

Health Claims in Foods

The Summary Description of content:

a. In this Notification, "Health Claims" means a declaration of statement, image, mark, symbol, trademark or any information related to a relationship between a food or a constituent of that food and health benefits both directly and indirectly, classified into 3 types:

1) "Nutrient function claim" means a declaration of benefits related to the physiological role of the nutrient in growth, development and normal functions of the body.

2) "Other function claim" means a declaration of 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.

3) "Reduction of disease risk claim" means a declaration of benefits related to consuming a food or food constituent to the reduced risk of developing a disease or health-related condition.

"Risk reduction" means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect.

"Food constituents" means a composition of food, including nutrients and other substances as a component of food, both naturally occurring and added to food.

"Nutrient" means any substance normally consumed as a constituent of food which provides energy or is needed for growth, development and maintenance of life or a deficit which will cause characteristic bio-chemical or physiological changes.

"Other substance" means a substance other than a nutrient that has a nutritional or physiological effect

b. Health claims must conform to the criteria and conditions as follows:

1) Food with health claims shall have the following:

(1) must be safe, and the qualities or standards are in accordance with a particular notification. In the case of novel food, it shall be evaluated on safety assessment prior to the claim.

(2) must have food constituents or nutrients or other substances for which the claim is made in a form and provides a significant quantity that has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence.

2) Health claims must be made to the general consumer to understand the beneficial effects as expressed in the claim and it must be on a ready-to-eat basis according to instructions for use or consumption on the label and must have a reasonable quantity of consumption.

3) Health claims must be based on current relevant scientific substantiation and recognized by a generally accepted scientific review of the data. The level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health. Health claims must be based on evidence provided by well-designed human intervention studies in the target group and can be measured by appropriate biomarkers, which consist of the following information:

(1) The quantity of the food or food constituent and consumption pattern required to obtain the claimed effect could reasonably be achieved as part of a balanced diet.

(2) Information on the composition of the food or food constituent relevant to the physiological role of the nutrient and the effect of the nutrient on a physiological role in case of nutrient function claims.

(3) Information on the composition of the food or food constituent relevant to the accepted diet-health relationship and the health effect of the food or food constituent in case of other function claims and reduction of disease risk claims.

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

(1) a source of or high in the constituent in the case where increased consumption is recommended; or,

(2) low in, reduced in, or free of the constituent in the case where reduced consumption is recommended, and the conditions for nutrition claims shall comply with the notification of the Ministry of Public Health regarding Nutrition labeling.

5) The quantity of the food or food constituent that forms the basis of the claim must be measured by a validated and appropriate method.

c. Nutrient function claims must conform to criteria as follows:

1) Nutrients must be in Annex 3 of the notification of the Ministry of Public Health regarding Nutrition labeling.

2) Nutrient function claim statements must comply with Annex 1 of this notification.

3) If food with nutrient function claims contains one or more of the following nutrients in excess of the levels listed below per reference amount and labeled serving or, for foods without reference amount, per 100 g or 100 mL, it must be labeled with a disclosure statement of adjacent to the claim printed in the largest type on that panel and maybe half the size of the claim:

Total fat 13 g

Saturated fat 4 g

Cholesterol 60 mg

Sodium 300 mg

Total sugar 13 g

d. Food with other function claims and reduction of disease risk claims must contain the following nutrients per reference amount and labeled serving or, for foods without reference amount, per 100 g or 100 mL:

Total fat less than 13 g

Saturated fat less than 4 g

Cholesterol less than 60 mg

Sodium less than 300 mg

Total sugar less than 13 g

e. Health claims other than those as specified in annexes 1, 2 and 3 attached to this notification shall be evaluated the claims assessment by a nutrition and health claim assessment center recognized by Food and Drug Administration. The result of the claims assessment and other relevant information described in annex 4 of this notification, shall be submitted and approved by Food and Drug Administration.

f. The declaration of health claims statement on the label shall comply with the conditions as follows:

1) It must be expressed in the Thai language with similar letters size, readily legible, and may also expressed in English or other foreign languages. The statement in other foreign languages must be certified with Thai or English translations from government agencies or internationally standard document translation private agencies.

However, the text in English or other foreign languages must have the same meaning as the Thai language and must be approved by Food and Drug Administration.

2) It must not be misleading that food or constituents' consumption could treat, relieve, cure or prevent disease.

3) Label of foods with health claims shall comply with the notification of the Ministry of Public Health regarding the Labeling of Prepackaged Foods and the particular notification. The following information should appear on the label of the food with health claims:

(a) the quantity of food constituents, nutrients, or other substances that is the subject of the claim

If other substance or nutrient which other than as specified in Annex 3 of the notification of the Ministry of Public Health regarding Nutritional Labeling and as specified in the nutrition panel, it must be declared type and content of other substance or nutrient under the nutrition panel;

(b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;

- (c) the target group, if any;
 - (d) advice statement on how to use the food for vulnerable groups and for groups who need to avoid the food, if any;
 - (e) warning statement for consumption or maximum safe intake of the food or constituent, if any;
 - (f) text of "Should eat varieties of five categories food in appropriate proportion";
 - (g) text of "No effect for treat, relief, cure or prevention disease" in some cases of other function claims or reduction of disease risk claims;
 - (h) additional texts as specified in Annex 1 and 2 of this notification;
 - (i) additional texts that permitted by the Thai Food and Drug Administration (Thai FDA)
- 4) Declaration of nutrition labeling must comply with the notification of the Ministry of Public Health regarding Nutritional Labeling. Unless the food with health claims is Food for the special purpose, the labeling must comply with the notification of the Ministry of Public Health regarding Food for special purpose.
- f. This notification shall not enforce the following foods:
- 1) Food for the special purpose intended for patients or physically irregular figures.
 - 2) Foods that are not produced or imported for sale in the country.
- g. Foods whose health claims are displayed on the label before the date of enforcement of this notification and contain details that do not comply with the conditions in this notification can still be sold but not more than three years as from the date of enforcement of this notification.
- h. This notification shall come into force after 180 days as from the date of its publication in the Government Gazette.