รายการสารสำคัญที่ได้รับให้อยู่ใน Positive list
เพื่อการกล่าวอ้างหน้าที่อื่น (Other function claims) จากประเทศต่าง ๆ

จัดทำโดย

คณะทำงาน Food Innovation and Regulation Network (FIRN)

โดยสมาคมวิทยาศาสตร์และเทคโนโลยีทางอาหารแห่งประเทศไทย (FoSTAT)

กิจกรรมการดำเนินงานภายใต้โครงการวิจัย เรื่อง

“โครงการจัดทำระบบ FFC Thailand (Food with Function Claims Thailand)
ออนไลน์และระบบประเมินการจดทะเบียนการกล่าวอ้างเชิงสุขภาพอาหารและสารสำคัญ
(Functional Ingredients) เพื่อการพัฒนาเศรษฐกิจตลอดห่วงโซ่”

สนับสนุนทุนโดย

หน่วยบริหารและจัดการทุนด้านการเพิ่มความสามารถในการแข่งขันของประเทศ (บพข.)

สารบัญ

เนื้อหา

ที่มาของการจัดทำรายการสารสำคัญที่ได้รับให้อยู่ใน Positive list เพื่อการกล่าวอ้างหน้าที่อื่น (Other function claims)

คณะทำงาน Food Innovation and Regulation Network (FIRN) โดยสมาคมวิทยาศาสตร์และเทคโนโลยีทางอาหารแห่งประเทศไทย (FoSTAT) ได้รวบรวมข้อมูลเพื่อศึกษาเปรียบเทียบสารสำคัญเชิงหน้าที่ (Functional bioactives) และข้อความกล่าวอ้างหน้าที่ของสารสำคัญเชิงหน้าที่อื่น หรือ Other functional bioactives ที่ให้กล่าวอ้างทางสุขภาพในประเทศต่าง ๆ โดยเปรียบเทียบข้อมูลจาก 6 ประเทศ ดังนี้ (ตารางที่ 1)

1. สหภาพยุโรป (European Union; EU)
2. แคนาดา (Canada)
3. ออสเตรเลีย-นิวซีแลนด์ (Australia New Zealand; AU-NZ)
4. เกาหลีใต้ (Korea)
5. สิงคโปร์ (Singapore)
6. มาเลเซีย (Malaysia)

ตารางที่ 1: รายชื่อประเทศ หน่วยงาน และแหล่งของข้อมูล positive list ที่นำมาใช้เปรียบเทียบ

No	Ref. Country	อักษรย่อ	หน่วยงาน	Regulation	Link	QR Code
1	European Union	EU	European Food Safety Authorit (EFSA) European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA)	Article 13 of Regulation (EC) No 1924/2006	https://www.efsa.europa.eu/en	
2	Canada	Ca	Goverment of Canada Published by the Minister of Justice	Food and Drug Regulations C.R.C., c. 870	https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/health-	

No	Ref. Country	อักษรย่อ	หน่วยงาน	Regulation	Link	QR Code
					claims/assessments.html	
3	Australia - New Zealand	AUS-NZ	Federal Register of legislation	Standard 1.2.7 – Nutrition, health and related claims	https://www.foodstandards.gov.au/industry/labelling/fhr/Pages/default.aspx	
4	Korea	KR	Ministry of Food and Drug Safety	Health Functional Food Code 2021	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1	
5	Singapore	SG	Singapore Food Agency	A Guide to Food Labelling and Advertisements	https://www.sfa.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/aguidetofoodlabellingandadvertisements.pdf	
6	Malaysia	MYS	The Ministry of Health Malaysia	Malaysian Dietary Guidelines Key Message 14 Make effective use of nutrition information on food labels	https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf	

สรุปข้อมูลบัญชีแสดงข้อความการกล่าวอ้างหน้าที่อื่นจาก 6 ประเทศ

จากข้อมูลการเปรียบเทียบรายการสารสำคัญเชิงหน้าที่อื่นที่ต่างประเทศอนุญาตให้กล่าวอ้างเชิงหน้าที่ (Functional claim) คณะทำงานได้คัดเลือกรายการสารสำคัญและส่วนประกอบอาหารเชิงฟังก์ชันที่มีข้อมูลสนับสนุน จำนวน 17 สำหรับรายงานเพื่อพิจารณาในคณะกรรมการของสำนักงานคณะกรรมการอาหารและยา (อย.) รายการ โดยสามารถสรุปรายชื่อสารสำคัญ/ส่วนประกอบเชิงหน้าที่และจำนวนประเทศที่รับรองรายการดังกล่าวใน positive list ของประเทศนั้น

ตารางที่ 2: ประเทศที่รับรองรายการสารสำคัญ/ส่วนประกอบเชิงฟังก์ชันใน positive list

No.	Functional ingredients (nutrients, substances)	ประเทศที่รับรองรายการดังกล่าวใน positive list					
		EU	Canada	AUS-New Zealand	Korea	Singapore	Malaysia
1	Alpha-linolenic acid (ALA)	✓					
2	Beta-glucans	✓	✓	✓	✓	✓	✓
3	Chitosan	✓			✓		
4	Conjugated Linoleic acid				✓		
5	EPA and DHA	✓	✓	✓	✓		
6	Fructooligosaccharides				✓	✓	✓
7	Glucomannan (konjac mannan)	✓			✓		
8	Guar gum	✓			✓		
9	Indigestible maltodextrin				✓		
10	Inulin	✓			✓	✓	✓
11	Live yoghurt cultures	✓		✓			
12	Oleic acid	✓					
13	Olive oil polyphenols	✓					
14	Plant sterols and plant stanols (Phytosterols, phytostanols and their esters)	✓	✓	✓	✓	✓	✓
15	Red yeast rice (*Monascus purpureous*)	✓			✓		
16	Resistant starch	✓					✓
17	Soybean protein	✓	✓		✓		✓

คณะทำงานได้สรุปข้อมูลบัญชีแสดงข้อความการกล่าวอ้างหน้าที่อื่นจาก 6 ประเทศ (ตารางที่ 3) โดยมีข้อมูลในแต่ละหัวข้อ ดังนี้

- **No. :** ลำดับ
- **Functional ingredients (nutrients, substance) :** รายชื่อสารสำคัญ/ส่วนประกอบเชิงหน้าที่ (สารตัวเดียวกันอาจมีคำเรียกที่แตกต่างกันไปในแต่ละประเทศ)
- **Reference Country :** อักษรย่อแสดงแหล่งข้อมูลของประเทศที่นำมาอ้างอิง

1. Characterisation of the food/constituent : คุณลักษณะของสารสำคัญ/ส่วนประกอบเชิงหน้าที่

1.1 Standards for manufacturing : มาตรฐานการผลิตส่วนประกอบเชิงฟน้าที่ เช่น แหล่งวัตถุดิบที่ใช้, วิธีการสกัด, ปริมาณสารสำคัญที่กำหนด

1.2 Specifications : คุณลักษณะหรือมาตรฐานของสารสำคัญ/ส่วนประกอบเชิงหน้าที่ เช่น ลักษณะปรากฏ, คุณภาพด้านความปลอดภัยที่กำหนด

2. Cause and Effect : อธิบายเหตุผลของการสนับสนุนคำกล่าวอ้างทางสุขภาพ

3. Claimed effect to human health : ผลทางสรีระต่อมนุษย์ของสารสำคัญ/ส่วนประกอบเชิงหน้าที่

4. Claim statement : ข้อความกล่าวอ้างทางสุขภาพ

5. Conditions and possible restrictions of use : เงื่อนไขและข้อกำหนดของการใช้สารสำคัญ/ส่วนประกอบเชิงหน้าที่ในผลิตภัณฑ์

6. References : แหล่งที่มาของข้อมูล

7. Links : ลิงค์เว็บไซต์แหล่งที่มาของข้อมูล

ตารางที่ 3: ตารางสรุปข้อมูลบัญชีแสดงข้อความการกล่าวอ้างหน้าที่อื่นจาก 6 ประเทศ

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
1	**Alpha-linolenic acid (ALA)**	**EU**	The food constituent that is the subject of the health claims is alpha-linolenic acid (ALA), an essential n-3 polyunsaturated fatty acid with 18 carbon atoms and three double bonds. ALA is a well recognised nutrient, is well absorbed when consumed in the form of triglycerides and is measurable in foods by well established methods.		Clinical trials comparing the effects of different vegetable oils on serum lipids in normolipidaemic subjects have shown that the effect of alpha-linolenic acid (ALA) on serum cholesterol is similar to that of linoleic acid (LA) (Mantzioris *et al*., 1994; Valsta *et al*., 1995; Pand *et al*., 1998). In a meta- analysis of 60 randomised controlled clinical trials, the replacement of 1% of energy from carbohydrates by polyunsaturated fatty acids (PUFA), mainly as LA, reduced serum LDL cholesterol levels by 0.02 mmol/l (Mensink *et al*., 2003). The estimated change in the total to HDL cholesterol ratio was -0.032. Although LA was the main source of PUFA in the studies above, smaller amounts of ALA were also used in some of the studies. Moreover, as indicated in the studies by Mantzioris *et al*. (1994), Valsta *et al*. (1995) and Pand *et al*. (1998), the effects of LA and ALA on serum lipoproteins are similar and the n-6/n-3 ratio of dietary PUFA does not affect the serum lipid profile (Goyens and Mensink, 2005).	The claimed effect is “contributes to healthy blood cholesterol level/helps to maintain normal cholesterol level/maintenance of normal blood cholesterol level”. The target population is the general population. Maintenance of normal blood cholesterol concentrations is beneficial to human health.	“Alpha-linolenic acid contributes to maintenance of normal blood cholesterol concentrations”.	In order to bear the claim a food should contain at least 15% of the proposed labelling reference intake value of 2 g ALA per day. Such an amount can be easily consumed as part of a balanced diet. The target population is the general population.	EFSA journal number: 2009; 7(9):1252	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.1252
									EFSA Journal number: 2011;9(6):2203	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2203

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
2	**Beta-glucans**	EU	Beta-glucans are soluble cereal fibres. They are non-starch polysaccharides composed of glucose molecules in long linear glucose polymers with mixed β-(1⟶4) and β-(1⟶3) links with an approximate distribution of 30 % to 70 %. Their molecular weight varies from 50 to 2,000 kDa. Beta-glucans occur naturally in the bran of cereal grasses such as barley (~7 %), oats (~5 %), rye and wheat (1-2 %), and are measurable in foods by established methods. This opinion applies to beta- glucans naturally present in foods, and added to foods.		In weighing the evidence, the Panel took into account that, although some human intervention studies using high doses of beta-glucans (about 10g/d) in food matrices like juices or baked products have not observed a statistically significant reduction in LDL-cholesterol concentrations, most of the randomised controlled trials investigating the effects of non-processed or minimally processed oat or barley beta-glucans at doses of at least 3g/d have shown a statistically significant decrease in LDL-cholesterol in both normocholesterolaemic and hypercholesterolaemic subjects. The Panel also considers that beta-glucans from oat bran and barley bran have similar effects on serum LDL-cholesterol.	The claimed effect is “blood lipids”. Maintenance of normal blood cholesterol concentrations is beneficial to human health.	“Regular consumption of beta-glucans contributes to maintenance of normal blood cholesterol concentrations”	In order to bear the claim, foods should provide at least 3 g/d of beta-glucans from oats, oat bran, barley, barley bran, or from mixtures of non-processed or minimally processed beta-glucans in one or more servings. The target population is adults with normal or mildly elevated blood cholesterol concentrations.	EFSA Journal number: 2009; 7(9):1254	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.1254
					The mechanism by which beta-glucans from oats or barley could exert the claimed effect is well established, and relates to the increased viscosity of the meal bolus when beta-glucans are added. When the meal bolus reaches the small intestine, a high viscosity delays the rate of absorption of nutrients, including glucose (Battilana *et al*., 2001; Wood *et al*., 2000; Wursch and Pi-Sunyer, 1997). In weighing the evidence, the Panel took into	The claimed effect is “carbohydrate metabolism and insulin sensitivity”.	“Consumption of beta-glucans from oats or barley contributes to the reduction of the glucose rise after a meal”.	In order to obtain the claimed effect, 4 g of beta-glucans from oats or barley for each 30 g of available carbohydrates should be consumed per meal. The target population is individuals who wish to reduce their post-prandial glycaemic responses.	EFSA Journal number: 2011;9(6):2207	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2207

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
					account that intervention studies in healthy subjects consistently show an effect of oat and barley beta-glucans in decreasing post-prandial glycaemic responses, without disproportionally increasing post-prandial insulinaemic responses, at doses of about 4 g per 30 g of available carbohydrates in bread and pasta products when consumed alone or in the context of a meal, and that the mechanism by which beta-glucans could exert the claimed effect is well established.					
	Barley Products (barley beta-glucan)	**Ca**	Barley grain products include dehulled or hulless barley, pearl barley, barley flakes, grits, meal, flour, bran as well as beta-glucan enriched milling fractions derived from sieving or air classifying ground material or flour fractions, but they exclude extracted barley beta-glucan.		A daily intake of a minimum of 3 g of beta-glucan from barley grain products resulted in a physiologically relevant LDL cholesterol lowering comparable to the LDL cholesterol lowering effect of oat beta-glucan. The magnitude of the cholesterol-lowering effect in the relevant studies was variable. When only the higher-quality studies using barley grain products (no extracts) were taken into account [Anonymous, 2005; Behall, 2004a; Behall 2004b; Rondanelli, 2011; Shimizu, 2008; Sundberg, 2008], the reduction in total cholesterol levels ranged from -0.06 to -0.50 mmol/L (-1.1% to -7.5%) while the reduction in LDL-cholesterol levels	Barley Products and Blood Cholesterol Lowering	"[serving size from Nutrition Facts table in metric and common household measures] of (Brand name) [name of food] [with name of eligible fibre source]* supplies/provides X% of the daily amount of the fibre shown to help reduce/lower cholesterol." The following additional statements could be placed, adjacent to the primary statement, in	1. The "daily amount" referred to in the primary statement is 3 grams of barley beta-glucan. In this statement, the percentage of the daily amount of barley beta-glucan provided in one serving should be expressed to the nearest multiple of 5%. 2. Conditions for Foods to Carry the Claim: The following qualifying criteria apply to all food products carrying the above-mentioned health claim. a) The food contains at least 1g of beta-glucan from barley grain products† per reference amount	Summary of Health Canada's Assessment of a Health Claim about Barley Products and Blood Cholesterol Lowering (2012)	https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/label-etiquet/claims-reclam/assess-evalu/barley-orge-eng.pdf

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
					ranged from 0 to -0.32 mmol/L (0% to -8.5%). In addition, subgroup analyses in a meta-analysis conducted by the petitioner showed that consumption of beta-glucan from barley grain products lowered total cholesterol by 0.29 mmol/L and LDL cholesterol by 0.26 mmol/L compared to control.		letters up to twice the size and prominence as those of the primary statement: • “Barley fibre helps reduce/lower cholesterol” • “High cholesterol is a risk factor for heart disease” • “Barley fibre helps reduce/lower cholesterol, (which is) a risk factor for heart disease”	and per serving of stated size; b) The food contains at least 10% weighted recommended nutrient intake (WRNI) of a vitamin or mineral nutrient i. per reference amount and per serving of stated size, or ii. per serving of stated size, if the food is a prepackaged meal; c) The food contains 100 mg or less of cholesterol per 100 g of food; d) The food contains 0.5% or less alcohol; e) The food contains i. 480 mg or less of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 ml or less, or ii. 960 mg or less of sodium per serving of stated size, if the food is a prepackaged meal; f) The food meets the conditions for “low in saturated fatty acids” or “free of saturated fatty acids”. † Barley grain products include dehulled or hulless barley, pearl barley, barley flakes, grits, meal, flour, bran as well as beta-glucan enriched milling fractions derived from sieving or air classifying		

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
								ground material or flour fractions, but they exclude extracted barley beta-glucan.		
	Oat product (beta-glucan oat fibre)	Ca	For the purposes of this decision document, Health Canada has determined that the eligible sources of beta-glucan oat fibre are: oat bran, rolled oats (also known as oatmeal), and whole oat flour, either as food themselves (oat bran and rolled oats) or as ingredients (oat bran, rolled oats and whole oat flour) in formulated foods. The specifications for the eligible sources of oat beta- glucan are as follows: • Oat bran: oat bran is produced by grinding clean oat groats or rolled oats and separating the resulting oat flour by suitable means into fractions such that the oat bran fraction is not more than 50 percent of the original starting material and provides at least 5.5 percent (dry weight basis		Health Canada has concluded that scientific evidence exists in support of the claim linking the consumption of beta-glucan oat fibre to a reduction of blood cholesterol. The claim is relevant and generally applicable to the Canadian population given that a high proportion of the population (44 to 69%) is hyperlipidemic and that adults with normal or mildly elevated blood cholesterol concentrations could also benefit from increased oat intake.	Oat Products and Blood Cholesterol Lowering	“[serving size from Nutrition Facts table in metric and common household measures]2 of (Brand name) [name of food] [with name of eligible fibre source]* supplies/provides [X % of the daily amount] of the fibres shown to help reduce/lower cholesterol.” The following additional statements, which can be placed, adjacent to	The “daily amount” referred to in the primary statement is 3 grams beta-glucan oat fibre. In this statement, the percentage of the daily amount of beta-glucan oat fibre provided in one serving should be expressed to the nearest multiple of 5%. Conditions for foods to carry the claim Oat products, whether consumed as food or as ingredients, must meet the specifications for eligible sources of oat beta-glucan described in section 1 of this document.	Oat Products and Blood Cholesterol Lowering Summary of Assessment of a Health Claim about Oat Products and Blood Cholesterol Lowering (2010)	https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/label-etiquet/claims-reclam/assess-evalu/oat_avoine-

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
			(dwb)) beta-glucan soluble fibre and at least 16 percent (dwb) total dietary fibre, and such that at least one-third of the total dietary fibre is soluble fibre. • Rolled oats: rolled oats, also known as oatmeal, are produced from 100 percent dehulled, clean oat groats, by steaming, cutting, rolling, and flaking, and provide at least 4 percent (dwb) of beta-glucan soluble fibre, and at least 10 percent (dwb) total dietary fibre. • Whole oat flour: whole oat flour is produced from 100 percent dehulled, clean oat groats, by steaming and grinding, such that there is no significant loss of oat bran in the final product, and provides at least 4 percent (dwb) of beta-glucan soluble fibre and at least 10 percent (dwb) total dietary fibre. The AOAC method 992.28 is applicable to measure 1–12% β-glucans in oat and barley fractions, unsweetened oat cereals, and ready-to-eat cereals				the primary statement, in letters up to twice the size and prominence as those of the primary statement: 1) Oat fibre helps reduce/lower cholesterol 2) High cholesterol is a risk factor for heart disease 3) Oat fibre helps reduce/lower cholesterol, (which is) a risk factor for heart disease.	Where the food carrying the claim is a formulated food to which oat products are added as ingredients, the formulated food must not be subject to non-typical or novel treatments. Formulated food products containing the eligible oat products, but processed by non-typical or novel treatments, may require individual authorization in order to carry the claim. In addition, the food must meet the following qualifying criteria: 1. Contain at least 0.75 g beta-glucan oat fibre3 per reference amount and per serving of stated size from the eligible sources; 2. Contain at least 10% of the weighted recommended nutrient intake of a vitamin or a mineral nutrient per reference amount and per serving of stated size; 3. Contain 100 mg or less of cholesterol per 100 g of food; 4. Contain 0.5% or less of alcohol; 5. Contain 480 mg or less of sodium per reference amount and per serving of stated size, and per 50 g if the reference is 30 g or		eng.pdf

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
								less; and 6. Meet the definition of "free of saturated fatty acids" or "low in saturated fatty acids".		
	Beta-glucan	**AUS-NZ**	Diet low in saturated fatty acids / Diet containing 3 g of beta-glucan per day			Reduces dietary biliary cholesterol absorption		Condition: The food must contain: (a) one or more of the following oat or barley foods (i) oat bran; or (ii) wholegrain oats; or (iii) wholegrain barley; and (b) at least 1 g per serving of beta-glucan from the foods listed in (a).	Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claims (F2017C00711) Authorised Version F2017C00711 registered 08/09/2017	https://irp.cdn-website.com/69f086d6/files/uploaded/FSANZ%20Food%20Standards%20Schedule%204.pdf
	Ganoderma lucidum fruit body extracts **(B-glucan is functioncal compound)**	**KR**	(1) Raw material: Ganoderma lucidum (*Ganoderma lucidum* or *Ganoderma tsugae*) fruit body (2) Preparation and/or processing: It shall be in edible form by filtering and concentrating after extracting the raw materials with hot water. (3) Content of functional compounds	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) B-Glucan (The B-glucan originated from other ingredients shall be labeled separately.) (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of the labeled amount (3) Coliform: Negative		Health claims: May help to maintain healthy blood flow		(1) Daily intake amount: 24 ~ 42 mg as B-glucan	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
			(or marker compounds): B-Glucan shall be contained 10 mg/g or more.							
	***Phellinus linteus* extracts** **(B-glucan is functional compound)**		(1) Raw materials: *Phellinus linteus* (3 ~ 4 years old dry) (2) Preparation andor processing: It shall be in edible form by pulverizing the raw material under 3mm size, extracting (1100C, 96 ~ 100 hours) with water (10 times more amount than materials), high-press filtering, drying (75 ~ 800C, heat dry), pulverizing. (3) Content of functional compounds (or marker compounds): B-glucan shall be contained 87 mg/g or more. (4) Conditions for manufacturing: Raw material shall be in	(1) Appearance: Unique color and flavor, no off-taste and no off-flavor (2) B-glucan (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of labeled amount (3) Heavy metal (a) Lead (mg/kg): No more than 1.0 (b) Cadmium (mgkg): No more than 0.4 (c) Mercury (mg/kg): No more than 0.3 (d) Arsenic (mgkg): No more than 1.0 (4) Coliform: Negative		Health claims: May help to support immune function		(1) Daily intake amount: 3.3 g as *Phellinus linteus* extracts (287.1 ~ 534.6 mg as B-glucan)		https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
			confirmed as *Phellinus linteus* by ITS-5.8S rDNA sequence analysis, shall be inoculation with nutrient culture medium which protected from microbial contamination and cultivated for 3~4 years, *Phellinus linteus* shall be obtained in the form of dark brown firit body which has been identified the spore formation.							
	Barley or Oat beta-glucan	**SG**					Claim: Barley beta-glucans / Oat beta-glucans have been shown to lower/reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease.	Criteria: 1. The cholesterol, saturated fatty acids and trans fatty acids present in the food must be within the following levels: (i) in the case of solid food — a. not more than 20 mg of cholesterol per 100 g; b. not more than 1.5 g of saturated fatty acids and c. trans fatty acids per 100 g; and d. not more than 10% of	A Guide to Food Labelling and Advertisements	https://www.sfa.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/aguidetofoodlabellinganadvertisements.pdf

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			1.1 Standards for manufacturing	1.2 Specifications				kilocalories from e. saturated fatty acids and trans fatty acids; or (ii) in the case of liquid food — a. not more than 10 mg of cholesterol per 100 ml; b. not more than 0.75 g of saturated fatty acids and c. trans fatty acids per 100 ml; and d. not more than 10% of kilocalories from e. saturated fatty acids and trans fatty acids. 2. The following mandatory information must be declared on the product label: (i) a statement or statements to the like effect that consumption of at least 3 g of barley beta-glucans or oat beta-glucans (as the case may be) in a day has been shown to lower blood cholesterol levels; and (ii) the amounts of barley beta-glucan or oat beta-glucans (as the case may be), cholesterol, saturated fatty acids and trans fatty acids, present in		

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			1.1 Standards for manufacturing	1.2 Specifications						
								the food under the nutrition information panel.		
	Oat soluble fibre (beta-glucan)	MYS				Oat soluble fibre (beta-glucan) : i. Oat soluble fibre (beta-glucan) helps lower or reduce cholesterol ii. Oat soluble fibre (beta-glucan) helps to lower the rise of blood glucose provided it is not consumed together with other food		(B-glucan) Oat soluble fibre in relation to cholesterol claim Minimum amount: 2 g per 100 g (solids) Other conditions: Must also contains total dietary fibre not less than amount required to claim as "source": 3 g per 100 g (solids) 1.5 g per 100 ml (liquids)	Malaysian Dietary Guidelines Key Message 14 Make effective use of nutrition information on food labels	https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf
								(B-glucan) Oat soluble fibre in relation to blood glucose claim Other conditions: i. Addition and claim for oat soluble fibre (B-glucan) only permitted incereal and cereal based product. ii. Claim only permitted for product where the macronutrient profile (carbohydrate, protein and fat) complies with Recommended Nutrient Intake (RNI) Malaysia. iii. There shall be written on the label of food making such claim		

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								statement "For advice regarding consuming this consult product, your medical professional"		
3	Chitosan	EU	Chitosan is a linear cationic polysaccharide composed of randomly distributed -(1-4)-linked D-glucosamine and N-acetyl-D-glucosamine produced commercially by the deacetylation of chitin, which is a component of the exoskeleton of crustaceans and the cell walls of fungi. The degree of deacetylation can be measured by established methods, and ranges from 60-100 % in commercial preparations. The molecular weight of chitosan in commercial preparations ranges from 3,800 to 20,000 Da. Chitosan is insoluble in water.		The mechanism by which chitosan is presumed to exert the claimed effect is by binding to negatively charged lipids and hence reducing their gastro-intestinal uptake, and these effects were observed in some animal studies (Deuchi *et al*., 1995; Sugano *et al*., 1980; Zacour *et al*., 1992). The effects of chitosan on 24 h faecal fat excretion in healthy human volunteers at doses of about 3 g daily were not statistically significant (Guerciolini *et al*., 2001), and it is unclear whether this could play a role on the claimed effect. In weighing the evidence, the Panel took into account that a meta-analysis of RCTs, which investigated the effects of chitosan consumption on blood lipids, showed a small but statistically significant reduction in total and LDL-cholesterol concentrations.	Maintenance of normal blood cholesterol concentrations	"Chitosan may contribute to maintaining normal blood cholesterol levels".	In order to obtain the claimed effect, 3 g of chitosan should be consumed daily. The target population is adults.	EFSA journal number: 2011;9(6):2214	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2214

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	Chitosan / Chitooligosaccharide	KR	(1) Raw material: A shell of crustacean (crab, shrimp, etc.), Mollusk (squid, cuttlefish, etc.) bone (2) Preparation and/or processing (a) Chitosan: It shall be in edible form by diacetylating chitin (β-1,4 bound polymer of N-acetylglucosamine) obtained by deproteinizing and decalcifying the raw materials. (b) Chitooligosaccharide: It shall be in edible form by hydrolyzing chitosan obtained from preparation and/or processing of (a) with enzyme. (3) Content of functional compounds (or marker compounds): The degree of deacetylation (glucosamine remaining ratio in sugar chains) of	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) Chitosan or Chitooligosaccharide (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of labeled amount (3) Heavy metal (a) Lead (mg/kg): No more than 3.0 (b) Cadmium (mg/kg): No more than 1.0 (c) Mercury (mg/kg): No more than 1.0		Health claims: May help to maintain healthy blood cholesterol level, reduce body fat		(1) Daily intake amount (a) May help to maintain health blood cholesterol level: 1.2 ~ 4.5 g as sum of chitosan and chitooligosaccharide (b) May help to reduce body fat: 3.0 ~ 4.5 g as chitosan, 3 g as chitooligosaccharide (2) Warning notice for intake: The individual who has an allergy to crab and/or shrimp should be cautious to intake (limited to using crab and/or shrimp as raw material)	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1

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			chitosan shall be contained 80% or more. Chitosan (as glucosamine) shall be contained 800 mg/g or more and chitooligosaccharide 200 mg/g or more.							
4	**Conjugated linoleic acid**	KR	(1) Raw material: Safflower seed oil 2) Preparation and/or processing (a) After saponifying and conjugated isomerizing the raw materials, the fatty acid shall be in edible form by extracting with fermented ethanol or hexane, or purifying, deodorizing and filtering. (b) Triglyceride form: After glycerifying conjugated linoleic acid in fatty acid form with lipase, it shall be in edible form by extracting with	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) Content of conjugated linoleic acid (The sum of cis-9/trans-11, trans-10/cis-12. cis-9/cis-11, and trans-9/trans-11 conjugated linoleic acids). (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of labeled amount (3) Contents of cis-9/trans-11 and trans-10/cis-12 conjugated linoleic acids (%): No less than 90% of		(1) Health claims: May help to reduce body fat in the overweight adult		(1) Daily intake amount: 1.4 ~ 4.2 g as conjugated linoleic acid 2) Warning notice for intake (a) It may cause gastrointestinal disorder (b) Infant and pregnant women should be avoid intake (c) Diet control and exercises together are effective in reducing body fat	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1

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			fermented ethanol or hexane, or purifying, deodorizing and filtering. (3) Content of functional compounds (or marker compounds): Conjugated linoleic acid (the sum of cis-9 and trans-11 conjugated linoleic acid, trans-10 and cis-12 conjugated linoleic acid, and cis-9 and cis-11 conjugated linoleic acid) shall be contained 660 mg/g or more.	conjugated linoleic acid content						
5	**Eicosapentaenoic acid and docosahexaenoic acid (EPA/DHA)**	**EU**	The food constituent which is the subject of the health claims is mixed long-chain n-3 polyunsaturated fatty acids (n-3 LCPUFA), namely docosahexaenoic acid (DHA) in combination with eicosapentaenoic acid (EPA)		EPA and DHA intakes could reduce the risk of coronary heart disease mortality by different (but often overlapping) mechanisms (e.g. through antiarrhythmic and antithrombotic effects, by reducing blood pressure, heart rate and plasma concentrations of triglycerides), and the doses of EPA and DHA (100->2,500 mg/d) as well as the time required to observe clinical effects and/or alter clinical events	Maintenance of normal cardiac function	"EPA and DHA contribute to the normal function of the heart".	Intakes of EPA and DHA of about 250 mg per day are required to obtain the claimed effect. Such an amount can be consumed as part of a balanced diet. The target population is the general population.	EFSA journal number: 2010;8(10):1796	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1796

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					(weeks to years) through each mechanism may vary widely (Mozaffarian and Rimm, 2006). The Panel concludes that a cause and effect relationship has been established between the consumption of EPA and DHA and maintenance of normal cardiac function.					
					A claim on EPA and DHA and the maintenance of normal (fasting) blood concentrations of triglycerides has been already assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009). The Panel considered that intakes of EPA and DHA of about 2-4 g per day were required to obtain the claimed effect. With reference to its previous opinion, the Panel considers that intakes of EPA and DHA of 2 g per day are required to obtain the claimed effect.	Maintenance of normal (fasting) blood concentrations of triglycerides		Intakes of EPA and DHA of 2 g per day are required to obtain the claimed effect. Such an amount can be consumed as part of a balanced diet. The target population is adult men and women.		
	EPA and/or DHA	**Ca**	The foods that are the subject of the health claim are foods containing eicosapentaenoic acid (EPA) and/or docosahexaenoic acid (DHA). EPA and DHA are long-chain omega-3 fatty acids with lipid structures of 20:5(n-3) and 22:6(n-3), respectively.		The evidence consistently supports a highly consistent direction of effect towards a reduction in triglyceride levels when EPA and DHA are consumed. The vast majority (>80%) of the treatment arms from the larger studies (≥30 participants) administering a daily intake of at least 1.5 g of EPA+DHA demonstrated a statistically significant reduction in	EPA+DHA shown to help reduce triglyceride levels.	[serving size from Nutrition Facts table in metric and common household measures] of (brand name) [name of food] supplies/provides X% of the daily amount of (long-chain) omega-3 (fatty acids) EPA4 and DHA5	The “daily amount” referred to in the primary statement is 1.5 g of EPA+DHA. In this statement, the percentage of the daily amount of EPA+DHA provided in one serving should be rounded to the nearest multiple of 5%. Conditions for food to carry the claim: The following qualifying	Summary of Health Canada's assessment of a health claim about eicosapentaenoic acid, docosahexaenoic acid and triglyceride	https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/label/label-

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					triglyceride levels. Health Canada's Food Directorate has concluded that scientific evidence exists to support a claim about EPA+DHA and triglyceride lowering. The claim is relevant and generally applicable to the Canadian adult population on the basis that approximately 25% of Canadian adults aged 20 to 79 had unhealthy triglyceride levels1 (>1.7 mmol/L) from 2007 to 2009.		shown to help reduce/lower triglycerides. Additional statements; (Long-chain) (omega-3) EPA and DHA help reduce/lower triglycerides	criteria apply to all food products carrying the above-mentioned health claim. The food: a) contains at least 0.5 g of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) combined i. per reference amount and per serving of stated size, or ii. per serving of stated size, if the food is a prepackaged meal, a nutritional supplement or a meal replacement; b) contains at least 10% of the weighted recommended nutrient intake (WRNI) of a vitamin or mineral nutrient i. per reference amount and per serving of stated size, or ii. per serving of stated size, if the food is a prepackaged meal, a nutritional supplement or a meal replacement; c) contains 0.5% or less alcohol; d) contains i. less than 15% of the Daily value (DV) of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less, or ii. less than 15% of the Daily value (DV) of	lowering (2016)	etiquet/claims-reclam/assess-evalu/eicosapentaenoic-acid-acide-eicosapentaenoique-eng.pdf

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								sodium per serving of stated size, if the food is a nutritional supplement or a meal replacement, or iii. less than 25% of the Daily value (DV) of sodium per serving of stated size, if the food is a prepackaged meal; e) contains i. less than 15 g of total sugars per reference amount and per serving of stated size, or ii. less than 15 g of total sugars per serving of stated size, if the food is a prepackaged meal, a nutritional supplement or a meal replacement; f) is not one of the types of fish for which Health Canada recommends limiting consumption, due to their mercury concentrations, that is, fresh and frozen tuna, shark, swordfish, escolar, marlin, orange roughy and canned albacore (white) tuna.		
	Eicosapentaenoic acid (EPA)and docosahexaenoic acid (DHA)(but not	**AUS-NZ**	Diet containing 500mg of EPA and DHA per day			Contributes to heart health	-	(a) The food must contain a minimum of 50mg EPA and DHA combined in a serving of food; and (b) other than for fish or fish products with no added saturated fatty acids—the food	Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claims	https://irp.cdn-website.com/69f086d6/files/uploaded/FSANZ

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	Omega-3)							contains: (i) as a proportion of the total fatty acid content, no more than 28% *saturated fatty acids and trans fatty acids; or (ii) no more than 5 g per 100 g saturated fatty acids and trans fatty acids	(F2017C00711) Authorised Version F2017C00711 registered 08/09/2017	%20Food%20Standards%20Schedule%204.pdf
	Edible oil containing EPA and DHA (KR)	KR	(1) Raw material: Edible fishes, seaweeds, Pagophilus groenlandicus (2) Preparation and/or processing: The oil shall be in edible form by heating the raw material, pressing and extracting with hexane or carbon dioxide (supercritical fluid extraction) and then filtering or esterification after extraction. (3) Content of functional compounds (or marker compounds): As the sum of EPA and DHA, it shall be contained 180 mg/g or more from	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) The sum of EPA and DHA (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of labeled amount (3) Solvent residue (mg/kg): No more than 5.0 (in case of using hexane)		(1) Health claims: May help to maintain healthy triglyceride level, maintain healthy blood flow, improve memory, maintain eye health as the improvement of dry eyes		(1) Daily intake amount (a) May help to maintain healthy triglyceride level, maintain healthy blood flow: 0.5 ~ 2 g as the sum of EPA and DHA (b) May help to improve memory: 0.9 ~ 2 g as the sum of EPA and DHA (c) May help to maintain eye health as the improvement of dry eyes: 0.6 ~ 1 g as the sum of EPA and DHA (2) Warning notice for intake (a) Consult a health care practitioner prior to intake if you are taking medicines related with blood coagulation and/or anti-platelet and/or antihypertensive agents (b) It may cause side-effect such as skin reaction (c) Consult a health care	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety.	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1

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			edible fishes, 120 mg/g or more from Pagophilus groenlandicus and 300 mg/g or more from seaweeds.					practitioner and stop intake if you are having adverse event		
6	**Fructooligosaccharide**	**KR**	(1) Raw material and preparation and/or processing (a) Beta-1,2 oligosaccharides bound sucrose with 1~3 fructose units shall be manufactured-processed with transferase or microorganisms having transferase after making liquid by melting sugar. (b) It shall be manufactured-processed by hydrolyzing inulin with enzyme. (2) Content of functional compounds (or marker	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) Fructooligosaccharide (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of labeled amount (3) Lead (mg/kg): No more than 1.0		(1) Health claims: May help to maintain healthy gastrointestinal bacteria population, maintain healthy bowel function		(1) Daily intake amount: 3 ~ 8 g as fructooligosaccharide (2) Warning notice for intake (a) It may cause gastrointestinal gas, burp, stomachache, abdominal inflation (b) Consult a health care practitioner and stop intake if you are having adverse event	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1

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			1.1 Standards for manufacturing	1.2 Specifications						
			compounds): Fructooligosaccharide shall be contained 410 mg/g or more. The content of fructo-oligosaccharide shall be calculated by sum of 1-kestose (GF2), nystose (GF3) and fructofuranosylnystose (GF4).							
	Fructooligosaccharide	**SG**					Claim: Oligofructose stimulates the bifidobacteria, resulting in a significant increase of the beneficial bifidobacteria in the intestinal tract. At the same time, the presence of less desirable bacteria is significantly reduced	Criteria: Food manufacturer/importer to ensure that the amount of inulin present in the product is able to bring about the claimed effect.	A Guide to Food Labelling and Advertisements	https://www.sfa.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/aguidetofoodlabellingandadvertisements.pdf

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	Inulin and oligofructose (fructo-oligosaccharide)	MYS				i. Inulin helps increase intestinal bifidobacteria and helps maintain a good intestinal environment ii. Oligofructose (fructo-oligosaccharide) helps increase intestinal bifidobacteria and helps maintain a good intestinal environment iii. Inulin is bifidogenic iv. Oligofructose (fructo-oligosaccharide) is bifidogenic v. Inulin is prebiotic vi. Oligofructose (fructo-oligosaccharide) is prebiotic		Inulin: 2 g per serving FOS: 1.25 g per serving This minimum level is for other food except infant formula. 0.4 g / 100 ml on a ready to drink basis. This minimum level is specified for infant formula only.	Malaysian Dietary Guidelines Key Message 14 Make effective use of nutrition information on food labels	https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf
7	Glucomannan (konjac mannan)	EU	glucomannan (Konjac mannan). Glucomannan is a water-soluble type of fibre composed of a straight chain of β-1⟶4 D-mannose and D-glucose units in a ratio of 1.6:1 with a small amount of branching (8 %) through β-(1⟶6)-glucosyl linkages. It is derived from the tuberous roots of the Konjac plant (Amorphophallus konjac). Glucomannan is non-digestible in the human small intestine. It has a high molecular weight (200-2000 kDa) and high viscosity in water solution. Glucomannan does not occur naturally in foods, is a food additive used as emulsifier and thickener, and is usually consumed in the form of food supplements.		In weighing the evidence, the Panel took into account that a statistically significant effect on either total or LDL-cholesterol was not observed following the consumption of glucomannan in all of these studies, that reduction in total and/or LDL-cholesterol concentrations did not always lead to significant reductions in the total/HDL cholesterol ratio, that the vast majority of these studies had small samples sizes, and that no clear dose-response relationship was established between the consumption of glucomannan and the claimed effect.	Maintenance of normal blood cholesterol concentrations is beneficial to human health.	“Regular consumption of glucomannan helps maintain normal blood cholesterol concentrations”	a food should provide at least 4 g/d of glucomannan in one or more servings. The target population is the general population.	EFSA journal number: 2009; 7(9):1258	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.1258

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					However, the Panel considers that most studies showed a consistent effect in the reduction of serum total and LDL-cholesterol concentrations at doses of about 4g/d of glucomannan, that the effect has been observed not only in hypercholesterolaemic subjects but also in normocholesterolemic individuals, and that the mechanisms by which the consumption of the food may exert the claimed effect (biological plausibility) are established.					
					The Panel notes that no long-term studies (>3 months) on the effects of glucomannan on body weight are available. The Panel also notes that glucomannan is a soluble-type of fibre which forms a viscous, gel-like mass in the stomach when hydrated, and that this "mass effect" could delay gastric emptying and induce satiety leading to a decrease in subsequent energy intake (Keithley and Swanson, 2005). In weighing the evidence, the Panel took into account that most of the intervention studies, which were of adequate sample size and duration, found a statistically significant effect of glucomannan on body weight loss in the context of a hypocaloric diet	Reduction of body weight	"Glucomannan contributes to the reduction of body weight in the context of an energy-restricted diet". The following additional statements may be placed adjacent to the primary statement, in letters up to twice the size and prominence of those in the primary statement: • PGX® helps reduce/lower cholesterol • High cholesterol is a risk factor for heart disease • PGX® helps reduce/lower	In order to obtain the claimed effect, at least 3 g of glucomannan should be consumed daily in three doses of at least 1 g each, together with 1-2 glasses of water before meals, in the context of an energy-restricted diet. The target population is overweight adults.	EFSA journal number: 2010;8(10):1798	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1798

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					when administered as a pre-load before meals, and that the mechanism by which glucomannan could exert the claimed effect is established. Panel concludes that a cause and effect relationship has been established between the consumption of glucomannan and the reduction of body weight in the context of an energy-restricted diet.		cholesterol, (which is) a risk factor for heart disease			
	Glucomannan (Konjac, Konjacmannan)	**KR**	(1) Raw material: Arum family konjac (*Amorphophallus konjq*) rhizome (2) Preparation and/or processing: Polysaccharides shall be in edible form by extracting the raw materials with isopropyl alcohol and purifying. (3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 690 mg/g or more.	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) Dietary fiber (a) Semi-processed product: No less than labeled amount (b) Final product: No less than 80% of labeled amount (3) Solvent residue (mgkg): No more than 50.0		(1) Health claims: May help to maintain healthy blood cholesterol level, maintain healthy bowel function		(1) Daily intake amount: 2.7 ~ 17 g as glucomannan dietary fiber (2) Warning notice for intake: Should be taken with sufficient water except for liquid type product	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1

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			1.1 Standards for manufacturing	1.2 Specifications						
8	Guar gum	EU	Guar gum is a water-soluble type of fibre, a galactomannan composed of a backbone of D-mannose units with D-galactose attached at every second mannose unit. It is derived from the cluster bean (Cyamopsis tetragonoloba (L.) Taub.). Guar gum is non-digestible in the human small intestine. The molecular weight is about 220 kDa. Guar gum is not naturally occurring in foods and is usually consumed in the form of food supplements. Guar gum has a high viscosity, it is used as a thickener by the food industry, and can be measured in foods by established methods.		The effect of water-soluble fibre on blood (LDL) cholesterol concentrations is likely to depend on its viscosity, which reduces the reabsorption of bile acids, increases the synthesis of bile acids from cholesterol, and reduces circulating blood cholesterol concentrations. The Panel concludes that a cause and effect relationship has been established between the consumption of guar gum and the reduction of blood cholesterol concentrations.	Maintenance of normal blood cholesterol concentrations.	"Regular consumption of guar gum contributes to the maintainance of normal blood cholesterol levels".	In order to bear a claim, foods should provide at least 10 g per day of guar gum in one or more servings. The target population is adults. Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake :-advice on taking with plenty of water to ensure substance reaches stomach.	EFSA journal number: 2010;8(2):1464	https://efsa.onlinelibrary.wiley.com/doi/pdfdirect/10.2903/j.efsa.2010.1464?download=true
	Guar gum	KR	(1) Raw material: Legume family guar (Cyamopsis tetragonolobus TAUB) (2) Preparation and'or processing (a) High molecular weight galactomannan polysaccharide shall be in edible form obtained by pulverizing the seed albumen parts from the raw materials or extracting with warm or hot water.	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) Dietary fiber (a) Semi-processed product: No less than labeled amount (b) Final product: No less than 80% of labeled amount (3) Lead (mg/kg): No more than 2.0		(1) Health claims: May help to maintain healthy blood cholesterol level, maintain healthy postprandial glucose level, maintain healthy bowel function, maintain healthy gastrointestinal bacteria population		(1) Daily intake amount (a) May help to maintain healthy blood cholesterol level, maintain healthy postprandial glucose level, maintain healthy bowel function: 9.9 ~ 27 g as dietary fiber of guar gum or its hydrolysate (b) May help to maintain healthy gastrointestinal bacteria population: 4.6 ~ 27 g as dietary fiber of guar gum or its hydrolysate (2) Warning notice for intake: Should be taken with sufficient water except for liquid type	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1

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			(b) Galactomannan obtained by method of (a) shall be in edible form by hydrolysis. (3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 660 mg/g or more.					product		
9	**Indigestible maltodextrin**	KR	1) Raw material: Corn starch (2) Preparation and/or processing: The roasted-dextrin shall be obtained by heating the raw materials. The indigestible components shall be in edible form by hydrolyzing the roasted-dextrin with a-amylase (*Bacillus subtilis* or *Bacillus licheniformis* origin) and amyloglucosidase (*Aspergillus niger* origin)	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) Dietary fiber (a) Semi-processed product: No less than labeled amount (b) Final product: No less than 80% of labeled amount (3) Dextrose equivalent (D.E.): 8.0 ~ 18.0 (limited to Semi-processed product)		(1) Health claims: May help to maintain healthy postprandial glucose level, maintain healthy triglyceride level, maintain healthy bowel function		(1) Daily intake amount (a) May help to maintain healthy postprandial glucose level: 11.9 ~ 30 g as indigestible maltodextrin dietary fiber (in case of liquid ingredients, 11.6 ~ 44 g) (b) May help to maintain healthy triglyceride level: 12.7 ~ 30 g as indigestible maltodextrin dietary fiber (in case of liquid ingredients, 12.7 ~ 44 g) (c) May help to maintain healthy bowel function: 2.5 ~ 30 g as indigestible maltodextrin dietary fiber (in case of liquid ingredients, 2.3 ~ 44 g) (2) Warning notice for intake:	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1

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			and purifying and then separating from dextrin. (3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 850 mg/g or more (In case of liquid, 580 mg/g or more).					Should be taken with sufficient water except for liquid type product		
10	**Inulin (Native chicory inulin)**	EU	The applicant initially stated that the food constituent that is the subject of the health claim is “Orafti®Inulin”. In response to the EFSA’s request for clarification, the applicant explained that “chicory inulin” is the food constituent that is the subject of the health claim. Chemically, inulin is a linear β(2⟶1)-fructan with a degree of polymerisation (DP) > 9 which typically has a terminal α-glucose (EFSA NDA Panel, 2010). Chicory (Chicorium intybus) root is one of the plants with the highest concentration of inulin. “Native chicory inulin” is extracted as a non-fractionated mixture of monosaccharides, disaccharides, oligosaccharides (inulin-type fructans, DP 3 – 9) and non-starch polysaccharides (inulin, DP > 9). Influencing factors for chain length distribution are growth conditions and harvest time as well as process technology. From the information		The Panel notes that inulin and inulin-type fructans in “native chicory inulin” are non-digestible carbohydrates which could exert an effect on stool frequency by stimulating bacterial growth in the gut and by increasing bacterial cell mass and faecal bulk. The Panel also notes that mono- and disaccharides present in “native chicory inulin” in small amounts are unlikely to contribute to the claimed effect. In weighing the evidence, the Panel took into account that six studies involving 86 subjects consistently showed that consumption of at least 12 g/day “native chicory inulin” increases stool frequency. The Panel also notes the plausible mechanisms by which inulin and inulin-type fructans in “native chicory inulin”	Improves bowel function by increasing stool frequency	“Chicory inulin contributes to maintenance of normal defecation by increasing stool frequency”.	In order to obtain the claimed effect, 12 g of “native chicory inulin” should be consumed daily. The target population is the general population.	EFSA Journal 2015;13(1):3951	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.3951

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			provided, including the human studies submitted for the scientific substantiation of the claim, the Panel notes that this claim relates to "native chicory inulin", a non-fractionated mixture of monosaccharides (< 10%), disaccharides, oligosaccharides (inulin-type fructans) and polysaccharides (inulin) extracted from fresh chicory roots characterised by its mean DP (> 9).		could exert the claimed effect. The Panel concludes that a cause and effect relationship has been established between the consumption of "native chicory inulin", a non-fractionated mixture of monosaccharides (< 10%), disaccharides, inulin-type fructans and inulin extracted from chicory with a mean DP ≥ 9, and maintenance of normal defecation by increasing stool frequency. The Panel could have reached the conclusion that "native chicory inulin" contributes to the maintenance of normal defecation by increasing stool frequency without the data identified as proprietary by the applicant (Schulz *et al*., 2012, unpublished). However, this study (Schulz *et al*., 2012, unpublished) was used to establish the conditions of use for this claim.					
	Inulin / Chicory extract	**KR**	(1) Raw material: Chicory (*Chicorium intybus*) or other Compositae family plants (2) Preparation and/or processing: It shall be in edible form by extracting the root of	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) Dietary fiber (a) Semi-processed product: No less than labeled amount (b) Final product: No less than 80% of		(1) Health claims: May help to maintain healthy blood cholesterol level, maintain healthy postprandial glucose level, maintain healthy bowel function		(1) Daily intake amount (a) May help to maintain healthy blood cholesterol level, maintain healthy postprandial glucose level: 7.2 ~ 20 g as inulin / chicory dietary fiber (b) May help to maintain healthy bowel function: 6.4 ~ 20 g as inulin / chicory dietary fiber	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1

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			raw materials with hot water and then purifying. (3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 800 mg/g or more.	labeled amount (3) Coliform: Negative				(2) Warning notice for intake: Should be taken with sufficient water except for liquid type product		
	Inulin	SG					Claim: 1. Inulin helps in calcium absorption	Criteria: 1. ≥ 133.33mg of calcium in per reference quantity of the food as specified Table II in section “Nutrition claims” 2. The amount of calcium has to be declared under the nutrition information panel 3. The amount of inulin present in each serving or other equivalents of the product must be declared on the product label 4. Food manufacturer/importer to ensure that the amount and combinations of shorter and longer chain inulin present in the product is able to bring about the claimed effect.	A Guide to Food Labelling and Advertisements	https://www.sfa.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/aguidetofoodlabellinganadvertisements.pdf

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							Claim: 2. Inulin helps support growth or benefical bacteria/good intestinal flora in gut 3. Inulin helps increase intestinal bifidobacteria and helps maintain a good intestinal environment	Criteria: Food manufacturer/importer to ensure that the amount of inulin present in the product is able to bring about the claimed effect.		
	Inulin and oligofructose (fructo-oligosaccharide)	MYS				i. Inulin helps increase intestinal bifidobacteria and helps maintain a good intestinal environment ii. Oligofructose (fructo-oligosaccharide) helps increase intestinal bifidobacteria and helps maintain a good intestinal environment iii. Inulin is bifidogenic iv. Oligofructose (fructo-oligosaccharide) is bifidogenic v. Inulin is prebiotic vi. Oligofructose (fructo-oligosaccharide) is prebiotic		Inulin: 2 g per serving FOS: 1.25 g per serving This minimum level is for other food except infant formula. 0.4 g / 100 ml on a ready to drink basis. This minimum level is specified for infant formula only.	Malaysian Dietary Guidelines Key Message 14 Make effective use of nutrition information on food labels	https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf
11	**Live yoghurt cultures**	EU	The food constituent that is the subject of the health claim is “yoghurt cultures (live)”, which contain the starter micro-organisms “Lactobacillus delbrueckii subsp. bulgaricus and	In weighing the evidence, the Panel took into consideration that thirteen of fourteen human studies showed enhanced digestion of lactose in yoghurt	Improved lactose digestion.	“Live yoghurt cultures in yoghurt improve digestion of lactose in yoghurt in individuals with lactose	In order to bear the claim, the yoghurt should contain at least 108 CFU live starter microorganisms (Lactobacillus	EFSA journal number: 2010;8(10):1763	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2

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			Streptococcus thermophilus". These starter cultures "Lactobacillus delbrueckii subsp. bulgaricus and Streptococcus thermophilus" are well specified for their use in yoghurt manufacture by Codex Alimentarius Standard No. 243/2003.		in lactose maldigesters, when live yoghurt starter cultures were ingested in yoghurt, that the one study which did not show such an effect reported reduced symptoms and that there was strong evidence for the biological plausibility of the effect. The Panel concludes that a cause and effect relationship has been established between the consumption of live yoghurt cultures in yoghurt and improved digestion of lactose in yoghurt in individuals with lactose maldigestion.		maldigestion".	delbrueckii subsp. bulgaricus and Streptococcus thermophilus) per gram. 16 The target population is individuals with lactose maldigestion.		903/j.efsa.2010.1763
	Live yoghurt cultures	**AUS-NZ**				Improved lactose digestion.	-	The food must: (a) be yoghurt or fermented milk; and (b) contain at least 10 8 cfu/g (Lactobacillus delbrueckii subsp. bulgaricus and Streptococcus thermophilus). Relevant population: Individuals who have difficulty digesting lactose	Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claims (F2017C00711) Authorised Version F2017C00711 registered 08/09/2017	https://irp.cdn-website.com/69f086d6/files/uploaded/FSANZ%20Food%20Standards%20Schedule%204.pdf
12	**Oleic acid**	**EU**	The foods/food constituents that are the subject of the health claims are "monounsaturated fatty acids (mainly oleic acid)", "oleic acid" and "extravirgin olive oil". In the context of the proposed wordings, clarifications provided by Member States and references submitted for the		The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus that a mixture of SFAs increases total and blood LDL-cholesterol concentrations relative to mixtures of cis-	Maintenance of normal blood LDL-cholesterol concentrations	"Replacing saturated fats in the diet with unsaturated fats contributes to the main tenance of normal blood cholesterol levels. Oleic	10-20 energy % (around. 22-44 g/day). The product shall contain a significant amount of MUFA compared to the recommended daily allowance. Health claims can be applied on foods	EFSA journal number: 2011;9(4):2043	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2043

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			scientific substantiation of the health claims, the Panel assumes that the food constituent that is the subject of the health claims is oleic acid, which should replace saturated fatty acids (SFAs) in foods or diets in order to obtain the claimed effects. Oleic acid is the monounsaturated fatty acid (MUFA) with 18 carbon atoms and the double bond in the 9-cis position. It is found in varying amounts in dietary fats. Beef tallow contains about 43 % oleic acid and 47 % SFAs, lard about 44 % oleic acid and 43 % SFAs, palm oil about 40 % oleic acid and 45 % SFAs, rapeseed oil about 60 % oleic acid and 6 % SFAs. A high proportion of oleic acid is found in olive oil, 71 %, together with 15.5 % SFAs and 12 % polyunsaturated fatty acids (PUFAs). High-oleic acid varieties of sunflower oil and rapeseed oil contain about 75-85 % oleic acid. Saturated fatty acids (SFAs) are aliphatic monocarboxylic acids with (generally) an even number of carbon atoms (usually from 4 to 20) and no double bonds which can be liberated by hydrolysis of triacylglycerols from fats and oils. The most prevailing SFAs in the diet are lauric acid (12:0), myristic acid (14:0), palmitic acid (16:0), and stearic acid (18:0). This opinion applies to the replacement of mixtures of SFAs as present in foods or diets with oleic acid.		MUFAs (EFSA, 2004; EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; IoM, 2005; Lichtenstein *et al*., 2006; Mensink *et al*., 2003; WHO/FAO, 2003), and that there is a linear dose-response relationship between blood LDL-cholesterol concentrations and the amounts of long-chain SFAs consumed. It is also well established that consumption of a mixture of SFAs results in increased blood HDL-cholesterol concentrations compared with consumption of mixtures of cis-MUFAs (e.g. oleic acid), and that incomparison with other fatty acids, except trans fatty acids (TFAs), SFAs increase the total–to-HDL cholesterol ratio (Mensink *et al*., 2003). SFAs differ in their potential to change blood lipid and lipoprotein concentrations. While lauric, myristic and palmitic acid raise blood total and LDL-cholesterol concentrations, effects of stearic acid and short and medium chain SFAs (with 4-10 carbon atoms) are similar to those of carbohydrates and oleic acid (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; Mensink *et al*., 2003). However, SFAs are present in foods as		acid is an unsaturated fat."	complying with requirements of nutrition claims “High mono-unsaturated fatty acids”.		

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					mixtures, so that stearic acid, and short and medium chain SFAs, are consumed in foods that also contain other long-chain SFAs (with 12-16 carbon atoms), which are known to increase LDL-cholesterol concentrations. A claim on the replacement of mixtures of SFAs with cis-MUFAs and/or cis-PUFAs in foods or diets and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011). The scientific conclusions in that opinion apply to the replacement of mixtures of SFAs as present in foods or diets with oleic acid.					
13	**Olive oil polyphenols**	EU	The food constituent that is the subject of the health claims is polyphenols (e.g. hydroxytyrosol and oleuropein complex) in olive (olive fruit, olive mill waste waters or olive oil, Olea europaea L. extract and leaf). The conditions of use specify 200 mg/day of polyphenols (ID 1638, 1882, 2865), 2-15 mg per day of hydroxytyrosyl or oleuropein complex (ID 1638, 1639, 1696), and 250-500 mg of an Olea europaea L. extract standardised to 4-23% oleuropein (ID 3467, 3468, 3779, 3781). Polyphenols comprise a very wide group (several thousands of compounds)		In weighing the evidence, the Panel took into account that a well conducted and powered study, and two smaller-scale studies, showed a dose-dependent and significant effect of olive oil polyphenol consumption (for three weeks) on appropriate markers of LDL peroxidation (oxLDL), that these results were supported by one short-term and one acute study, and by supportive markers of LDL peroxidation (conjugated dienes, ex vivo resistance of LDL to oxidation) going in the	Protection of LDL particles from oxidative damage	"Consumption of olive oil polyphenols contributes to the protection of blood lipids from oxidative damage."	In order to bear the claim, 5 mg of hydroxytyrosol and its derivatives (e.g. oleuropein complex and tyrosol) in olive oil should be consumed daily. These amounts, if provided by moderate amounts of olive oil, can be easily consumed in the context of a balanced diet. The concentrations in some olive oils may be too low to allow the consumption of this amount of	EFSA journal number: 2011;9(4):2033	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2033

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			of plant secondary metabolites including flavonoids, isoflavonoids, phenolic acids, proanthocyanidins and other tannins, and lignans with different biological activities. The major polyphenols in olive oil are phenolic acids (e.g. hydroxytyrosol and tyrosol), secoiridoids (e.g. oleuropein) and lignans (e.g. pinoresinol). Table olives typically contain hydroxytyrosol, tyrosol, caffeoylquinic acid, verbacoside, luteolin and rutin. Hydroxytyrosol, a major polyphenol typically present in olives, is also present in olive mill waste water. In nature, hydroxytyrosol is found in olives in the form of its elenolic acid ester, oleuropein. These polyphenolic compounds can be measured in foods by established methods. Total polyphenols are usually expressed as gallic acid equivalents (GAE), but other phenolic compounds such as catechin/epicatechin or caffeic acid have also been used for standardisation. This standardisation refers to the traditional spectrophotometrical measurement of total polyphenols using the Folin-Ciocalteau method (Singleton and Rossi, 1965), which is based on reducing capacity. The method is not specific for polyphenols because other reducing compounds such as ascorbic acid, sugars and proteins will also be included in the quantification, thus leading to an overestimation		same direction, and that evidence for a biologically plausible mechanism by which olive oil polyphenols could exert the claimed effect has been provided. The Panel concludes that a cause and effect relationship has been established between the consumption of olive oil polyphenols (standardised by their content of hydroxytyrosol and its derivatives) and protection of LDL particles from oxidative damage.			polyphenols in the context of a balanced diet. The target population is the general population.		

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			of the actual polyphenol content. The total polyphenol content assessed with this method is not suitable for characterisation of polyphenols in foods. The Panel considers that polyphenols (e.g. hydroxytyrosol and oleuropein complex) in olive (olive fruit, olive mill waste waters or olive oil, Olea europaea L. extract and leaf) can be characterised by their content of hydroxytyrosol and its derivatives (e.g. oleuropein complex).							
14	**Plant sterols and plant stanols (Phytosterols, phytostanols and their esters)**	EU	In the context of this opinion, the term plant sterols (present as free sterols or esterified) refers specifically to plant sterols from natural sources with a composition as specified in the Commission Decisions authorising the placing on the market of food products with added plant sterols under Regulation (EC) No 258/976. The term “plant stanol ester” refers to a blend of the plant stanols sitostanol and campestanol, which are obtained from the reduction of plant sterols from food grade plant oils (mainly soybean oil) or tall oil or blends thereof. The Panel notes that claims ID 1234 and 1235 refer to polyphenols present or extracted from Maritime Pine (Pinus pinaster Aiton). However, the only reference cited in the list referring to procyanidins (a type of polyphenol) from French maritime pine bark was not accessible to the Panel after having made every reasonable effort		In the most recent meta-analysis on the LDL-cholesterol lowering effects of plant sterols/stanols, 84 clinical trials were included (Demonty *et al*., 2009). In nine of the studies, daily doses of 0.80-1.0 g had been used. In seven of these studies a statistically significant reduction of LDL-cholesterol concentrations (range -0.19 to -0.33 mmol/L) was found (Beer *et al*., 2001; Hendriks *et al*., 1999; Hironaka *et al*., 2006; Niittynen *et al*., 2007; Sierksma *et al*., 1999; Ishizaki T, 2003; Vanhanen, 1994). In one study (Matsuoka *et al*., 2004) no effect was found with free sterols, and in the study by Miettinen and Vanhanen (1994) the reduction in LDL-cholesterol of 0.26 mmol/L was not statistically significant. Plant sterols were used in seven studies, stanols in one study and in	Maintenance of normal blood cholesterol concentrations	“Plant sterols/stanols help to maintain normal blood cholesterol levels”.	In order to bear the claim, a food should provide at least 0.8 g per day of plant sterols/stanols in one or more servings.	EFSA journal number: 2010;8(10):1813 2011;9(6):2203	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1813. https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2203

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			1.1 Standards for manufacturing	1.2 Specifications						
			to retrieve it (Assouad and Piriou, 2007), and no references on the effects of polyphenols present or extracted from Maritime Pine on blood lipids or any other health outcome were provided.		another study a mixture of sterols and stanols was tested. The results of these studies indicate statistically significant lowering of LDL-cholesterol concentrations by consuming moderate doses (0.8-1.0 g per day) of plant sterols or stanols in subjects with normal or mildly elevated LDL-cholesterol concentrations. All but one (Hironaka *et al*., 2006) of the studies mentioned above were conducted with plant sterols or stanols added to foods such as margarine-type spreads, mayonnaise, and dairy products such as milk and yoghurts including low-fat yoghurts (Demonty *et al*., 2009; EFSA, 2009). The Panel concludes that a cause and effect relationship has been established between the consumption of plant sterols and plant stanols and reduction of blood cholesterol concentrations.					
	Phytosterols	**Ca**	The term “phytosterols” is used in this document as a collective term for plant sterols, and their hydrogenated stanol forms, whether used in the free sterol form or esterified with fatty acids (also known as sterol esters or phytosterol esters). There is a diversity in the composition of phytosterols and over 40		The evidence provided by the petitioner included 84 randomized controlled trials (comprising 141 pertinent trial arms) published from 1994 to 2007. Overall, an 8.8% reduction in LDL-cholesterol as observed with an average intake of 2 g/day of plant sterols. A dose-response	Plant Sterols and Blood Cholesterol Lowering	Primary statement: “[serving size from Nutrition Facts table in metric and common household measures] of [naming the product] provides X% of the daily	Conditions for foods to carry the claim: The food (a) contains a minimum level equivalent to 0.65 g of free plant sterols or stanols per reference amount and per serving of stated size; (b) contains at least 10% of the	Summary of Health Canada’s Assessment of a Health Claim about Plant Sterols in Foods and Blood Cholesterol	https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_form

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			phytosterols have been identified in nature. The safety assessment considered phytosterols and stanols as a group. Phytosterols occur naturally in plants, and vegetable oils are the major source of phytosterols in Canadian diets. Phytosterols, when consumed at sufficiently high levels, have been shown to reduce serum total and LDL cholesterol levels.		relationship was observed up to about 3 g/day in these studies which included doses ranging from about 0.5 g/day to 9.0 g/day. At the average intake of 2 g/day, the effect of plant sterols appeared to be largely independent of the food matrix. Most of the studies were carried out with moderately to highly hypercholesterolemic subjects. Health Canada has concluded that acceptable scientific evidence exists in support of the claim about the relationship between the consumption of plant sterol-enriched foods as foods and blood cholesterol lowering. Consumption of these foods results in the lowering of total blood cholesterol as well as LDL-cholesterol levels, while having no detrimental effect on HDL-cholesterol levels, resulting in overall improvements in the blood lipid profile.		amount* of plant sterols shown to help reduce/lower cholesterol in adults." Two additional statements that could be used in combination or alone, adjacent to the primary statement, without any intervening printed, written or graphic material: 1) "Plant sterols help reduce [or help lower] cholesterol." This statement when used, shall be shown in letters up to twice the size and prominence as those of the primary statement. 2) "High cholesterol is a risk factor for heart disease." This statement when used, shall be shown in letters up to the same size and prominence as those of the primary statement.	weighted recommended nutrient intake of a vitamin or mineral per reference amount and per serving of stated size; (c) contains 100 mg or less of cholesterol per 100 g of food; (d) contains 0.5% or less alcohol; (e) contains 480 mg or less of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less; (f) meets the criterion "low in saturated fatty acids."	Lowering. 2010.	ats/pdf/label-etiquet/claims-reclam/assess-evalu/phytosterols-claim-allegation-eng.pdf
									Notice of Assessment of Certain Categories	https://www.canada.ca/content/dam/hc-

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
									of Foods Containing Added Phytosterols. 2010.	sc/migration/hc-sc/fn-an/alt_formats/pdf/gmf-agm/appro/phytosterols-eng.pdf
	*Phytosterols, phytostanols and their esters	AUS-NZ				Reduces blood cholesterol		Diet low in saturated fatty acid. Diet containing 2 g of *phytosterols, phytostanols and their esters per day. The food must: (a) meet the relevant conditions specified in the table in section S25—2; and (b) contain a minimum of 0.8 g total plant sterol equivalents content/serving.	Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claims (F2017C00711) Authorised Version F2017C00711 registered 08/09/2017	https://irp.cdn-website.com/69f086d6/files/uploaded/FSANZ%20Food%20Standards%20Schedule%204.pdf

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
	Phytosterol / Phytosterolester	**KR**	(1) Raw material and preparation and/or processing (a) The mixture of Beta-sitosterol, brassicasterol, stigmasterol and campesterol, as distillate which are obtained during deodorization of soybean, corn or canola oil, shall be in edible form by extracting and purifying. (b) The substance of above (a) shall be in edible form by esterifying fatty acids originated from edible oil. (2) Content of fumctional compounds (or marker compounds): Phytosterol shall be contained 900 mgg or more. However, in	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) Phytosterol (in case of using phytosterol as ingredients) (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of labeled amount (3) Content of phytosterolester (in case of using phytosterolester as ingredients) (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of labeled amount		(1) Health claims: May help to maintain healthy blood cholesterol level		(1) Daily intake amount (a) 0.8 ~ 3 g as phytosterol (in case of using phytosterol as ingredients) (b) 1.28 ~ 4.8 g as phytosterolester (in case of using phytosterolester as ingredients) (2) Warning notice for intake: It may inhibit the absorption of β-carotene	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
			case of using phytosterol ester as ingredients, the sum of total phytosterol and free phytosterol shall be contained 800 mg/g or more and contents of free phytosterol 100 mg/g or less. (3) Conditions for manufacturing: When analyzing phytosterol, all of Beta-sitosterol, brassicasterol, stigmasterol and campesterol shall be detected.							
	Plant sterols/stanols	**SG**					Claim: Plant sterols/stanols have been shown to lower/reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease	Criteria: 1. Phytosterols, phytosterol esters, phytostanols or phytostanol esters may only be added to — (i) any edible vegetable fat or oil containing not more than 20 g of	A Guide to Food Labelling and Advertisement. A publication of the Singapore Food Agency (SFA).2019.	https://www.sfa.gov.sg/docs/default-source/tools-and-resources/resources-for-

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
								saturated fat per 100 g of total fat; (ii) any margarine or fat spread containing not more than 27 g of saturated fat per 100 g of total fat; or (iii) any other food containing not more than 3 g of total fat per 100 g or 1.5 g of total fat per 100 ml. 2. The following mandatory information must be declared on the product label: (i) The product is a special purpose food intended for people who want to lower their blood cholesterol level; (ii) The product may not be nutritionally appropriate for pregnant and breast-feeding women and children under the age of 5 years; (iii) The product should be used as part of a balanced and varied diet; (iv) Consumption in a day of a total of more than 3g of phytosterols and/or phytostanols does not provide any additional		businesses/aguidetofoodlabellinganadvertisements.pdf

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
								benefit in lowering blood cholesterol levels; (v) Consumption in a day of a total of at least 2g of phytosterols and/or phytostanols has been shown to lower blood cholesterol levels; and (vi) A statement suggesting the amount of the food (in g or ml) to be consumed each time (referred to as a serving), and a statement of the total amount of phytosterols and phytostanols that each serving contains.		
	Plant sterol or plant stanol	MYS				Plant sterol or plant stanol helps lower or reduce cholesterol		Minimum amount required: - 1.3 g per 100 (solids) - 160 mg per 100 ml (liquids) i. Addition and claim for plant sterol/plant stanol only permitted in milk, milk product, soya bean milk and soya bean drink (Reg. 82, 83, 357 & 358 respectively). ii. Types of plant sterol or plant stanol permitted: "plant sterol/plant stanol,	Malaysian Dietary Guidelines Key Message 14 Make effective use of nutrition information on food labels	https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications				phytosterols/phytostanol, sitosterol, campesterol, stigmasterol or other related plant stanol". iii. Maximum amount in daily serving for product added with plant sterol/plant stanol is not more than 3 g plant sterol/plant stanol per day. iv. Declaration of the total amount of plant sterol/plant stanol contained in the products shall be expressed in metric units per 100 g or per 100 ml or per package if the package contains only a single portion and per serving as quantified on the label. v. Only the terms "plant sterols" or "plant stanols" shall be used in declaring the presence of such components. vi. There shall be written on the		

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
								label of food making such claim a statement: a. "Not recommended for pregnant and lactating women and children under the age of five years". b. "Persons on cholesterol- lowering medication shall seek medical advice before consuming this product". c. That the product is consumed as part of a balanced and varied diet and shall include regular consumption of fruits and vegetables to help maintain the carotenoid level. d. "With added plant sterols" or "With added plant stanols" in not less than 10 point lettering.		
15	*Monascus purpureous* (red yeast rice)	EU	The food that is the subject of the health claim is red yeast rice (i.e. rice fermented with the red yeast Monascus purpureus). Red yeast rice is a traditional Chinese food product which is still a dietary staple in many Asian countries (Heber *et*		Pure monacolin K (lovastatin) has been shown to be effective in reducing total cholesterol and LDL-cholesterol concentrations in individuals with hypercholesterolaemia and is a well-	Maintenance of normal blood LDL-cholesterol concentrations.	"Monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol concentrations".	In order to obtain the claimed effect, 10 mg of monacolin K from fermented red yeast rice preparations should be consumed daily. The target	EFSA journal number: 2011;9(7):2304	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.20

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
			al., 1999). Various red yeast rice preparations are available as food supplements. The preparations from red yeast rice typically contain starch, protein, fat (including monounsaturated fatty acids, plant sterols), isoflavones, and other compounds. Depending on the Monascus strains used and the fermentation conditions, the products may contain polyketides called monacolins, which are secondary metabolites produced during fermentation (Liu *et al*., 2006). Monacolin K, in lactone (also known as lovastatin or mevinolin) and hydroxy acid forms, is the main monacolin in Monascus purpureus-fermented rice (75-90 % of total monacolin content) (Heber *et al*., 1999; Li *et al*., 2004). Commercial red yeast rice products have variable contents of monacolin K and total monacolins (Gordon *et al*., 2010; Li *et al*., 2004). From the conditions of use provided, the Panel notes that monacolin K from Monascus purpureus-fermented rice has been specified as the food constituent which may be responsible for the claimed effect considered in this opinion. Monacolin K from Monascus purpureus-fermented rice is a well defined compound, which can be measured in foods by established methods		known inhibitor of HMG-CoA reductase. A significant inhibitory effect of a fermented red yeast rice preparation (Cholestin) on HMG-CoA reductase activity and cholesterol concentrations was observed in vitro in human hepatic cells (HepG2) (Man *et al*., 2002). In weighing the evidence, the Panel took into account that two RCTs provided from which conclusions could be drawn for the scientific substantiation of the claim showed an effect of red yeast rice preparations providing a daily dose of about 10 mg monacolin K on LDL-cholesterol concentrations in individuals with hypercholesterolaemia, that the effect of pure monacolin K on LDL-cholesterol concentrations is well established and that the mechanism by which monacolin K can contribute to the claimed effect is well known. The Panel concludes that a cause and effect relationship has been established between the consumption of monacolin K from red yeast rice and maintenance of normal blood LDL-cholesterol concentrations.			population is adults in the general population.		11.2304

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
	Red yeast rice	**KR**	(1) Raw material: Rice and red yeast (*Monascus anka. Monascus purpures, Monascus pilosus*, and *Monascus ruber*) (2) Preparation and/or processing: It shall be in edible form by pulverizing after solid-state fermentation by inoculating rice (except for steamed rice) with red yeast. (3) Content of functional compounds (or marker compounds): Total monacolin K shall be contained 0.5 mg/g or more, and active form of monacolin K shall be confirmed.	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) Total monacolin K (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of labeled amount (3) Active form of monacolin K: It shall be confimed		(1) Health claims: May help to maintain healthy blood cholesterol level		(2) Daily intake amount: 4 ~ 8 mg as total monacolin K	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety.	https://www.mfds.go.kr/eng/brd/m_15/view.do?seq=70011
16	**Resistant starch**	**EU**	The food constituent that is the subject of the health claim is resistant starch-type 2 from high amylose maize. Resistant starch (RS) is defined as starch that escapes digestion and absorption in the small intestine of healthy subjects, and can be classified into four types: RS1 is		In weighing the evidence, the Panel took into account that most of the studies provided reported a significant decrease in post-prandial glycaemic responses, without significantly increasing insulinaemic responses, following	Reduction of post-prandial glycaemic responses	"Replacing digestible starch with resistant starch induces a lower blood glucose rise after a meal".	The Panel considers that in order to bear the claim, high carbohydrate baked foods should contain at least 14 % of total starch as resistant starch, in replacement to digestible starch.	EFSA journal number: 2011;9(4):2024	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2024

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
			physically inaccessible to digestion, RS2 describes native starch granules that are protected from digestion by the conformation or structure of the granule, RS3 refers to non-granular starch-derived materials which are generally formed during retrogradation of starch granules in food processing, and RS4 are starches not found in nature which have been chemically modified to decrease their digestibility (Nugent, 2005). RS from high amylose maize (amylose content between 50 % and 90 %) is categorised as RS2, and is produced from a traditionally bred hybrid of high amylose maize that contains a mixture of digestible and resistant starch. The starch granules in high amylose maize are very stable, and tend not to gelatinise when subjected to the processing conditions used in the manufacture of many common foods. Methods are available to measure these starch fractions in the laboratory (McCleary and Monaghan, 2002).		consumption of RS2 as a partial replacement of digestible starch in baked foods, and that the effect is generally not observed when the amount of available carbohydrates is maintained constant in the test and control products. This suggests that the replacement of digestible starch in carbohydrate-containing foods with RS2 from high amylose maize would decrease post-prandial glycaemic and insulinaemic responses due to the replacement of digestible carbohydrates by indigestible carbohydrates, so that the amount of available glucose contributing to glycaemia is reduced, whereas the addition of RS2 to carbohydrate-containing foods does not appear to modify the post-prandial glucose responses to digestible starch (i.e. when the amount of glycaemic carbohydrates is kept constant). The Panel notes that the effect of replacing digestible starch in foods with resistant starch on post-prandial glycaemic responses could be expected from all types of resistant starch, and that this effect is not specific to RS2 from high amylose maize.			The target population is individuals wishing to reduce their post-prandial glycaemic responses.		

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
					The Panel concludes that a cause and effect relationship has been established between the consumption of resistant starch from all sources, when replacing digestible starch in baked foods, and a reduction of post-prandial glycaemic responses.					
	High Amylose Maize Resistant Starch	**MYS**				High Amylose Maize Resistant Starch (HAMRS) helps improve/promote colonic/bowel/intestinal function/environment		Minimum amount: 2.5 g per serving	Malaysian Dietary Guidelines Key Message 14 Make effective use of nutrition information on food labels	https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf
17	**Soy protein**	**Ca**	The foods that are the subject of the proposed health claim are foods or food ingredients that contain proteins derived from the soybean (Glycine max (L.) Merr., Fabaceae). Foods and ingredients eligible for the claim include soy beverages, tofu, miso, tempeh, natto, soy cheese, soy nuts, isolated soy protein (ISP), soy protein concentrate (SPC), textured soy protein (TSP) and soy flour (SF). Soy sauce and soybean oil are excluded from the claim because they lack substantial amounts of soy protein.		The evidence consistently supports a direction of effect towards a reduction in total and LDL cholesterol levels when soy protein is consumed. A meta-analysis showed a statistically significant reduction in total and LDL cholesterol levels with soy protein consumption and no detrimental effect on HDL cholesterol and triglyceride levels. Health Canada's Food Directorate has concluded that scientific evidence exists to support a claim about soy protein and blood cholesterol lowering. The claim is relevant and generally applicable to the Canadian population on the basis that	Soy Protein and Cholesterol Lowering	Primary statement3: [Serving size from Nutrition Facts table in metric and common household measures] of (brand name) [name of food] supplies/provides X% of the daily amount of soy protein shown to help reduce/lower cholesterol. Additional statements: The following additional statements could be placed adjacent to the primary statement,	The food: a) contains at least 6 g of soy protein i. per reference amount and per serving of stated size, or ii. per serving of stated size, if the food is a prepackaged meal, a nutritional supplement or a meal replacement; b) contains at least 10% of the weighted recommended nutrient intake (WRNI) of a vitamin or mineral nutrient i. per reference amount and per serving of stated size, or ii. per serving of stated size, if the food is a prepackaged meal, a nutritional supplement	Summary of Health Canada's Assessment of a Health Claim about Soy Protein and Cholesterol Lowering (2015)	https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/label-etiquet/claims-reclam/assess-evalu/Sum-Assessment-

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
					39% of Canadians aged 6 to 79 years had unhealthy levels of total cholesterol (>5.2 mmol/L for adults) during the time period of 2009-20111		in letters up to twice the size and prominence of those in the primary statement: -Soy protein helps reduce/lower cholesterol - High cholesterol is a risk factor for heart disease - Soy protein helps reduce/lower cholesterol, (which is) a risk factor for heart disease	or a meal replacement; c) contains 100 mg or less of cholesterol per 100 g of food; d) contains 0.5% or less alcohol; e) contains i. less than 15% of the Daily Value (DV) of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less, or ii. less than 15% of the Daily Value (DV) of sodium per serving of stated size, if the food is a nutritional supplement or a meal replacement, or iii. less than 25% of the Daily Value (DV) of sodium per serving of stated size, if the food is a prepackaged meal; f) meets the conditions for “free of saturated fatty acids” or “low in saturated fatty acids” (Items 18 and 19, respectively, in the table following section B.01.513 of the Food and Drug Regulations); g) meets the requirements for fortified plant-based beverages if it is a soy beverage5.		Soy-April-2015-eng.pdf

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
	Soybean protein	KR	(1) Raw materials: Soybean (*Glycine max* L.N) (2) Preparation and'or processing (a) It shall be in edible form by separating and purifying after removing lipid from the raw materials. (b) It shall be in edible form by separating and purifying with pulverizing after soaking the raw material. (3) Content of functional compounds (or marker compounds): Crude protein shall be contained 400 mg/g or more based on dried materials and daidzein and genistein shall be confirmed.	(1) Appearance: Unique color and flavor, no off-taste and no off-flavor (2) Crude protein (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of labeled amount (3) Daidzein: It shall be confirmed.		(1) Health claims: May help to maintain healthy blood cholesterol level		(1) Daily intake amount: 15 g or more as soybean protein (2) Waming notice for intake: The individual who has an allergy to soybean protein should be cautious to intake	Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety	https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1
	Soya protein	MYS				Soya protein helps to reduce cholesterol		Minimum amount required: 5 g per serving Other conditions:	Malaysian Dietary Guidelines Key Message 14	https://www.moh.gov.my/moh/imag

No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of the food/constituent		2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			1.1 Standards for manufacturing	1.2 Specifications						
								To include the statement: "Amount recommended to give the lowering effect on the blood cholesterol is 25 g per day".	Make effective use of nutrition information on food labels	es/gallery/Garispanduan/diet/km14.pdf

สรุปข้อมูลสารสำคัญ/ส่วนประกอบเชิงหน้าที่ในรูปแบบโมโนกราฟ

คณะทำงานได้สรุปข้อมูลสารสำคัญ/ส่วนประกอบเชิงหน้าที่ในรูปแบบโมโนกราฟ โดยจัดทำเป็นเอกสาร 17 รายการ ดังนี้

รายการ **หน้า**

Alpha-linolenic acid (ALA)

1. Characterisation of the food/constituent

Alpha-linolenic acid (ALA), an essential n-3 polyunsaturated fatty acid with 18 carbon atoms and three double bonds. ALA is a well recognised nutrient, is well absorbed when consumed in the form of triglycerides and is measurable in foods by well established methods. (EU)

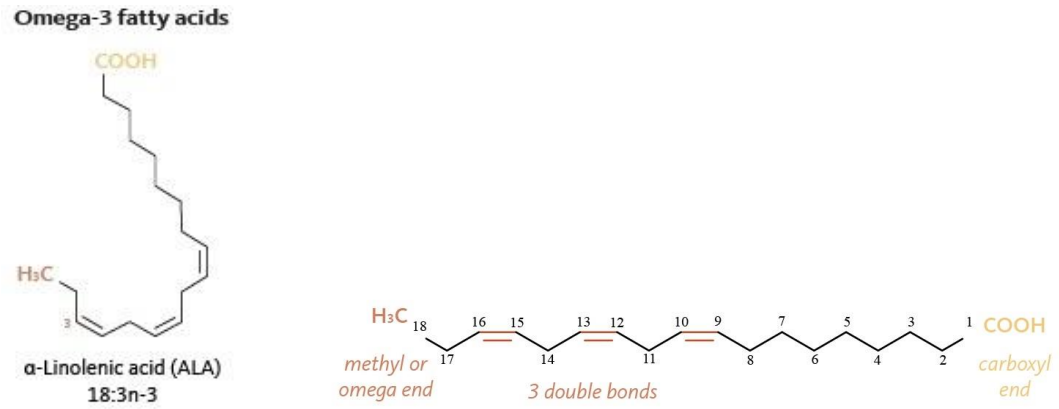

Figure 1. (a) The chemical structure of Alpha-linolenic acid (ALA)
(b) The molecular structure of Alpha-linolenic acid (ALA)

2. Cause and Effect

Maintenance of normal blood cholesterol concentrations (ID 493)

Clinical trials comparing the effects of different vegetable oils on serum lipids in normolipidaemic subjects have shown that the effect of alpha-linolenic acid (ALA) on serum cholesterol is similar to that of linoleic acid (LA) (Mantzioris *et al*., 1994; Valsta *et al*., 1995; Pand *et al*., 1998). In a meta- analysis of 60 randomised controlled clinical trials, the replacement of 1% of energy from carbohydrates by polyunsaturated fatty acids (PUFA), mainly as LA, reduced serum LDL cholesterol levels by 0.02 mmol/l (Mensink *et al*., 2003). The estimated change in the total to HDL cholesterol ratio was -0.032. Although LA was the

main source of PUFA in the studies above, smaller amounts of ALA were also used in some of the studies. Moreover, as indicated in the studies by Mantzioris *et al*. (1994), Valsta *et al*. (1995) and Pand *et al*. (1998), the effects of LA and ALA on serum lipoproteins are similar and the n-6/n-3 ratio of dietary PUFA does not affect the serum lipid profile (Goyens and Mensink, 2005).

The Panel considers that a cause and effect relationship has been established between the dietary intake of ALA and the reduction of blood cholesterol concentrations.

3. Claimed effect to human health

The claimed effect is "contributes to healthy blood cholesterol level/helps to maintain normal cholesterol level/maintenance of normal blood cholesterol level". Maintenance of normal blood cholesterol concentrations is beneficial to human health. (EU)

4. Claim statement

"Alpha-linolenic acid contributes to maintenance of normal blood cholesterol concentrations". (EU)

5. Conditions and possible restrictions of use

A food should contain at least 15% of the proposed labelling reference intake value of 2 g ALA per day. Such an amount can be easily consumed as part of a balanced diet.

The target population is the general population. (EU)

6. References

1. EFSA journal number: 2009; 7(9):1252. (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.1252)
2. EFSA Journal number: 2011;9(6):2203. (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2203).
3. Essential Fatty Acids. Oregon state University. (https://lpi.oregonstate.edu/mic/other-nutrients/essential-fatty-acids)

Beta-Glucans

1. Characterisation of the food/constituent

EU:

Beta-glucans, which are soluble cereal fibres. Beta-glucans are non-starch polysaccharides composed of glucose molecules in long linear glucose polymers with mixed β-(1⟶4) and β-(1⟶3) links with an approximate distribution of 70% to 30%. The molecular weight varies between 50 and 2000 kDa. Beta-glucans occur naturally in the bran of cereal grasses such as barley (~7 %), oats (~5 %), rye and wheat (1-2 %) and are measurable in foods by established methods. This opinion applies to beta-glucans naturally present in foods and those forms added to foods.

The mixed linkages are important for the physical properties, such as solubility and viscosity. The viscosity is a function of the concentration of dissolved beta-glucans and of its molecular weight (Wood *et al*, 2000) and further depends on differences in raw materials, processing and methods of determination.

Canada:

Barley grain products include dehulled or hulless barley, pearl barley, barley flakes, grits, meal, flour, bran as well as beta-glucan enriched milling fractions derived from sieving or air classifying ground material or flour fractions, but they exclude extracted barley beta-glucan.

Health Canada has determined that the eligible sources of beta-glucan oat fibre are: oat bran, rolled oats (also known as oatmeal), and whole oat flour, either as food themselves (oat bran and rolled oats) or as ingredients (oat bran, rolled oats and whole oat flour) in formulated foods. The specifications for the eligible sources of oat beta- glucan are as follows:

• Oat bran: oat bran is produced by grinding clean oat groats or rolled oats and separating the resulting oat flour by suitable means into fractions such that the oat bran fraction is not more than 50 percent of the original starting material and provides at least 5.5 percent (dry

weight basis (dwb)) beta-glucan soluble fibre and at least 16 percent (dwb) total dietary fibre, and such that at least one-third of the total dietary fibre is soluble fibre.

• Rolled oats: rolled oats, also known as oatmeal, are produced from 100 percent dehulled, clean oat groats, by steaming, cutting, rolling, and flaking, and provide at least 4 percent (dwb) of beta-glucan soluble fibre, and at least 10 percent (dwb) total dietary fibre.

• Whole oat flour: whole oat flour is produced from 100 percent dehulled, clean oat groats, by steaming and grinding, such that there is no significant loss of oat bran in the final product, and provides at least 4 percent (dwb) of beta-glucan soluble fibre and at least 10 percent (dwb) total dietary fibre. The AOAC method 992.28 is applicable to measure 1–12% β-glucans in oat and barley fractions, unsweetened oat cereals, and ready-to-eat cereals.

AUS-NZ:

Diet low in saturated fatty acids / Diet containing 3 g of beta-glucan per day.

Korea:

	Ganoderma lucidum fruit body extracts	*Phellinus linteus* extracts
1.1) Standards for manufacturing	(1) Raw material: Ganoderma lucidum (*Ganoderma lucidum* or *Ganoderma tsugae*) fruit body (2) Preparation and/or processing: It shall be in edible form by filtering and concentrating after extracting the raw materials with hot water. (3) Content of functional compounds (or marker	(1) Raw materials: *Phellinus linteus* (3 ~ 4 years old dry) (2) Preparation and/or processing: It shall be in edible form by pulverizing the raw material under 3mm size, extracting (110℃, 96 ~ 100 hours) with water (10 times more amount than materials), high-press filtering, drying (75 ~ 80℃, heat dry), pulverizing. (3) Content of functional compounds (or marker compounds): β-glucan shall be contained 87 mg/g or more. (4) Conditions for manufacturing: Raw material shall be in confirmed as

	Ganoderma lucidum fruit body extracts	*Phellinus linteus* extracts
	compounds): β-Glucan shall be contained 10 mg/g or more.	*Phellinus linteus* by ITS-5.8S rDNA sequence analysis, shall be inoculation with nutrient culture medium which protected from microbial contamination and cultivated for 3~4 years, *Phellinus linteus* shall be obtained in the form of dark brown fruit body which has been identified the spore formation.
1.2) Specifications	(1) Appearance: Unique color and flavor, no off-taste and off-flavor (2) β-Glucan (The β-glucan originated from other ingredients shall be labeled separately.) (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of the labeled amount (3) Coliform: Negative	(1) Appearance: Unique color and flavor, no off-taste and no off-flavor (2) β-glucan (a) Semi-processed product: No less than labeled amount (b) Final product: 80 ~ 120% of labeled amount (3) Heavy metal (a) Lead (mg/kg): No more than 1.0 (b) Cadmium (mg/kg): No more than 0.4 (c) Mercury (mg/kg): No more than 0.3 (d) Arsenic (mg/kg): No more than 1.0 (4) Coliform: Negative
1.3) Testing methods	(1) Appearance: Chapter 4. 2-7 Appearance testing method (2) β-Glucan: Chapter 4. 3-25 β-glucan (3) Coliform: Referred to [Annexed the Table 4]	(1) Appearance: Chapter 4. 2-7 Appearance testing method (2) β-glucan: Chapter 4. 3-25 β-glucan (3) Lead, Cadmium, Mercury, Arsenic: Referred to [Annexed the Table 4] (4) Coliform: Referred to [Annexed the Table 4]

2. Cause and Effect

EU:

- **Maintenance of normal blood cholesterol concentrations (ID 754, 755, 757, 801, 1465, 2934)**

In weighing the evidence, the Panel took into account that, although some human intervention studies using high doses of beta-glucans (about 10g/d) in food matrices like juices or baked products have not observed a statistically significant reduction in LDL-cholesterol concentrations, most of the randomised controlled trials investigating the effects of non-processed or minimally processed oat or barley beta-glucans at doses of at least 3g/d have shown a statistically significant decrease in LDL-cholesterol in both normocholesterolaemic and hypercholesterolaemic subjects. The Panel also considers that beta-glucans from oat bran and barley bran have similar effects on serum LDL-cholesterol.

The Panel concludes that a cause and effect relationship has been established between the consumption of beta-glucans and the reduction of blood cholesterol concentrations.

- **Reduction of post-prandial glycaemic responses (ID 821, 824)**

The mechanism by which beta-glucans from oats or barley could exert the claimed effect is well established, and relates to the increased viscosity of the meal bolus when beta-glucans are added. When the meal bolus reaches the small intestine, a high viscosity delays the rate of absorption of nutrients, including glucose (Battilana *et al*., 2001; Wood *et al*., 2000; Wursch and Pi-Sunyer, 1997).

In weighing the evidence, the Panel took into account that intervention studies in healthy subjects consistently show an effect of oat and barley beta-glucans in decreasing post-prandial glycaemic responses, without disproportionally increasing post-prandial insulinaemic responses, at doses of about 4 g per 30 g of available carbohydrates in bread and pasta products when consumed alone or in the context of a meal, and that the mechanism by which beta-glucans could exert the claimed effect is well established.

The Panel concludes that a cause and effect relationship has been established between the consumption of beta-glucans from oats and barley and a reduction of post-prandial glycaemic responses.

Canada:

- **Barley Products and Blood Cholesterol Lowering**

A daily intake of a minimum of 3 g of beta-glucan from barley grain products resulted in a physiologically relevant LDL cholesterol lowering comparable to the LDL cholesterol lowering effect of oat beta-glucan. The magnitude of the cholesterol-lowering effect in the relevant studies was variable. When only the higher-quality studies using barley grain products (no extracts) were taken into account [Anonymous, 2005; Behall, 2004a; Behall 2004b; Rondanelli, 2011; Shimizu, 2008; Sundberg, 2008], the reduction in total cholesterol levels ranged from -0.06 to -0.50 mmol/L (-1.1% to -7.5%) while the reduction in LDL-cholesterol levels ranged from 0 to -0.32 mmol/L (0% to -8.5%). In addition, subgroup analyses in a meta-analysis conducted by the petitioner showed that consumption of beta-glucan from barley grain products lowered total cholesterol by 0.29 mmol/L and LDL cholesterol by 0.26 mmol/L compared to control.

- **Oat Products and Blood Cholesterol Lowering**

Based on information provided in the petition to the US FDA (1995), regression analyses of a dose-response study suggested that about 3 grams of beta-glucan oat fibre would result in total and LDL-cholesterol reductions of about 5% and 8%, respectively. Overall, in the PFSNRA literature review (2006), an intake of 3 grams of beta-glucan resulted in a physiologically meaningful LDL-cholesterol reduction that was nevertheless quite variable (ranging from 0.15% to 4% LDL-cholesterol reduction on a per gram of beta-glucan basis). No dose-response was observed. Most of the studies were carried out with moderately to highly hypercholesterolemic subjects. The PFSNRA review did not provide any evidence contrary to the previous findings upon which FDA based its final health claim rule on beta-glucan oat fibre and reduced risk of coronary heart disease (by lowering blood cholesterol).

Health Canada has concluded that scientific evidence exists in support of the claim linking the consumption of beta-glucan oat fibre to a reduction of blood cholesterol. The claim is

relevant and generally applicable to the Canadian population given that a high proportion of the population (44 to 69%) is hyperlipidemic and that adults with normal or mildly elevated blood cholesterol concentrations could also benefit from increased oat intake.

3. Claimed effect to human health

EU:

- The claimed effect is “blood lipids”. Maintenance of normal blood cholesterol concentrations is beneficial to human health.
- The claimed effect is “carbohydrate metabolism and insulin sensitivity”.

Canada:

- Barley Products and Blood Cholesterol Lowering.
- Oat Products and Blood Cholesterol Lowering.

AUS-NZ:

- Reduces dietary biliary cholesterol absorption.

Korea:

- May help to maintain healthy blood flow. (β-Glucan from Ganoderma lucidum fruit body extracts)
- May help to support immune function. (β-Glucan from *Phellinus linteus* extracts)

Malaysia:

- Oat soluble fibre (beta-glucan) helps lower or reduce cholesterol.
- Oat soluble fibre (beta-glucan) helps to lower the rise of blood glucose provided it is not consumed together with other food.

4. Claim statement

EU:

- “Regular consumption of beta-glucans contributes to maintenance of normal blood cholesterol concentrations”

- "Consumption of beta-glucans from oats or barley contributes to the reduction of the glucose rise after a meal".

Canada:

"[serving size from Nutrition Facts table in metric and common household measures] of (Brand name) [name of food] [with name of eligible fibre source]* supplies/provides X% of the daily amount of the fibre shown to help reduce/lower cholesterol."

The following additional statements could be placed, adjacent to the primary statement, in letters up to twice the size and prominence as those of the primary statement:

• "Barley fibre helps reduce/lower cholesterol"

• "High cholesterol is a risk factor for heart disease"

• "Barley fibre helps reduce/lower cholesterol, (which is) a risk factor for heart disease"

"[serving size from Nutrition Facts table in metric and common household measures] of (Brand name) [name of food] [with name of eligible fibre source]* supplies/provides [X % of the daily amount] of the fibres shown to help reduce/lower cholesterol."

The following additional statements, which can be placed, adjacent to the primary statement, in letters up to twice the size and prominence as those of the primary statement:

1) Oat fibre helps reduce/lower cholesterol

2) High cholesterol is a risk factor for heart disease

3) Oat fibre helps reduce/lower cholesterol, (which is) a risk factor for heart disease.

Singapore:

- Claim: Barley beta-glucans / Oat beta-glucans have been shown to lower/reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease.

5. Conditions and possible restrictions of use

EU:

- **Maintenance of normal blood cholesterol concentrations is beneficial to human health.**

In order to bear the claim, foods should provide at least 3 g/d of beta-glucans from oats, oat bran, barley, barley bran, or from mixtures of non-processed or minimally processed beta-glucans in one or more servings. The target population is adults with normal or mildly elevated blood cholesterol concentrations.

- **Carbohydrate metabolism and insulin sensitivity.**

In order to obtain the claimed effect, 4 g of beta-glucans from oats or barley for each 30 g of available carbohydrates should be consumed per meal. The target population is individuals who wish to reduce their post-prandial glycaemic responses.

Canada:

- **Barley Products and Blood Cholesterol Lowering**

The “daily amount” referred to in the primary statement is 3 grams of barley beta-glucan. In this statement, the percentage of the daily amount of barley beta-glucan provided in one serving should be expressed to the nearest multiple of 5%.

Conditions for Foods to Carry the Claim:

The following qualifying criteria apply to all food products carrying the above-mentioned health claim. a) The food contains at least 1g of beta-glucan from barley grain products† per reference amount and per serving of stated size; b) The food contains at least 10% weighted recommended nutrient intake (WRNI) of a vitamin or mineral nutrient i. per reference amount and per serving of stated size, or ii. per serving of stated size, if the food is a prepackaged meal; c) The food contains 100 mg or less of cholesterol per 100 g of food; d) The food contains 0.5% or less alcohol; e) The food contains i. 480 mg or less of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 ml or less, or ii. 960 mg or less of sodium per serving of stated size, if the food is a prepackaged meal; f) The food meets the conditions for “low in saturated fatty acids” or “free of saturated fatty acids”. † Barley grain products include dehulled or hulless barley,

pearl barley, barley flakes, grits, meal, flour, bran as well as beta-glucan enriched milling fractions derived from sieving or air classifying ground material or flour fractions, but they exclude extracted barley beta-glucan.

- **Oat Products and Blood Cholesterol Lowering**

The “daily amount” referred to in the primary statement is 3 grams beta-glucan oat fibre. In this statement, the percentage of the daily amount of beta-glucan oat fibre provided in one serving should be expressed to the nearest multiple of 5%. Conditions for foods to carry the claim Oat products, whether consumed as food or as ingredients, must meet the specifications for eligible sources of oat beta-glucan described in section 1 of this document. Where the food carrying the claim is a formulated food to which oat products are added as ingredients, the formulated food must not be subject to non-typical or novel treatments. Formulated food products containing the eligible oat products, but processed by non-typical or novel treatments, may require individual authorization in order to carry the claim.

In addition, the food must meet the following qualifying criteria:

1. Contain at least 0.75 g beta-glucan oat fibre per reference amount and per serving of stated size from the eligible sources;
2. Contain at least 10% of the weighted recommended nutrient intake of a vitamin or a mineral nutrient per reference amount and per serving of stated size;
3. Contain 100 mg or less of cholesterol per 100 g of food;
4. Contain 0.5% or less of alcohol;
5. Contain 480 mg or less of sodium per reference amount and per serving of stated size, and per 50 g if the reference is 30 g or less; and
6. Meet the definition of “free of saturated fatty acids” or “low in saturated fatty acids”.

<u>AUS-NZ:</u>

The food must contain:

(a) one or more of the following oat or barley foods
(i) oat bran; or (ii) wholegrain oats; or (iii) wholegrain barley; and

(b) at least 1 g per serving of beta-glucan from the foods listed in (a).

Korea:

- (Ganoderma lucidum fruit body extracts) Daily intake amount: 24 ~ 42 mg as B-glucan
- (*Phellinus linteus* extracts) Daily intake amount: 3.3 g as *Phellinus linteus* extracts (287.1 ~ 534.6 mg as B-glucan)

Singapore:

Criteria: The cholesterol, saturated fatty acids and trans fatty acids present in the food must be within the following levels:

(i) in the case of solid food —

a. not more than 20 mg of cholesterol per 100 g;

b. not more than 1.5 g of saturated fatty acids and

c. trans fatty acids per 100 g; and

d. not more than 10% of kilocalories from

e. saturated fatty acids and trans fatty acids; or

(ii) in the case of liquid food —

a. not more than 10 mg of cholesterol per 100 ml;

b. not more than 0.75 g of saturated fatty acids and

c. trans fatty acids per 100 ml; and

d. not more than 10% of kilocalories from

e. saturated fatty acids and trans fatty acids.

The following mandatory information must be declared on the product label:

(i) a statement or statements to the like effect that consumption of at least 3 g of barley beta-glucans or oat beta-glucans (as the case may be) in a day has been shown to lower blood cholesterol levels; and

(ii) the amounts of barley beta-glucan or oat beta-glucans (as the case may be), cholesterol, saturated fatty acids and trans fatty acids, present in the food under the nutrition information panel.

"Criteria":

1. The cholesterol, saturated fatty acids and trans fatty acids present in the food must be within the following levels:

(i) in the case of solid food —

a. not more than 20 mg of cholesterol per 100 g;

b. not more than 1.5 g of saturated fatty acids and

c. trans fatty acids per 100 g; and

d. not more than 10% of kilocalories from

e. saturated fatty acids and trans fatty acids; or

(ii) in the case of liquid food —

a. not more than 10 mg of cholesterol per 100 ml;

b. not more than 0.75 g of saturated fatty acids and

c. trans fatty acids per 100 ml; and

d. not more than 10% of kilocalories from

e. saturated fatty acids and trans fatty acids.

2. The following mandatory information must be declared on the product label:

(i) a statement or statements to the like effect that consumption of at least 3 g of barley beta-glucans or oat beta-glucans (as the case may be) in a day has been shown to lower blood cholesterol levels; and

(ii) the amounts of barley beta-glucan or oat beta-glucans (as the case may be), cholesterol, saturated fatty acids and trans fatty acids, present in the food under the nutrition information panel.

Malaysia:

- (β -glucan) Oat soluble fibre in relation to cholesterol claim. Minimum amount: 2 g per 100 g (solids)
  Other conditions: Must also contains total dietary fibre not less than amount required to claim as "source":
  - 3 g per 100 g (solids)
  - 1.5 g per 100 ml (liquids)"
- (β -glucan) Oat soluble fibre in relation to blood glucose claim
  Other conditions:
  i. Addition and claim for oat soluble fibre (B-glucan) only permitted incereal and cereal based product.
  ii. Claim only permitted for product where the macronutrient profile (carbohydrate, protein and fat) complies with Recommended Nutrient Intake (RNI) Malaysia.

iii. There shall be written on the label of food making such claim statement "For advice regarding consuming this consult product, your medical professional"

6. References

1. EFSA Journal number: 2009; 7(9):1254. (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.1254)

2. EFSA Journal number: 2011;9(6):2207. https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2207).

3. Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety. (https://www.mfds.go.kr/eng/brd/m_15/view.do?seq=70011).

4. Summary of Health Canada's Assessment of a Health Claim about Barley Products and Blood Cholesterol Lowering (2012) (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/label-etiquet/claims-reclam/assess-evalu/barley-orge-eng.pdf)

5. Oat Products and Blood Cholesterol Lowering Summary of Assessment of a Health Claim about Oat Products and Blood Cholesterol Lowering (2010) (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/label-etiquet/claims-reclam/assess-evalu/oat_avoine- eng.pdf)

6. Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claims (F2017C00711) Authorised Version F2017C00711 registered 08/09/2017 (https://irp.cdn-website.com/69f086d6/files/uploaded/FSANZ%20Food%20Standards%20Schedule%204.pdf)

7. Singapore. A Guide to Food Labelling and Advertisements. (https://www.sfa.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/aguidetofoodlabellingandadvertisements.pdf)

8. Malaysian Dietary Guidelines Key Message 14 Make effective use of nutrition information on food labels (https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf)

Chitosan

1. Characterisation of the food/constituent

Chitosan is a linear cationic polysaccharide composed of randomly distributed -(1-4)-linked D-glucosamine and N-acetyl-D-glucosamine produced commercially by the deacetylation of chitin, which is a component of the exoskeleton of crustaceans and the cell walls of fungi. The degree of deacetylation can be measured by established methods, and ranges from 60-100 % in commercial preparations. The molecular weight of chitosan in commercial preparations ranges from 3,800 to 20,000 Da. Chitosan is insoluble in water. (EU)

1.1) Standards for manufacturing (KR)

(1) Raw material: A shell of crustacean (crab, shrimp, etc.), Mollusk (squid, cuttlefish, etc.) bone

(2) Preparation and/or processing

a. Chitosan: It shall be in edible form by diacetylating chitin (β-1,4 bound polymer of N-acetylglucosamine) obtained by deproteinizing and decalcifying the raw materials.

b. Chitooligosaccharide: It shall be in edible form by hydrolyzing chitosan obtained from preparation and/or processing of (a) with enzyme.

(3) Content of functional compounds (or marker compounds): The degree of deacetylation (glucosamine remaining ratio in sugar chains) of chitosan shall be contained 80% or more. Chitosan (as glucosamine) shall be contained 800 mg/g or more and chitooligosaccharide 200 mg/g or more.

1.2) Specifications (KR)

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Chitosan or Chitooligosaccharide

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120% of labeled amount

(3) Heavy metal

(a) Lead (mg/kg): No more than 3.0

(b) Cadmium (mg/kg): No more than 1.0 (c) Mercury (mg/kg): No more than 1.0

(4) Coliform: Negative

1.3) Testing methods (KR)

(1) Appearance: Chapter 4. 2-7 Appearance testing method

(2) Chitosan: Chapter 4. 3-29 Chitosan (as total glucosamine)

(3) Chitooligosaccharide: Chapter 4. 3-30 Chitooligosaccharide

(4) Lead, Cadmium, Mercury: Referred to [Annexed the Table 4]

(5) Coliform: Referred to [Annexed the Table 4]

2. Cause and Effect

EU:

- **Maintenance of normal blood LDL-cholesterol concentrations (ID 4663)**

The mechanism by which chitosan is presumed to exert the claimed effect is by binding to negatively charged lipids and hence reducing their gastro-intestinal uptake, and these effects were observed in some animal studies (Deuchi *et al*., 1995; Sugano *et al*., 1980; Zacour *et al*., 1992). The effects of chitosan on 24 h faecal fat excretion in healthy human volunteers at doses of about 3 g daily were not statistically significant (Guerciolini *et al*., 2001), and it is unclear whether this could play a role on the claimed effect.

In weighing the evidence, the Panel took into account that a meta-analysis of RCTs, which investigated the effects of chitosan consumption on blood lipids, showed a small but statistically significant reduction in total and LDL-cholesterol concentrations.

The Panel concludes that a cause and effect relationship has been established between the consumption of chitosan and maintenance of normal blood LDL-cholesterol concentrations.

3. Claimed effect to human health

- Maintenance of normal blood cholesterol concentrations. (EU)
- May help to maintain healthy blood cholesterol level, reduce body fat (KR)

4. Claim statement

"Chitosan may contribute to maintaining normal blood cholesterol levels". (EU)

5. Conditions and possible restrictions of use

EU:

In order to obtain the claimed effect, 3 g of chitosan should be consumed daily. The target population is adults.

Korea:

Daily intake amount;

(a) May help to maintain health blood cholesterol level: 1.2 ~ 4.5 g as sum of chitosan and chitooligosaccharide

(b) May help to reduce body fat: 3.0 ~ 4.5 g as chitosan, 3 g as chitooligosaccharide"

Warning notice for intake: The individual who has an allergy to crab and/or shrimp should be cautious to intake (limited to using crab and/or shrimp as raw material)

6. References

1. EFSA journal number: 2011;9(6):2214 (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2214)

2. Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety. (https://www.mfds.go.kr/eng/brd/m_15/view.do?seq=70011).

Conjugated linoleic acid

1. Characterisation of the food/constituent

1.1) Standards for manufacturing (KR)

(1) Raw material: Safflower seed oil

(2) Preparation and/or processing

(a) After saponifying and conjugated isomerizing the raw materials, the fatty acid shall be in edible form by extracting with fermented ethanol or hexane, or purifying, deodorizing and filtering.

(b) Triglyceride form: After glycerifying conjugated linoleic acid in fatty acid form with lipase, it shall be in edible form by extracting with fermented ethanol or hexane, or purifying, deodorizing and filtering.

(3) Content of functional compounds (or marker compounds): Conjugated linoleic acid (the sum of cis-9 and trans-11 conjugated linoleic acid, trans-10 and cis-12 conjugated linoleic acid, and cis-9 and cis-11 conjugated linoleic acid) shall be contained 660 mg/g or more.

1.2) Specifications (KR)

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Content of conjugated linoleic acid (The sum of cis-9/trans-11, trans-10/cis-12, cis-9/cis-11, and trans-9/trans-11 conjugated linoleic acids).

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120% of labeled amount

(3) Contents of cis-9/trans-11 and trans-10/cis-12 conjugated linoleic acids (%): No less than 90% of conjugated linoleic acid content

(4) Contents of trans-9/trans-11 conjugated linoleic acid (%): No more than 3.0 (limited to semi-processed product)

(5) Acid value: No more than 10.0 (limited to semi-processed product of glyceride form)

(6) Lead (mg/kg): No more than 3.0

(7) Cadmium (mg/kg): No more than 1.5

(8) Arsenic (mg/kg): No more than 5.0

(9) Mercury (mg/kg): No more than 0.5

(10) Solvent residue (mg/kg): No more than 5.0 (in case of using hexane)

(11) Coliform: Negative

1.3) Testing methods (KR)

(1) Appearance: Chapter 4. 2-7 Appearance testing method

(2) Content of conjugated linoleic acid: Chapter 4. 3-32 Fatty acid

(3) Content of cis-9/trans-11 and trans-10/cis-12 conjugated linoleic acids (%): Chapter 4. 3-32 Fatty acid

(4) Content of trans-9/trans-11 conjugated linoleic acid (%): Chapter 4. 3-32 Fatty acid

(5) Acid value: Referred to [Annexed the Table 4]

(6) Lead, Cadmium, Mercury, Arsenic: Referred to [Annexed the Table 4]

(7) Solvent residue: Referred to [Annexed the Table 4]

(8) Coliform: Referred to [Annexed the Table 4]

2. Claimed effect to human health (KR)

May help to reduce body fat in the overweight adult.

3. Claim statement

-

4. Conditions and possible restrictions of use (KR)

- Daily intake amount: 1.4 ~ 4.2 g as conjugated linoleic acid
- Warning notice for intake:
  - It may cause gastrointestinal disorder
  - Infant and pregnant women should be avoid intake
  - Diet control and exercises together are effective in reducing body fat

5. References

1. Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety. (https://www.mfds.go.kr/eng/brd/m_15/view.do?seq=70011).

Eicosapentaenoic acid and docosahexaenoic acid (EPA/DHA)

1. Characterisation of the food/constituent

The food constituent which is the subject of the health claims is mixed long-chain n-3 polyunsaturated fatty acids (n-3 LCPUFA), namely docosahexaenoic acid (DHA) in combination with eicosapentaenoic acid (EPA). (EU)

The foods that are the subject of the health claim are foods containing eicosapentaenoic acid (EPA) and/or docosahexaenoic acid (DHA). EPA and DHA are long-chain omega-3 fatty acids with lipid structures of 20:5(n-3) and 22:6(n-3), respectively. (Ca)

Diet containing 500mg of EPA and DHA per day. (AUS-NZ)

1.1) Standards for manufacturing (KR)

(1) Raw material: Edible fishes, seaweeds, Pagophilus groenlandicus.

(2) Preparation and/or processing: The oil shall be in edible form by heating the raw material, pressing and extracting with hexane or carbon dioxide (supercritical fluid extraction) and then filtering or esterification after extraction.

(3) Content of functional compounds (or marker compounds): As the sum of EPA and DHA, it shall be contained 180 mg/g or more from edible fishes, 120 mg/g or more from Pagophilus groenlandicus and 300 mg/g or more from seaweeds.

1.2) Specifications (KR)

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) The sum of EPA and DHA

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120% of labeled amount

(3) Solvent residue (mg/kg): No more than 5.0 (in case of using hexane)
(4) Acid value: no more than 3.0 (semi-processed product and product with antioxidant added to them)
(5) Peroxide value: no more than 5.0 (semi-processed product and product with antioxidant added to them)
(6) Anisidine value: no more than 20.0 (semi-processed product and product with antioxidant added to them)
(7) Total Oxidation value (TOTOX) (2 × peroxide value + anisidine value): no more than 26.0 (semi-processed product and product with antioxidant added to them)
(8) Heavy metal
(a) Lead (mg/kg): No more than 3.0
(b) Cadmium (mg/kg): No more than 1.0 (c) Mercury (mg/kg): No more than 0.5
(9) Coliform: Negative

1.3) Testing methods (KR)
(1) Appearance: Chapter 4. 2-7 Appearance testing method
(2) EPA and DHA: Chapter 4. 3-32 fatty acids
(3) Solvent residue: Referred to [Annexed the Table 4]
(4) Acid value: Referred to [Annexed the Table 4]
(5) Peroxide value: Referred to [Annexed the Table 4]
(6) Anisidine value: Chapter 4. 2-6-1 Anisidine value
(7) Lead, Cadmium, Mercury: Referred to [Annexed the Table 4]
(8) Coliform: Referred to [Annexed the Table 4]

2. Cause and Effect

EU:

- **Maintenance of normal cardiac function (ID 504, 506, 516, 527, 538, 703, 1128, 1317, 1324, 1325)**

EPA and DHA intakes could reduce the risk of coronary heart disease mortality by different (but often overlapping) mechanisms (e.g. through antiarrhythmic and antithrombotic effects, by reducing blood pressure, heart rate and plasma concentrations of triglycerides), and the

doses of EPA and DHA (100->2,500 mg/d) as well as the time required to observe clinical effects and/or alter clinical events (weeks to years) through each mechanism may vary widely (Mozaffarian and Rimm, 2006).

The Panel concludes that a cause and effect relationship has been established between the consumption of EPA and DHA and maintenance of normal cardiac function.

- **Maintenance of normal (fasting) blood concentrations of triglycerides (ID 506, 527, 538, 1317, 1324, 1325)**

A claim on EPA and DHA and the maintenance of normal (fasting) blood concentrations of triglycerides has been already assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009). The Panel considered that intakes of EPA and DHA of about 2-4 g per day were required to obtain the claimed effect.

With reference to its previous opinion, the Panel considers that intakes of EPA and DHA of 2 g per day are required to obtain the claimed effect.

Canada:

- **EPA, DHA and triglyceride lowering**

The evidence consistently supports a highly consistent direction of effect towards a reduction in triglyceride levels when EPA and DHA are consumed. The vast majority (>80%) of the treatment arms from the larger studies (≥30 participants) administering a daily intake of at least 1.5 g of EPA+DHA demonstrated a statistically significant reduction in triglyceride levels.

Health Canada's Food Directorate has concluded that scientific evidence exists to support a claim about EPA+DHA and triglyceride lowering. The claim is relevant and generally applicable to the Canadian adult population on the basis that approximately 25% of Canadian adults aged 20 to 79 had unhealthy triglyceride levels1 (>1.7 mmol/L) from 2007 to 2009.

3. Claimed effect to human health

- Maintenance of normal cardiac function. (EU)

- Maintenance of normal (fasting) blood concentrations of triglycerides. (EU)
- EPA+DHA shown to help reduce triglyceride levels. (Canada)
- Contributes to heart health. (AUS-NZ)
- May help to maintain healthy triglyceride level, maintain healthy blood flow, improve memory, maintain eye health as the improvement of dry eyes. (KR)

4. Claim statement

- "EPA and DHA contribute to the normal function of the heart". (EU)
  [serving size from Nutrition Facts table in metric and common household measures] of (brand name) [name of food] supplies/provides X% of the daily amount of (long-chain) omega-3 (fatty acids) EPA4 and DHA5 shown to help reduce/lower triglycerides.
- Additional statements; (Long-chain) (omega-3) EPA and DHA help reduce/lower triglycerides. (Canada)

5. Conditions and possible restrictions of use

EU:

- **Maintenance of normal cardiac function**

Intakes of EPA and DHA of about 250 mg per day are required to obtain the claimed effect. Such an amount can be consumed as part of a balanced diet. The target population is the general population.

- **Maintenance of normal (fasting) blood concentrations of triglycerides.**

Intakes of EPA and DHA of 2 g per day are required to obtain the claimed effect. Such an amount can be consumed as part of a balanced diet. The target population is adult men and women.

Canada:

The "daily amount" referred to in the primary statement is 1.5 g of EPA+DHA. In this statement, the percentage of the daily amount of EPA+DHA provided in one serving should be rounded to the nearest multiple of 5%.

Conditions for food to carry the claim:

The following qualifying criteria apply to all food products carrying the above-mentioned health claim.

The food:

a) contains at least 0.5 g of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) combined

i. per reference amount and per serving of stated size, or

ii. per serving of stated size, if the food is a prepackaged meal, a nutritional supplement or a meal replacement;

b) contains at least 10% of the weighted recommended nutrient intake (WRNI) of a vitamin or mineral nutrient i. per reference amount and per serving of stated size, or ii. per serving of stated size, if the food is a prepackaged meal, a nutritional supplement or a meal replacement;

c) contains 0.5% or less alcohol;

d) contains i. less than 15% of the Daily value (DV) of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less, or ii. less than 15% of the Daily value (DV) of sodium per serving of stated size, if the food is a nutritional supplement or a meal replacement, or iii. less than 25% of the Daily value (DV) of sodium per serving of stated size, if the food is a prepackaged meal;

e) contains i. less than 15 g of total sugars per reference amount and per serving of stated size, or ii. less than 15 g of total sugars per serving of stated size, if the food is a prepackaged meal, a nutritional supplement or a meal replacement;

f) is not one of the types of fish for which Health Canada recommends limiting consumption, due to their mercury concentrations, that is, fresh and frozen tuna, shark, swordfish, escolar, marlin, orange roughy and canned albacore (white) tuna.

AUS-NZ:

(a) The food must contain a minimum of 50mg EPA and DHA combined in a serving of food; and

(b) other than for fish or fish products with no added saturated fatty acids—the food contains:

(i) as a proportion of the total fatty acid content, no more than 28% *saturated fatty acids and trans fatty acids; or

(ii) no more than 5 g per 100 g saturated fatty acids and trans fatty acids

Korea:

(1) Daily intake amount

(a) May help to maintain healthy triglyceride level, maintain healthy blood flow: 0.5 ~ 2 g as the sum of EPA and DHA

(b) May help to improve memory: 0.9 ~ 2 g as the sum of EPA and DHA

(c) May help to maintain eye health as the improvement of dry eyes: 0.6 ~ 1 g as the sum of EPA and DHA

(2) Warning notice for intake

(a) Consult a health care practitioner prior to intake if you are taking medicines related with blood coagulation and/or anti-platelet and/or antihypertensive agents

(b) It may cause side-effect such as skin reaction

(c) Consult a health care practitioner and stop intake if you are having adverse event

6. References

1. EFSA journal number: 2010;8(10):1796 (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2214)

2. Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety. (https://www.mfds.go.kr/eng/brd/m_15/view.do?seq=70011).

3. Summary of Health Canada's assessment of a health claim about eicosapentaenoic acid, docosahexaenoic acid and triglyceride lowering (2016). (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/label-etiquet/claims-reclam/assess-evalu/eicosapentaenoic-acid-acide-eicosapentaenoique-eng.pdf)

4. Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claims (F2017C00711) Authorised Version F2017C00711 registered 08/09/2017. (https://irp.cdn-website.com/69f086d6/files/uploaded/FSANZ%20Food%20Standards%20Schedule%204.pdf)

Fructo-oligosaccharide

1. Characterisation of the food/constituent

Korea:

1.1 Standard for manufacturing

(1) Raw material and preparation and/or processing

(a) Beta-1,2 oligosaccharides bound sucrose with 1~3 fructose units shall be manufactured-processed with transferase or microorganisms having transferase after making liquid by melting sugar.

(b) It shall be manufactured-processed by hydrolyzing inulin with enzyme.

(2) Content of functional compounds (or marker compounds): Fructooligosaccharide shall be contained 410 mg/g or more. The content of fructo-oligosaccharide shall be calculated by sum of 1-kestose (GF2), nystose (GF3) and fructofuranosylnystose (GF4).

1.2 Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Fructooligosaccharide

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120% of labeled amount

(3) Lead (mgkg): No more than 1.0

1.3 Testing methods

(1) Appearance: Chapter 4. 2-7 Appearance testing method

(2) Fructooligosaccharide: Chapter 4. 3-31 Fructooligosaccharide

(3) Lead: Referred to [Annexed the Table 4]

2. Cause and Effect

-

3. Claimed effect to human health

3.1 Korea:

May help to maintain healthy gastrointestinal bacteria population, maintain healthy bowel function

3.2 Singapore:

Oligofructose stimulates the bifidobacteria, resulting in a significant increase of the beneficial bifidobacteria in the intestinal tract. At the same time, the presence of less desirable bacteria is significantly reduced

3.3 Malaysia:

i. Inulin helps increase intestinal bifidobacteria and helps maintain a good intestinal environment

ii. Oligofructose (fructo-oligosaccharide) helps increase intestinal bifidobacteria and helps maintain a good intestinal environment

iii. Inulin is bifidogenic

iv. Oligofructose (fructo-oligosaccharide) is bifidogenic

v. Inulin is prebiotic

vi. Oligofructose (fructo-oligosaccharide) is prebiotic

4. Claim statement

4.1 Singapore: Oligofructose stimulates the bifidobacteria, resulting in a significant increase of the beneficial bifidobacteria in the intestinal tract. At the same time, the presence of less desirable bacteria is significantly reduced

5. Conditions and possible restrictions of use

5.1 Korea:

(1) Daily intake amount: 3 ~ 8 g as fructooligosaccharide

(2) Warning notice for intake

(a) It may cause gastrointestinal gas, burp, stomachache, abdominal inflation

(b) Consult a health care practitioner and stop intake if you are having adverse event

5.2 Singapore: Food manufacturer/importer to ensure that the amount of inulin present in the product is able to bring about the claimed effect.

5.3 Malaysia:

(1) Inulin: 2 g per serving ; FOS: 1.25 g per serving

This minimum level is for other food except infant formula.

(2) 0.4 g / 100 ml on a ready to drink basis.

This minimum level is specified for infant formula only.

6. References

1. Ministry of Food and Drug Safety. Korea Health Functional Food Code 2021. (https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1)
2. Singapore Food Agency. A Guide to Food Labelling and Advertisements (https://www.sfa.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/aguidetofoodlabellingandadvertisements.pdf)
3. The Ministry of Health Malaysia. Malaysian Dietary Guidelines
   Key Message 14: Make effective use of nutrition information on food labels
   (https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf)

Glucomannan (konjac mannan)

1. Characterisation of the food/constituent

Glucomannan is a water-soluble type of fibre composed of a straight chain of β-1⟶4 D-mannose and D-glucose units in a ratio of 1.6:1 with a small amount of branching (8 %) through β-(1⟶6)-glucosyl linkages. It is derived from the tuberous roots of the Konjac plant (Amorphophallus konjac). Glucomannan is non-digestible in the human small intestine. It has a high molecular weight (200-2000 kDa) and high viscosity in water solution. Glucomannan does not occur naturally in foods, is a food additive used as emulsifier and thickener, and is usually consumed in the form of food supplements. (EU)

1.1) Standards for manufacturing (KR)

(1) Raw material: Arum family konjac (*Amorphophallus konjq*) rhizome

(2) Preparation and/or processing: Polysaccharides shall be in edible form by extracting the raw materials with isopropyl alcohol and purifying.

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 690 mg/g or more.

1.2) Specifications (KR)

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80% of labeled amount

(3) Solvent residue (mg/kg): No more than 50.0

(4) Lead (mg/kg): No more than 2.0

(5) Coliform: Negative

1.3) Testing methods (KR)

(1) Appearance: Chapter 4. 2-7 Appearance testing method

(2) Dietary fiber: Chapter 4. 3-26 Dietary fiber

(3) Solvent residue: Referred to [Annexed the Table 4]

(4) Lead: Referred to [Annexed the Table 4]

(5) Coliform: Referred to [Annexed the Table 4]

2. Cause and Effect

EU:

- **maintenance of normal blood cholesterol concentrations (ID 836, 1560)**

In weighing the evidence, the Panel took into account that a statistically significant effect on either total or LDL-cholesterol was not observed following the consumption of glucomannan in all of these studies, that reduction in total and/or LDL-cholesterol concentrations did not always lead to significant reductions in the total/HDL cholesterol ratio, that the vast majority of these studies had small samples sizes, and that no clear dose-response relationship was established between the consumption of glucomannan and the claimed effect. However, the Panel considers that most studies showed a consistent effect in the reduction of serum total and LDL-cholesterol concentrations at doses of about 4g/d of glucomannan, that the effect has been observed not only in hypercholesterolaemic subjects but also in normocholesterolemic individuals, and that the mechanisms by which the consumption of the food may exert the claimed effect (biological plausibility) are established.

The Panel concludes that a cause and effect relationship has been established between the consumption of glucomannan and the reduction of blood cholesterol concentrations.

- **Reduction of body weight (ID 854, 1556, 3725)**

The Panel notes that no long-term studies (>3 months) on the effects of glucomannan on body weight are available.

The Panel also notes that glucomannan is a soluble-type of fibre which forms a viscous, gel-like mass in the stomach when hydrated, and that this “mass effect” could delay gastric emptying and induce satiety leading to a decrease in subsequent energy intake (Keithley and Swanson, 2005).

In weighing the evidence, the Panel took into account that most of the intervention studies, which were of adequate sample size and duration, found a statistically significant effect of glucomannan on body weight loss in the context of a hypocaloric diet when administered as

a pre-load before meals, and that the mechanism by which glucomannan could exert the claimed effect is established.

Panel concludes that a cause and effect relationship has been established between the consumption of glucomannan and the reduction of body weight in the context of an energy-restricted diet.

3. Claimed effect to human health

EU:

1. Maintenance of normal blood cholesterol concentrations is beneficial to human health.
2. Reduction of body weight.

Korea:

May help to maintain healthy blood cholesterol level, maintain healthy bowel function

4. Claim statement

EU:

- "Regular consumption of glucomannan helps maintain normal blood cholesterol concentrations"
- "Glucomannan contributes to the reduction of body weight in the context of an energy-restricted diet".

5. Conditions and possible restrictions of use

EU:

- **Maintenance of normal blood cholesterol concentrations is beneficial to human health.**

A food should provide at least 4 g/d of glucomannan in one or more servings. The target population is the general population.

- **Reduction of body weight.**

In order to obtain the claimed effect, at least 3 g of glucomannan should be consumed daily in three doses of at least 1 g each, together with 1-2 glasses of water before meals, in the context of an energy-restricted diet. The target population is overweight adults.

Korea:

- Daily intake amount: 2.7 ~ 17 g as glucomannan dietary fiber
- Warning notice for intake: Should be taken with sufficient water except for liquid type product

6. References

1. EFSA journal number: 2009; 7(9):1258 (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.1258)

2. EFSA journal number: 2010;8(10):1798 (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1798)

3. Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety. (https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1).

Guar gum

1. Characterisation of the food/constituent

Guar gum is a water-soluble type of fibre, a galactomannan composed of a backbone of D-mannose units with D-galactose attached at every second mannose unit. It is derived from the cluster bean (*Cyamopsis tetragonoloba* (L.) Taub.).

Guar gum is non-digestible in the human small intestine. The molecular weight is about 220 kDa. Guar gum is not naturally occurring in foods and is usually consumed in the form of food supplements. Guar gum has a high viscosity, it is used as a thickener by the food industry, and can be measured in foods by established methods. (EU)

1.1) Standards for manufacturing (KR)

(1) Raw material: Legume family guar (Cyamopsis tetragonolobus TAUB)

(2) Preparation and/or processing

(a) High molecular weight galactomannan polysaccharide shall be in edible form obtained by pulverizing the seed albumen parts from the raw materials or extracting with warm or hot water.

(b) Galactomannan obtained by method of (a) shall be in edible form by hydrolysis.

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 660 mg/g or more.

1.2) Specifications (KR)

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80% of labeled amount

(3) Lead (mg/kg): No more than 2.0

(4) Coliform: Negative

1.3) Testing methods (KR)

(1) Appearance: Chapter 4. 2-7 Appearance testing method

(2) Dietary fiber: Chapter 4. 3-26 Dietary fiber

(3) Lead: Referred to [Annexed the Table 4]

(4) Coliform: Referred to [Annexed the Table 4]

2. Cause and Effect

- **Maintenance of normal blood cholesterol concentrations (ID 808)** (EU)

The effect of water-soluble fibre on blood (LDL) cholesterol concentrations is likely to depend on its viscosity, which reduces the reabsorption of bile acids, increases the synthesis of bile acids from cholesterol, and reduces circulating blood cholesterol concentrations. The Panel concludes that a cause and effect relationship has been established between the consumption of guar gum and the reduction of blood cholesterol concentrations.

3. Claimed effect to human health

- Maintenance of normal blood cholesterol concentrations. (EU)
- May help to maintain healthy blood cholesterol level, maintain healthy postprandial glucose level, maintain healthy bowel function, maintain healthy gastrointestinal bacteria population. (KR)

4. Claim statement

“Regular consumption of guar gum contributes to the maintainance of normal blood cholesterol levels”. (EU)

5. Conditions and possible restrictions of use

EU:

In order to bear a claim, foods should provide at least 10 g per day of guar gum in one or more servings. The target population is adults.

KR:

Daily intake amount:

(a) May help to maintain healthy blood cholesterol level, maintain healthy postprandial glucose level, maintain healthy bowel function: 9.9 ~ 27 g as dietary fiber of guar gum or its hydrolysate

(b) May help to maintain healthy gastrointestinal bacteria population: 4.6 ~27 g as dietary fiber of guar gum or its hydrolysate

Warning

- Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake : -advice on taking with plenty of water to ensure substance reaches stomach. (EU)
- Warning notice for intake: Should be taken with sufficient water except for liquid type product. (KR)

6. References

1. EFSA journal number: 2010;8(2):1464 (https://efsa.onlinelibrary.wiley.com/doi/pdfdirect/10.2903/j.efsa.2010.1464?download=true)

2. Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety. (https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1)

Indigestible Maltodextrin

1. Characterisation of the food/constituent

Korea:

1.1 Standards for manufacturing

(1) Raw material: Corn starch

(2) Preparation and/or processing: The roasted-dextrin shall be obtained by heating the raw materials. The indigestible components shall be in edible form by hydrolyzing the roasted-dextrin with a-amylase (*Bacillus subtilis* or *Bacillus licheniformis* origin) and amyloglucosidase (*Aspergillus niger* origin) and purifying and then separating from dextrin.

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 850 mg/g or more (In case of liquid, 580 mg/g or more).

1.2 Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80% of labeled amount"

3) Dextrose equivalent (D.E.): 8.0 ~ 18.0 (limited to Semi-processed product)

1.3 Testing method

(1) Appearance: Chapter 4. 2-7 Appearance testing method

(2) Dietary fiber: Chapter 4. 3-26 Dietary fiber (method 2)

(3) Dextrose equivalent (D.E.): Referred to [Annexed the Table 4]

2. Cause and Effect

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3. Claimed effect to human health

- Health claims: May help to maintain healthy postprandial glucose level, maintain healthy triglyceride level, maintain healthy bowel function

4. Claim statement

-

5. Conditions and possible restrictions of use

(1) Daily intake amount

(a) May help to maintain healthy postprandial glucose level: 11.9 ~ 30 g as indigestible maltodextrin dietary fiber (in case of liquid ingredients, 11.6 ~ 44 g)

(b) May help to maintain healthy triglyceride level: 12.7 ~ 30 g as indigestible maltodextrin dietary fiber (in case of liquid ingredients, 12.7 ~ 44 g)

(c) May help to maintain healthy bowel function: 2.5 ~ 30 g as indigestible maltodextrin dietary fiber (in case of liquid ingredients, 2.3 ~ 44 g)"

(2) Warning notice for intake: Should be taken with sufficient water except for liquid type product

6. References

1. Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety. (https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1)

Inulin

1. Characterisation of the food/constituent

EU:

The applicant initially stated that the food constituent that is the subject of the health claim is “Orafti®Inulin”. In response to the EFSA’s request for clarification, the applicant explained that “chicory inulin” is the food constituent that is the subject of the health claim. Chemically, inulin is a linear β(2⟶1)-fructan with a degree of polymerisation (DP) > 9 which typically has a terminal α-glucose (EFSA NDA Panel, 2010). Chicory (*Chicorium intybus*) root is one of the plants with the highest concentration of inulin. “Native chicory inulin” is extracted as a non-fractionated mixture of monosaccharides, disaccharides, oligosaccharides (inulin-type fructans, DP 3 – 9) and non-starch polysaccharides (inulin, DP > 9). Influencing factors for chain length distribution are growth conditions and harvest time as well as process technology. From the information provided, including the human studies submitted for the scientific substantiation of the claim, the Panel notes that this claim relates to “native chicory inulin”, a non-fractionated mixture of monosaccharides (< 10%), disaccharides, oligosaccharides (inulin-type fructans) and polysaccharides (inulin) extracted from fresh chicory roots characterised by its mean DP (> 9).

Korea:

1.1 Standard for manufacturing

(1) Raw material: Chicory (*Chicorium intybus*) or other Compositae family plants

(2) Preparation and/or processing: It shall be in edible form by extracting the root of raw materials with hot water and then purifying.

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 800 mg/g or more.

1.2 Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80% of labeled amount

(3) Coliform: Negative

1.3 Testing methods

(1) Appearance: Chapter 4. 2-7 Appearance testing method

(2) Dietary fiber: Chapter 4. 3-26 Dietary fiber

(3) Coliform: Referred to [Annexed the Table 4]

2. Cause and Effect

The Panel notes that inulin and inulin-type fructans in "native chicory inulin" are non-digestible carbohydrates which could exert an effect on stool frequency by stimulating bacterial growth in the gut and by increasing bacterial cell mass and faecal bulk. The Panel also notes that mono- and disaccharides present in "native chicory inulin" in small amounts are unlikely to contribute to the claimed effect.

In weighing the evidence, the Panel took into account that six studies involving 86 subjects consistently showed that consumption of at least 12 g/day "native chicory inulin" increases stool frequency. The Panel also notes the plausible mechanisms by which inulin and inulin-type fructans in "native chicory inulin" could exert the claimed effect.

The Panel concludes that a cause and effect relationship has been established between the consumption of "native chicory inulin", a non-fractionated mixture of monosaccharides (< 10%), disaccharides, inulin-type fructans and inulin extracted from chicory with a mean DP ≥ 9, and maintenance of normal defecation by increasing stool frequency.

The Panel could have reached the conclusion that "native chicory inulin" contributes to the maintenance of normal defecation by increasing stool frequency without the data identified as proprietary by the applicant (Schulz *et al*., 2012, unpublished). However, this study (Schulz *et al*., 2012, unpublished) was used to establish the conditions of use for this claim.

3. Claimed effect to human health

3.1 EU: Improves bowel function by increasing stool frequency.

3.2. Korea: Health claims: May help to maintain healthy blood cholesterol level, maintain healthy postprandial glucose level, maintain healthy bowel function

3.3 Malaysia:

1) Inulin helps increase intestinal bifidobacteria and helps maintain a good intestinal environment

2) Inulin is bifidogenic

3) Inulin is prebiotic

4. Claim statement

4.1 EU: "Chicory inulin contributes to maintenance of normal defecation by increasing stool frequency".

4.2 Singapore: "Inulin helps in calcium absorption"

4.3 Singapore: Claim:

1) Inulin helps support growth or benefical bacteria/good intestinal flora in gut

2) Inulin helps increase intestinal bifidobacteria and helps maintain a good intestinal environment

5. Conditions and possible restrictions of use

5.1 EU: In order to obtain the claimed effect, 12 g of "native chicory inulin" should be consumed daily. The target population is the general population. (EU)

5.2 Korea:

(1) Daily intake amount (Korea)

(a) May help to maintain healthy blood cholesterol level, maintain healthy postprandial glucose level: 7.2 ~ 20 g as inulin / chicory dietary fiber

(b) May help to maintain healthy bowel function: 6.4 ~ 20 g as inulin / chicory dietary fiber"

(2) Warning notice for intake: Should be taken with sufficient water except for liquid type product

5.3 Singapore: Criteria for claim "Inulin helps in calcium absorption

1. ≥ 133.33mg of calcium in per reference quantity of the food as specified Table II in section "Nutrition claims"

2. The amount of calcium has to be declared under the nutrition information panel

3. The amount of inulin present in each serving or other equivalents of the product must be declared on the product label

4. Food manufacturer/importer to ensure that the amount and combinations of shorter and longer chain inulin present in the product is able to bring about the claimed effect.

5.4 Singapore: Criteria for claim 1) Inulin helps support growth or benefical bacteria/good intestinal flora in gut 2) Inulin helps increase intestinal bifidobacteria and helps maintain a good intestinal environment

Food manufacturer/importer to ensure that the amount of inulin present in the product is able to bring about the claimed effect.

5.5 Malaysia: Criteria

5.5.1) Inulin: 2 g per serving

This minimum level is for other food except infant formula.

5.5.2) 0.4 g / 100 ml on a ready to drink basis.

This minimum level is specified for infant formula only.

6. References

1. European Food Safety Authority (EFSA). EFSA Journal 2015;13(1):3951 (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.3951)
2. Ministry of Food and Drug Safety (Korea). Health Functional Food Code 2021 (https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1)
3. Singapore Food Agency. A Guide to Food Labelling and Advertisements (https://www.sfa.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/aguidetofoodlabellingandadvertisements.pdf)
4. The Ministry of Health Malaysia. Malaysian Dietary Guidelines
   Key Message 14: Make effective use of nutrition information on food labels
   (www.moh.gov.my)

Live yoghurt cultures

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is "yoghurt cultures (live)", which contain the starter micro-organisms "*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus"*. These starter cultures "*Lactobacillus delbrueckii subsp. bulgaricus* and *Streptococcus thermophilus"* are well specified for their use in yoghurt manufacture by Codex Alimentarius Standard No. 243/2003. (EU)

Codex Alimentarius Standard No. 243/2003

Standard for fermented milk. 2018.

DESCRIPTION

Fermented Milk is a milk product obtained by fermentation of milk, which milk may have been manufactured from products obtained from milk with or without compositional modification as limited by the provision in Section 3.3, by the action of suitable microorganisms and resulting in reduction of pH with or without coagulation (iso-electric precipitation). These starter microorganisms shall be viable, active and abundant in the product to the date of minimum durability. If the product is heat treated after fermentation the requirement for viable microorganisms does not apply.

Certain Fermented Milks are characterized by specific starter culture(s) used for fermentation as follows:

Yoghurt:	Symbiotic cultures of *Streptococcus thermophilus* and *Lactobacillus delbrueckii* subsp. *bulgaricus.*
Alternate culture yoghurt:	Cultures of *Streptococcus thermophilus* and any *Lactobacillus* species.
Acidophilus milk:	*Lactobacillus acidophilus.*
Kefir:	Starter culture prepared from kefir grains, *Lactobacillus kefiri,* species of the genera *Leuconostoc, Lactococcus* and *Acetobacter* growing in a strong specific relationship. Kefir grains constitute both lactose fermenting yeasts *(Kluyveromyces marxianus*) and non-lactose-fermenting yeasts *(Saccharomyces unisporus, Saccharomyces cerevisiae* and *Saccharomyces exiguus*).
Kumys:	*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Kluyveromyces marxianus.*

Other microorganisms than those constituting the specific starter culture(s) specified above may be added.

Concentrated Fermented Milk is a Fermented Milk the protein of which has been increased prior to or after fermentation to minimum 5.6%. Concentrated Fermented Milks includes traditional products such as Stragis to (strained yoghurt), Labneh, Ymer and Ylette.

Flavoured Fermented Milks are composite milk products, as defined in Section 2.3 of the General Standard for the Use of Dairy Terms (CXS 206-1999) which contain a maximum of 50% (m/m) of non-dairy ingredients (such as nutritive and non nutritive sweeteners, fruits and vegetables as well as juices, purees, pulps, preparations and preserves derived there from, cereals, honey, chocolate, nuts, coffee, spices and other harmless natural flavouring foods) and/or flavours. The non-dairy ingredients can be mixed in prior to/or after fermentation.

Drinks based on Fermented Milk are composite milk products, as defined in Section Flavoured Fermented Milks of the General Standard for the Use of Dairy Terms (CXS 206-1999), obtained by mixing Fermented Milk as described in Section 2.1 with potable water with or without the addition of other ingredients such as whey, other non-dairy ingredients, and flavourings. Drinks Based on Fermented Milk contain a minimum of 40% (m/m) fermented milk.

Other microorganisms than those constituting the specific starter culture(s) specified above may be added.

ESSENTIAL COMPOSITION AND QUALITY FACTORS

Raw materials

• Milk and/or products obtained from milk.

• Potable water for the use in reconstitution or recombination.

Permitted ingredients

• Starter cultures of harmless microorganisms including those specified in Section 2;

• Other suitable and harmless microorganisms (in products covered by Section 2.4);

• Sodium chloride;

• Non-dairy ingredients as listed in Section 2.3 (Flavoured Fermented Milks);

• Potable water (in products covered by Section 2.4);

• Milk and milk products (in products covered by Section 2.4);

• Gelatine and starch in:

- fermented milks heat-treated after fermentation;

- flavoured fermented milk;

- drinks based on fermented milk; and

- plain fermented milks if permitted by national legislation in the country of sale to the final consumer;

provided they are added only in amounts functionally necessary as governed by Good Manufacturing Practice, taking into account any use of the stabilizers/thickeners listed in Section 4. These substances may be added either before or after adding the non-dairy ingredients.

Composition

	Fermented Milk	Yoghurt, Alternate Culture Yoghurt and Acidophilus milk	Kefir	Kumys
Milk protein[a] (% m/m)	min. 2.7%	min. 2.7%	min. 2.7%	
Milk fat (% m/m)	less than 10%	less than 15%	less than 10%	less than 10%
Titrable acidity, expressed as % lactic acid (% m/m)	min. 0.3%	min. 0.6%	min. 0.6%	min. 0.7%
Ethanol (% vol./w)				min. 0.5%
Sum of microorganisms constituting the starter culture defined in section 2.1 (cfu/g, in total)	min. 10^7	min. 10^7	min. 10^7	min. 10^7
Labelled microorganisms[b] (cfu/g, total)	min. 10^6	min. 10^6		
Yeasts (cfu/g)			min. 10^4	min. 10^4

a. Protein content is 6.38 multiplied by the total Kjeldahl nitrogen determined.

b. Applies where a content claim is made in the labelling that refers to the presence of a specific microorganism (other than those specified in section 2.1 for the product concerned) that has been added as a supplement to the specific starter culture.

In Flavoured Fermented Milks and Drinks based on Fermented Milk the above criteria apply to the fermented milk part. The microbiological criteria (based on the proportion of fermented milk product) are valid up to the date of minimum durability. This requirement does not apply to products heat-treated after fermentation.

Compliance with the microbiological criteria specified above is to be verified through analytical testing of the product through to “the date of minimum durability” after the product has been stored under the storage conditions specified in the labelling.

Essential manufacturing characteristics

Whey removal after fermentation is not permitted in the manufacture of fermented milks, except for Concentrated Fermented Milk

2. Cause and Effect

In weighing the evidence, the Panel took into consideration that thirteen of fourteen human studies showed enhanced digestion of lactose in yoghurt in lactose maldigesters, when live yoghurt starter cultures were ingested in yoghurt, that the one study which did not show such an effect reported reduced symptoms and that there was strong evidence for the biological plausibility of the effect.

The Panel concludes that a cause and effect relationship has been established between the consumption of live yoghurt cultures in yoghurt and improved digestion of lactose in yoghurt in individuals with lactose maldigestion. (EU)

3. Claimed effect to human health

Improved lactose digestion. (EU) (AUS-NZ)

4. Claim statement

“Live yoghurt cultures in yoghurt improve digestion of lactose in yoghurt in individuals with lactose maldigestion”. (EU)

5. Conditions and possible restrictions of use

EU:

In order to bear the claim, the yoghurt should contain at least 108 CFU live starter microorganisms (Lactobacillus delbrueckii subsp. bulgaricus and Streptococcus thermophilus) per gram. 16 The target population is individuals with lactose maldigestion.

AUS-NZ:

The food must:

(a) be yoghurt or fermented milk; and

(b) contain at least 10^{8} cfu/g (*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*).

Relevant population: Individuals who have difficulty digesting lactose.

6. References

1. Codex Alimentarius Standard No. 243/2003. Standard for fermented milk. 2018.

2. EFSA journal number: 2010;8(10):1763
(https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1763)
3. Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claims (F2017C00711) Authorised Version F2017C00711 registered 08/09/2017.
(https://irp.cdn-website.com/69f086d6/files/uploaded/FSANZ%20Food%20Standards%20Schedule%204.pdf)

Oleic acid

1. Characterisation of the food/constituent

The foods/food constituents that are the subject of the health claims are "monounsaturated fatty acids (mainly oleic acid)", "oleic acid" and "extravirgin olive oil".

In the context of the proposed wordings, clarifications provided by Member States and references submitted for the scientific substantiation of the health claims, the Panel assumes that the food constituent that is the subject of the health claims is oleic acid, which should replace saturated fatty acids (SFAs) in foods or diets in order to obtain the claimed effects.

Oleic acid is the monounsaturated fatty acid (MUFA) with 18 carbon atoms and the double bond in the 9-cis position. It is found in varying amounts in dietary fats. Beef tallow contains about 43 % oleic acid and 47 % SFAs, lard about 44 % oleic acid and 43 % SFAs, palm oil about 40 % oleic acid and 45 % SFAs, rapeseed oil about 60 % oleic acid and 6 % SFAs. A high proportion of oleic acid is found in olive oil, 71 %, together with 15.5 % SFAs and 12 % polyunsaturated fatty acids (PUFAs). High-oleic acid varieties of sunflower oil and rapeseed oil contain about 75-85 % oleic acid.

Saturated fatty acids (SFAs) are aliphatic monocarboxylic acids with (generally) an even number of carbon atoms (usually from 4 to 20) and no double bonds which can be liberated by hydrolysis of triacylglycerols from fats and oils. The most prevailing SFAs in the diet are lauric acid (12:0), myristic acid (14:0), palmitic acid (16:0), and stearic acid (18:0).

This opinion applies to the replacement of mixtures of SFAs as present in foods or diets with oleic acid. (EU)

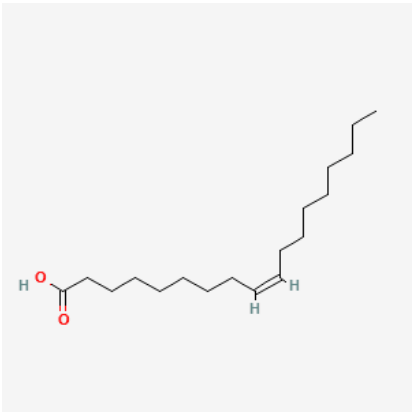
(a)  (b) $C_{18}H_{34}O_2$ or $C_8H_{17}CH{=}CH(CH_2)_7COOH$

Figure 1. (a) The chemical structure of Oleic acid
(b) The molecular formula of Oleic acid

2. Cause and Effect

- **Maintenance of normal blood LDL-cholesterol concentrations (ID 673, 728, 729, 1302, 4334)** (EU)

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus that a mixture of SFAs increases total and blood LDL-cholesterol concentrations relative to mixtures of cis-MUFAs (EFSA, 2004; EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; IoM, 2005; Lichtenstein *et al*., 2006; Mensink *et al*., 2003; WHO/FAO, 2003), and that there is a linear dose-response relationship between blood LDL-cholesterol concentrations and the amounts of long-chain SFAs consumed. It is also well established that consumption of a mixture of SFAs results in increased blood HDL-cholesterol concentrations compared with consumption of mixtures of cis-MUFAs (e.g. oleic acid), and that incomparison with other fatty acids, except trans fatty acids (TFAs), SFAs increase the total–to-HDL cholesterol ratio (Mensink *et al*., 2003).

SFAs differ in their potential to change blood lipid and lipoprotein concentrations. While lauric, myristic and palmitic acid raise blood total and LDL-cholesterol concentrations, effects of stearic acid and short and medium chain SFAs (with 4-10 carbon atoms) are similar to those of carbohydrates and oleic acid (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; Mensink *et al*., 2003). However, SFAs are present in foods as mixtures, so that stearic acid, and short and medium chain SFAs, are consumed in foods that also contain other long-chain SFAs (with 12-16 carbon atoms), which are known to increase LDL-cholesterol concentrations.

A claim on the replacement of mixtures of SFAs with cis-MUFAs and/or cis-PUFAs in foods or diets and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011). The scientific conclusions in that opinion apply to the replacement of mixtures of SFAs as present in foods or diets with oleic acid.

3. Claimed effect to human health

- Maintenance of normal blood LDL-cholesterol concentrations. (EU)

4. Claim statement

- "Replacing saturated fats in the diet with unsaturated fats contributes to the maintenance of normal blood cholesterol levels. Oleic acid is an unsaturated fat." (EU)

5. Conditions and possible restrictions of use

- 10-20 energy % (around. 22-44 g/day). The product shall contain a significant amount of MUFA compared to the recommended daily allowance. Health claims can be applied on foods complying with requirements of nutrition claims “High mono-unsaturated fatty acids”. (EU)

6. References

1. Oleic acid COMPOUND SUMMARY. PubChem. National Library of Medicine. (https://pubchem.ncbi.nlm.nih.gov/compound/Oleic-acid)

2. EFSA journal number: 2011;9(4):2043 (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2043)

3. EFSA (European Food Safety Authority), 2004. Opinion of the Scientific Panel on Dietetic products, nutrition and allergies (NDA) related to the presence of trans fatty acids in foods and the effect on human health of the consumption of trans fatty acids (Request No EFSA-Q-2003-022). The EFSA Journal. 81, 1-49.

4. EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010. Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol. EFSA Journal, 8(3):1461, 107 pp.

5. EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011. Scientific Opinion on the substantiation of health claims related to the replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of monounsaturated fatty acids (MUFAs) and/or mixtures of polyunsaturated fatty acids (PUFAs), and maintenance of normal blood LDL-cholesterol concentrations (ID 621, 1190, 1203, 2906, 2910, 3065) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 9(4):2069, 18 pp.

6. IoM (Institute of Medicine), 2005. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. National Academies Press, Washington D.C.

7. Lichtenstein AH, Appel LJ, Brands M, Carnethon M, Daniels S, Franch HA, Franklin B, Kris-Etherton P, Harris WS, Howard B, Karanja N, Lefevre M, Rudel L, Sacks F, Van Horn L, Winston M and Wylie-Rosett J, 2006. Diet and lifestyle recommendations revision 2006: a scientific statement from the American Heart Association Nutrition Committee. Circulation, 114, 82-96.

8. Mensink RP, Zock PL, Kester AD and Katan MB, 2003. Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials. American Journal of Clinical Nutrition, 77, 1146-1155.

9. WHO/FAO (World Health Organization/Food and Agriculture Organization), 2003. Expert Report: Diet, nutrition and prevention of chronic diseases. Report of a Joint WHO/FAO Expert Consultation. WHO Technical Report Series. WHO Technical Report Series 916.

Olive oil polyphenols

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is polyphenols (e.g. hydroxytyrosol and oleuropein complex) in olive (olive fruit, olive mill waste waters or olive oil, Olea europaea L. extract and leaf).

The conditions of use specify 200 mg/day of polyphenols (ID 1638, 1882, 2865), 2-15 mg per day of hydroxytyrosyl or oleuropein complex (ID 1638, 1639, 1696), and 250-500 mg of an Olea europaea L. extract standardised to 4-23% oleuropein (ID 3467, 3468, 3779, 3781).

Polyphenols comprise a very wide group (several thousands of compounds) of plant secondary metabolites including flavonoids, isoflavonoids, phenolic acids, proanthocyanidins and other tannins, and lignans with different biological activities. The major polyphenols in olive oil are phenolic acids (e.g. hydroxytyrosol and tyrosol), secoiridoids (e.g. oleuropein) and lignans (e.g. pinoresinol). Table olives typically contain hydroxytyrosol, tyrosol, caffeoylquinic acid, verbacoside, luteolin and rutin. Hydroxytyrosol, a major polyphenol typically present in olives, is also present in olive mill waste water. In nature, hydroxytyrosol is found in olives in the form of its elenolic acid ester, oleuropein. These polyphenolic compounds can be measured in foods by established methods.

Total polyphenols are usually expressed as gallic acid equivalents (GAE), but other phenolic compounds such as catechin/epicatechin or caffeic acid have also been used for standardisation. This standardisation refers to the traditional spectrophotometrical measurement of total polyphenols using the Folin-Ciocalteau method (Singleton and Rossi, 1965), which is based on reducing capacity. The method is not specific for polyphenols because other reducing compounds such as ascorbic acid, sugars and proteins will also be included in the quantification, thus leading to an overestimation of the actual polyphenol content. The total polyphenol content assessed with this method is not suitable for characterisation of polyphenols in foods.

The Panel considers that polyphenols (e.g. hydroxytyrosol and oleuropein complex) in olive (olive fruit, olive mill waste waters or olive oil, Olea europaea L. extract and leaf) can be

characterised by their content of hydroxytyrosol and its derivatives (e.g. oleuropein complex). (EU)

2. Cause and Effect

EU:

In weighing the evidence, the Panel took into account that a well conducted and powered study, and two smaller-scale studies, showed a dose-dependent and significant effect of olive oil polyphenol consumption (for three weeks) on appropriate markers of LDL peroxidation (oxLDL), that these results were supported by one short-term and one acute study, and by supportive markers of LDL peroxidation (conjugated dienes, ex vivo resistance of LDL to oxidation) going in the same direction, and that evidence for a biologically plausible mechanism by which olive oil polyphenols could exert the claimed effect has been provided.

The Panel concludes that a cause and effect relationship has been established between the consumption of olive oil polyphenols (standardised by their content of hydroxytyrosol and its derivatives) and protection of LDL particles from oxidative damage.

3. Claimed effect to human health

Protection of LDL particles from oxidative damage. (EU)

4. Claim statement

“Consumption of olive oil polyphenols contributes to the protection of blood lipids from oxidative damage.” (EU)

5. Conditions and possible restrictions of use

EU:

In order to bear the claim, 5 mg of hydroxytyrosol and its derivatives (e.g. oleuropein complex and tyrosol) in olive oil should be consumed daily. These amounts, if provided by moderate amounts of olive oil, can be easily consumed in the context of a balanced diet. The concentrations in some olive oils may be too low to allow the consumption of this amount of polyphenols in the context of a balanced diet. The target population is the general population.

6. References

1. EFSA journal number: 2011;9(4):2033
(https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2033)

Plant sterols and plant stanols (Phytosterols, phytostanols and their esters)

1. Characterisation of the food/constituent

EU:

In the context of this opinion, the term plant sterols (present as free sterols or esterified) refers specifically to plant sterols from natural sources with a composition as specified in the Commission Decisions authorising the placing on the market of food products with added plant sterols under Regulation (EC) No 258/976. The term “plant stanol ester” refers to a blend of the plant stanols sitostanol and campestanol, which are obtained from the reduction of plant sterols from food grade plant oils (mainly soybean oil) or tall oil or blends thereof. The Panel notes that claims ID 1234 and 1235 refer to polyphenols present or extracted from Maritime Pine (Pinus pinaster Aiton). However, the only reference cited in the list referring to procyanidins (a type of polyphenol) from French maritime pine bark was not accessible to the Panel after having made every reasonable effort to retrieve it (Assouad and Piriou, 2007), and no references on the effects of polyphenols present or extracted from Maritime Pine on blood lipids or any other health outcome were provided.

Canada:

The term “phytosterols” is used in this document as a collective term for plant sterols, and their hydrogenated stanol forms, whether used in the free sterol form or esterified with fatty acids (also known as sterol esters or phytosterol esters). There is a diversity in the composition of phytosterols and over 40 phytosterols have been identified in nature. The safety assessment considered phytosterols and stanols as a group. Phytosterols occur naturally in plants, and vegetable oils are the major source of phytosterols in Canadian diets. Phytosterols, when consumed at sufficiently high levels, have been shown to reduce serum total and LDL cholesterol levels.

Korea:

1.1) Standards for manufacturing

(1) Raw material and preparation and/or processing

(a) The mixture of β-sitosterol, brassicasterol, stigmasterol and campesterol, as distillate which are obtained during deodorization of soybean, corn or canola oil, shall be in edible form by extracting and purifying.

(b) The substance of above (a) shall be in edible form by esterifying fatty acids originated from edible oil.

(2) Content of functional compounds (or marker compounds): Phytosterol shall be contained 900 mg/g or more. However, in case of using phytosterol ester as ingredients, the sum of total phytosterol and free phytosterol shall be contained 800 mg/g or more and contents of free phytosterol 100 mg/g or less.

(3) Conditions for manufacturing: When analyzing phytosterol, all of β -sitosterol, brassicasterol, stigmasterol and campesterol shall be detected.

1.2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Phytosterol (in case of using phytosterol as ingredients)

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120% of labeled amount

(3) Content of phytosterolester (in case of using phytosterolester as ingredients)

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120% of labeled amount

(4) Coliform: Negative

1.3) Testing methods

(1) Appearance: Chapter 4. 2-7 Appearance testing method

(2) Phytosterol: Chapter 4. 3-38 Phytosterol

(3) Phytosterolester

(a) Content of total phytosterol: Chapter 4. 3-38 Phytosterol

(b) Free phytosterol: Chapter 4. 3-39 Free phytosterol

(c) Content of phytosterolester = (total phytosterol - free phytosterol) × 1.6

(4) Coliform: Referred to [Annexed the Table 4]

2. Cause and Effect

EU:

In the most recent meta-analysis on the LDL-cholesterol lowering effects of plant sterols/stanols, 84 clinical trials were included (Demonty *et al*., 2009). In nine of the studies, daily doses of 0.80-1.0 g had been used. In seven of these studies a statistically significant reduction of LDL-cholesterol concentrations (range -0.19 to -0.33 mmol/L) was found (Beer *et al*., 2001; Hendriks *et al*., 1999; Hironaka *et al*., 2006; Niittynen *et al*., 2007; Sierksma *et al*., 1999; Ishizaki T, 2003; Vanhanen, 1994). In one study (Matsuoka *et al*., 2004) no effect was found with free sterols, and in the study by Miettinen and Vanhanen (1994) the reduction in LDL-cholesterol of 0.26 mmol/L was not statistically significant. Plant sterols were used in seven studies, stanols in one study and in another study a mixture of sterols and stanols was tested. The results of these studies indicate statistically significant lowering of LDL-cholesterol concentrations by consuming moderate doses (0.8-1.0 g per day) of plant sterols or stanols in subjects with normal or mildly elevated LDL-cholesterol concentrations. All but one (Hironaka *et al*., 2006) of the studies mentioned above were conducted with plant sterols or stanols added to foods such as margarine-type spreads, mayonnaise, and dairy products such as milk and yoghurts including low-fat yoghurts (Demonty *et al*., 2009; EFSA, 2009).

The Panel concludes that a cause and effect relationship has been established between the consumption of plant sterols and plant stanols and reduction of blood cholesterol concentrations.

Canada:

The evidence provided by the petitioner included 84 randomized controlled trials (comprising 141 pertinent trial arms) published from 1994 to 2007. Overall, an 8.8% reduction in LDL-cholesterol as observed with an average intake of 2 g/day of plant sterols. A dose-response relationship was observed up to about 3 g/day in these studies which included doses ranging from about 0.5 g/day to 9.0 g/day. At the average intake of 2 g/day, the effect of plant sterols appeared to be largely independent of the food matrix. Most of the studies were carried out with moderately to highly hypercholesterolemic subjects.

Health Canada has concluded that acceptable scientific evidence exists in support of the claim about the relationship between the consumption of plant sterol-enriched foods as foods and blood cholesterol lowering. Consumption of these foods results in the lowering of total blood cholesterol as well as LDL-cholesterol levels, while having no detrimental effect on HDL-cholesterol levels, resulting in overall improvements in the blood lipid profile.

3. Claimed effect to human health

- Maintenance of normal blood cholesterol concentrations. (EU)
- Plant Sterols and Blood Cholesterol Lowering. (Canada)
- Reduces blood cholesterol. (AUS-NZ)
- May help to maintain healthy blood cholesterol level. (Korea)
- Plant sterol or plant stanol helps lower or reduce cholesterol. (Malaysia)

4. Claim statement

EU:

“Plant sterols/stanols help to maintain normal blood cholesterol levels”.

Canada:

Primary statement: “[serving size from Nutrition Facts table in metric and common household measures] of [naming the product] provides X% of the daily amount* of plant sterols shown to help reduce/lower cholesterol in adults.”

Two additional statements that could be used in combination or alone, adjacent to the primary statement, without any intervening printed, written or graphic material:

1) “Plant sterols help reduce [or help lower] cholesterol.” This statement when used, shall be shown in letters up to twice the size and prominence as those of the primary statement.

2) “High cholesterol is a risk factor for heart disease.” This statement when used, shall be shown in letters up to the same size and prominence as those of the primary statement.

Singapore:

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

5. Conditions and possible restrictions of use

EU:

In order to bear the claim, a food should provide at least 0.8 g per day of plant sterols/stanols in one or more servings.

Canada:

Conditions for foods to carry the claim: The food (a) contains a minimum level equivalent to 0.65 g of free plant sterols or stanols per reference amount and per serving of stated size; (b) contains at least 10% of the weighted recommended nutrient intake of a vitamin or mineral per reference amount and per serving of stated size; (c) contains 100 mg or less of cholesterol per 100 g of food; (d) contains 0.5% or less alcohol; (e) contains 480 mg or less of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less; (f) meets the criterion "low in saturated fatty acids.

AUS-NZ:

Diet low in saturated fatty acid.

Diet containing 2 g of phytosterols, phytostanols and their esters per day.

The food must:

(a) meet the relevant conditions specified in the table in section S25—2; and

(b) contain a minimum of 0.8 g total plant sterol equivalents content/serving.

Singapore:

1. Phytosterols, phytosterol esters, phytostanols or phytostanol esters may only be added to —

(i) any edible vegetable fat or oil containing not more than 20 g of saturated fat per 100 g of total fat;

(ii) any margarine or fat spread containing not more than 27 g of saturated fat per 100 g of total fat; or

(iii) any other food containing not more than 3 g of total fat per 100 g or 1.5 g of total fat per 100 ml. —

2. The following mandatory information must be declared on the product label:

(i) The product is a special purpose food intended for people who want to lower their blood cholesterol level;

(ii) The product may not be nutritionally appropriate for pregnant and breast-feeding women and children under the age of 5 years;

(iii) The product should be used as part of a balanced and varied diet;

(iv) Consumption in a day of a total of more than 3g of phytosterols and/or phytostanols does not provide any additional benefit in lowering blood cholesterol levels;

(v) Consumption in a day of a total of at least 2g of phytosterols and/or phytostanols has been shown to lower blood cholesterol levels; and

(vi) A statement suggesting the amount of the food (in g or ml) to be consumed each time (referred to as a serving), and a statement of the total amount of phytosterols and phytostanols that each serving contains."

Malaysia:

Minimum amount required:

- 1.3 g per 100 (solids)
- 160 mg per 100 ml (liquids)"

i. Addition and claim for plant sterol/plant stanol only permitted in milk, milk product, soya bean milk and soya bean drink (Reg. 82, 83, 357 &358 respectively).

ii. Types of plant sterol or plant stanol permitted: "plant sterol/plant stanol, phytosterols/phytostanol, sitosterol, campesterol, stigmasterol or other related plant stanol".

iii. Maximum amount in daily serving for product added with plant sterol/plant stanol is not more than 3 g plant sterol/plant stanol per day.

iv. Declaration of the total amount of plant sterol/plant stanol contained in the products shall be expressed in metric units per 100 g or per 100 ml or per package if the package contains only a single portion and per serving as quantified on the label.

v. Only the terms "plant sterols" or "plant stanols" shall be used in declaring the presence of such components.

vi. There shall be written on the label of food making such claim a statement:

a. "Not recommended for pregnant and lactating women and children under the age of five years".

b. "Persons on cholesterol-lowering medication shall seek medical advice before consuming this product".

c. That the product is consumed as part of a balanced and varied diet and shall include regular consumption of fruits and vegetables to help maintain the carotenoid level.

d. "With added plant sterols" or "With added plant stanols" in not less than 10 point lettering.

6. References

1. EFSA journal number: 2010;8(10):1813
2011;9(6):2203. (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1813. https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2203)

2. Health Functional Food Code 2021. Ministry of Food and Drug Safety. (https://www.mfds.go.kr/eng/brd/m_15/view.do?seq=70011).

3. Summary of Health Canada's Assessment of a Health Claim about Plant Sterols in Foods and Blood Cholesterol Lowering. 2010. (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/label-etiquet/claims-reclam/assess-evalu/phytosterols-claim-allegation-eng.pdf)

4. Notice of Assessment of Certain Categories of Foods Containing Added Phytosterols. 2010. (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/gmf-agm/appro/phytosterols-eng.pdf)

5. Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claims (F2017C00711) Authorised Version F2017C00711 registered 08/09/2017. (https://irp.cdn-website.com/69f086d6/files/uploaded/FSANZ%20Food%20Standards%20Schedule%204.pdf)

6. A Guide to Food Labelling and Advertisement. A publication of the Singapore Food Agency (SFA). 2019. (https://www.sfa.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/aguidetofoodlabellingandadvertisements.pdf)

7. Malaysian Dietary Guidelines Key Message 14: Make effective use of nutrition information on food labels (https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf)

Red yeast rice

1. Characterisation of the food/constituent

The food that is the subject of the health claim is red yeast rice (i.e. rice fermented with the red yeast *Monascus purpureus*).

Red yeast rice is a traditional Chinese food product which is still a dietary staple in many Asian countries (Heber *et al*., 1999). Various red yeast rice preparations are available as food supplements. The preparations from red yeast rice typically contain starch, protein, fat (including monounsaturated fatty acids, plant sterols), isoflavones, and other compounds. Depending on the Monascus strains used and the fermentation conditions, the products may contain polyketides called monacolins, which are secondary metabolites produced during fermentation (Liu *et al*., 2006).

Monacolin K, in lactone (also known as lovastatin or mevinolin) and hydroxy acid forms, is the main monacolin in *Monascus purpureus*-fermented rice (75-90 % of total monacolin content) (Heber *et al*., 1999; Li *et al*., 2004). Commercial red yeast rice products have variable contents of monacolin K and total monacolins (Gordon *et al*., 2010; Li *et al*., 2004). From the conditions of use provided, the Panel notes that monacolin K from *Monascus purpureus*-fermented rice has been specified as the food constituent which may be responsible for the claimed effect considered in this opinion. Monacolin K from *Monascus purpureus*-fermented rice is a well defined compound, which can be measured in foods by established methods. (EU)

1.1) Standards for manufacturing (KR)

(1) Raw material: Rice and red yeast (*Monascus anka, Monascus purpures, Monascus pilosus,* and *Monascus ruber*)

(2) Preparation and/or processing: It shall be in edible form by pulverizing after solid-state fermentation by inoculating rice (except for steamed rice) with red yeast.

(3) Content of functional compounds (or marker compounds): Total monacolin K shall be contained 0.5 mg/g or more, and active form of monacolin K shall be confirmed.

1.2) Specifications (KR)

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Total monacolin K

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120% of labeled amount

(3) Active form of monacolin K: It shall be confirmed

(4) Citrinin (mg/kg): No more than 0.05

(5) Coliform: Negative (KR)

1.3) Testing methods (KR)

(1) Appearance: Chapter 4. 2-7 Appearance testing method

(2) Total monacolin K: Chapter 4. 3-51 Total monacolin K

(3) Active form of monacolin K: It shall be confirmed according to total monacolin K testing method of above (1).

(4) Citrinin: Chapter 4. 2-5-4 Citrinin

(5) Coliform: Referred to [Annexed the Table 4]

2. <u>Cause and Effect</u>

Pure monacolin K (lovastatin) has been shown to be effective in reducing total cholesterol and LDL-cholesterol concentrations in individuals with hypercholesterolaemia and is a well-known inhibitor of HMG-CoA reductase. A significant inhibitory effect of a fermented red yeast rice preparation (Cholestin) on HMG-CoA reductase activity and cholesterol concentrations was observed in vitro in human hepatic cells (HepG2) (Man *et al*., 2002).

In weighing the evidence, the Panel took into account that two RCTs provided from which conclusions could be drawn for the scientific substantiation of the claim showed an effect of red yeast rice preparations providing a daily dose of about 10 mg monacolin K on LDL-cholesterol concentrations in individuals with hypercholesterolaemia, that the effect of pure monacolin K on LDL-cholesterol concentrations is well established and that the mechanism by which monacolin K can contribute to the claimed effect is well known.

The Panel concludes that a cause and effect relationship has been established between the consumption of monacolin K from red yeast rice and maintenance of normal blood LDL-cholesterol concentrations.

3. Claimed effect to human health

Maintenance of normal blood LDL-cholesterol concentrations. (EU)

May help to maintain healthy blood cholesterol level. (KR)

4. Claim statement

“Monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol concentrations”. (EU)

5. Conditions and possible restrictions of use

EU:

In order to obtain the claimed effect, 10 mg of monacolin K from fermented red yeast rice preparations should be consumed daily. The target population is adults in the general population.

Korea:

Daily intake amount: 4 ~ 8 mg as total monacolin K.

6. References

1. EFSA journal number: 2011;9(7):2304 (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2304)

2. Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety. (https://www.mfds.go.kr/eng/brd/m_15/view.do?seq=70011).

Resistance starch

1. Characterisation of the food/constituent

EU:

The food constituent that is the subject of the health claim is resistant starch-type 2 from high amylose maize. Resistant starch (RS) is defined as starch that escapes digestion and absorption in the small intestine of healthy subjects, and can be classified into four types: RS1 is physically inaccessible to digestion, RS2 describes native starch granules that are protected from digestion by the conformation or structure of the granule, RS3 refers to non-granular starch-derived materials which are generally formed during retrogradation of starch granules in food processing, and RS4 are starches not found in nature which have been chemically modified to decrease their digestibility (Nugent, 2005).

RS from high amylose maize (amylose content between 50 % and 90 %) is categorised as RS2, and is produced from a traditionally bred hybrid of high amylose maize that contains a mixture of digestible and resistant starch. The starch granules in high amylose maize are very stable, and tend not to gelatinise when subjected to the processing conditions used in the manufacture of many common foods. Methods are available to measure these starch fractions in the laboratory (McCleary and Monaghan, 2002).

2. Cause and Effect

EU:

In weighing the evidence, the Panel took into account that most of the studies provided reported a significant decrease in post-prandial glycaemic responses, without significantly increasing insulinaemic responses, following consumption of RS2 as a partial replacement of digestible starch in baked foods, and that the effect is generally not observed when the amount of available carbohydrates is maintained constant in the test and control products. This suggests that the replacement of digestible starch in carbohydrate-containing foods with RS2 from high amylose maize would decrease post-prandial glycaemic and insulinaemic responses due to the replacement of digestible carbohydrates by indigestible carbohydrates, so that the amount of available glucose contributing to glycaemia is reduced, whereas the

addition of RS2 to carbohydrate-containing foods does not appear to modify the post-prandial glucose responses to digestible starch (i.e. when the amount of glycaemic carbohydrates is kept constant). The Panel notes that the effect of replacing digestible starch in foods with resistant starch on post-prandial glycaemic responses could be expected from all types of resistant starch, and that this effect is not specific to RS2 from high amylose maize.

The Panel concludes that a cause and effect relationship has been established between the consumption of resistant starch from all sources, when replacing digestible starch in baked foods, and a reduction of post-prandial glycaemic responses.

3. Claimed effect to human health

3.1 Reduction of post-prandial glycaemic responses. (EU)

3.2 High Amylose Maize Resistant Starch (HAMRS) helps improve/promote colonic/bowel/intestinal function/environment (Malaysia)

4. Claim statement

- "Replacing digestible starch with resistant starch induces a lower blood glucose rise after a meal". (EU)
- "High Amylose Maize Resistant Starch (HAMRS) helps improve/promote colonic/bowel/intestinal function/environment" (words/sentences of similar meaning can also be used) (Malaysia)

5. Conditions and possible restrictions of use

- High carbohydrate baked foods should contain at least 14 % of total starch as resistant starch, in replacement to digestible starch. The target population is individuals wishing to reduce their post-prandial glycaemic responses. (EU)
- Minimum amount: 2.5 g per serving (Malaysia)

6. References

1. EFSA journal number: 2011;9(4):2024 (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2024)
2. Malaysian Dietary Guidelines
   Key Message 14: Make effective use of nutrition information on food labels (www.moh.gov.my)

Soybean protein

1. Characterisation of the food/constituent

Canada:

The foods that are the subject of the proposed health claim are foods or food ingredients that contain proteins derived from the soybean (Glycine max (L.) Merr., Fabaceae). Foods and ingredients eligible for the claim include soy beverages, tofu, miso, tempeh, natto, soy cheese, soy nuts, isolated soy protein (ISP), soy protein concentrate (SPC), textured soy protein (TSP) and soy flour (SF). Soy sauce and soybean oil are excluded from the claim because they lack substantial amounts of soy protein.

Korea:

1.1 Standard for manufacturing

(1) Raw materials: Soybean (Glycine max L.N)

(2) Preparation and'or processing

(a) It shall be in edible form by separating and purifying after removing lipid from the raw materials.

(b) It shall be in edible form by separating and purifying with pulverizing after soaking the raw material.

(3) Content of functional compounds (or marker compounds): Crude protein shall be contained 400 mg/g or more based on dried materials and daidzein and genistein shall be confirmed.

1.2 Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Crude protein

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120% of labeled amount

(3) Daidzein: It shall be confirmed.

1.3 Testing methods

(1) Appearance: Chapter 4. 2-7 Appearance testing method

(2) Crude protein: Chapter 4. 3-21 Crude protein

(3) Daidzein, Genistein: Chapter 4. 3-50 Confirmation of daidzein and genistein

2. Cause and Effect

Canada:

The evidence consistently supports a direction of effect towards a reduction in total and LDL cholesterol levels when soy protein is consumed. A meta-analysis showed a statistically significant reduction in total and LDL cholesterol levels with soy protein consumption and no detrimental effect on HDL cholesterol and triglyceride levels.

Health Canada's Food Directorate has concluded that scientific evidence exists to support a claim about soy protein and blood cholesterol lowering. The claim is relevant and generally applicable to the Canadian population on the basis that 39% of Canadians aged 6 to 79 years had unhealthy levels of total cholesterol (>5.2 mmol/L for adults) during the time period of 2009-20111

3. Claimed effect to human health

3.1 Canada: Soy Protein and Cholesterol Lowering

3.2. Korea: Health claims: May help to maintain healthy blood cholesterol level

3.3 Malaysia: Soya protein helps to reduce cholesterol

4. Claim statement

4.1 Canada: Primary statement3: [Serving size from Nutrition Facts table in metric and common household measures] of (brand name) [name of food] supplies/provides X% of the daily amount of soy protein shown to help reduce/lower cholesterol. Additional statements: The following additional statements could be placed adjacent to the primary statement, in letters up to twice the size and prominence of those in the primary statement: -Soy protein helps reduce/lower cholesterol - High cholesterol is a risk factor for heart disease - Soy protein helps reduce/lower cholesterol, (which is) a risk factor for heart disease

5. Conditions and possible restrictions of use

5.1 Canada:

The food: a) contains at least 6 g of soy protein i. per reference amount and per serving of stated size, or ii. per serving of stated size, if the food is a prepackaged meal, a nutritional supplement or a meal replacement; b) contains at least 10% of the weighted recommended

nutrient intake (WRNI) of a vitamin or mineral nutrient i. per reference amount and per serving of stated size, or ii. per serving of stated size, if the food is a prepackaged meal, a nutritional supplement or a meal replacement; c) contains 100 mg or less of cholesterol per 100 g of food; d) contains 0.5% or less alcohol; e) contains i. less than 15% of the Daily Value (DV) of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less, or ii. less than 15% of the Daily Value (DV) of sodium per serving of stated size, if the food is a nutritional supplement or a meal replacement, or iii. less than 25% of the Daily Value (DV) of sodium per serving of stated size, if the food is a prepackaged meal; f) meets the conditions for “free of saturated fatty acids” or “low in saturated fatty acids” (Items 18 and 19, respectively, in the table following section B.01.513 of the Food and Drug Regulations); g) meets the requirements for fortified plant-based beverages if it is a soy beverage.

5.2 Korea:

(1) Daily intake amount: 15 g or more as soybean protein

(2) Warning notice for intake: The individual who has an allergy to soybean protein should be cautious to intake

5.3 Malaysia: Criteria

- Minimum amount required: 5 g per serving"
- Other conditions: To include the statement: Amount recommended to give the lowering effect on the blood cholesterol is 25 g per day.

6. References

1. Summary of Health Canada's Assessment of a Health Claim about Soy Protein and Cholesterol Lowering (2015) (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/label-etiquet/claims-reclam/assess-evalu/Sum-Assessment-Soy-April-2015-eng.pdf)
2. Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety (https://www.mfds.go.kr/eng/brd/m_15/down.do?brd_id=eng0001&seq=70011&data_tp=A&file_seq=1)
3. The Ministry of Health Malaysia. Malaysian Dietary Guidelines. Key Message 14: Make effective use of nutrition information on food labels (https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf)

เอกสารประกอบเพิ่มเติม

รายการเอกสารอ้างอิงที่ได้รับจาก EFSA (เรียงตามหมายเลข ID number)

List	Link	QR code
Consolidated list of Article 13 health claims List of references received by EFSA Part 1 IDs 1-1000	https://www.efsa.europa.eu/sites/default/files/topic/ndaart13ref01.pdf	
Consolidated list of Article 13 health claims List of references received by EFSA Part 2 IDs 1001-2000	https://www.efsa.europa.eu/sites/default/files/topic/ndaart13ref02.pdf	
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Consolidated list of Article 13 health claims List of references received by EFSA Part 4 IDs 3001-4705	https://www.efsa.europa.eu/sites/default/files/topic/ndaart13ref04.pdf	