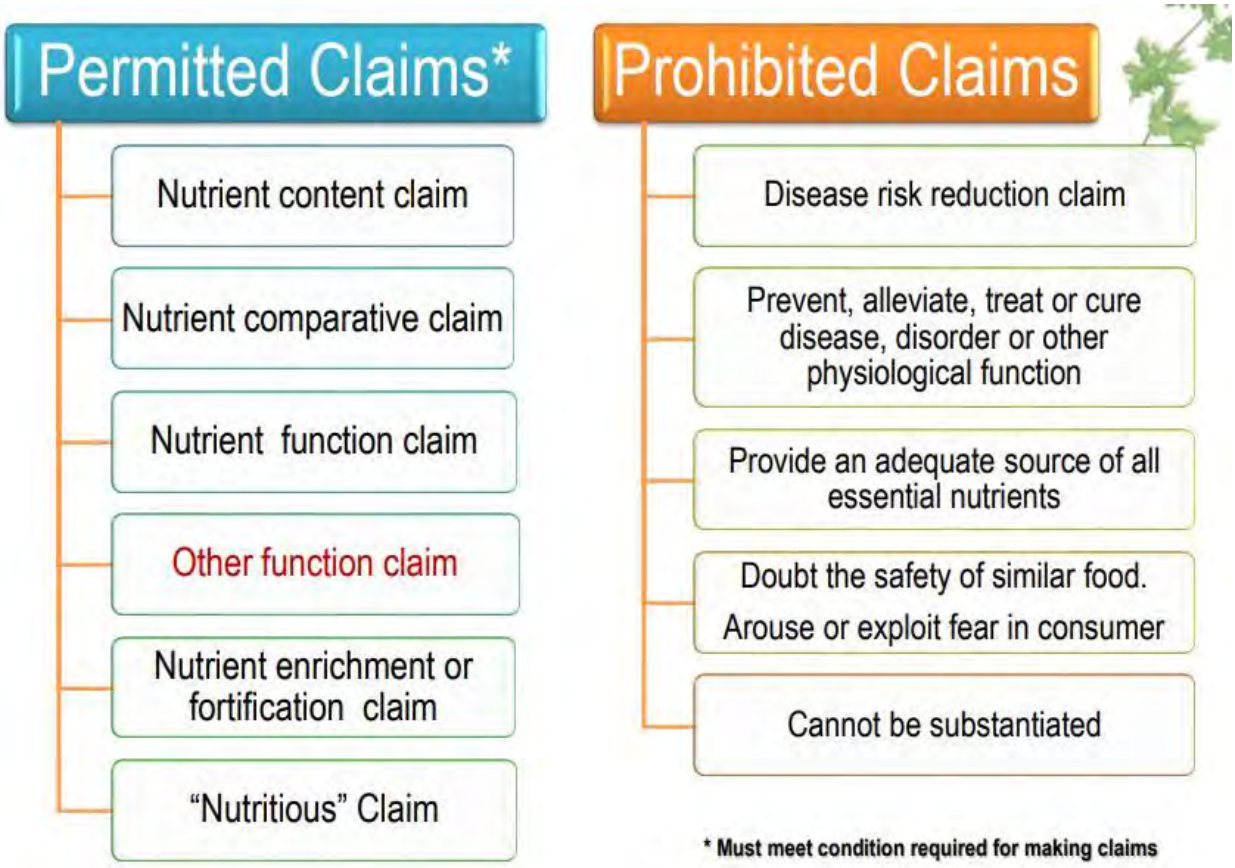
4.9.4 He**alth claims on 'other food components'**

Since 2003, health claims are allowed on other food components listed as 'permitted added nutrient' if the food meets the requirement for such claim. A list of 29 other function claims for bioactive ingredients with proven physiological functions was approved and gazetted in April 2017. The list includes several dietary fibres eg, high-amylose maize, resistant starch, isomaltulose, d-ribose and slowly digestible starch (SDS). To apply for this health claim, industries must follow the same conditions for applying for a nutrient function claim and some additional conditions which include additional labelling requirements (where applicable) and restriction to selected foods (if relevant). More information can be obtained here

4.9.5 Health claims on imported foods

Approval of a nutrient function claim from another country would be considered supporting evidence, and in the application for a new nutrient function claim, the applicant can provide examples of the nutrient function claim being approved in other countries. The applicant would still need to make an application showing clinical evidence that supports the new nutrient function claim.

Figure 6: Permitted and prohibited claims in Malaysia.



From 'Regulatory Update on Functional Ingredients: Permitted Health Claims in Malaysia' presented by Nasir and E-Siong on the 34th Scientific Conference- Healthy Nutrition: Key to Disease Prevention.

Last updated 9th July, 2019

4.10 PHILIPPINES

4.10.1 Regulatory authority and documents

Philippines Food and Drug Administration (FDA)

Regulatory documents

The Philippines has adopted the Codex Alimentarius Commission 'Guidelines for Use of Nutrition and Health Claims' (CAC/GL 23-1997). Some health claims will be regulated by specific laws for certain foods or food groups e.g. the Milk Code.

4.10.2 Pre-approved health claims

There is no list of pre-approved health claims.

4.10.3 Process for getting new nutrient function claims approved

In the Philippines, all food products must be registered with the FDA. Nutrition and health claims will be evaluated by the FDA's Product Services Division based on their compliance with the Codex Guidelines on Nutrition and Health Claims. This process includes the scientific substantiation of the health claim that is based on current relevant scientific evidence and the level of proof should be sufficient to support the proposed effect and the relationship to health. There should also be a validated method to quantify the component in the food that forms the basis of the health claim. The claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituent.

Other conditions for health claims are:

a. If the claimed benefit is attributed to a nutrient with established reference value, the food should be a source of or high in the nutrient/constituent and low in or reduced in or free of the nutrient/food constituent.
b. Only those essential nutrients for which nutrient reference values have been established should be the subject of a nutrient function claim.

Health claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use and must have a validated method to measure the food constituent that forms the basis of the claim

4.10.4 Health claims on imported foods

Health claims that have been approved in other countries/jurisdictions are not automatically recognised in the Philippines and would be required to undergo going the mandatory application process to the Philippines FDA.

Last updated 10th October, 2015

4.11 SINGAPORE

4.11.1 Regulatory authority and documents

Agri-Food and Veterinary Authority (AVA) and Health Promotion Board (HPB) of Singapore 'Food Regulations' *(on the AVA website)*

4.11.2 Pre-approved nutrient function claims

There is a list of 121 pre-approved nutrient function claims for macronutrients, vitamins and minerals; 17 other function claims and 6 reduction of disease risk that are available in 'A Guide to Food Labelling and Advertisements' (on the AVA website).

Other function claims are for foods that contain collagen, probiotics or prebiotics. There is also a list of acceptable nutrient function claims for infant foods and foods for children younger than six years in the guide. There is also a claim for foods containing plant sterols/stanols.

4.11.3 Process for getting new nutrient-function claims approved

Applicants for new nutrient-function claims (not reduction of disease risk claims) need to submit a peer-reviewed report of a systematic review containing at least five human intervention studies (published in the past 10 years) showing the proposed health effect. The nutrient content of the food product must be verified by a suitable testing laboratory to ensure that the nutrient information displayed on the food is accurate. The proposal should include official statements by recognised expert scientific bodies and an indication of the information regarded as proprietary should be accompanied by verifiable jurisdictions where applicable. More information on how to apply for a new nutrient-function claim is available in 'A Guide to Food Labelling and Advertisements' and on the AVA website.

The approved nutrient function claims and criteria have been developed based on Singapore's existing national nutrient claims guidelines formulated by the Health Promotion Board and are based on Codex Alimentarius' recommendations on the scientific basis for health claims.

4.11.4 Reduction of disease risk claims

There are five disease risk reduction claims listed in the Fourteenth Schedule of the Food Regulations. However, in order to use these claims, local food manufacturers and importers must first apply to the Health Promotion Board who will provide approval for the food to carry the Healthier Choice Symbol. The Healthier Choice Symbol indicates that foods are the healthier option within the same food category, and takes into consideration total fat, saturated fat, sodium and sugar as well as considering the dietary fibre and calcium content. They must then apply to the AVA for use of the intended nutrient specific diet-related health claims. The AVA will then conduct a pre-market evaluation of the food.

4.11.5 Health claims on imported foods

As part of the application form for new health claims, the applicant must state whether the health claims have been assessed and approved by any other regulatory body. Moreover, supporting documents such as an approval letter from national food authorities can be included in the application for a new nutrient function claim.

Last updated April, 2019

4.12 SOUTH KOREA

4.12.1 Regulatory authority and documents

The Ministry of Food and Drug Safety.

The Health Functional Food Act and the Health Functional Food Code.

4.12.2 Pre-approved nutrient function claims

There are over 100 nutrients and ingredient function health claims that have been approved for use and are listed in the Health Functional Food Code. Foods that use the health claim must be as low in fat, cholesterol, sodium, saturated fat and trans fat as possible.

"Functional health foods" are defined in the Heath Functional Food Act as being foods manufactured with functional raw materials or ingredients beneficial to the human body. These functional ingredients or raw materials include processed raw material originating from animal, plant or microorganisms; and extract or purified substance of any ingredient originated from animal, plant or microorganisms. The majority of health functional foods are in the form of tablets, capsules, powders, pastes jellies, gels and bars. In 2008, the scope of the Health Functional Food Act was extended to include conventional foods and other dietary supplements.

The Korean Ministry for Food and Drug Safety currently recognises 37 ingredients for generic health functional foods. If the food contains a new active ingredient that is not one of the 37 generic ingredients, the health functional food can be approved for use as a product-specific health functional food or a new ingredient. The following documentation must be submitted to the Korean Ministry for Food and Drug Safety and these are assessed by government officials, nutritionists, members of consumer unions and members of the industrial sector.

1. Standards for the manufacturing of the functional ingredient
    - Origin information including development history, current history of approval and use in domestic or foreign countries should be provided
    - Provide information on the method used to manufacture the functional ingredient
    - Information about the characteristics of the ingredient, structure and production yield
2. Safety evaluation
    - Provide information on the history of use, results from toxicology tests, amount to be consumed
    - Provide data on the scientific validation of the safety of the functional ingredient
3. Evaluation of efficacy
    - Provide data to substantiate the function of the ingredient including non-clinical studies (*in vitro*, *in vivo* and mode of action) and clinical studies
4. Specification
    - Provide a sample of the final product

- Provide consumption amount, consumption method, warning notice for consumption and related data.
- Specification on hazardous substances and related data for test method should be provided.
- Confirmation data that the ingredients are not identical with or similar to medicine.
- Ensure that the nutrient content and the ratio for the nutrients are provided where applicable.
- More information about the requirements for submission can be found here

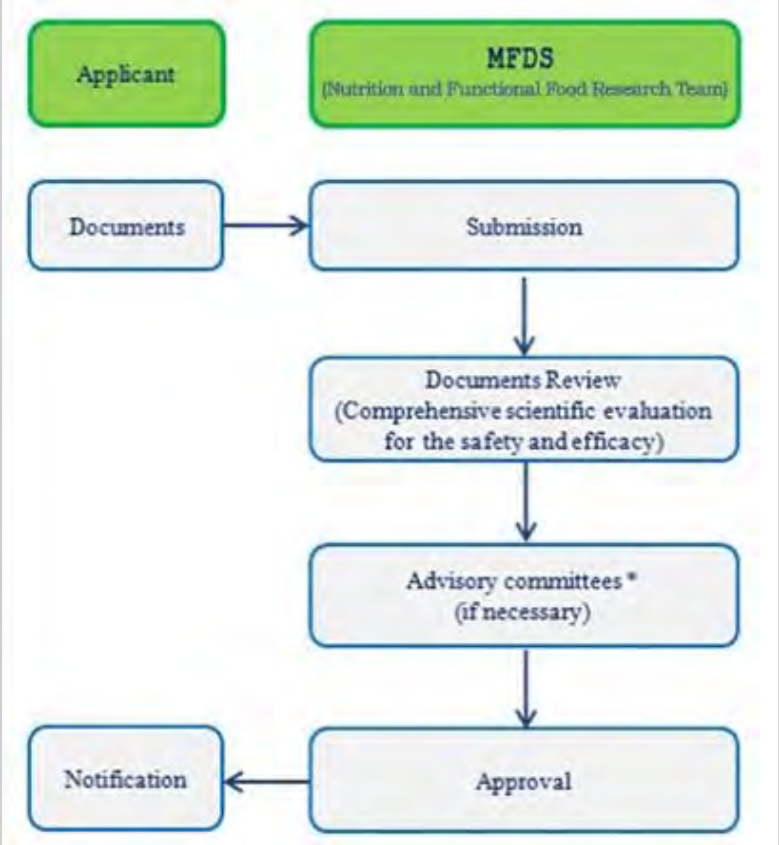
If the decision is made to grant approval for the product as a health functional food, then the product is given hygiene specifications and a period for which the product certification is valid. Once the health functional food has been certified it is assigned one of four grades that represents the amount of scientific evidence backing the health claim (Table 6).

Table 6. Grades of the health claim allowed for health functional foods

Scientific evidence	Health claim allowed
Significant scientific agreement	Can help reduce the risk of (disease)
Convincing	Can have a beneficial effect on…
Probable	May improve…
Insufficient	May have the possibility of improving…, but the evidence is limited and not conclusive

For new health functional foods, only the business organisation that obtains the certificate of approval for use can use it.

Figure 7. Process for approval for the use of product specific health functional foods in South Korea.



Last updated 13th September 2020

4.13 SWITZERLAND

4.13.1 Regulatory authority and documents

Federal Food Safety and Veterinary Office (FSVO)

SR 817.022.21 Ordinance of the Federal Department of Home Affairs (FDHA) on the labelling and advertising of foodstuffs

4.13.2 Pre-approved health claims

There is a list of over 200 pre-approved nutrient function and reduction of disease risk claims for macronutrients, vitamins and minerals that are available in the Ordinance on Information on Foodstuffs (FoodIO) (on the FSVO website).

4.13.3 Process for getting new health claims approved

All nutrient function and reduction of disease risk claims that are not listed in Ordinance on Information on Foodstuffs (FoodIO) must be approved by the FSVO. Applications for new health claims must fulfil the following:

- The food or food component is adequately defined and characterised.
- The health claim effect is based on the beneficial function for the target population.
- The food/constituent is required for normal human body functions.
- The quantity of the food/constituent and pattern of consumption required to obtain the claimed effect should reasonably be achieved as part of a balanced diet.
- A dose-effect relationship between the consumption of the food and the advertised effect in humans has been scientifically proven.

Applicants must submit evidence from relevant clinical trials and other studies not involving humans demonstrating an effect of the food/food component on health with the studies submitted representing the totality of the relevant evidence. The proposed effect of the food/food component must be beneficial to health. The evidence presented must also show a cause and effect relationship that is, dose-response, validity, consistency, specificity and biological plausible.

More information on the requirements of the scientific evidence for the application can be found here.

4.13.4 Health claims on imported foods

All imported foods must comply with the provisions in the Ordinance on Information on Foodstuffs (FoodIO).

Last updated 13th September, 2019

4.14 TAIWAN

4.14.1 Regulatory authority and documents

Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare

Health Food Control Act of Taiwan (in Mandarin)

4.14.2 Pre-approved health claims

There is a list of approximately 70 nutrient function claims that are permitted on foods, these can be found in 'Schedule of Vitamin or Mineral Statements' (Mandarin) and an (unofficial) English version is available in Appendix 1. In addition, there is a list of about 20 broad claims/slogans that are permissible e.g. "preserves health", "vigorous energy", "assists digestion" and "promotes metabolism".

4.14.3 Health Food Products

Health food products are foods with health care effects and all health food products must be approved by the TFDA. There is a list of 13 permissible health claims to do with the maintenance of health that can be made on these food products such as "promotion of gastrointestinal function", "alleviation of osteoporosis", "regulation of blood lipid" and "reducing allergic reactions". All health foods must be assessed and approved by the Department of Health and registered for use. The Health Food Evaluation Committee will assess whether the claimed health effect has been scientifically substantiated in accordance with criteria laid out in the "Methods of Assessing the Health Maintenance Effects of Health Foods".

Once a health food product has been approved for use and registered, the food is labelled with a well-recognised Green TFDA "Health Food" mark and the registration is valid for five years.

4.14.4 Health Food registration procedure

The food manufacturers or importers shall provide documents and information that covers the list of ingredients, their composition and specified content, an assessment report on product safety and health maintenance effects, a verification report on the ingredients supplying health maintenance effects and the method of testing, summary report of the good manufacturing process, stability of the health maintenance effects and general nutrient content. More information can be found here.

Figure 8. Flowchart on handling of applications for a health food permit in Taiwan.

From 'Taiwan Health Food Legislation', 2020.

4.14.5 Health claims on imported foods

Taiwan does not recognise health claims that have been approved in other countries. An application for a health food permit must be made.

Last updated 3rd February 2020

4.15 THAILAND

4.15.1 Regulatory authority and documents

Thailand Food and Drug Administration

According to Food Act B.E (2522), applications making health claims on foods in Thailand should be made to The Ministry of Public Health.

4.15.2 Pre-approved health claims

There are 29 pre-approved nutrient function claims and all must be based on reliable scientific evidence. The following conditions also apply:

- The nutrient should have a Thai Recommended Daily Intake (RDI) for ages six years and over
- The nutrient content of the claimed product in the level of reference serving size and serving size as displayed on the label needs to be a 'source' of that nutrient.
- if those food contain; total fat more than 13 grams or saturated fat more than 4 grams or cholesterol more than 60 milligrams or sodium more than 360 milligrams in the amount of one recommended serving size must be declared on labels.

4.15.3 Guidelines for use of health claims

1. It must be safe and its standard and quality comply with the regulations of the Notification of the Ministry of Public Health (MoPH)
2. Novel food must pass safety assessment
3. The food must display nutrition labelling as designated in MoPH No. 182 (1998) 'Nutrition labelling' except special purposed foods which shall follow the Notification of the MoPH regarding special purposed foods.

Conditions for health claims and other function claims

1. The health claim benefit should come from the consumption of a reasonable quantity of the food or food constituents in the context of a healthy diet.
2. No permission for other function claims and reduction of disease risk claims, if those foods contain; total fat more than 13 grams or saturated fat more than 4 grams or cholesterol more than 60 milligrams or sodium more than 360 milligrams in the amount of one recommended serving size and must be declared on labels.

More information can be found here

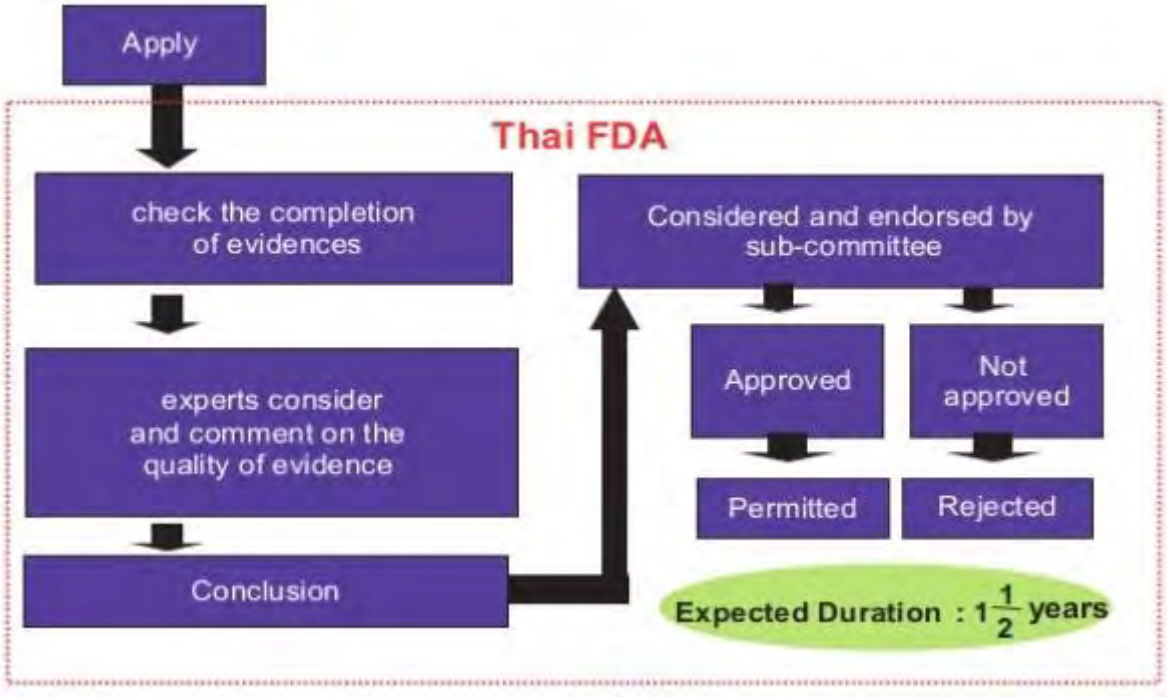
4.15.4 Process for getting new health claims approved

Domestic producers and importers of food can make an application to the Thai FDA (part of the Ministry of Public Health) to have a new nutrient function claim or a reduction of disease risk claim approved. They are required to submit a systematic review, meta-analysis or a scientific opinion of department organisation or expert scientific bodies or a well-designed human intervention study (full version) to self-substantiate their health claims. However, given the lack of a strong regulatory framework for health claims in Thailand, such applications are rarely approved because it may take up to a year and six months for it to be approved.

4.15.5 Health claims on imported foods

If a health claim has been approved in another country, the food producer or importer would still have to make an application to the Thai FDA for approval of that health claim.

Figure 9: Approval process for a health claim in Thailand



From Dr. Tipvon Parinyasiri, Director of Bureau of Food Thai Food and Drug Administration, presentation slides on 'Updates on Nutrition Labelling and Claims Regulations in Thailand' at the 9th Seminar on Nutrition Labelling, Claims and Communication, 4-5 August 2015

Last updated 5th August,2015

4.16 UNITED KINGDOM

4.16.1 Regulatory authority and documents

- UK Nutrition and Health Claims Committee (UKNHCC) is a committee that provides scientific evidence to the UK government on the substantiation of scientific evidence supporting nutrition and health claims applications.
- The evaluation follows a similar approach to that of the Scientific Advisory Committee on Nutrition (SACN)'s code of practice, the SACN framework for the evaluation of evidence and the European Food Safety Authority (EFSA)'s scientific and technical guidance.

4.16.2 Pre-approved health claims

Food businesses can use the list of pre-approved health claims but will have to apply for approval of any new health claim that has not been authorised. The list of authorised (and non-authorised) health claims is available on the European Commission website.

4.16.3 Process for approval of health claims under Articles 13(5), 14, and 19

Proposals for health claims (i.e. applications) will be submitted to UKNHCC as of 1st January, 2021 which will provide a scientific evaluation of the application and consider whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence which takes into account the totality of the available scientific data and weighs the evidence. Human data are central to the substantiation of a claim.

The applications for health claim authorisation, i.e. the format and content, should follow the EFSA Scientific and technical guidance for the preparation and presentation of an application for authorization of a health claim (revision 2), which formed the basis of Commission Regulation (EC) No 353/2008 establishing and implementing rules for applications for authorisation of health claim.

To assist applicants in submitting health claim applications, EFSA has published:

- general guidance document for stakeholders; and
- guidance on the substantiation of health claims in specific areas

In deciding whether a health claim has been substantiated, the UKNHCC evaluates the evidence provided in the application for the health claim. First, they make an assessment as to whether the food or the component in the food has been defined and sufficiently characterised, to establish that the studies provided for substantiation of the claim were performed with the food/constituent for which the claim is proposed, and they consider whether the information provided includes those characteristics considered pertinent to the claimed effect.

The second aspect of the application that the UKNHCC considers is whether the claimed health effect is defined and whether the health effect is a beneficial physiological effect for the target population, particularly if the claimed effect refers to a specific function of the body and can be measured *in vivo* in humans by generally accepted methods. For example, if the health effect was functioning of the gastrointestinal tract (which is too general and is unclear what outcome measure can be used), the specific effect must be stated – e.g. increased absorption of certain essential nutrients. This health effect would be considered as a beneficial physiological effect. An aspect of the functioning of the gastrointestinal tract that would not be considered a beneficial physiological effect on its own would be change to the gut

microbiota as this effect would have to be accompanied by a clinical outcome or specific beneficial health effect.

The third aspect that the panel considers is deciding whether there is a causal relationship between the consumption of the food or the constituent in the food and the claimed effect on health (i.e. for the target group under the proposed conditions of use). In doing so, the UKNHCC evaluates all of the studies included in the dossier to decide whether they were designed and conducted in a way that would allow the effect of the food or the property of the food to be established. For example, if the food or the property of the food was a single microorganism but one of the studies they provided examined the effect of a combination of microorganisms or a different health effect from the claimed health effect, then that study would not provide information that could be used to substantiate the health claim. Relevant and applicable human studies are an absolute requirement for the scientific substantiation of the claimed effect on health and the efficacy of the studies are at the top of the hierarchy that informs decisions on substantiation. The Committee will consider aspects of the way the studies are conducted (quality) when deciding whether a study can provide evidence for an effect of the food on health. The Committee then weighs the evidence from the studies they have considered as relevant to the health claim, with respect to its overall strength, consistency and biological plausibility, taking into account the quality of individual studies and with particular regard to the population group for which the claim is intended, and to the conditions of use proposed for the claimed effect, giving the greatest weighting to well-designed human intervention studies. Animal, *in vitro* and mechanistic studies will provide supporting evidence, especially for the biological plausibility of the health claim which is an important part of considering whether there is a causal relationship.

For Article 13.5 and 14 health claims, it is important that the applicant provides all the available relevant scientific literature in the application, paying particular attention to ensuring that this represents the totality of the pertinent evidence. UKNHCC makes the summary of the application public as stated in the Regulation, excluding the information considered as confidential. If the health claim meets the requirement, the Four Nations Nutrition Group (made up of representatives from England, Scotland, Wales and Northern Ireland) decides whether to authorise the health claims and the scientific opinion of the health claim will be published on a government website by the Department of Health and Social Care. Northern Ireland, part of the Four Nations Nutrition Group, continues to adopt EU laws.

4.16.4 Health claims on imported foods

The health claims must be approved for use in the UK regardless of whether it has been accepted for use in another country.

Last updated 28th October, 2020

4.17 UNITED STATES OF AMERICA

4.17.1 Regulatory authority and documents

Food and Drug Administration (FDA)

Nutritional Labelling and Education Act (NLEA) Requirements (8/94 – 2/95)

4.17.2 Pre-approved disease risk reduction claims

The Federal Regulations for Food and Drugs has a list of 12 authorised disease risk reduction claims. Details of the specific requirements for making these health claims are found here.

4.17.3 Process for getting new health claims approved

The food business can submit a petition to the FDA in which the evidence for the effect of the nutrient on the disease must meet a high standard of 'significant scientific agreement' for approval. This means that the FDA will authorise a health claim if it "determines based on the totality of the publicly available evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognised scientific procedures and principles), that there is significant scientific agreement (SSA) among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." Details for making a petition for health claims can be found under 101.70 'Petitions for health claims' of the Federal Regulations for Food and Drugs. The FDA has some guidance for the scientific evaluation of health claims on their website.

If a health claim is reviewed under the SSA standard but does not meet the level for significant scientific agreement, the FDA can consider the health claim as a qualified health claim. Qualified health claims must be accompanied by a disclaimer or be otherwise qualified. More information about qualified health claims can be found in 'A Food Labelling Guide – Guidance for industry'.

Health claims are not permitted on foods that contain more than certain amounts of fat, saturated fat, cholesterol, or sodium. Details of these levels can be found under 101.14 'Health claims: general requirements' of the Federal Regulations for Food and Drugs. Health claims are also not allowed for conventional foods or dietary supplements of vitamins, minerals, herbs or other similar substances.

4.17.4 Health claims on imported foods

Health claims that are not reduction of disease risk claims so-called structure/function claims can be made on foods in the USA as long as they are truthful and not misleading. If a structure/function claim has been approved in another country, it is likely to be truthful and not misleading and would therefore, be allowed. For a new reduction of disease risk claim it is likely that an application would have to be made to the FDA for scientific evaluation and approval.

Last updated 17th November, 2020

4.18 VIETNAM

4.18.1 Regulatory authority and documents

Vietnam Ministry of Health

- *Circular No. 08/2004/TT-BYT 'Guiding the management of functional foodstuff products' (current)*
- *Circular No. 43/2014 'Rules of management for functional foods' which is effective 15 May 2015 (Vietnamese)*

4.18.2 Functional foodstuffs

Functional foodstuffs are foods that are used to support human's organ functions, have nutrient effects, increase resistance and reduce risk of infection.

The new regulations which came into effect on the 15th of May 2015 are currently available but are written in Vietnamese. Functional foodstuffs cover the following:

1. Food supplements (Supplemented Food)
2. Food health protection (Health Supplement, Food Supplement, Dietary Supplement) – product made in the form of capsules, tablets, powder, liquid-containing vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, and bioactive substances.
3. Food nutrition medicine called nutritious food for special medical purposes (Food for Special Medical Purposes, Medical Food) – used only under the supervision of medical staff.
4. Food for special diets (Food for Special Dietary Uses) are those that are specially formulated or blended to meet the requirements of diet-specific physical conditions.

From this document it appears that there are a number of requirements that must be met in order to sell a functional foodstuff in Vietnam. These include the health claims should be made when the product content reaches 10% recommended nutrient intake or above and is supported with scientific evidence. An application for a functional foodstuff should be submitted to the Ministry of Health (Department of Food Safety) and include evidence of the effectiveness on human health. The clinical trials (if conducted outside Vietnam) must be conducted at accredited medical institutions or be published in scientific journals. The functional foodstuff must also comply with the appropriate Vietnamese Food Safety Provisions. The Ministry of Health will establish a Scientific Council of experts in the field who will assess the scientific evidence for an effect of the functional foodstuff on human health. More information on the process of application can be found here.

4.18.3 Health claims on imported foods

Given that there is a large flow of counterfeit food products from China to Vietnam, having an official assurance mark from a government agency would help to assure consumers but sufficient market recognition and trust would have to be developed. Furthermore, care would have to be taken to ensure that the mark of quality assurance is not copied.

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5 Appendix 1

5.1 TAIWAN FOOD HEALTH CLAIMS TAIWAN FOOD AND DRUG ADMINISTRATION GUIDANCE (UNOFFICIAL TRANSLATION)

The following are acceptable and do not breach obligations to avoid 'creating confusion, exaggeration or claims of medical effect':

1. Phrases that can be used:
   Normal development of teeth and bones. Help digestion. Help maintain digestive function. Change the ecology of bacteria. Defaecation. Adjust physique. Regulating physiological function. Nourishing bodies. Build up strength. Strong spirit. Skincare. Help to fall asleep. Nutritional supplements. Health maintenance. Youthful and beauty. Nourishing in prenatal and postnatal, or after disease. Promote metabolism. Cool thirst. Stimulates the appetite. Annealing. Reduce anger. Mouth fragrance. Stimulate saliva production. Nourishing throat. "Compendium of Materia Medica" records plum smell, creatinine, thirst-quenching (not mentioning medical effect).
2. Pre-approved general-level health claims:

Table 7: Wording options of Vitamin or Minerals

Nutrients	Sentence used to describe physical functions
Vitamin A or β- carotene	Assist to maintain eyesight in dark place. Promote health to skin and mucous membrane. Assist development and growth of teeth and bone.
Vitamin D	Assist absorption of calcium. Assist development of bone and teeth. Promote the release of bone calcium to maintain balance of blood and calcium. Assist to maintain normal physical function of nerve and muscle.
Vitamin E	Reduce the oxidation of unsaturated fatty acid. Assist the completeness of cell membrane. Anti-oxidation. Promote health of skin and blood cell. Assist to reduce production of free radicals.
Vitamin K	Assist blood coagulation. Promote bone calcification. Activation of the coagulation protein in liver and blood.
Vitamin C	Assist the formation of collagen. Assist healing of wounds. Assist the density of cell arrangement. Promote the body connective tissue. Growth of bone and teeth Promote absorption of iron. Anti-oxidant
Vitamin B1	Assist normal metabolism of energy. Assist functions of skin, heart and nerve system. Maintain normal appetite.
Vitamin B2	Assist normal metabolism of energy. Maintain health of skin.
Niacin	Assist normal metabolism of energy. Enhance health of skin, nerve system and membrane.
Vitamin B 6	Help to maintain the normal metabolism of amino acids. Contribute to the formation of red blood cells in rhodopsin. Help convert tryptophan into niacin. Help red blood cells to maintain normal patterns. Promote the health of the nervous system.

Nutrients	Sentence used to describe physical functions
Folic acid	Contribute to the formation of red blood cells. Contribute to the formation of nucleic acids and nucleoprotein. Help the normal development and growth of the foetus.
Vitamin B12	Assist formation of red blood cell and increase health of nerve system
Biotin	Helps maintain normal energy and amino acid metabolism. Contribute to fat and glycogen synthesis. Help purine synthesis. Improve the health of the skin and mucous membranes.
Pantothenic acid	Helps maintain normal metabolism of energy. Improve the health of the skin and mucous membranes. Contribute to body fat, cholesterol synthesis and metabolism of amino acids.
Calcium	Help maintain the normal growth and health of bones and teeth. Help normal blood coagulation. Contribute to normal muscle and heart contraction and nerve induction. Activation of prothrombin into thrombin, help blood clotting. Regulation of cell permeability.
Iron	Contribute to the formation of normal erythrocytes. Constitute important component of haemoglobin and myoglobin. Contribute to the delivery and utilization of oxygen.
Iodine	The main ingredient of synthetic thyroid hormone. Help maintain normal growth, development, and neuromuscular function. Regulation of cell oxidation. Helps maintain normal thyroid hormone secretion. Help maintain normal basal metabolism.
Magnesium	Contribute to the normal development of bones and teeth. Helps to maintain normal metabolism of saccharides. Help the normal function of the heart, muscles and nerves. Help the body to normal metabolism.
Zinc	Component of insulin and a variety of enzymes. Help to maintain the normal metabolism of energy, carbohydrates, proteins and nucleic acids. Improve skin health. Help maintain normal taste and appetite. Help to maintain the growth and development of the reproductive function.

Table 8: Other nutrients

Nutrient	Sentence used to describe physical functions
Dietary Fibre	Can promote intestinal peristalsis. Increase satiety. The stool is soft and easy to discharge. Amount of dietary fibre in the diet can increase the amount of stool.

The following wording is considered to amount to claiming health effect:

1. Prevent, recover, reduce, diagnose or cure specific physical situation such as cure near-sightedness. Prevent constipation, improve allergies etc.
2. Reduce or lower symptoms which might causes disease such as lower liver fat.
3. Claim to have positive effect on disease or symptoms such as reduce cardiac dysrhythmia etc.
4. Cite or excerpt from publication, books and mentions medical effect such as citing *Bencao Gangmu,* also known as *Compendium of Materia Medica.*

The following terms are considered to constitute exaggeration, or easily confuse:

1. Mentions physical function such as enhance cell function, increase memory etc.
2. Mentions internal organs such as eye protection and increase flexibility of blood vessel etc.
3. Mentions changing body outlook such as increase height, make hair darker and prevent aging.

6 Bibliography

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