# 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.)











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## ที่มาของการจัดทำรายการสารสำคัญที่ได้รับให้อยู่ใน Positive list เพื่อการกล่าวอ้างหน้าที่อื่น (Other function claims)

คณะทำงาน Food Innovation and Regulation Network (FIRN) โดยสมาคมวิทยาศาสตร์และ เทคโนโลยีทางอาหารแห่งประเทศไทย (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.	อักษร	หน่วยงาน	Regulation	Link	QR Code
	Country	ย่อ				
1	European	EU	European Food	Article 13 of	https://www.efsa.europa.eu	
	Union		Safety Authorit	Regulation (EC) No	<u>/en</u>	
			(EFSA) European	1924/2006		<b>网络安徽</b>
			Commission, the			回原機
			Panel on Dietetic			
			Products, Nutrition			
			and Allergies (NDA)			
2	Canada	Ca	Goverment of	Food and Drug	https://www.canada.ca/en/	
			Canada	Regulations C.R.C.,	<u>health-</u>	
			Published by the	с. 870	canada/services/food-	
			Minister of Justice		nutrition/food-	
					labelling/health-	







No	Ref.	อักษร	หน่วยงาน	Regulation	Link	QR Code
	Country	ย่อ				
					claims/assessments.html	
3	Australia -	AUS-	Federal Register of	Standard 1.2.7 –	https://www.foodstandards.	
	New	NZ	legislation	Nutrition, health	gov.au/industry/labelling/fh	
	Zealand			and related claims	r/Pages/default.aspx	
4	Korea	KR	Ministry of Food	Health Functional	https://www.mfds.go.kr/eng	
			and Drug Safety	Food Code 2021	/brd/m_15/down.do?brd_id	
					<u>=eng0001&amp;seq=70011&amp;data</u>	
					_tp=A&file_seq=1	
5	Singapore	SG	Singapore Food	A Guide to Food	https://www.sfa.gov.sg/docs	具態機能具
			Agency	Labelling and	<u>/default-source/tools-and-</u>	
				Advertisements	resources/resources-for-	
					businesses/aguidetofoodlab	
					ellingandadvertisements.pd	
					f	
6	Malaysia	MYS	The Ministry of	Malaysian Dietary	https://www.moh.gov.my/	
			Health Malaysia	Guidelines	moh/images/gallery/Garispa	基準的發
				Key Message 14	nduan/diet/km14.pdf	
				Make effective use		
				of nutrition		
				information on		
				food labels		







#### สรุปข้อมูลบัญชีแสดงข้อความการกล่าวอ้างหน้าที่อื่นจาก 6 ประเทศ

จากข้อมูลการเปรียบเทียบรายการสารสำคัญเชิงหน้าที่อื่นที่ต่างประเทศอนุญาตให้กล่าวอ้างเชิงหน้าที่ (Functional claim) คณะทำงานได้คัดเลือกรายการสารสำคัญและส่วนประกอบอาหารเชิงฟังก์ชันที่มีข้อมูล สนับสนุน จำนวน 17 สำหรับรายงานเพื่อพิจารณาในคณะกรรมการของสำนักงานคณะกรรมการอาหารและ ยา (อย.) รายการ โดยสามารถสรุปรายชื่อสารสำคัญ/ส่วนประกอบเชิงหน้าที่และจำนวนประเทศที่รับรอง รายการดังกล่าวใน positive list ของประเทศนั้น

ตารางที่ 2: ประเทศที่รับรองรายการสารสำคัญ/ส่วนประกอบเชิงฟังก์ชันใน positive list

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







คณะทำงานได้สรุปข้อมูลบัญชีแสดงข้อความการกล่าวอ้างหน้าที่อื่นจาก 6 ประเทศ (ตารางที่ 3) โดยมี ข้อมูลในแต่ละหัวข้อ ดังนี้

- No. : ลำดับ
- Functional ingredients (nutrients, substance): รายชื่อสารสำคัญ/ส่วนประกอบเชิงหน้าที่ (สาร ตัวเดียวกันอาจมีคำเรียกที่แตกต่างกันไปในแต่ละประเทศ)
- Reference Country : อักษรย่อแสดงแหล่งข้อมูลของประเทศที่นำมาอ้างอิง
- 1. Characterisation of the food/constituent : คุณลักษณะของสารสำคัญ/ส่วนประกอบเชิงหน้าที่
  - 1.1 Standards for manufacturing : มาตรฐานการผลิตส่วนประกอบเชิงฟน้าที่ เช่น แหล่ง วัตถุดิบที่ใช้, 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	Ref.		f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications		health		restrictions of use		
1	Alpha-linolenic	EU	The food constituent th	at is the subject of the	Clinical trials comparing the effects of	The claimed effect is	"Alpha-linolenic acid	In order to bear the claim a food	EFSA journal	https://efsa.o
	acid (ALA)		health claims is alpha-li	nolenic acid (ALA), an	different vegetable oils on serum lipids in	"contributes to healthy blood	contributes to	should contain at least 15% of	number: 2009;	nlinelibrary.wi
			essential n-3 polyunsatu	urated fatty acid with 18	normolipidaemic subjects have shown that	cholesterol level/helps to	maintenance of normal	the proposed labelling reference	7(9):1252	ley.com/doi/
			carbon atoms and three	e double bonds. ALA is a	the effect of alpha-linolenic acid (ALA) on	maintain normal cholesterol	blood cholesterol	intake value of 2 g ALA per day.		pdf/10.2903/j.
			well recognised nutrient	t, is well absorbed when	serum cholesterol is similar to that of	level/maintenance of normal	concentrations".	Such an amount can be easily		efsa.2009.125
			consumed in the form o	of triglycerides and is	linoleic acid (LA) (Mantzioris <i>et al.</i> , 1994;	blood cholesterol level". The		consumed as part of a balanced		2
			measurable in foods by	well established	Valsta et al., 1995; Pand et al., 1998). In a	target population is the		diet. The target population is the	EFSA Journal	https://efsa.o
			methods.		meta- analysis of 60 randomised controlled	general population.		general population.	number:	nlinelibrary.wi
					clinical trials, the replacement of 1% of	Maintenance of normal blood			2011;9(6):2203	ley.com/doi/
					energy from carbohydrates by	cholesterol concentrations is				pdf/10.2903/j.
					polyunsaturated fatty acids (PUFA), mainly	beneficial to human health.				efsa.2011.220
					as LA, reduced serum LDL cholesterol					3
					levels by 0.02 mmol/l (Mensink <i>et al.</i> ,					
					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 <i>et al.</i> (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).					







Ne	0.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of      1.1 Standards for     manufacturing	the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
2	В	eta-glucans	EU	Beta-glucans are soluble non-starch polysaccharic glucose molecules in lor polymers with mixed β-links with an approximat 70 %. Their molecular w 2,000 kDa. Beta-glucans obran of cereal grasses su oats (~5 %), rye and whe measurable in foods by This opinion applies to be present in foods, and ad	des composed of ang linear glucose $(1\rightarrow 4)$ and $\beta$ - $(1\rightarrow 3)$ we distribution of 30 % to reight varies from 50 to occur naturally in the ach as barley (~7 %), eat (1-2 %), and are established methods.	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/10.2 903/j.efsa.20 09.1254
						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/10.2 903/j.efsa.20 11.2207







No.	Functional ingredients	Ref.	1. Characterisation of	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
NO.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	o. References	7. LITIKS
					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)		milling fractions derived	rley, barley flakes, grits, l as beta-glucan enriched from sieving or air rial or flour fractions, but	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	the daily amount of barley beta- glucan provided in one serving should be expressed to the nearest multiple of 5%.	Summary of Health Canada's Assessment of a Health Claim about Barley Products and Blood Cholesterol Lowering (2012)	.canada.ca/c ontent/dam







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of     Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
	substance		manufacturing		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" t 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	Ref.	1. Characterisation of	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
NO.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	o. hererences	7. LIIIKS
								ground material or flour fractions, but they exclude extracted barley beta-glucan.		
	Oat product	Ca	For the purposes of this	decision document,	Health Canada has concluded that	Oat Products and Blood	"[serving size from	The "daily amount" referred to	Oat Products and	https://www
	(beta-glucan		Health Canada has dete		scientific evidence exists in support of the	Cholesterol Lowering	Nutrition Facts table in	·	Blood Cholesterol	.canada.ca/c
	oat fibre)		sources of beta-glucan o	oat fibre are: oat bran,	claim linking the consumption of beta-		metric and common	grams beta-glucan oat fibre. In	Lowering Summary	ontent/dam
			rolled oats (also known	as oatmeal), and whole	glucan oat fibre to a reduction of blood		household measures]2	this statement, the percentage of	of Assessment of a	<u>/hc-</u>
			oat flour, either as food	themselves (oat bran	cholesterol. The claim is relevant and		of (Brand name) [name	the daily amount of beta-glucan	Health Claim about	sc/migration
			and rolled oats) or as in	gredients (oat bran,	generally applicable to the Canadian		of food] [with name of	oat fibre provided in one serving	Oat Products and	<u>/hc-sc/fn-</u>
			rolled oats and whole o	oat flour) in formulated	population given that a high proportion of		eligible fibre source]*	should be expressed to the	Blood Cholesterol	an/alt_form
			foods. The specifications	s for the eligible sources	the population (44 to 69%) is		supplies/provides [X %	nearest multiple of 5%.	Lowering (2010)	ats/pdf/labe
			of oat beta- glucan are a	as follows: • Oat bran:	hyperlipidemic and that adults with		of the daily amount] of	Conditions for foods to carry the		<u>L</u>
			oat bran is produced by	grinding clean oat	normal or mildly elevated blood		the fibres shown to	claim Oat products, whether		etiquet/clai
			groats or rolled oats and	d separating the resulting	cholesterol concentrations could also		help reduce/lower	consumed as food or as		ms-
			oat flour by suitable me		benefit from increased oat intake.		cholesterol." The	ingredients, must meet the		reclam/asse
			that the oat bran fractio				following additional	specifications for eligible sources		SS=
			percent of the original s	-			statements, which can	of oat beta-glucan described in		evalu/oat_a
			provides at least 5.5 per	rcent (dry weight basis			be placed, adjacent to	section 1 of this document.		<u>voine-</u>







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







Function ingrediction (nutrie	ients	Ref. Country	Characterisation o     1.1 Standards for	f 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
substa	ance		manufacturing	1.2 Specifications						
				•				less; and 6. Meet the definition of		
								"free of saturated fatty acids" or		
								"low in saturated fatty acids".		
Beta-gluc	can .	AUS-NZ	Diet low in saturated fa	tty acids / Diet containing		Reduces dietary biliary		Condition: The food must	Australia New	https://irp.c
			3 g of beta-glucan per c	day		cholesterol absorption		contain: (a) one or more of the	Zealand Food	<u>dn-</u>
								following oat or barley foods (i)	Standards Code –	website.co
								oat bran; or (ii) wholegrain oats;	Schedule 4 –	m/69f086d6
								or (iii) wholegrain barley; and (b)	Nutrition, health	/files/uploa
								at least 1 g per serving of beta-	and related claims	ded/FSANZ
								glucan from the foods listed in	(F2017C00711)	%20Food%2
								(a).	Authorised Version	<u>OStandards</u>
									F2017C00711	%20Schedul
									registered	e%204.pdf
				1					08/09/2017	
Ganodern	ma	KR	(1) Raw material:	(1) Appearance: Unique		Health claims: May help to		(1) Daily intake amount: 24 ~ 42	Korea Health	https://www
lucidum 1	fruit		Ganoderma lucidum	color and flavor, no off-		maintain healthy blood flow		mg as B-glucan	Functional Food	.mfds.go.kr/
body extr	tracts		(Ganoderma lucidum	taste and off-flavor					Code 2021. Ministry	eng/brd/m_
			or Ganoderma tsugae)	(2) B-Glucan (The B-					of Food and Drug	15/down.do
(B-glucan	n is		fruit body	glucan originated from					Safety	?brd_id=eng
function	cal		(2) Preparation and/or	other ingredients shall						0001&seq=7
compoun	nd)		processing: It shall be	be labeled separately.)						0011&data_t
			in edible form by	(a) Semi-processed						p=A&file_se
			filtering and	product: No less than						<u>q=1</u>
			concentrating after	labeled amount						
			extracting the raw	(b) Final product: 80 ~						
			materials with hot	120% of the labeled						
			water.	amount						
			(3) Content of	(3) Coliform: Negative						
			functional compounds							







Ne	Functional ingredients	Ref.	1. Characterisation of	f the food/constituent	0.6	3. Claimed effect to human	4.61.	5. Conditions and possible	( Defense	7.11.1
No.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	6. References	7. Links
			(or marker							
			compounds): B-Glucan							
			shall be contained 10							
			mg/g or more.							
	Phellinus		(1) Raw materials:	(1) Appearance: Unique		Health claims: May help to		(1) Daily intake amount: 3.3 g as		https://www
	linteus extracts		Phellinus linteus (3 ~ 4	color and flavor, no off-		support immune function		Phellinus linteus extracts (287.1		.mfds.go.kr/
			years old dry)	taste and no off-flavor				~ 534.6 mg as B-glucan)		eng/brd/m_
	(B-glucan is		(2) Preparation andor	(2) B-glucan						15/down.do
	functional		processing: It shall be	(a) Semi-processed						?brd_id=eng
	compound)		in edible form by	product: No less than						0001&seq=7
			pulverizing the raw	labeled amount						0011&data_t
			material under 3mm	(b) Final product: 80 ~						p=A&file_se
			size, extracting (1100C,	120% of labeled						<u>q=1</u>
			96 ~ 100 hours) with	amount						
			water (10 times more	(3) Heavy metal						
			amount than	(a) Lead (mg/kg): No						
			materials), high-press	more than 1.0						
				(b) Cadmium (mgkg): No						
			drying (75 ~ 800C, heat							
			dry), pulverizing.	(c) Mercury (mg/kg): No						
			(3) Content of	more than 0.3						
			functional compounds							
			(or marker	more than 1.0						
			compounds): B-glucan	(4) Coliform: Negative						
			shall be contained 87							
			mg/g or more.							
			(4) Conditions for							
			manufacturing: Raw							
			material shall be in							







	Functional ingredients	Ref.	1. Characterisation of	the food/constituent		3. Claimed effect to human		5. Conditions and possible		
No.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	6. References	7. Links
			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/aguidetofoodlabellingandadvertisements.pdf







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of     Standards for     manufacturing	the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
								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		







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of     Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			3					the food under the nutrition information panel.		
	Oat soluble	MYS				Oat soluble fibre (beta-glucan)		(B-glucan)	Malaysian Dietary	https://www
	fibre (beta-					:		Oat soluble fibre in relation to	Guidelines	.moh.gov.m
	glucan)					i. Oat soluble fibre (beta-		cholesterol claim	Key Message 14	y/moh/imag
						glucan) helps lower or reduce		Minimum amount: 2 g per 100 g	Make effective use	es/gallery/G
						cholesterol		(solids)	of nutrition	<u>arispanduan</u>
						ii. Oat soluble fibre (beta-		Other conditions: Must also	information on	/diet/km14.
						glucan) helps to lower the rise		contains total dietary fibre not	food labels	pdf
						of blood glucose provided it is		less than amount required to		
						not consumed together with		claim as "source":		
						other food		3 g per 100 g (solids)		
								1.5 g per 100 ml (liquids)		
								(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		







								1 1811 136 1811 181 181 181 181 181 181 181 181		
No	(nutrients,	Ref. Country	1.1 Standards for	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
	substance		manufacturing							
								statement "For advice regarding		
								consuming this consult product,		
								your medical professional"		
3	Chitosan	EU	Chitosan is a linear catio	onic polysaccharide	The mechanism by which chitosan is	Maintenance of normal blood	"Chitosan may contribute	In order to obtain the claimed	EFSA journal	https://efsa.
			composed of randomly	distributed -(1-4)-linked	presumed to exert the claimed effect is by	cholesterol concentrations	to maintaining normal	effect, 3 g of chitosan should be	number:	<u>onlinelibrary</u>
			D-glucosamine and N-ac	cetyl-D-glucosamine	binding to negatively charged lipids and		blood cholesterol levels".	consumed daily. The target	2011;9(6):2214	.wiley.com/
			produced commercially	by the deacetylation of	hence reducing their gastro-intestinal			population is adults.		doi/pdf/10.2
			chitin, which is a compo	onent of the exoskeleton	uptake, and these effects were observed					903/j.efsa.20
			of crustaceans and the	cell walls of fungi. The	in some animal studies (Deuchi et al.,					11.2214
			degree of deacetylation	can be measured by	1995; Sugano <i>et al.</i> , 1980; Zacour <i>et al.</i> ,					
			established methods, ar	nd ranges from 60-100 %	1992). The effects of chitosan on 24 h					
			in commercial preparati	ions. The molecular	faecal fat excretion in healthy human					
			weight of chitosan in co	mmercial preparations	volunteers at doses of about 3 g daily					
			ranges from 3,800 to 20	,000 Da. Chitosan is	were not statistically significant (Guerciolini					
			insoluble in water.		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.					







	Functional ingredients	Ref.	1. Characterisation of	f the food/constituent		3. Claimed effect to human	,	5. Conditions and possible		
No.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	6. References	7. Links
	Chitosan /	KR	(1) Raw material: A shell	(1) Appearance: Unique		Health claims: May help to		(1) Daily intake amount	Korea Health	https://www
	Chitooligosacc		of crustacean (crab,	color and flavor, no off-		maintain healthy blood		(a) May help to maintain health	Functional Food	.mfds.go.kr/
	haride		shrimp, etc.), Mollusk	taste and off-flavor		cholesterol level, reduce body		blood cholesterol level: 1.2 ~ 4.5	Code 2021. Ministry	eng/brd/m_
			(squid, cuttlefish, etc.)	(2) Chitosan or		fat		g as sum of chitosan and	of Food and Drug	15/down.do
			bone	Chitooligosaccharide (a)				chitooligosaccharide	Safety	?brd_id=eng
			(2) Preparation and/or	Semi-processed				(b) May help to reduce body fat:		0001&seq=7
			processing	product: No less than				3.0 ~ 4.5 g as chitosan, 3 g as		0011&data_t
			(a) Chitosan: It shall be in	labeled amount (b)				chitooligosaccharide		p=A&file_se
			edible form by	Final product: 80 ~				(2) Warning notice for intake: The		<u>q=1</u>
			diacetylating chitin ( $eta$ -1,4	120% of labeled				individual who has an allergy to		
			bound polymer of N-	amount				crab and/or shrimp should be		
			acetylglucosamine)	(3) Heavy metal				cautious to intake (limited to		
			obtained by	(a) Lead (mg/kg): No				using crab and/or shrimp as raw		
			deproteinizing and	more than 3.0				material)		
			decalcifying the raw	(b) Cadmium (mg/kg):						
			materials.	No more than 1.0						
			(b) Chitooligosaccharide:	(c) Mercury (mg/kg): No						
			It shall be in edible form	more than 1.0						
			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							







	Functional		1. Characterisation o	f the food/constituent						
No.	ingredients (nutrients, substance	Ref. Country	1.1 Standards for	1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
	substance		manufacturing							
			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.							
			200 mg/g or more.							
4	Conjugated	KR	(1) Raw material:	(1) Appearance: Unique		(1) Health claims: May help to		(1) Daily intake amount: 1.4 ~ 4.2	Korea Health	https://www
	linoleic acid		Safflower seed oil	color and flavor, no off-		reduce body fat in the		g as conjugated linoleic acid	Functional Food	.mfds.go.kr/
			2) Preparation and/or	taste and off-flavor		overweight adult		2) Warning notice for intake	Code 2021. Ministry	eng/brd/m_
			processing	(2) Content of				(a) It may cause gastrointestinal	of Food and Drug	15/down.do
			(a) After saponifying	conjugated linoleic acid				disorder	Safety	?brd_id=eng
			and conjugated	(The sum of cis-9/trans-				(b) Infant and pregnant women		0001&seq=7
			isomerizing the raw	11, trans-10/cis-12. cis-				should be avoid intake		0011&data_t
			materials, the fatty	9/cis-11, and trans-				(c) Diet control and exercises		p=A&file_se
			acid shall be in edible	9/trans-11 conjugated				together are effective in reducing		<u>q=1</u>
			form by extracting with	linoleic acids).				body fat		
			fermented ethanol or	(a) Semi-processed						
			hexane, or purifying,	product: No less than						
			deodorizing and	labeled amount						
			filtering.	(b) Final product: 80 ~						
			(b) Triglyceride form:	120% of labeled						
			After glycerifying	amount						
			conjugated linoleic	(3) Contents of cis-						
			acid in fatty acid form	9/trans-11 and trans-						
			with lipase, it shall be	10/cis-12 conjugated						
			in edible form by	linoleic acids (%): No						
			extracting with	less than 90% of						







No.	Functional ingredients	Ref.		f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications		health		restrictions of use		
			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	conjugated linoleic acid content						
5	Eicosapentaen oic acid and docosahexaen oic acid (EPA/DHA)		more.  The food constituent whealth claims is mixed lipolyunsaturated fatty anamely docosahexaeno combination with eicosa	ong-chain n-3 cids (n-3 LCPUFA), ic acid (DHA) in	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".	250 mg per day are required to	EFSA journal number: 2010;8(10):1796	https://efsa. onlinelibrary wiley.com/ doi/pdf/10.2 903/j.efsa.20 10.1796







No.	Functional ingredients	Ref.	1. Characterisation of	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
140.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	o. nererences	7. LITIKS
					(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.		
	PA and/or IHA		The foods that are the sclaim are foods containing acid (EPA) and/or docost EPA and DHA are long-cwith lipid structures of 2 respectively.	ing eicosapentaenoic ahexaenoic acid (DHA). hain omega-3 fatty acids	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	.canada.ca/c ontent/dam







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of     1.1 Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
					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 abovementioned 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/clai ms- reclam/asse ss- evalu/eicosa pentaenoic- acid-acide- eicosapenta enoique- eng.pdf







Functional ingredients	Ref.	1. Characterisation of	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	o. References	7. LITIKS
							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.		
Eicosapentaen	AUS-NZ	Diet containing 500mg o	of EPA and DHA per day		Contributes to heart health	-	(a) The food must contain a	Australia New	https://irp.c
oic acid							minimum of 50mg EPA and DHA	Zealand Food	<u>dn-</u>
(EPA)and							combined in a serving of food;	Standards Code –	website.co
docosahexaen							and (b) other than for fish or fish	Schedule 4 –	m/69f086d6
oic acid							products with no added	Nutrition, health	/files/uploa
(DHA)(but not							saturated fatty acids—the food	and related claims	ded/FSANZ







No.	Functional ingredients (nutrients,	Ref.	Characterisation of      1.1 Standards for	f 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
	substance		manufacturing	1.2 Specifications						
	Omega-3)							contains: (i) as a proportion of	(F2017C00711)	%20Food%2
								the total fatty acid content, no	Authorised Version	<u>OStandards</u>
								more than 28% *saturated fatty	F2017C00711	%20Schedul
								acids and trans fatty acids; or (ii)	registered	e%204.pdf
								no more than 5 g per 100 g	08/09/2017	
								saturated fatty acids and trans		
								fatty acids		
	Edible oil	KR	(1) Raw material: Edible	(1) Appearance: Unique		(1) Health claims: May help to		(1) Daily intake amount	Korea Health	https://www
	containing EPA		fishes, seaweeds,	color and flavor, no off-		maintain healthy triglyceride		(a) May help to maintain healthy	Functional Food	.mfds.go.kr/
	and DHA (KR)		Pagophilus	taste and off-flavor		level, maintain healthy blood		triglyceride level, maintain	Code 2021. Ministry	eng/brd/m_
			groenlandicus	(2) The sum of EPA and		flow, improve memory,		healthy blood flow: $0.5 \sim 2$ g as	of Food and Drug	15/down.do
			(2) Preparation and/or	DHA		maintain eye health as the		the sum of EPA and DHA	Safety.	?brd_id=eng
			processing: The oil shall	(a) Semi-processed		improvement of dry eyes		(b) May help to improve		0001&seq=7
			be in edible form by	product: No less than				memory: 0.9 ~ 2 g as the sum of		0011&data_t
			heating the raw	labeled amount				EPA and DHA		p=A&file_se
			material, pressing and	(b) Final product: 80 ~				(c) May help to maintain eye		<u>q=1</u>
			extracting with hexane	120% of labeled				health as the improvement of		
			or carbon dioxide	amount				dry eyes: 0.6 ~ 1 g as the sum of		
			(supercritical fluid	(3) Solvent residue				EPA and DHA		
			extraction) and then	(mg/kg): No more than				(2) Warning notice for intake		
			filtering or esterification	5.0 (in case of using				(a) Consult a health care		
			after extraction.	hexane)				practitioner prior to intake if you		
			(3) Content of					are taking medicines related with		
			functional compounds					blood coagulation and/or anti-		
			(or marker					platelet and/or antihypertensive		
			compounds): As the					agents		
			sum of EPA and DHA, it					(b) It may cause side-effect such		
			shall be contained 180					as skin reaction		
			mg/g or more from					(c) Consult a health care		







	Functional ingredients	Ref.	1. Characterisation of	f the food/constituent		3. Claimed effect to human		5. Conditions and possible		
No.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	6. References	7. Links
			edible fishes, 120 mg/g					practitioner and stop intake if		
			or more from					you are having adverse event		
			Pagophilus							
			groenlandicus and 300							
			mg/g or more from							
			seaweeds.							
6	Fructooligosacc	KR	(1) Raw material and	(1) Appearance: Unique		(1) Health claims: May help to		(1) Daily intake amount: 3 ~ 8 g	Korea Health	https://www
	haride		preparation and/or	color and flavor, no off-		maintain healthy		as fructooligosaccharide	Functional Food	.mfds.go.kr/
			processing	taste and off-flavor		gastrointestinal bacteria		(2) Warning notice for intake	Code 2021. Ministry	eng/brd/m_
			(a) Beta-1,2	(2)		population, maintain healthy		(a) It may cause gastrointestinal	of Food and Drug	15/down.do
			oligosaccharides	Fructooligosaccharide		bowel function		gas, burp, stomachache,	Safety	?brd_id=eng
			bound sucrose with	(a) Semi-processed				abdominal inflation		0001&seq=7
			1~3 fructose units	product: No less than				(b) Consult a health care		0011&data_t
			shall be	labeled amount				practitioner and stop intake if		p=A&file_se
			manufactured-	(b) Final product: 80 ~				you are having adverse event		<u>q=1</u>
			processed with	120% of labeled						
			transferase or	amount						
				(3) Lead (mgkg): No						
			transferase after	more than 1.0						
			making liquid by							
			melting sugar.							
			(b) It shall be							
			manufactured-							
			processed by							
			hydrolyzing inulin with							
			enzyme.							
			(2) Content of							
			functional compounds							
			(or marker							







	Functional		1 Characterisation of	the food/constituent		,		THE THE THE THE TENT TO THE TE		https://www .sfa.gov.sg/d ocs/default- source/tools -and- resources/re
lo.	ingredients (nutrients, substance	Ref. Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			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).							
	Fructooligosacc haride	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	manufacturer/importer to ensure	A Guide to Food Labelling and Advertisements	.sfa.gov.sg/c ocs/default source/tool -and-







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of      1.1 Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
	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.m y/moh/imag es/gallery/G arispanduan /diet/km14. pdf
7	Glucomannan (konjac mannan)		a water-soluble type of straight chain of $\beta$ -1—aglucose units in a ratio camount of branching (8 glucosyl linkages. It is deroots of the Konjac plankonjac). Glucomannan is human small intestine. I weight (200-2000 kDa) ar	4 D-mannose and D- of 1.6:1 with a small %) through β-(1→6)- erived from the tuberous at (Amorphophallus s non-digestible in the lt has a high molecular and high viscosity in water does not occur naturally ive used as emulsifier ually consumed in the	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 doseresponse 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/10.2 903/j.efsa.20 09.1258







No.	Functional ingredients	Ref.	1. Characterisation of	the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications		health		restrictions of use		
					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	Reduction of body weight	"Glucomannan	In order to obtain the claimed	EFSA journal	https://efsa.
					(>3 months) on the effects of		contributes to the	effect, at least 3 g of	number:	<u>onlinelibrary</u>
					glucomannan on body weight are		reduction of body weight	glucomannan should be	2010;8(10):1798	.wiley.com/
					available. The Panel also notes that		in the context of an	consumed daily in three doses of		doi/pdf/10.2
					glucomannan is a soluble-type of fibre		energy-restricted diet".	at least 1 g each, together with		903/j.efsa.20
					which forms a viscous, gel-like mass in the		The following additional	1-2 glasses of water before		10.1798
					stomach when hydrated, and that this		statements may be	meals, in the context of an		
					"mass effect" could delay gastric		placed adjacent to the	energy-restricted diet. The target		
					emptying and induce satiety leading to a		primary statement, in	population is overweight adults.		
					decrease in subsequent energy intake		letters up to twice the			
					(Keithley and Swanson, 2005). In weighing		size and prominence of			
					the evidence, the Panel took into account		those in the primary			
					that most of the intervention studies,		statement: • PGX® helps			
					which were of adequate sample size and		reduce/lower cholesterol			
					duration, found a statistically significant		High cholesterol is a risk			
					effect of glucomannan on body weight		factor for heart disease •			
					loss in the context of a hypocaloric diet		PGX® helps reduce/lower			







No.	Functional ingredients (nutrients,	Ref.	Characterisation of     1.1 Standards for	f 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
	substance		manufacturing	1.2 Specifications						
					when administered as a pre-load before meals, and that the mechanism by which		cholesterol, (which is) a risk factor for heart			
					glucomannan could exert the claimed		disease			
					effect is established. Panel concludes that		discuse			
					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.					
				Т						
	Glucomannan	KR		(1) Appearance: Unique		(1) Health claims: May help to		(1) Daily intake amount: 2.7 ~ 17	Korea Health	https://www
	(Konjac,		family konjac	color and flavor, no off-		maintain healthy blood		g as glucomannan dietary fiber	Functional Food	.mfds.go.kr/
	Konjacmannan		(Amorphophallus	taste and off-flavor		cholesterol level, maintain		(2) Warning notice for intake:	1	
	)		konjq) rhizome	(2) Dietary fiber		healthy bowel function		Should be taken with sufficient	of Food and Drug	15/down.do
			(2) Preparation and/or	(a) Semi-processed				water except for liquid type	Safety	?brd_id=eng
			processing:	product: No less than				product		0001&seq=7
			Polysaccharides shall	labeled amount						0011&data_t
			-	(b) Final product: No						p=A&file_se
			extracting the raw materials with	less than 80% of labeled amount						q=1
			isopropyl alcohol and	(3) Solvent residue						
			purifying.	(mgkg): No more than						
			(3) Content of	50.0						
			functional compounds	30.0						
			(or marker							
			compounds): Dietary							
			fiber shall be							
			contained 690 mg/g or							
			more.							







No.	Functional ingredients (nutrients, substance	Ref. Country	1. Characterisation of     1.1 Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
8	Guar gum	EU	Guar gum is a water-solu galactomannan compos mannose units with D-ga every second mannose the cluster bean (Cyamo	ded of a backbone of D- alactose attached at unit. It is derived from opsis tetragonoloba (L.) -digestible in the human decular weight is about of naturally occurring in assumed in the form of r gum has a high thickener by the food	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/pdfdirec t/10.2903/j.e fsa.2010.146 4?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://ww w.mfds.go.k r/eng/brd/ m_15/down .do?brd_id =eng0001& seq=70011 &data_tp= A&file_seq =1







No.	Functional ingredients	Ref.	1. Characterisation of	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
NO.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	o. References	7. LITIKS
			(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)	product: No less than labeled amount (b) Final product: No		(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=eng 0001&seq=7 0011&data_t p=A&file_se q=1







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of      Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			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)		The applicant initially st constituent that is the s claim is "Orafti®Inulin". EFSA's request for clarif explained that "chicory constituent that is the s claim. Chemically, inulir fructan with a degree of which typically has a tern NDA Panel, 2010). Chico root is one of the plants concentration of inulin. extracted as a non-fract monosaccharides, disaccoligosaccharides (inulinand non-starch polysaccolifluencing factors for chare growth conditions an as process technology. In the plants of the plants	ubject of the health. In response to the fication, the applicant inulin" is the food ubject of the health in is a linear $\beta(2\rightarrow 1)$ -f polymerisation (DP) > 9 rminal $\alpha$ -glucose (EFSA ary (Chicorium intybus) is with the highest "Native chicory inulin" is ionated mixture of charides, type fructans, DP 3 – 9) charides (inulin, DP > 9). The hain length distribution and harvest time as well	The Panel notes that inulin and inulintype 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 inulintype 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/10.2 903/j.efsa.20 15.3951







No.	Functional ingredients	Ref.	1. Characterisation o	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
NO.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	o. neierences	7. LITIKS
			provided, including the	human studies	could exert the claimed effect.					
			submitted for the scien	tific substantiation of the	The Panel concludes that a cause and					
			claim, the Panel notes	that this claim relates to	effect relationship has been established					
			"native chicory inulin",	a non-fractionated	between the consumption of "native					
			mixture of monosaccha	rides (< 10%),	chicory inulin", a non-fractionated mixture					
			disaccharides, oligosacc	harides (inulin-type	of monosaccharides (< 10%),					
			fructans) and polysacch	arides (inulin) extracted	disaccharides, inulin-type fructans and					
			from fresh chicory roots	characterised by its	inulin extracted from chicory with a mean					
			mean DP (> 9).		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.					
lı	nulin / Chicory	KR	(1) Raw material:	(1) Appearance: Unique		(1) Health claims: May help to		(1) Daily intake amount	Korea Health	https://www
e	extract		Chicory (Chicorium	color and flavor, no off-		maintain healthy blood		(a) May help to maintain healthy	Functional Food	.mfds.go.kr/
			intybus) or other	taste and off-flavor		cholesterol level, maintain		blood cholesterol level, maintain	Code 2021. Ministry	eng/brd/m_
			Compositae family	(2) Dietary fiber		healthy postprandial glucose		healthy postprandial glucose	of Food and Drug	15/down.do
			plants	(a) Semi-processed		level, maintain healthy bowel		level: 7.2 ~ 20 g as inulin /	Safety	?brd_id=eng
			(2) Preparation and/or	product: No less than		function		chicory dietary fiber		0001&seq=7
			processing: It shall be	labeled amount				(b) May help to maintain healthy		<u>0011&amp;data_t</u>
			in edible form by	(b) Final product: No				bowel function: 6.4 ~ 20 g as		p=A&file_se
			extracting the root of	less than 80% of				inulin / chicory dietary fiber		q=1







No.	Functional ingredients	Ref.		f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications		health		restrictions of use		
			raw materials with hot	labeled amount				(2) Warning notice for intake:		
			water and then	(3) Coliform: Negative				Should be taken with sufficient		
			purifying.					water except for liquid type		
			(3) Content of					product		
			functional compounds							
			(or marker							
			compounds): Dietary							
			fiber shall be							
			contained 800 mg/g or							
			more.							
	Inulin	SG					Claim:	Criteria:	A Guide to Food	https://www
							1. Inulin helps in calcium		Labelling and	.sfa.gov.sg/d
							absorption	reference quantity of the food as	Advertisements	ocs/default-
								specified Table II in section		source/tools
								"Nutrition claims"		<u>-and-</u>
								2. The amount of calcium has to		resources/re
								be declared under the nutrition		sources-for-
								information panel		businesses/
								3. The amount of inulin present		<u>aguidetofoo</u>
								in each serving or other equivalents of the product must		dlabellingan dadvertisem
								be declared on the product		ents.pdf
								label		ents.pai
								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.		







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of      Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
							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.m y/moh/imag es/gallery/G arispanduan /diet/km14. pdf
11	Live yoghurt cultures		The food constituent th health claim is "yoghurt contain the starter micro "Lactobacillus delbruec	t cultures (live)", which o-organisms	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







No.	Functional ingredients (nutrients,	Ref.	1.1 Standards for	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
	substance		manufacturing  Streptococcus thermop cultures "Lactobacillus bulgaricus and Streptoc well specified for their umanufacture by Codex No. 243/2003.	delbrueckii subsp. occus thermophilus" are use 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.		maldigestion".	delbrueckii subsp. bulgaricus and Streptococcus thermophilus) per gram. 16 The target population is individuals with lactose maldigestion.		903/j.efsa.20 10.1763
	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.c dn- website.co m/69f086d6 /files/uploa ded/FSANZ %20Food%2 0Standards %20Schedul e%204.pdf
12	Oleic acid	EU	of the health claims are acids (mainly oleic acid) "extravirgin olive oil". Ir proposed wordings, clar	n the context of 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/10.2 903/j.efsa.20 11.2043







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of     1.1 Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			scientific substantiation	of the health claims, the	MUFAs (EFSA, 2004; EFSA Panel on Dietetic		acid is an unsaturated fat."	complying with requirements of		
			Panel assumes that the	food constituent that is	Products Nutrition and Allergies (NDA),			nutrition claims "High mono-		
			the subject of the healtl	h claims is oleic acid,	2010; IoM, 2005; Lichtenstein <i>et al.</i> , 2006;			unsaturated fatty acids".		
			which should replace sa	aturated fatty acids (SFAs)	Mensink et al., 2003; WHO/FAO, 2003), and					
			in foods or diets in orde	er to obtain the claimed	that there is a linear dose-response					
			effects. Oleic acid is the	monounsaturated fatty	relationship between blood LDL-					
			acid (MUFA) with 18 carb	bon atoms and the	cholesterol concentrations and the					
			double bond in the 9-ci	is position. It is found in	amounts of long-chain SFAs consumed. It					
			varying amounts in dieta	ary fats. Beef tallow	is also well established that consumption					
			contains about 43 % ole	eic acid and 47 % SFAs,	of a mixture of SFAs results in increased					
			lard about 44 % oleic ac	cid and 43 % SFAs, palm	blood HDL-cholesterol concentrations					
			oil about 40 % oleic acid	d and 45 % SFAs,	compared with consumption of mixtures					
			rapeseed oil about 60 %	6 oleic acid and 6 %	of cis-MUFAs (e.g. oleic acid), and that					
			SFAs. A high proportion	of oleic acid is found in	incomparison with other fatty acids,					
			olive oil, 71 %, together	with 15.5 % SFAs and	except trans fatty acids (TFAs), SFAs					
			12 % polyunsaturated fa	atty acids (PUFAs). High-	increase the total–to-HDL cholesterol ratio					
			oleic acid varieties of su	inflower oil and	(Mensink <i>et al.</i> , 2003).					
			rapeseed oil contain abo	out 75-85 % oleic acid.						
			Saturated fatty acids (SF	As) are aliphatic	SFAs differ in their potential to change					
			monocarboxylic acids w	rith (generally) an even	blood lipid and lipoprotein concentrations.					
			number of carbon atom	ns (usually from 4 to 20)	While lauric, myristic and palmitic acid					
			and no double bonds w	which can be liberated by	raise blood total and LDL-cholesterol					
			hydrolysis of triacylglyce	erols from fats and oils.	concentrations, effects of stearic acid and					
			The most prevailing SFA		short and medium chain SFAs (with 4-10					
			acid (12:0), myristic acid	•	carbon atoms) are similar to those of					
			(16:0), and stearic acid (1	·	carbohydrates and oleic acid (EFSA Panel					
			applies to the replacem		on Dietetic Products Nutrition and Allergies					
i			as present in foods or di	iets with oleic acid.	(NDA), 2010; Mensink <i>et al.</i> , 2003).					
					However, SFAs are present in foods as					







No.	Functional ingredients (nutrients,	Ref.	Characterisation of     1.1 Standards for	f 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
	substance		manufacturing	·						
					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	EU	The food constituent th	nat is the subject of the	In weighing the evidence, the Panel took	Protection of LDL particles	"Consumption of olive oil	In order to bear the claim, 5 mg	EFSA journal	https://efsa.
	polyphenols		health claims is polyphe	enols (e.g. hydroxytyrosol	into account that a well conducted and	from oxidative damage	polyphenols contributes	of hydroxytyrosol and its	number:	<u>onlinelibrary</u>
			and oleuropein comple	x) in olive (olive fruit,	powered study, and two smaller-scale		to the protection of blood	derivatives (e.g. oleuropein	2011;9(4):2033	.wiley.com/
			olive mill waste waters	or olive oil, Olea	studies, showed a dose-dependent and		lipids from oxidative	complex and tyrosol) in olive oil		doi/pdf/10.2
			europaea L. extract and	I leaf). The conditions of	significant effect of olive oil polyphenol		damage."	should be consumed daily.		903/j.efsa.20
			use specify 200 mg/day	of polyphenols (ID 1638,	consumption (for three weeks) on			These amounts, if provided by		11.2033
			1882, 2865), 2-15 mg pe	er day of hydroxytyrosyl	appropriate markers of LDL peroxidation			moderate amounts of olive oil,		
			or oleuropein complex	(ID 1638, 1639, 1696),	(oxLDL), that these results were supported			can be easily consumed in the		
			and 250-500 mg of an C	Olea europaea L. extract	by one short-term and one acute study,			context of a balanced diet. The		
			standardised to 4-23% of	oleuropein (ID 3467,	and by supportive markers of LDL			concentrations in some olive oils		
			3468, 3779, 3781). Polyp	phenols comprise a very	peroxidation (conjugated dienes, ex vivo			may be too low to allow the		
			wide group (several tho	usands of compounds)	resistance of LDL to oxidation) going in the			consumption of this amount of		







No.	Functional ingredients	Ref.		f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications		health		restrictions of use		
			of plant secondary meta	abolites including	same direction, and that evidence for a			polyphenols in the context of a		
			flavonoids, isoflavonoids	s, phenolic acids,	biologically plausible mechanism by which			balanced diet. The target		
			proanthocyanidins and	other tannins, and	olive oil polyphenols could exert the			population is the general		
			lignans with different bid	ological activities. The	claimed effect has been provided.			population.		
			major polyphenols in ol	live oil are phenolic acids						
			(e.g. hydroxytyrosol and	tyrosol), secoiridoids	The Panel concludes that a cause and					
			(e.g. oleuropein) and ligi	nans (e.g. pinoresinol).	effect relationship has been established					
			Table olives typically co	ontain hydroxytyrosol,	between the consumption of olive oil					
			tyrosol, caffeoylquinic a	cid, verbacoside, luteolin	polyphenols (standardised by their					
			and rutin. Hydroxytyroso	ol, a major polyphenol	content of hydroxytyrosol and its					
			typically present in olive	es, is also present in	derivatives) and protection of LDL particles					
			olive mill waste water. I	n nature, hydroxytyrosol	from oxidative damage.					
			is found in olives in the	form of its elenolic acid						
			ester, oleuropein. These	e polyphenolic						
			compounds can be mea	asured in foods by						
			established methods. To	otal polyphenols are						
			usually expressed as gal	llic acid equivalents						
			(GAE), but other phenol	ic compounds such as						
			catechin/epicatechin or	caffeic acid have also						
			been used for standardi	isation. This						
			standardisation refers to	the traditional						
			spectrophotometrical m	neasurement of total						
			-	Folin-Ciocalteau method						
			(Singleton and Rossi, 19							
			- , .	method is not specific for						
			polyphenols because of	3						
			compounds such as asc	-						
			proteins will also be inc							
			quantification, thus lead	ling to an overestimation						







No.	Functional ingredients (nutrients, substance	Ref. Country	1.1 Standards for	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
	substance		manufacturing of the actual polypheno	ol content. The total						
			polyphenol content ass							
			is not suitable for charac							
			polyphenols in foods. T	he Panel considers that						
				xytyrosol and oleuropein						
			complex) in olive (olive fruit, olive mill waste							
			waters or olive oil, Olea europaea L. extract and							
			eaf) can be characterised by their content of							
			nydroxytyrosol and its derivatives (e.g.							
			oleuropein complex).							
14	Plant sterols	EU	In the context of this op	oinion, the term plant	In the most recent meta-analysis on the	Maintenance of normal blood	"Plant sterols/stanols	In order to bear the claim, a food	EFSA journal	https://efsa.
	and plant		sterols (present as free s	sterols or esterified)	LDL-cholesterol lowering effects of plant	cholesterol concentrations	help to maintain normal	should provide at least 0.8 g per	number:	onlinelibrary
	stanols		refers specifically to pla	nt sterols from natural	sterols/stanols, 84 clinical trials were		blood cholesterol levels".	day of plant sterols/stanols in	2010;8(10):1813	.wiley.com/
	(Phytosterols,		sources with a composit	tion as specified in the	included (Demonty et al., 2009). In nine of			one or more servings.	2011;9(6):2203	doi/pdf/10.2
	phytostanols		Commission Decisions a	uthorising the placing on	the studies, daily doses of 0.80-1.0 g had					903/j.efsa.20
	and their		the market of food prod	ducts with added plant	been used. In seven of these studies a					<u>10.1813.</u>
	esters)		sterols under Regulation	n (EC) No 258/976. The	statistically significant reduction of LDL-					https://efsa.
			term "plant stanol ester	r" refers to a blend of	cholesterol concentrations (range -0.19 to					onlinelibrary
			the plant stanols sitosta	anol and campestanol,	-0.33 mmol/L) was found (Beer <i>et al.</i> ,					.wiley.com/
			which are obtained from	n the reduction of plant	2001; Hendriks <i>et al.</i> , 1999; Hironaka <i>et al.</i> ,					doi/pdf/10.2
			sterols from food grade		2006; Niittynen <i>et al.</i> , 2007; Sierksma <i>et</i>					903/j.efsa.20
			soybean oil) or tall oil o		al., 1999; Ishizaki T, 2003; Vanhanen,					11.2203
			Panel notes that claims		1994). In one study (Matsuoka <i>et al.</i> , 2004)					
			to polyphenols present		no effect was found with free sterols, and					
			Maritime Pine (Pinus pin		in the study by Miettinen and Vanhanen					
			the only reference cited	_	(1994) the reduction in LDL-cholesterol of					
			, , ,		0.26 mmol/L was not statistically					
			maritime pine bark was		significant. Plant sterols were used in					
			Panel after having made	e every reasonable effort	seven studies, stanols in one study and in					







	Functional ingredients	Ref.	1. Characterisation of	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	o. nererences	7. LITIKS
			to retrieve it (Assouad a	nd Piriou, 2007), and no	another study a mixture of sterols and					
			references on the effect	ts of polyphenols	stanols was tested. The results of these					
			present or extracted fro	m Maritime Pine on	studies indicate statistically significant					
			blood lipids or any othe	er health outcome were	lowering of LDL-cholesterol concentrations					
			provided.		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 <i>et al</i> ., 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 <i>et al.</i> , 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.					
Ph	ytosterols	Ca	The term "phytosterols	" is used in this	The evidence provided by the petitioner	Plant Sterols and Blood	Primary statement:	Conditions for foods to carry the	Summary of Health	https://www
			document as a collectiv	e term for plant sterols,	included 84 randomized controlled trials	Cholesterol Lowering	"[serving size from	claim: The food (a) contains a	Canada's	.canada.ca/c
			and their hydrogenated	stanol forms, whether	(comprising 141 pertinent trial arms)		Nutrition Facts table in	minimum level equivalent to	Assessment of a	ontent/dam
			used in the free sterol f	orm or esterified with	published from 1994 to 2007. Overall, an		metric and common	0.65 g of free plant sterols or	Health Claim about	<u>/hc-</u>
			fatty acids (also known a	as sterol esters or	8.8% reduction in LDL-cholesterol as		household measures] of	stanols per reference amount	Plant Sterols in	sc/migration
			phytosterol esters). The	re is a diversity in the	observed with an average intake of 2		[naming the product]	and per serving of stated size; (b)	Foods and Blood	/hc-sc/fn-
			composition of phytoste	erols and over 40	g/day of plant sterols. A dose-response		provides X% of the daily	contains at least 10% of the	Cholesterol	an/alt_form







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of     Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			phytosterols have been	identified in nature. The	relationship was observed up to about 3		amount* of plant sterols	weighted recommended nutrient	Lowering. 2010.	ats/pdf/labe
			safety assessment consi	idered phytosterols and	g/day in these studies which included		shown to help	intake of a vitamin or mineral per		<u>l-</u>
			stanols as a group. Phyt	osterols occur naturally	doses ranging from about 0.5 g/day to 9.0		reduce/lower cholesterol	reference amount and per		etiquet/clai
			in plants, and vegetable	e oils are the major	g/day. At the average intake of 2 g/day,		in adults." Two additional	serving of stated size; (c) contains		ms-
			source of phytosterols i	n Canadian diets.	the effect of plant sterols appeared to be		statements that could be	100 mg or less of cholesterol per		reclam/asse
			Phytosterols, when con	sumed at sufficiently	largely independent of the food matrix.		used in combination or	100 g of food; (d) contains 0.5%		SS-
			high levels, have been s	shown to reduce serum	Most of the studies were carried out with		alone, adjacent to the	or less alcohol; (e) contains 480		evalu/phyto
			total and LDL cholester	ol levels.	moderately to highly		primary statement,	mg or less of sodium per		sterols-
					hypercholesterolemic subjects.		without any intervening	reference amount and per		<u>claim-</u>
							printed, written or graphic	serving of stated size, and per 50		allegation-
					Health Canada has concluded that		material: 1) "Plant sterols	g if the reference amount is 30 g		eng.pdf
					acceptable scientific evidence exists in		help reduce [or help	or 30 mL or less; (f) meets the		
					support of the claim about the		lower] cholesterol." This	criterion "low in saturated fatty		
					relationship between the consumption of		statement when used,	acids."		
					plant sterol-enriched foods as foods and		shall be shown in letters			
					blood cholesterol lowering. Consumption		up to twice the size and			
					of these foods results in the lowering of		prominence as those of			
					total blood cholesterol as well as LDL-		the primary statement. 2)			
					cholesterol levels, while having no		"High cholesterol is a risk			
					detrimental effect on HDL-cholesterol		factor for heart disease."			
					levels, resulting in overall improvements		This statement when			
					in the blood lipid profile.		used, shall be shown in			
							letters up to the same			
							size and prominence as			
							those of the primary			
							statement.			
									Notice of	https://www.c
									Assessment of	anada.ca/cont
									Certain Categories	ent/dam/hc-







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of     1.1 Standards for     manufacturing	the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
									of Foods Containing Added Phytosterols. 2010.	sc/migration/h c-sc/fin- an/alt_format s/pdf/gmf- agm/appro/p hytosterols- 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.c dn- website.co m/69f086d6 /files/uploa ded/FSANZ %20Food%2 0Standards %20Schedul e%204.pdf







No.	Functional ingredients	Ref.	1. Characterisation of	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
110.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	27 cause and 21 cee	health	4. Cum succinent	restrictions of use	o. Hererences	7. Elliks
	Phytosterol /	KR	(1) Raw material and	(1) Appearance: Unique		(1) Health claims: May help to		(1) Daily intake amount	Korea Health	https://www
	Phytosterolest		preparation and/or	color and flavor, no off-		maintain healthy blood		(a) 0.8 ~ 3 g as phytosterol (in	Functional Food	.mfds.go.kr/
	er		processing	taste and off-flavor		cholesterol level		case of using phytosterol as	Code 2021. Ministry	eng/brd/m_
			(a) The mixture of	(2) Phytosterol (in case				ingredients)	of Food and Drug	15/down.do
			Beta-sitosterol,	of using phytosterol as				(b) 1.28 ~ 4.8 g as	Safety	?brd_id=eng
			brassicasterol,	ingredients)				phytosterolester (in case of using		0001&seq=7
			stigmasterol and	(a) Semi-processed				phytosterolester as ingredients)		0011&data_t
			campesterol, as	product: No less than				(2) Warning notice for intake: It		p=A&file_se
			distillate which are	labeled amount				may inhibit the absorption of $oldsymbol{eta}$ -		<u>q=1</u>
			obtained during	(b) Final product: 80 ~				carotene		
			deodorization of	120% of labeled						
			soybean, corn or	amount						
			canola oil, shall be in	(3) Content of						
			edible form by	phytosterolester (in						
			extracting and	case of using						
			purifying.	phytosterolester as						
			(b) The substance of	ingredients)						
			above (a) shall be in	(a) Semi-processed						
			edible form by	product: No less than						
			esterifying fatty acids	labeled amount						
			originated from edible	(b) Final product: 80 ~						
			oil.	120% of labeled						
			(2) Content of	amount						
			fumctional							
			compounds (or marker							
			compounds):							
			Phytosterol shall be							
			contained 900 mgg or							
			more. However, in							







ingr	unctional gredients	Ref.	1. Characterisation of	the food/constituent	2. Cause and Effect	3. Claimed effect to human	4 Claim data	5. Conditions and possible	( Defe	7. Links
	utrients, ubstance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	6. References	7. LINKS
			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 sterol	t bls/stanols	SG						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://ww .sfa.gov.sg/ ocs/defaul source/toc -and- resources/ sources-fo







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of     1.1 Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
NO.	(nutrients,	Country		1.2 Specifications	2. Cause and Effect	health	4. Claim statement	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	o. References	businesses/ aguidetofoo dlabellingan dadvertisem ents.pdf
								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		







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of     1.1 Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
								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 stanol	MYS				Plant sterol or plant stanol helps lower or reduce cholesterol		- 160 mg per 100 ml (liquids)	Malaysian Dietary Guidelines Key Message 14 Make effective use of nutrition information on food labels	https://www .moh.gov.m y/moh/imag es/gallery/G arispanduan /diet/km14. pdf







No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of     1.1 Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
								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	Ref.	1. Characterisation of	the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
140.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	o. Hererences	r. Elliks
								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	EU	The food that is the sub	ject of the health claim	Pure monacolin K (lovastatin) has been	Maintenance of normal blood	"Monacolin K from red	In order to obtain the claimed	EFSA journal	https://efsa.
	purpureous		is red yeast rice (i.e. rice	fermented with the red	shown to be effective in reducing total	LDL-cholesterol	yeast rice contributes to	effect, 10 mg of monacolin K	number:	<u>onlinelibrary</u>
	(red yeast rice)		yeast Monascus purpure	us). Red yeast rice is a	cholesterol and LDL-cholesterol	concentrations.	the maintenance of	from fermented red yeast rice	2011;9(7):2304	.wiley.com/
			traditional Chinese food	product which is still a	concentrations in individuals with		normal blood cholesterol	preparations should be		doi/pdf/10.2
			dietary staple in many A	sian countries (Heber <i>et</i>	hypercholesterolaemia and is a well-		concentrations".	consumed daily. The target		903/j.efsa.20







							9.1	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
No.	Functional ingredients	Ref.	1. Characterisation of	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
110.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. cause and threat	health	4. Cam statement	restrictions of use	o. Hererenees	
			al., 1999). Various red ye	east rice preparations are	known inhibitor of HMG-CoA reductase. A			population is adults in the		11.2304
			available as food supple	ements. The preparations	significant inhibitory effect of a fermented			general population.		
			from red yeast rice typic	cally contain starch,	red yeast rice preparation (Cholestin) on					
			protein, fat (including m	nonounsaturated fatty	HMG-CoA reductase activity and					
			acids, plant sterols), isof	flavones, and other	cholesterol concentrations was observed					
			compounds. Depending	on the Monascus strains	in vitro in human hepatic cells (HepG2)					
			used and the fermentat	ion conditions, the	(Man et al., 2002). In weighing the					
			products may contain p	oolyketides called	evidence, the Panel took into account					
			monacolins, which are s	secondary metabolites	that two RCTs provided from which					
			produced during fermer	ntation (Liu <i>et al.</i> , 2006).	conclusions could be drawn for the					
			Monacolin K, in lactone	(also known as	scientific substantiation of the claim					
			lovastatin or mevinolin)	and hydroxy acid forms,	showed an effect of red yeast rice					
			is the main monacolin i	n Monascus purpureus-	preparations providing a daily dose of					
			fermented rice (75-90 %	6 of total monacolin	about 10 mg monacolin K on LDL-					
			content) (Heber <i>et al.</i> , 1	1999; Li <i>et al.</i> , 2004).	cholesterol concentrations in individuals					
			Commercial red yeast ri	ice products have	with hypercholesterolaemia, that the					
			variable contents of mo	onacolin K and total	effect of pure monacolin K on LDL-					
			monacolins (Gordon et	al., 2010; Li et al., 2004).	cholesterol concentrations is well					
			From the conditions of	use provided, the Panel	established and that the mechanism by					
			notes that monacolin K	from Monascus	which monacolin K can contribute to the					
			purpureus-fermented ric	ce has been specified as	claimed effect is well known. The Panel					
			the food constituent wh	nich may be responsible	concludes that a cause and effect					
			for the claimed effect of	onsidered in this opinion.	relationship has been established					
			Monacolin K from Mona	ascus purpureus-	between the consumption of monacolin K					
			fermented rice is a well	·	from red yeast rice and maintenance of					
			which can be measured	I in foods by established	normal blood LDL-cholesterol					
			methods		concentrations.					







No.	Functional ingredients	gredients Ref.	1. Characterisation of	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. 3033 3. 3 2. 333	health	. Cum Sutement	restrictions of use	or nerel eneed	.,
	Red yeast rice	KR	(1) Raw material: Rice	(1) Appearance: Unique		(1) Health claims: May help to		(2) Daily intake amount: 4 ~ 8 mg	Korea Health	https://www
			and red yeast	color and flavor, no off-		maintain healthy blood		as total monacolin K	Functional Food	.mfds.go.kr/
			(Monascus anka.	taste and off-flavor		cholesterol level			Code 2021. Ministry	eng/brd/m_
			Monascus purpures,	(2) Total monacolin K					of Food and Drug	15/view.do?
			Monascus pilosus, and	(a) Semi-processed					Safety.	seq=70011
			Monascus ruber)	product: No less than						
			(2) Preparation and/or	labeled amount						
			processing: It shall be	(b) Final product: 80 ~						
			in edible form by	120% of labeled						
			pulverizing after solid-	amount						
			state fermentation by	(3) Active form of						
			inoculating rice (except	monacolin K: It shall be						
			for steamed rice) with	confimed						
			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.							
16	Resistant	EU	The food constituent th	at is the subject of the	In weighing the evidence, the Panel took	Reduction of post-prandial	"Replacing digestible	The Panel considers that in order	EFSA journal	https://efsa.
	starch		health claim is resistant	starch-type 2 from high	into account that most of the studies	glycaemic responses	starch with resistant starch	to bear the claim, high	number:	onlinelibrary
			amylose maize. Resistar	nt starch (RS) is defined	provided reported a significant decrease in		induces a lower blood	carbohydrate baked foods	2011;9(4):2024	.wiley.com/
			as starch that escapes c		post-prandial glycaemic responses,		glucose rise after a meal".	should contain at least 14 % of		doi/pdf/10.2
			in the small intestine of	-	without significantly increasing			total starch as resistant starch, in		903/j.efsa.20
			can be classified into fo		insulinaemic responses, following			replacement to digestible starch.		11.2024







	Functional	Def	1. Characterisation of the food/constituent Ref.			·	,	Conditions and associate		
No.	ingredients (nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
			physically inaccessible t	to digestion, RS2	consumption of RS2 as a partial			The target population is		
			describes native starch	granules that are	replacement of digestible starch in baked			individuals wishing to reduce		
			protected from digestion	n by the conformation or	foods, and that the effect is generally not			their post-prandial glycaemic		
			structure of the granule	, RS3 refers to non-	observed when the amount of available			responses.		
			granular starch-derived i	materials which are	carbohydrates is maintained constant in					
			generally formed during	retrogradation of starch	the test and control products. This					
			granules in food process	sing, and RS4 are	suggests that the replacement of					
			starches not found in na	ature which have been	digestible starch in carbohydrate-					
			chemically modified to	decrease their	containing foods with RS2 from high					
			digestibility (Nugent, 200	05). RS from high	amylose maize would decrease post-					
			amylose maize (amylose	e content between 50 %	prandial glycaemic and insulinaemic					
			and 90 %) is categorised	d as RS2, and is produced	responses due to the replacement of					
			from a traditionally bred	d hybrid of high amylose	digestible carbohydrates by indigestible					
			maize that contains a m	nixture of digestible and	carbohydrates, so that the amount of					
			resistant starch. The star	rch granules in high	available glucose contributing to					
			amylose maize are very	stable, and tend not to	glycaemia is reduced, whereas the					
			gelatinise when subjecte	ed to the processing	addition of RS2 to carbohydrate-containing					
			conditions used in the r	manufacture of many	foods does not appear to modify the post-					
			common foods. Method	ds are available to	prandial glucose responses to digestible					
			measure these starch fra	actions in the laboratory	starch (i.e. when the amount of glycaemic					
			(McCleary and Monagha	n, 2002).	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.					







No.	Functional ingredients	Ref.	1. Characterisation of	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4 Claim statement	5. Conditions and possible	( Defense	7 1:-1-
INO.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	z. Cause and Effect	health	4. Claim statement	restrictions of use	6. References	7. Links
	High Amylose Maize Resistant Starch	MYS			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 (HAMRS) helps improve/promote colonic/bowel/intestinal		Minimum amount: 2.5 g per serving	Malaysian Dietary Guidelines Key Message 14 Make effective use	https://www .moh.gov.m y/moh/imag es/gallery/G
						function/environment			of nutrition information on food labels	arispanduan /diet/km14. pdf
17	Soy protein	Са	The foods that are the shealth claim are foods of contain proteins derived (Glycine max (L.) Merr., I ingredients eligible for the beverages, tofu, miso, to cheese, soy nuts, isolate protein concentrate (SPO (TSP) and soy flour (SF). oil are excluded from the lack substantial amount	or food ingredients that d from the soybean Fabaceae). Foods and he claim include soy empeh, natto, soy ed soy protein (ISP), soy C), textured soy protein Soy sauce and soybean he claim because they	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	Canada's	https://www .canada.ca/c ontent/dam /hc- sc/migration /hc-sc/fn- an/alt_form ats/pdf/labe L- etiquet/clai ms- reclam/asse ss- evalu/Sum- Assessment-







1	No.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of      Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
						39% of Canadians aged 6 to 79 years had		in letters up to twice the	or a meal replacement; c)		Soy-April-
						unhealthy levels of total cholesterol (>5.2		size and prominence of	contains 100 mg or less of		<u>2015-</u>
						mmol/L for adults) during the time period		those in the primary	cholesterol per 100 g of food; d)		eng.pdf
						of 2009-20111		statement: -Soy protein	contains 0.5% or less alcohol; e)		
								helps reduce/lower	contains i. less than 15% of the		
								cholesterol - High	Daily Value (DV) of sodium per		
								cholesterol is a risk factor	reference amount and per		
								for heart disease - Soy	serving of stated size, and per 50		
								protein helps	g if the reference amount is 30 g		
								reduce/lower cholesterol,	or 30 mL or less, or ii. less than		
								(which is) a risk factor for	15% of the Daily Value (DV) of		
								heart disease	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.		







No.	Functional ingredients	Ref.	1. Characterisation of	f the food/constituent	2. Cause and Effect	3. Claimed effect to human	4. Claim statement	5. Conditions and possible	6. References	7. Links
NO.	(nutrients, substance	Country	1.1 Standards for manufacturing	1.2 Specifications	2. Cause and Effect	health	4. Claim statement	restrictions of use	o. neielelices	7. LITIKS
:	Soybean	KR	(1) Raw materials:	(1) Appearance: Unique		(1) Health claims: May help to		(1) Daily intake amount: 15 g or	Korea Health	https://www
	protein		Soybean (Glycine max	color and flavor, no off-		maintain healthy blood		more as soybean protein	Functional Food	.mfds.go.kr/
			L.N)	taste and no off-flavor		cholesterol level		(2) Warning notice for intake: The	Code 2021. Ministry	eng/brd/m_
			(2) Preparation and or	(2) Crude protein				individual who has an allergy to	of Food and Drug	15/down.do
			processing	(a) Semi-processed				soybean protein should be	Safety	?brd_id=eng
			(a) It shall be in edible	product: No less than				cautious to intake		0001&seq=7
			form by separating and	labeled amount						0011&data_t
			purifying after	(b) Final product: 80 ~						p=A&file_se
			removing lipid from	120% of labeled						<u>q=1</u>
			the raw materials.	amount						
			(b) It shall be in edible	(3) Daidzein: It shall be						
			form by separating and	confirmed.						
			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.							
	Soya protein	MYS				Soya protein helps to reduce		Minimum amount required:	Malaysian Dietary	https://www
						cholesterol		5 g per serving	Guidelines	.moh.gov.m
								Other conditions:	Key Message 14	y/moh/imag







N	0.	Functional ingredients (nutrients, substance	Ref. Country	Characterisation of     Standards for     manufacturing	f the food/constituent  1.2 Specifications	2. Cause and Effect	3. Claimed effect to human health	4. Claim statement	5. Conditions and possible restrictions of use	6. References	7. Links
									To include the statement:	Make effective use	es/gallery/G
									"Amount recommended to give	of nutrition	<u>arispanduan</u>
									the	information on	/diet/km14.
									lowering effect on the blood	food labels	pdf
									cholesterol is 25 g per day".		







# สรุปข้อมูลสารสำคัญ/ส่วนประกอบเชิงหน้าที่ในรูปแบบโมโนกราฟ

คณะทำงานได้สรุปข้อมูลสารสำคัญ/ส่วนประกอบเชิงหน้าที่ในรูปแบบโมโนกราฟ โดยจัดทำเป็น เอกสาร 17 รายการ ดังนี้

รายการ	หน้า
Alpha-linolenic acid (ALA)	59
Beta-Glucans	61
Chitosan	73
Conjugated linoleic acid	76
Eicosapentaenoic acid and docosahexaenoic acid (EPA/DHA)	79
Fructo-oligosaccharide	85
Glucomannan (konjac mannan)	88
Guar gum	92
Indigestible Maltodextrin	95
Inulin	97
Live yoghurt cultures	101
Oleic acid	107
Olive oil polyphenols	111
Plant sterols and plant stanols (Phytosterols, phytostanols and their esters)	114
Red yeast rice	121
Resistance starch	124
Soybean protein	126





# 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)

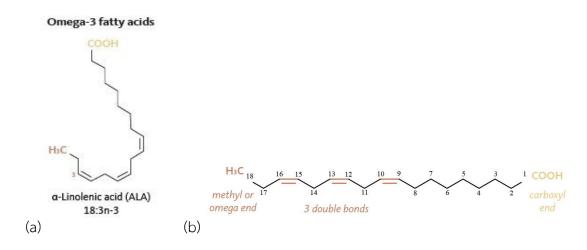


Figure 1. (a) The chemical structure of Alpha-linolenic acid (ALA)

(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.wilev.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. (<a href="https://lpi.oregonstate.edu/mic/other-nutrients/essential-fatty-acids">https://lpi.oregonstate.edu/mic/other-nutrients/essential-fatty-acids</a>)









# 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  $\beta$ -(1 $\rightarrow$ 4) and  $\beta$ -(1 $\rightarrow$ 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 ( $\sim$ 7 %), oats ( $\sim$ 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.

สนับสนุนโดยหน่วยบริหารและจัดการทุนด้านการเพิ่มความสามารถในการแข่งขันของประเทศ (บพข.)

- 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% eta-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	<ul> <li>(1) Raw materials: Phellinus linteus (3 ~ 4 years old dry)</li> <li>(2) Preparation and/or processing: It shall be in edible form by pulverizing the raw material under 3mm size, extracting (110°C, 96 ~ 100 hours) with water (10 times more amount than materials), high-press filtering, drying (75 ~ 80°C, heat dry), pulverizing.</li> <li>(3) Content of functional compounds (or marker compounds): β-glucan shall be contained 87 mg/g or more.</li> <li>(4) Conditions for manufacturing: Raw</li> </ul>
	compounds (or marker	material shall be in confirmed as







	Ganoderma lucidum fruit body extracts	Phellinus linteus extracts
	compounds): <b>β</b> -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) $\beta$ -Glucan (The $\beta$ -glucan originated from other ingredients shall be labeled separately.) (a) Semi-processed product: No less than labeled amount (b) Final product: 80 $\sim$ 120% of the labeled amount (3) Coliform: Negative	<ul> <li>(1) Appearance: Unique color and flavor, no off-taste and no off-flavor (2) β-glucan</li> <li>(a) Semi-processed product: No less than labeled amount</li> <li>(b) Final product: 80 ~ 120% of labeled amount (3) Heavy metal</li> <li>(a) Lead (mg/kg): No more than 1.0</li> <li>(b) Cadmium (mg/kg): No more than 0.4 (c)</li> <li>Mercury (mg/kg): No more than 0.3 (d)</li> <li>Arsenic (mg/kg): No more than 1.0</li> <li>(4) Coliform: Negative</li> </ul>
1.3) Testing methods	<ul> <li>(1) Appearance: Chapter 4.</li> <li>2-7 Appearance testing method (2) β-Glucan:</li> <li>Chapter 4. 3-25 β-glucan</li> <li>(3) Coliform: Referred to [Annexed the Table 4]</li> </ul>	<ul> <li>(1) Appearance: Chapter 4. 2-7 Appearance testing method</li> <li>(2) β-glucan: Chapter 4. 3-25 β-glucan</li> <li>(3) Lead, Cadmium, Mercury, Arsenic: Referred to [Annexed the Table 4]</li> <li>(4) Coliform: Referred to [Annexed the Table 4]</li> </ul>







# 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 LDLcholesterol 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 postprandial 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:

- ullet May help to maintain healthy blood flow. (eta-Glucan from Ganoderma lucidum fruit body extracts)
- $\bullet \quad \text{May help to support immune function. } (\beta \text{-Glucan from } \textit{Phellinus linteus} \text{ extracts})$

# 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

สนับสนุนโดยหน่วยบริหารและจัดการทุนด้านการเพิ่มความสามารถในการแข่งขันของประเทศ (บพข.)









# • 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.

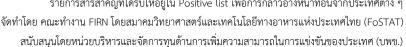
In addition, the food must meet the following qualifying criteria:

- 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".

#### **AUS-NZ:**

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:

• ( $\beta$  -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":

- O 3 g per 100 g (solids)
- O 1.5 g per 100 ml (liquids)"
- $\bullet \quad (\beta \text{ -glucan}) \text{ Oat soluble fibre in relation to blood glucose claim } \\ \text{Other conditions:}$ 
  - 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 (eta-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:  $1.2 \sim 4.5 \text{ g}$  as sum of chitosan and chitooligosaccharide
- (b) May help to reduce body fat:  $3.0 \sim 4.5$  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).









#### 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

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#### 4. Conditions and possible restrictions of use (KR)

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







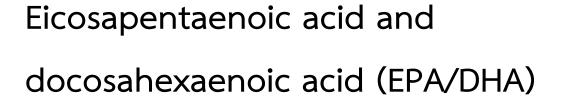
#### 5. References

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).









#### 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) ( $2 \times \text{peroxide value} + \text{anisidine value}$ ): 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  $\sim$  2 g as the sum of FPA and DHA
  - (b) May help to improve memory:  $0.9 \sim 2$  g as the sum of EPA and DHA
- (c) May help to maintain eye health as the improvement of dry eyes: 0.6  $\sim$  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.wilev.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?sea=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)







#### 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  $1\sim3$  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

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#### 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 <u>Singapore</u>: 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 <u>Singapore:</u> 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

- 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\_t p=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  $\beta$ -1 $\rightarrow$ 4 D-mannose and D-glucose units in a ratio of 1.6:1 with a small amount of branching (8 %) through  $\beta$ -(1 $\rightarrow$ 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)

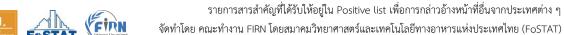
- (1) Raw material: Arum family konjac (Amorphophallus konjq) rhizome
- (2) Preparation and/or processing: Polysaccharides shall be in edible form by extracting the raw materials with isopropyl alcohol and purifying.
- (3) Content of functional compounds (or marker compounds): Dietary fiber shall be 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]



สนับสนุนโดยหน่วยบริหารและจัดการทุนด้านการเพิ่มความสามารถในการแข่งขันของประเทศ (บพข.)

(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, gellike 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.

(<a href="https://www.mfds.go.kr/eng/brd/m\_15/down.do?brd\_id=eng0001&seq=70011&data\_tp=A&file\_seq=1">https://www.mfds.go.kr/eng/brd/m\_15/down.do?brd\_id=eng0001&seq=70011&data\_tp=A&file\_seq=1</a>).







### 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:  $9.9\sim27$  g as dietary fiber of guar gum or its hydrolysate
- (b) May help to maintain healthy gastrointestinal bacteria population:  $4.6 \sim 27$  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

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#### 5. Conditions and possible restrictions of use

- (1) Daily intake amount
- (a) May help to maintain healthy postprandial glucose level:  $11.9 \sim 30$  g as indigestible maltodextrin dietary fiber (in case of liquid ingredients,  $11.6 \sim 44$  g)
- (b) May help to maintain healthy triglyceride level:  $12.7 \sim 30$  g as indigestible maltodextrin dietary fiber (in case of liquid ingredients,  $12.7 \sim 44$  g)
- (c) May help to maintain healthy bowel function:  $2.5 \sim 30$  g as indigestible maltodextrin dietary fiber (in case of liquid ingredients,  $2.3 \sim 44$  g)"
- (2) Warning notice for intake: Should be taken with sufficient water except for liquid type product

#### 6. References

Korea Health Functional Food Code 2021. Ministry of Food and Drug Safety.
 (<a href="https://www.mfds.go.kr/eng/brd/m\_15/down.do?brd\_id=eng0001&seq=70011&data\_t">https://www.mfds.go.kr/eng/brd/m\_15/down.do?brd\_id=eng0001&seq=70011&data\_t</a>
 p=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  $\beta(2\rightarrow 1)$ -fructan with a degree of polymerisation (DP) > 9 which typically has a terminal  $\alpha$ -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 inulintype 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  $\geq$  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 <u>EU:</u> Improves bowel function by increasing stool frequency.
- 3.2. <u>Korea:</u> 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 <u>EU:</u> "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 <u>EU:</u> 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:  $7.2\sim20$  g as inulin / chicory dietary fiber
- (b) May help to maintain healthy bowel function: 6.4  $\sim$  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
- $1. \ge 133.33 \mathrm{mg}$  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 <u>Singapore</u>: 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

  (<a href="https://www.mfds.go.kr/eng/brd/m\_15/down.do?brd\_id=eng0001&seq=70011&data\_t">https://www.mfds.go.kr/eng/brd/m\_15/down.do?brd\_id=eng0001&seq=70011&data\_t</a>

  p=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:







Symbiotic cultures of *Streptococcus thermophilus* and

Lactobacillus delbrueckii subsp. bulgaricus.

Alternate culture

yoghurt:

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 <sup>(a)</sup> (% 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 <sup>7</sup>	min. 10 <sup>7</sup>	min. 10 <sup>7</sup>	min. 10 <sup>7</sup>
Labelled microorganisms <sup>(b)</sup> (cfu/g, total)	min. 10 <sup>6</sup>	min. 10 <sup>6</sup>		
Yeasts (cfu/g)			min. 10 <sup>4</sup>	min. 10 <sup>4</sup>

- 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)







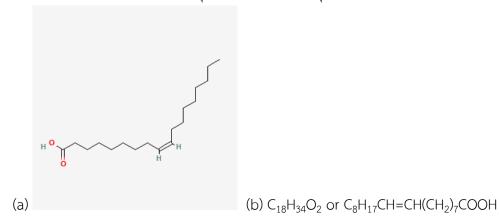


Figure 1. (a) The chemical structure of Oleic acid

(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 monounsaturated 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
- 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

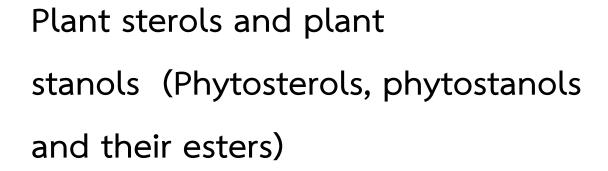
1. EFSA journal number: 2011;9(4):2033

(https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2033)









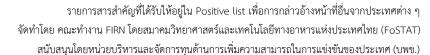
# 1. Characterisation of the food/constituent

#### 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  $\beta$ -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 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  $oldsymbol{\beta}$  -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)  $\times$  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 plant sterols and plant stanols and reduction 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."

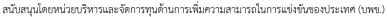
Two additional statements that could be used in combination or alone, adjacent to the primary statement, without any intervening printed, written or graphic material:

- 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".







#### 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. (<a href="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">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</a>)
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- 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. (<a href="https://www.sfa.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/aguidetofoodlabellingandadvertisements.pdf">https://www.sfa.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/aguidetofoodlabellingandadvertisements.pdf</a>)
- 7. Malaysian Dietary Guidelines Key Message 14: Make effective use of nutrition information on food labels (<a href="https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf">https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf</a>)







# 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. Cause and Effect

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).







#### 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)
- 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 <u>Canada:</u> 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

- Summary of Health Canada's Assessment of a Health Claim about Soy Protein and Cholesterol Lowering (2015) (<a href="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">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</a>)
- 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

  (<a href="https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf">https://www.moh.gov.my/moh/images/gallery/Garispanduan/diet/km14.pdf</a>)







# เอกสารประกอบเพิ่มเติม

# รายการเอกสารอ้างอิงที่ได้รับจาก EFSA (เรียงตามหมายเลข ID number)

List	Link	QR code
Consolidated list of Article 13 health claims	https://www.efsa.europa.	回窓能談回
List of references received by EFSA	eu/sites/default/files/top	
Part 1 IDs 1-1000	ic/ndaart13ref01.pdf	
Consolidated list of Article 13 health claims	https://www.efsa.europa.	
List of references received by EFSA	eu/sites/default/files/top	
Part 2 IDs 1001-2000	ic/ndaart13ref02.pdf	
Consolidated list of Article 13 health claims	https://www.efsa.europa.	
List of references received by EFSA	eu/sites/default/files/top	
Part 3 IDs 1-1000	ic/ndaart13ref03.pdf	
Consolidated list of Article 13 health claims	https://www.efsa.europa.	
List of references received by EFSA	eu/sites/default/files/top	
Part 4 IDs 3001-4705	ic/ndaart13ref04.pdf	