

(Unofficial)

**Notification of Ministry of Public Health**

**(No. 447) B.E. 2566 (2023)**

**Issued by virtue of the Food Act B.E. 2522**

**Re: Health Claims made on Food Labelling**

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Where it is appropriate to prescribe the criteria, procedures and conditions for health claims made on foods in order to protect consumers and facilitate trade.

By virtue of the provisions laid down in the first paragraph of Sections 5 and Section 6 (10) of the Food Act B.E.2522 (1979), the Minister of Public Health hereby issued a notification as follows;

Clause 1. In this notification,

“Health Claim” means any declaration of statement, image, mark, symbol, trademark or any information related to a relationship between a food or a constituent of food and health both directly and indirectly, which can be classified into three types:

1) Nutrient function claim means a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.

2) Other function claim means a claim 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 claim of benefits of the consumption of a food or food constituent related 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 constituent” means a composition of food, including nutrients and other substances both naturally occurring and adding to food.

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

“Other substance” means a substance other than a nutrient that has a nutritional or physiological effect.

Clause 2. The use of health claims shall comply with the criteria and conditions as follows:

1) Food with health claims shall

(1) be safe and comply with particular notifications. In case of novel food, it shall be evaluated on safety assessment prior to claim substantiation.

(2) have food constituent, nutrient or other substance for which the claim is made is in a form and a significant quantity that provides a beneficial nutritional or physiological effects, as established by generally accepted scientific evidence.

2) Health claims shall be understood the beneficial effects as expressed in the claims by general consumers. It shall refer to the food ready for consumption in accordance with the instruction indicated on the label. The quantity of consumption shall be in the appropriate proportion.

3) Health claims shall be based on and substantiated by current relevant generally accepted scientific evidences. The scientific evidences shall be sufficient to substantiate the physiological effect claimed. The scientific evidences provided shall be 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 pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet.

(2) In case of nutrient function claims, 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 physiological role.

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

4) If the nutritional claimed benefit is attributed to a constituent in the food, for which a Nutrient Reference Value is established, the food in question should be a source of or high in the constituent in the case where increased consumption is recommended; or low in, reduced in, or free of the constituent in the case where reduced consumption is recommended based on the amount of consumption as a reference amount and the amount per serving. In case of foods without reference amount established, it shall be based on 100 g or 100 mL of food. Criteria and 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 the claim is made shall be measured by a validated method.

Clause 3. Nutrient function claims shall comply with the criteria established in Clause 2. and the followings:

1) Nutrients shall be in the list of Thai Reference Daily Intakes (Thai RDIs) as shown in the Annex 3 of the notification of the Ministry of Public Health regarding Nutrition labeling.

2) Nutrient function claim statements shall comply with the 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 per serving, or per 100 g or 100 mL for foods without reference amount established, the amount of that or those nutrients shall be labeled with a disclosure statement of adjacent to the claim printed in largest character at least half size of the claim statement:

Total fat	more than 13 g
Saturated fat	more than 4 g
Cholesterol	more than 60 mg
Sodium	more than 300 mg
Total sugar	more than 13 g

Clause 4. Food with other function claims and reduction of disease risk claims shall contain the following nutrients per reference amount and per serving, or per 100 g or 100 mL for foods without reference amount established:

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

Clause 5. Health claims statements other than those specified in the annex 1, 2 and 3 attached to this notification shall be assessed by a nutrition and health claim assessment center recognized by the Food and Drug Administration, Thailand. The assessment report together with relevant information described in the annex 4 of this notification shall be submitted to and approved by the Food and Drug Administration.

Clause 6. Health claims made on food labelling shall comply with the following conditions:

1) The claim statement shall be expressed in Thai with the same letter size, readily legible and may also be expressed in English or other foreign languages. The statement in other foreign languages shall be translated into Thai or English by the government agencies or private companies in business of document translation.

The statement declared in English or other foreign languages shall have the same meaning as Thai and shall be approved by the Food and Drug Administration.

2) It shall not mislead consumers about the consumption of food or food constituents relating to treatment, relief, cure or prevention of disease.

3) Food labelling shall comply with the notification of the Ministry of Public Health regarding Labeling of Prepackaged Foods and the particular notifications. Additionally, the following information shall appear on the label:

(1) the quantity of food constituent, nutrient or other substance that is the subject of the claim.

In case of other substance or nutrient other than those specified in the nutrition information panel and in the Annex 3 of the notification of the Ministry of Public Health regarding Nutrition Labeling, it shall be declared type and content of that substance or nutrient under the nutrition information panel;

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

(3) the target group, if any;

(4) an indication of how to consume the food, particularly for vulnerable groups or a person who needs to avoid the food, if any;

(5) any precautions for consumption or maximum safe intake of the food or constituent, if any;

(6) a statement of “Should eat varieties of five categories of food in appropriate proportion”;

(7) a statement of “Not intended to treat, relieve, cure or prevent any disease” in case of other function claims or reduction of disease risk claims;

(8) additional statements as specified in the Annex 1 and 2 of this notification;

(9) any additional statements permitted by the Food and Drug Administration.

4) Declaration of nutrition labeling shall comply with the notification of the Ministry of Public Health regarding Nutritional Labeling. If the food with health claims falls into the category of food for special purpose, food labelling shall comply with the notification of the Ministry of Public Health regarding Food for Special Purpose.

Clause 7. This notification shall not enforce to the following:

1) food for special purpose intended for patients or physically irregular figure.

2) foods which are produced for export only.

Clause 8. Nutrient function claims which have been made on foods by food manufacturers, importers, or distributors prior to the enactment and effective date of this notification can still be sold but not more than three years from the date of enactment. After this period, food manufacturers, importers, or distributors shall comply with this notification.

Clause 9. This notification shall come into force after 180 days from its publication in the Government Gazette.

Given on the 17<sup>th</sup> December B.E. 2566 (2023)

Cholnan Srikaew

Minister of Public Health

**Disclaimer:** This translation is provided by the Food and Drug Administration as the competent authority for information purposes only. Whilst the Food and Drug Administration has made efforts to ensure the accuracy and correctness of the translation, the original Thai text as formally adopted and published shall in all events remain the sole authoritative text having the force of law.

## Annex 1

Attachment to the Notification of the Ministry of Public Health (No. 447) B.E. 2566 (2023)  
Issued by virtue of the Food Act B.E. 2522 Re: Health Claims made on foods

### Nutrient function claim statements

No.	Nutrients	Nutrient function claim statements
1	โปรตีน (Protein)	1.1 Protein contributes to a growth and help repair body tissue. 1.2 Protein contributes to a source of essential amino acids for body protein synthesis. 1.3 Protein contributes to the maintenance of normal bones. 1.4 Protein contributes to growth and maintenance of muscle mass.
2	ใยอาหาร (Dietary fiber)	2.1 Dietary fiber contributes to an increase in fecal bulk in GI tract and stimulates the bowel movement.
3	วิตามินเอ (Vitamin A)	3.1 Vitamin A has a role in body growth 3.2 Vitamin A contributes to the maintenance of normal vision. 3.3 Vitamin A contributes to the maintenance of normal mucous membranes. 3.4 Vitamin A contributes to normal iron metabolism. 3.5 Vitamin A contributes to the normal function of the immune system. 3.6 Vitamin A contributes to the maintenance of normal skin. <b>Remark:</b> Beta-carotene can only specify as “Beta-carotene is a precursor of Vitamin A”
4	วิตามินบี 1 (Thiamine)	4.1 Thiamine contributes to normal-energy yielding metabolism from carbohydrate. 4.2 Thiamine contributes to the normal function of muscle and nervous system. 4.3 Thiamine contributes to the normal function of the heart.
5	วิตามินบี 2 (Riboflavin)	5.1 Riboflavin contributes to normal-energy yielding metabolism from carbohydrate, protein and fat. 5.2 Riboflavin contributes to the normal function of the nervous system. 5.3 Riboflavin contributes to the maintenance of normal mucous membranes. 5.4 Riboflavin contributes to the maintenance of normal red blood cells. 5.5 Riboflavin contributes to the maintenance of normal skin. 5.6 Riboflavin contributes to the maintenance of normal vision.

No.	Nutrients	Nutrient function claim statements
		5.7 Riboflavin contributes to the normal metabolism of iron.
6	ไนอะซิน (Niacin)	<p>6.1 Niacin contributes to maintenance of normal mucous membrane of GI tract and normal skin.</p> <p>6.2 Niacin contributes to normal-energy yielding metabolism from carbohydrate, protein and fat.</p> <p>6.3 Niacin contributes to the normal function of the nervous system.</p>
7	วิตามินบี 6 (Vitamin B6)	<p>7.1 Vitamin B6 contributes to normal red blood cell formation.</p> <p>7.2 Vitamin B6 contributes to the normal function of the nervous system.</p> <p>7.3 Vitamin B6 contributes to normal energy-yielding metabolism.</p> <p>7.4 Vitamin B6 contributes to normal protein and glycogen metabolism.</p> <p>7.5 Vitamin B6 contributes to the normal function of the immune system.</p>
8	กรดโฟลิก/โฟเลต (Folic acid/ Folate)	<p>8.1 Folic acid/Folate contributes to normal red blood formation.</p> <p>8.2 Folic acid/Folate contributes to normal amino acid synthesis.</p> <p>8.3 Folic acid/Folate contributes to the normal function of the immune system.</p>
9	ไบโอติน (Biotin)	<p>9.1 Biotin contributes to normal energy-yielding metabolism.</p> <p>9.2 Biotin contributes to normal macronutrient metabolism.</p> <p>9.3 Biotin contributes to the normal function of the nervous system.</p> <p>9.4 Biotin contributes to the maintenance of normal hair.</p> <p>9.5 Biotin contributes to the maintenance of normal skin.</p> <p>9.6 Biotin contributes to the maintenance of normal mucous membranes.</p>
10	กรดแพนโทธีนิก (Pantothenic acid)	<p>10.1 Pantothenic acid contributes to normal energy-yielding metabolism.</p> <p>10.2 Pantothenic acid contributes to normal synthesis and metabolism of steroid hormones, vitamin D and some neurotransmitters.</p>
11	วิตามินบี 12 (Vitamin B12)	<p>11.1 Vitamin B12 contributes to the synthesis of essential substance for red blood cell formation.</p> <p>11.2 Vitamin B12 contributes to the normal function of the brain and nervous system.</p> <p>11.3 Vitamin B12 contributes to normal energy- yielding metabolism.</p> <p>11.4 Vitamin B12 contributes to the normal function of the immune</p>

No.	Nutrients	Nutrient function claim statements
		system.
12	วิตามินซี (Vitamin C)	12.1 Vitamin C contributes to strengthen blood vessel. 12.2 Vitamin C contributes to the protection of cells from oxidative stress. 12.3 Vitamin C contributes to the protection of cells from oxidative stress. 12.4 Vitamin C contributes to normal collagen formation for the normal function of cartilage. 12.5 Vitamin C contributes to normal collagen formation for the normal function of bones. 12.6 Vitamin C contributes to normal collagen formation for the normal function of gums. 12.7 Vitamin C contributes to normal collagen formation for the normal function of skin. 12.8 Vitamin C contributes to normal collagen formation for the normal function of teeth. 12.9 Vitamin C contributes to normal energy-yielding metabolism. 12.10 Vitamin C contributes to the normal function of the nervous system. 12.11 Vitamin C contributes to the normal function of the immune system. 12.12 Vitamin C contributes to the regeneration of the reduced form of vitamin E. 12.13 Vitamin C increases iron absorption.
13	วิตามินดี (Vitamin D)	13.1 Vitamin D contributes to normal absorption of calcium and phosphorous. 13.2 Vitamin D contributes to normal blood calcium levels. 13.3 Vitamin D contributes to the maintenance of normal bones. 13.4 Vitamin D contributes to the maintenance of normal teeth. 13.5 Vitamin D contributes to the maintenance of normal muscle function. 13.6 Vitamin D contributes to the normal function of the immune system.
14	วิตามินอี (Vitamin E)	14.1 Vitamin E contributes to the protection of cells from oxidative stress. 14.2 Vitamin E contributes to the protection of cells from oxidative stress.
15	วิตามินเค	15.1 Vitamin K contributes to normal blood clotting.

No.	Nutrients	Nutrient function claim statements
	(Vitamin K)	15.2 Vitamin K contributes to the maintenance of normal bones.
16	แคลเซียม (Calcium)	<p>16.1 Calcium is needed for the maintenance of normal bones and teeth.</p> <p>16.2 Calcium contributes to normal blood clotting.</p> <p>16.3 Calcium contributes to the synthesis of bones and teeth.</p> <p>16.4 Calcium contributes to normal energy-yielding metabolism.</p> <p>16.5 Calcium contributes to normal muscle function.</p> <p>16.6 Calcium contributes to normal neurotransmission.</p> <p>16.7 Calcium contributes to the normal function of digestive enzymes.</p>
17	ฟอสฟอรัส (Phosphorus)	<p>17.1 Phosphorus is needed for the maintenance of normal bones and teeth.</p> <p>17.2 Phosphorus contributes to the synthesis of bones and teeth.</p> <p>17.3 Phosphorus contributes to normal energy-yielding metabolism.</p> <p>17.4 Phosphorus contributes to normal function of cell membranes.</p>
18	เหล็ก (Iron)	<p>18.1 Iron contributes to normal formation of red blood cells and haemoglobin.</p> <p>18.2 Iron contributes to normal energy-yielding metabolism.</p> <p>18.3 Iron contributes to normal oxygen transport in the body.</p> <p>18.4 Iron contributes to the normal function of the immune system.</p>
19	ไอโอดีน (Iodine)	<p>19.1 Iodine contributes to the normal production of thyroid hormones and normal thyroid function</p> <p>19.2 Iodine contributes to normal energy-yielding metabolism.</p> <p>19.3 Iodine contributes to normal function of the nervous system.</p> <p>19.4 Iodine contributes to the maintenance of normal skin.</p>
20	แมกนีเซียม (Magnesium)	<p>20.1 Magnesium is a component of bones and teeth.</p> <p>20.2 Magnesium contributes to the normal function of the muscle and nervous system.</p> <p>20.3 Magnesium contributes to electrolyte balance.</p> <p>20.4 Magnesium contributes to normal energy-yielding metabolism.</p> <p>20.5 Magnesium contributes to normal protein synthesis.</p> <p>20.6 Magnesium contributes to the maintenance of normal bones.</p> <p>20.7 Magnesium contributes to the maintenance of normal teeth.</p>
21	สังกะสี (Zinc)	<p>21.1 Zinc contributes to growth.</p> <p>21.2 Zinc contributes to normal DNA synthesis.</p> <p>21.3 Zinc contributes to normal macronutrient metabolism.</p> <p>21.4 Zinc contributes to normal metabolism of fatty acids.</p>



No.	Nutrients	Nutrient function claim statements
		<p>21.5 Zinc contributes to normal metabolism of vitamin A.</p> <p>21.6 Zinc contributes to normal protein synthesis.</p> <p>21.7 Zinc contributes to the maintenance of normal bones.</p> <p>21.8 Zinc contributes to the maintenance of normal hair.</p> <p>21.9 Zinc contributes to the maintenance of normal nails.</p> <p>21.10 Zinc contributes to the maintenance of normal skin.</p> <p>21.11 Zinc contributes to the maintenance of normal vision.</p> <p>21.12 Zinc contributes to the normal function of the immune system.</p> <p>21.13 Zinc contributes to the protection of cells from oxidative stress.</p> <p>21.14 Zinc contributes to the protection of cells from oxidative stress.</p>
22	ทองแดง (Copper)	<p>22.1 Copper contributes to haemoglobin synthesis.</p> <p>22.2 Copper contributes to the maintenance of normal connective tissues.</p> <p>22.3 Copper contributes to normal energy-yielding metabolism.</p> <p>22.4 Copper contributes to the normal function of the nervous system.</p> <p>22.5 Copper contributes to normal iron transport in the body.</p> <p>22.6 Copper contributes to the normal function of the immune system.</p> <p>22.7 Copper contributes to the protection of cells from oxidative stress.</p> <p>22.8 Copper contributes to the protection of cells from oxidative stress.</p>
23	โพแทสเซียม (Potassium)	<p>23.1 Potassium contributes to acid-base and electrolyte balance.</p> <p>23.2 Potassium contributes to the normal function of the nervous system.</p> <p>23.3 Potassium contributes to normal muscle function.</p> <p><b>Warning:</b> Excessive potassium may cause abnormal heart rate.</p>
24	แมงกานีส (Manganese)	<p>24.1 Manganese contributes to the function of enzymes in the body.</p> <p>24.2 Manganese contributes to normal energy-yielding metabolism.</p> <p>24.3 Manganese contributes to the maintenance of normal bones.</p> <p>24.4 Manganese contributes to the normal formation of connective tissue.</p> <p>24.5 Manganese contributes to the protection of cells from oxidative stress.</p> <p>24.6 Manganese contributes to the protection of cells from</p>

No.	Nutrients	Nutrient function claim statements
		oxidative stress.
25	ซีลีเนียม (Selenium)	25.1 Selenium contributes to the protection of cells from oxidative stress. 25.2 Selenium contributes to the protection of cells from oxidative stress. 25.3 Selenium contributes to the maintenance of normal hair. 25.4 Selenium contributes to the maintenance of normal nails. 25.5 Selenium contributes to the normal function of the immune system. 25.6 Selenium contributes to the normal thyroid function.
26	โมลิบดีนัม (Molybdenum)	27.1 Molybdenum contributes to the normal function of some enzymes in the body.
27	โครเมียม (Chromium)	28.1 Chromium contributes to glucose-uptake function of insulin. 28.2 Chromium contributes to normal macronutrient metabolism.
28	คลอไรด์ (Chloride)	29.1 Chloride contributes to the maintenance of acid-base balance. 29.2 Chloride contributes to the normal digestion by production of hydrochloric acid in the stomach.

## Annex 2

Attachment to the Notification of the Ministry of Public Health (No. 447) B.E. 2566 (2023)  
Issued by virtue of the Food Act B.E. 2522 Re: Health Claims made on foods

### Other function claim statement

No.	Foods or Food constituents	Claim statement	Condition of claim
1	Beta-glucans from oat/barley	Beta-glucans from oat/barley contribute to the reduction of cholesterol absorption.	<p>1. The food must contain at least 1 g of non-processed or minimally processed beta-glucans from oats, oat bran, barley, barley bran per serving or 100 g or 100 ml<sup>1</sup>.</p> <p>2. The food should not use chemically concentrated or extracted forms of oats and barley.</p> <p>3. The food must be declared text of “Should be intake 3 g of beta-glucans per day.”</p>
2	Phytosterols/Phytostanols <sup>2</sup>	Phytosterols/Phytostanols contribute to the reduction of cholesterol absorption.	<p>1. Types of food that are permitted to be claimed;</p> <ol style="list-style-type: none"> <li>1) Dairy products such as flavored milk, fermented milk and yogurt;</li> <li>2) Butter, margarine and fat spread;</li> <li>3) Soy milk</li> <li>4) Dietary supplements which contain milk soy milk or fat as main ingredients.</li> </ol> <p>2. The food must contain at least 0.8 g of free phytosterol/phytostanol per serving or 100 g or 100 ml<sup>1</sup>.</p> <p>3. The following warning statements must be declared on the label in the clearly visible frame with red letters.</p> <ul style="list-style-type: none"> <li>● “Should not consumed more than 2 g of phytosterols/phytostanols per day”</li> <li>● “Consumed with meals”</li> <li>● “Patients should consult a doctor before consuming.”</li> <li>● “Should be consumed fruits and vegetables to help maintain the carotenoid levels”</li> <li>● “The vitamin E level may decrease, if</li> </ul>

No.	Foods or Food constituents	Claim statement	Condition of claim
			eaten continuously.” <ul style="list-style-type: none"> <li>• “Children, pregnant women, and breastfeeding should not consume”</li> </ul>
3	Choline	3.1 Choline contributes to normal lipid metabolism. 3.2 Choline contributes to the maintenance of normal liver function. 3.3 Choline contributes to normal homocysteine metabolism.	The food must contain at least 82.5 mg of choline per serving or 100 g or 100 ml <sup>1</sup> .
4	Docosa-hexaenoic acid (DHA) and Eicosa-pentaenoic acid (EPA)	Docosa-hexaenoic acid (DHA) and Eicosa-pentaenoic acid (EPA) contribute to the normal function of the heart.	The food must contain at least 40 mg of Docosa-hexaenoic acid (DHA) and Eicosa-pentaenoic acid (EPA) per serving or 100 g or 100 ml <sup>1</sup> and declare text of “Should be intake 250 mg of DHA and EPA per day.”
5	Foods with “low in sodium” “very low in sodium” “free of sodium” or “reduced sodium”	Reducing consumption of sodium contributes to the maintenance of normal blood pressure.	The food must comply with the criteria of “low in sodium” “very low in sodium” “free of sodium” or “reduced sodium” of Notification of the notification of the Ministry of Public Health regarding Nutritional Labeling.
6	Foods with “low in saturated fatty acids” “free of saturated fatty acids” or “reduced saturated fatty acids”	Reducing consumption of saturated fat contributes to the maintenance of normal blood cholesterol levels	The food must comply with the criteria of claim “low in saturated fatty acids” “free of saturated fatty acids” or “reduced saturated fatty acids” of the notification of the Ministry of Public Health regarding Nutritional Labeling.

<sup>1</sup> per reference amount and per serving, or per 100 g or 100 mL for foods without reference amount established.

<sup>2</sup> May be “Phytosterols” “Plant sterols” “Phytostanols” “Plant stanols” “Phytosterol esters” “Plant sterol esters” sterol esters”, “Phytostanol esters” or “Plant stanol esters” in accordance with the raw materials that used as an ingredient in products.

### Annex 3

Attachment to the Notification of the Ministry of Public Health (No. 447) B.E. 2566 (2023)

Issued by virtue of the Food Act B.E. 2522 Re: Health Claims made on foods

#### Reduction of disease risk claim statements

No.	Foods or Food constituents	Claim statement	Condition of claim
1	Foods with “low in sodium” “very low in sodium” or “free of sodium”	<p>1. A diet low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. This product is low in / very low in / free of sodium.</p> <p>2. Consumption of diet low in sodium may reduce blood pressure. High blood pressure is a risk factor in the development of stroke and heart disease. This product is low in / very low in / free of sodium.</p>	The food shall comply with the criteria of “low in sodium” “very low in sodium” or “free of sodium” of the notification of the Ministry of Public Health regarding Nutrition Labeling.
2	Foods with “low in saturated fatty acids” or “free of saturated fatty acids”	<p>1. A diet low in saturated fat may reduce the risk of high blood cholesterol, a risk factor for coronary heart disease. This product is low in / free of saturated fat.</p> <p>2. Consumption of diet low in saturated fat may reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease. This product is low in / free of saturated fat.</p>	The food shall comply with the criteria of “low in saturated fatty acids” or “free of saturated fatty acids” of the notification of the Ministry of Public Health regarding Nutrition Labeling.

## Annex 4

Attachment to Notification of the Ministry of Public Health (No. 447) B.E. 2566 (2023)

Issued by virtue of the Food Act B.E. 2522 Re: Health Claims in Foods on Label

Evidences submitted together with an application for consideration of  
health claims assessment results

### Part 1: General information

No.	List of document
1	<ul style="list-style-type: none"><li>- Product name in Thai</li><li>- Product name in English (if any)</li><li>- Food serial number (if any)</li></ul>
2	<b>Type of health claims</b> <ul style="list-style-type: none"><li><input type="checkbox"/> nutrient function claims</li><li><input type="checkbox"/> other function claims</li><li><input type="checkbox"/> reduction of disease risk claims</li></ul>
3	<b>Information on health claims</b> <ol style="list-style-type: none"><li>1) Specify the food or food constituent for which the health claim is made</li><li>2) Describe the relationship between the food or food constituent and the claimed effect</li><li>3) The outcome variable(s) used to assess the claimed effect in vivo in humans and the methods of measurement</li><li>4) Wording of the health claim as proposed by the applicant<ul style="list-style-type: none"><li>- Thai statement</li><li>- English statement (if any)</li><li>- Other foreign languages (if any)</li></ul></li><li>5) Conditions of health claim<ol style="list-style-type: none"><li>5.1 Specify the target population.</li><li>5.2 Indicate the quantity of the food or food constituent required to obtain the claimed effect</li><li>5.3 Indicate pattern of consumption required to obtain the claimed effect</li><li>5.4 Specify directions for preparation and/or use (if any)</li><li>5.5 Specify a warning and indications for any food or food constituent that is likely to present a health risk if consumed in excess or risk population, and provide a rationale. (if any)</li></ol></li></ol>

Part 2: Characterization of the food or food constituent information

No.	List of document
1	<p><b>the food/ food constituent information</b></p> <p>1) Food which the health claim is made</p> <p>2) Composition of food which the health claim is made</p> <p>    2.1 Nutrient in the list of Thai RDIs</p> <p>        - Name of nutrient</p> <p>        - Form of nutrient</p> <p>        - Source of nutrient</p> <p>        - Specification of nutrient (physical, chemical, microbiological, contaminant)</p> <p>    2.2 Nutrient other than those in the list of Thai RDIs</p> <p>        - Name of nutrient</p> <p>        - Form of nutrient</p> <p>        - Source of nutrient</p> <p>        - Specification of nutrient (physical, chemical, microbiological, contaminant)</p> <p>    2.3 Other substance</p> <p>        - Name of substance</p> <p>        - Source of substance</p> <p>        - Specification of substance (type and amount of active ingredients; physical, chemical, microbiological, contaminant)</p> <p>    2.4 Overall composition of food, in the case where the claimed cannot be specified main active ingredient</p> <p>3) Food composition/formulation</p> <p>4) Characteristic of food</p> <p>5) Nutritive value of food</p> <p>6) Content of the food or food constituent(s) which may contribute to the claimed effect</p> <p>7) Specification of food (type and amount of active ingredients; physical, chemical, microbiological, contaminant)</p> <p>8) Variability of active ingredients from batch to batch</p> <p>9) Analytical methods and report of analysis from government laboratory, or designated laboratory by government, or accredited laboratory conforms to the international standard</p>
2	Manufacturing process
3	Stability information

### Part 3: Information on the effect of the food or food constituent(s) on health according to the type of claim

#### 3.1 Nutrient function claims

- 1) The function of the body that is the subject of the claimed effect.
- 2) The rationale/reasons why the body function is a beneficial physiological effect for which the claim is intended.

#### 3.2 Other function claims

- 1) The specific body function that is the subject of the claimed effect.
- 2) The rationale why the specific body function is a beneficial physiological effect for which the claim is intended.
- 3) Indication of how the specific body function can be assessed in vivo in humans by generally accepted methods. Specify the outcome variable(s) and the methods of measurement proposed to assess the claimed effect in human studies.

#### 3.3 Reduction of disease risk claims

- 1) The risk factor for the development of the human disease.
- 2) Indication of how the specific risk factor can be assessed in vivo in humans. Specify the outcome variable(s) and the methods of measurement proposed to assess the risk factor in human studies.
- 3) The disease to which the risk factor relates.
- 4) The criteria used for the diagnosis of the disease (i.e. the criteria used for diagnosis are widely accepted by the medical community and can be verified by a physician).
- 5) The relationship between the reduction of risk factor and the disease risk, together with scientific evidences supported.

### Part 4: Other documents

No.	List of document
1	Scientific evidence documents for consideration with a list of reference documents
2	Certificate of free sale of food products with health claims (if any)
3	Examples of food labels sold in foreign countries which health claims is made on (if any)