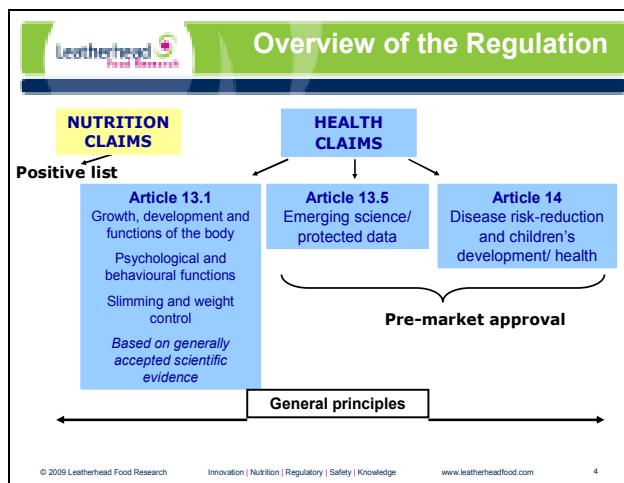




Regulation (EC) No 1924/2006 on nutrition and health claims made on foods

Entered into force 19 Jan 2007





Permitted Nutrition Claims

• Low energy	• Source of protein
• Energy-reduced	• High protein
• Energy-free	• Source of vitamin(s)/ mineral(s) X
• Low fat	• High vitamin(s)/ mineral(s) X
• Fat-free	• Contains (name of nutrient)
• Low saturated fat	• Increased (name of nutrient)
• Saturated fat-free	• Reduced (name of nutrient)
• Low sugars	• Light/lite
• Sugar-free	• Naturally/natural
• With no added sugars	• Source of omega-3 fatty acids
• Low sodium/salt	• High omega-3 fatty acids
• Very low sodium/salt	• High monounsaturated fat
• Sodium-free/salt-free	• High polyunsaturated fat
• Source of fibre	• High unsaturated fat
• High fibre	

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Nutrition Claims

ENERGY

<u>Claim</u>	<u>Condition</u>
Low energy	Max. 40 kcal/100g or 20 kcal/100ml
Energy-reduced	Min. 30% reduction
Energy-free	Max 4kcal/100ml

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Nutrition Claims

SUGAR

<u>Claim</u>	<u>Condition</u>
Low sugars	Max 5g/100g or 2.5g/100ml
Sugars-free	Max 0.5g/100g or 100ml
With no added sugars	No added mono- or disaccharides or any other food used for its sweetening properties*

* If sugars are naturally present in the food, "CONTAINS NATURALLY OCCURRING SUGARS" should also appear on the label



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Nutrition Claims

FIBRE

<u>Claim</u>	<u>Condition</u>
Source of fibre	Min 3g/100g or 1.5g/100kcal
High fibre	Min 6g/100g or 3g/100kcal

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Nutrition Claims

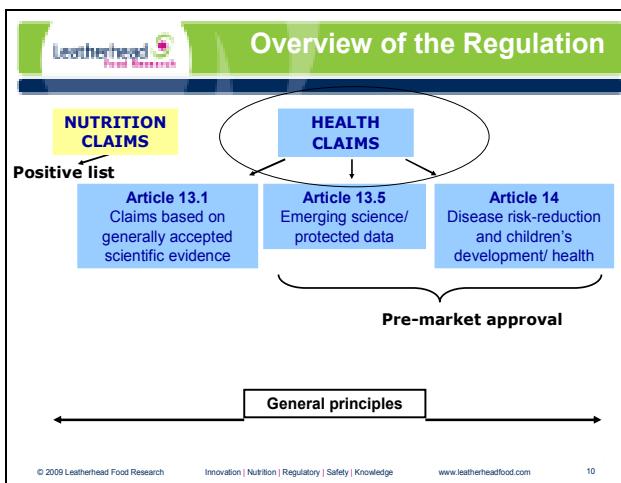
"X% Fat Free"

NOW PROHIBITED

BY LAW!



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Progress to Date

- EFSA's opinions released in batches
 - Batch 1: October 2009 (94 opinions on 525 claims)
 - Batch 2: February 2010 (~ 30 opinions covering 416 claims)
 - Batch 3: Summer 2010 (around 500 claims)
 - Last batch (? 2011)

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Positive Opinions

- Vitamin D and immune system and muscle function
- Meal replacements for weight control
- Melatonin and jet lag feeling
- Potassium and normal muscular and neurological function
- Guar gum and cholesterol lowering
- Omega 3 and contribution to normal cholesterol and BP

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Reasons for Negative Opinions

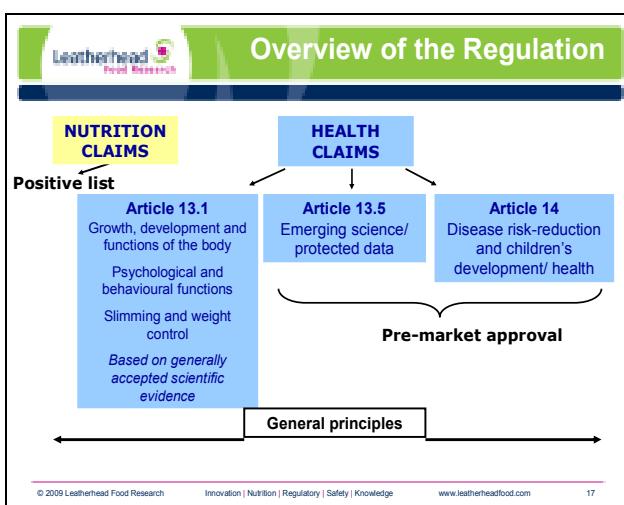
- Poorly characterised
- References on unrelated health outcomes
- Studies done on different population
- Non-significant results
- No human studies
- References in Chinese!
-

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Leatherhead Food Research Article 13 Health Claims

- Commission to vote on list of permitted health claims
⇒ list issued in batches?
- Rejected claims will be on an on-line register
- 6 months transition
- Claims without opinion can stay on the market until rejected
- Claims can be re-submitted via Article 13.5

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Leatherhead Food Research Article 13.5 and 14 Claims - Progress

- Around 200 claims of this type awaiting validation and evaluation:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_article14.htm

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Accepted Health claims (Art. 14)						
Application – Relevant provisions of Regulation (EC) No 1924/2006	Applicant – Address	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference
Article 14(I)(a) health claim referring to reduction of disease risk	Unilever PLC, Port Sunlight, Wirral, Merseyside, CH62 4ZD, UK and Unilever NV, Weena 455, Rotterdam, 3013 AL, Nederland	Plant sterols: Sterols extracted from plants, free or esterified with food grade fatty acids	Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	Information to the consumer that the beneficial effect is obtained with a daily intake of at least 2 g plant sterols		Q-2008-085
Article 14(I)(a) health claim referring to reduction of disease risk	McNeil Nutritionals, 1 Landis und Gyr Strasse, 6300 Zug, Switzerland	Plant stanol esters	Plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	Information to the consumer that the beneficial effect is obtained with a daily intake of at least 2 g plant stanols		Q-2008-118
Article 14(I)(b) health claim referring to children's development and health	Unilever PLC, Port Sunlight, Wirral, Merseyside, CH62 4ZD, UK and Unilever NV, Weena 455, Rotterdam, 3013 AL, Nederland	α-linolenic acid & linoleic acid	Essential fatty acids are needed for normal growth and development of children	Information to the consumer that the beneficial effect is obtained with a daily intake of 1 % of total energy for linoleic acid and 0.2 % of total energy of α-linolenic acid		Q-2008-079
Article 14(I)(b) health claim referring to children's development and health	Association de la Transformation Laitière Française (ATLA), 42, rue du Châteaudun, 75314 Paris Cedex 09, FRANCE	Calcium	Calcium is needed for normal growth and development of bone in children	The claim can be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN(S)] AND/OR [NAME OF MINERAL(S)] as listed in the Annex to Regulation (EC) No 1924/2006		Q-2008-322
Article 14(I)(b) health claim referring to children's development and health	Association de la Transformation Laitière Française (ATLA), 42, rue du Châteaudun, 75314 Paris Cedex 09, FRANCE	Protein	Protein is needed for normal growth and development of bone in children	The claim can be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation (EC) No 1924/2006		Q-2008-326



Rejected Health Claims (Art. 14)

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1)(a) health claim referring to reduction of disease risk	NeOpuntia®	NeOpuntia® helps to improve blood lipid parameters associated with cardiovascular risks, especially the HDL-cholesterol	EFSA-Q-2008-214
Article 14(1)(a) health claim referring to reduction of disease risk	Lactobacillus helveticus fermented Evolus®low-fat milk products	Evolus® reduces arterial stiffness	EFSA-Q-2008-218
Article 14(1)(b) health claim referring to children's development and health	regular®.pro.kid IMMUN	regular®.pro.kid IMMUN supports, stimulates and modulates the immune system of children during growth	EFSA-Q-2008-082
Article 14(1)(b) health claim referring to children's development and health	Dairy products	Three portions of dairy food everyday, as part of a balanced diet, may help promote a healthy body weight during childhood and adolescence	EFSA-Q-2008-110
Article 14(1)(b) health claim referring to children's development and health	Dairy products	Dairy foods (milk & cheese) promote dental health in children	EFSA-Q-2008-112
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and Arachidonic Acid (ARA)	DHA and ARA support neural development of the brain and eyes	EFSA-Q-2008-120
Article 14(1)(b) health claim referring to children's development and health	regular®.pro.kid BRAIN	regular®.pro.kid BRAIN contributes to mental and cognitive development of children	EFSA-Q-2008-083
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and eicosapentaenoic acid (EPA)	Calmng	EFSA-Q-2008-091 and EFSA-Q-2008-096
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and eicosapentaenoic acid (EPA)	Provide serenity and room for a beneficial development of the child	EFSA-Q-2008-092 and EFSA-Q-2008-097
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and eicosapentaenoic acid (EPA)	Help to support vision	EFSA-Q-2008-095 and EFSA-Q-2008-100
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and eicosapentaenoic acid (EPA)	Help to support mental development	EFSA-Q-2008-098 and EFSA-Q-2008-104

Food Safety - From the Farm to the Fork

Community Register of Authorised Health Claims and Health Claims Directive

General Food Law | Animal Nutrition | Labelling & Nutrition | Biopesticides | Noise | Head, Chemical Safety | Biological Safety | Official controls

Authorised health claims and the conditions applying to them provided for in Article 16(3) and (4) (1), 16(2), 21, 24(2) and 28(1) of Regulation (EC) No 1924/2006 and the national measures referred to in Article 23(3)

Authorised health claims

Authorised health claims that can be used by all food business operators provided that they comply with the following conditions to refer to the authorised claim area with the principles and requirements of Regulation (EC) No 1924/2006

- Article 16(3) health claims referring to the reduction of a risk factor in the development of a disease
- Article 16(4) health claims referring to children's development and health

Article 16(3) health claims referring to the reduction of a risk factor in the development of a disease

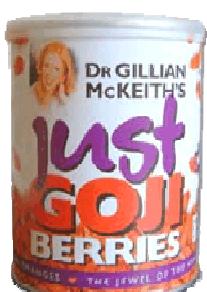
Health claim, based on food category	Date	Statement under Article 16(3) for food under additional requirement in Annex II	EU authorisation reference	Consumer Register
Plant sterols: Sterols enriched from plants, also in combination with food-grade beta-sitosterol	Plant sterols have been shown to lower plasma total cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of at least 2 g plant sterols.	Q-2006-005	Commission Regulation (EC) No 803/2006 of 21/4/2006 [PDF]
Plant stanols esters	Plant stanols esters have been shown to lower plasma total cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of at least 2 g plant sterols.	Q-2006-011	Commission Regulation (EC) No 803/2006 of 21/4/2006 [PDF]
Chewing gum sweetened with 100% xylitol	Chewing gum sweetened with 100% xylitol has been shown to reduce dental caries. High consumption of dental caries is a risk factor in the development of caries in children.	Information to the consumer that the beneficial effect is obtained with a daily consumption of 2-30 g chewing gum sweetened with 100% xylitol of at least 5 times per day after the meals.	Q-2006-025	Commission Regulation (EC) No 803/2006 of 21/4/2006 [PDF]

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http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/authorised_health_claims_en.htm

Leatherhead Food Research

Health professionals?

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Non-specific Well-being claims

'Body Balance'



Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being

Website states
"Provides your body with the elements it needs to be healthy"

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Additional Labelling

- **Group 2 nutrition labelling:**
energy value + amounts of protein, carbohydrate, sugars, fat, saturates, fibre and sodium
- **Indication of importance of a varied and balanced diet and healthy lifestyle**
- **Quantity of food and pattern of consumption required to obtain the claimed beneficial effect**
- **Indicate if anyone should avoid the food**
- **Where appropriate, a warning not to exceed quantities of the product that may represent a risk to health**

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Prohibited Claims

- ✖ **No claims on alcoholic beverages more than 1.2% alcohol (other than those which refer to low alcohol or a reduction in alcohol or energy content).**
- ✖ **Suggestions health affected by not consuming a food**
- ✖ **References to rate or amount of weight loss**
- ✖ **References to recommendations of individual doctors or health professionals**

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Nutrient Profiles

Exception where single nutrient exceeds profile



“Source of
Vitamins C & E ...”

+ “High Sugar
Content”

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General Requirements

All claims

- beneficial effect
- significant quantity
- bio-available
- reasonable amount consumed
- understood by average consumer
- claims must be **substantiated by generally accepted scientific evidence**



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The Future?



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