



Division Food, Feed and other consumption product



Les 27 se réunissent autour des allégations de santé

Ce vendredi, les Etats membres vont discuter des huit premiers avis de l'EFSA.

Les allégations alimentaires, nutritionnelles et de santé sont un dossier complexe et qui touche pour- tant directement le consommateur et les choix qu'il pose devant les rayons des supermarchés.

Aujourd'hui, une réunion d'experts des 27 Etats membres se tiendra à Bruxelles auprès de la Commission européenne pour discuter des huit premiers avis rendus en juillet et en août par l'EFSA, l'autorité européenne de sécurité des aliments (EFSA) et pierre angulaire de l'Union pour ce qui concerne l'évaluation des risques relatifs à la sécurité des aliments.

La Commission prendra acte de la position des Etats membres, qui suivent en général les avis scientifiques remis par l'EFSA (en l'occurrence sept négatifs et un seul vraiment positif) et fera ensuite une proposition, dans les semaines ou les mois à venir, formalisant les modalités dans lesquelles telle allégation de santé pourra être utilisée par un producteur d'aliments.

« Si certaines allégations sont refusées, elles devront disparaître du marché », explique Jean Fottier, expert en denrées alimentaires, étiquetage et allégations au SPF Santé publique, Sécurité de la Chaîne alimentaire et Environnement. Il y



Pour 2010, une liste communautaire d'allégations autorisées sera adoptée.

aura cependant une période de transition, le temps que les produits soient mis en règle. »

Ces réunions d'experts ont lieu tous les deux mois environ. C'est que les avis de l'EFSA vont affluer régulièrement.

Outre les 220 dossiers individuels de fabricants sur des allégations de santé (relevant de l'article 14, spécifiques aux enfants et relatives à la

réduction des risques de maladie), l'autorité scientifique a reçu pour évaluation une liste de quelque 2 870 allégations de santé génériques (relevant de l'article 13, du type « le calcium renforce les os »).

A ce jour, le groupe scientifique de l'EFSA sur les produits diététiques, la nutrition et les allergies (NDA) a donc adopté sa première série d'avis sur des allégations portant

sur la réduction des risques de maladie et le développement et la santé des enfants.

Les scientifiques du groupe NDA ont examiné et évalué les preuves scientifiques étayant les allégations de santé soumises par des demandeurs pour 8 allégations, 5 concernant la santé des enfants et 3 la réduction des risques de maladie.

« L'évaluation indépendante par l'EFSA des allégations de santé que les fabricants souhaitent faire associer à leurs denrées alimentaires est importante car les consommateurs veulent pouvoir se fier aux allégations », explique Albert Flynn, président du groupe scientifique NDA.

La liste d'allégations génériques a quant à elle été envoyée à l'EFSA en juillet 2008 par la Commission, qui a elle-même compilé les listes déposées par les Etats membres, suite à l'entrée en vigueur du nouveau règlement européen en juillet 2007. Il s'agit d'allégations qui ornaient déjà les produits sur le marché. L'EFSA a jusqu'en janvier 2010 pour terminer son travail d'évaluation.

Parmi ces 2 870 allégations, beaucoup sont farfelues. L'avis de l'EFSA rendu aux experts puis aux décideurs permettra donc de faire le tri et de mettre de l'ordre dans l'étiquetage de nos produits. ◇ F.A.

Etiquetage insuffisant

Biscuits fourrés à la vanille, charcuterie préemballée, corn-flakes, pizzas... Le Cric (Centre de recherche et d'information des organisations de consommateurs) a passé en revue 163 produits dans 21 catégories pour en déterminer le rapport qualité-prix. Pour chacune des catégories, les produits « premiers prix », des discounters, les marques de distributeurs et une marque nationale ont été comparés. Critères utilisés : le prix et l'information disponible sur l'emballage (présence de mentions obligatoires, liste des ingrédients, étiquetage nutritionnel). Le Cric a conclu de ses recherches que les produits les moins chers ne comportaient pas toujours une information suffisante pour pouvoir comprendre leur composition et choisir le produit en connaissance de cause. « Cet étiquetage doit apparaître sur tous les produits, quel que soit le prix de ces derniers. Bon marché ne peut être synonyme d'information adéquate ou inexistante », souligne le Cric. ◇

► L'étude sur www.cric.be

SPF SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT

4

REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 December 2006
on nutrition and health claims made on foods



.be



General provisions



Nutrient profiles



Nutrition claims



Health claims

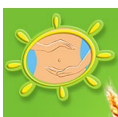
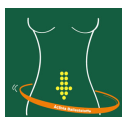


Scientific substantiation

6

Definitions: Claim

- Any non-mandatory message or representation ...
which states, suggests or implies ...
that a food has particular characteristics



Art. 2

.be

Definitions: Nutrition claim

- Beneficial properties are due to the energy, the nutrients or other substances the food
 - contains
 - contains in reduced or increased proportions
 - does not contain

→ Relates to the content



Art. 2

.be

Definitions: Health claim

- A relationship is made between a food category, a food or one of its constituents and health.

→ Relates to the effect



Antioxiçânt & gezone darmflera
Antioxidant & flore intestinale saine

Art. 2

.be

Scope of the regulation

- Voluntary claims
- On foods to be delivered as such to the final consumer
+ to mass caterers
- In commercial communications:
labelling, presentation or advertising



! including trademarks and brands names !



Art. 1

.be

Scope of the regulation

- Voluntary claims
- On foods to be delivered as such to the final consumer
+ to mass caterers
- In commercial communications:
labelling, presentation or advertising



! including trademarks and brands names !



Art. 1

.be

General conditions

- Claims may not
 - be false, ambiguous or misleading
 - encourage excess consumption of a food
 - give rise to doubt about safety or nutritional adequacy of others foods
 - suggest that a balanced diet cannot provide appropriate quantities of nutrients in general
 - give rise to or exploit fear in the consumer



Art. 3



General conditions

- The substance subject of the claim
 - has been shown to have a beneficial effect by “generally accepted scientific evidence”
 - is contained in the final product in a form that is available and in a quantity that will produce the effect claimed
 - is provided in a significant quantity by the quantity of the product reasonably expected to be consumed



Art. 5



Restrictions

- Categories of foods which may not bear nutrition or health claims:

Beverages containing more than 1,2% by volume of alcohol

(except to indicate a reduction in alcohol or energy content or low alcohol content)

ex: light beer

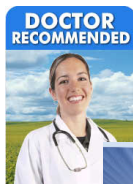


Art. 4

.be

Health claims: specific restrictions

- Are not allowed health claims which
 - suggest that health could be affected by not consuming the food;
 - make reference to recommendation of individual doctors.
 - make references to the rate or amount of weight loss;



Art. 12

.be



General provisions: transitional measures

- Foods placed on the market or imported prior to the date of application of this Regulation which do not comply with this Regulation may be marketed until their expiry date, but not later than 31 July 2009.

Outdated





General provisions



Nutrient profiles



Nutrition claims



Health claims



Scientific substantiation



nous voilà repartis !
Mais attention :
les arguments
santé de votre
en-cas, quoi qu'ils
affirment, n'en
font pas un copain
au quotidien.

Peu de bénéfices beaucoup de graisses

Il est presque impossible de trouver encore, aujourd'hui, des biscuits qui n'affichent pas leur atout santé : "riches en fibres", "moins de graisses saturées", "en-cas équilibré", etc. Les exemples ne manquent pas. Ces allégations, même si elles ne sont pas fausses a priori, servent surtout et en premier lieu les intérêts du fabricant. De nombreuses études ont dé-

*Les rayons
des magasins
regorgent de
biscuits aux
allégations
prometteuses
pour notre
santé*

Fort heureusement, la nouvelle loi nous promet des améliorations quant à ce type d'affirmations (voir TS 83, février/mars 2008). Mais que les choses soient claires : cela ne veut pas dire qu'à l'avenir, les emballages de nos produits seront parole d'évangile pour une alimentation saine... Notre test constitue un bon exemple à cet égard. Le marché des bis-

Les produits de notre sélection jouent explicitement la carte de l'en-cas sain. Nous avons voulu vérifier si leur valeur nutritive était réellement à ce point intéressante. Notre choix s'est porté sur des biscuits pour adultes. Seuls quelques-uns de ces produits s'adressent expressément aux enfants. Leur public cible est principale-

19

Nutrient profiles



Nutrition Facts
Serving Size 1 Cup (28g/1 oz.)
Servings Per Container About 12

Amount Per Serving	Cereal with 1/2 Cup Fat Free Milk	% Daily Value**
Calories	110	150
Calories from Fat	15	15
Total Fat 1.5g*	2%	2%
Saturated Fat 1g	5%	5%
Trans Fat 0g		
Cholesterol 0mg	0%	0%
Sodium 120mg	5%	6%
Potassium 20mg	1%	7%
Total Carbohydrate 24g	8%	10%
Dietary Fiber less than 1g		2%
Sugars 11g		
Other Carbohydrate 13g		
Protein 1g		

Art. 4

20

Nutrient profiles

- Food, or some categories of food, will have to comply with specific nutrient profiles to be allowed to bear claims
- Nutrients profiles will be established taking into account the quantity of particular nutrients in food
- Nutrient profiles should have been adopted by 19 January 2009 at the latest...



Art. 4

2009 Commission working document

	Eligibility criteria
Non-alcoholic beverages	/
Vegetable oil & spreadable fat	< Regulation 2991/94
Fruits, vegetables, and their products	> 50% fruit & VG
Seeds and their products	> 50% nuts
Meat & meat products	> 50% meat
Fish and fish products	> 50% fish
Dairy based products & Cheese	> 50% dairy constituents
Cereal, cereal products & breakfast cereals	> 50% cereal
Soups	> 200g
Ready meals & sandwiches	> 200g + 30g of two of Fruit, VG & nuts products, Cereals products, Meat products, Fish products, Milk
Other food	/

2009 Commission working document

Per 100g or 100ml	Na (mg)	SFA (g)	Sugars (g)
Non-alcoholic beverages	-	-	8
Vegetable oil & spreadable fat	-	30 kcal	-
Fruits & VG and their products	400	5	15
Seeds and their products	400	10	15
Meat & meat products	700	5	-
Fish and fish products	700	10	-
Dairy based products	300	2,5	15
Cheese	600	10	15
Cereal, cereal products	400	5	15
Breads (fiber > 3g/100g or 1,5/100kcal)	700/400	5	15
Breakfast cereals	500	5	25
Ready meal, soup & sandwich	400	5	10
Other food	300	2	10

	General provisions
	Nutrient profiles
	Nutrition claims
	Health claims
	Scientific substantiation

Nutrition claims

- Positive list of nutrition claims each with its relevant condition of use in the annex of the regulation

! And any claim likely to have the same meaning for the consumer !



ANNEX

Nutrition claims and conditions applying to them

LOW ENERGY

A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.

ENERGY-REDUCED

A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.

ENERGY-FREE

A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 4 kcal (17 kJ)/100 ml. For table-top sweeteners the limit of 0.4 kcal (1.7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.

LOW FAT

A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3 g of fat per 100 g for solids or 1.5 g of fat per 100 ml for liquids (1.8 g of

Nutrition claims

LOW ENERGY

the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/ 100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.

ENERGY-REDUCED

the energy value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.

ENERGY-FREE

the product does not contain more than 4 kcal (17 kJ)/100 ml. For table-top sweeteners the limit of 0.4 kcal (1.7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.

Nutrition claims

LOW-FAT

the product contains no more than 3 g of fat per 100 g for solids or 1,5 g of fat per 100ml for liquids (1,8 g of fat per 100 ml for semi-skimmed milk).

FAT-FREE

the product contains no more than 0,5 g of fat per 100 g or 100 ml. However, claims expressed as 'X % fat-free' shall be prohibited.

LOW-SATURATED FAT

the sum of saturated fatty acids and trans-fatty acids in the product does not exceed 1,5 g per 100 g for solids or 0,75 g/100 ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10 % of energy.

SATURATED FAT-FREE

the sum of saturated fat and trans-fatty acids does not exceed 0,1 g of saturated fat per 100 g or 100 ml.

Nutrition claims

LOW SUGAR

the product contains no more than 5g of sugar per 100 g for solids or 2,5 g of sugar per 100 ml for liquids.

SUGAR-FREE

the product contains no more than 0,5 g of sugar per 100 g or 100 ml.

WITH NO ADDED SUGAR

the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the following indication should also appear on the label: 'CONTAINS NATURALLY OCCURRING SUGARS'.

Nutrition claims

LOW SODIUM/SALT

the product contains no more than 0,12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml.

VERY LOW SODIUM/SALT

the product contains no more than 0,04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. This claim shall not be used for natural mineral waters and other waters.

SODIUM-FREE or SALT-FREE

the product contains no more than 0,005 g of sodium, or the equivalent value for salt, per 100 g.

Nutrition claims

LOW SODIUM/SALT

VERY LOW SODIUM/SALT

SODIUM-FREE or SALT-FREE

+

NO ADDED SODIUM / SALT

the product does not contain any added sodium/salt or any other ingredient containing added sodium/salt and the product contains no more than 0,12 g sodium, or the equivalent value for salt, per 100 g or 100 ml.

Nutrition claims

SOURCE OF FIBRE

the product contains at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal.

HIGH FIBRE

the product contains at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal.

SOURCE OF PROTEIN

at least 12 % of the energy value of the food is provided by protein.

HIGH PROTEIN

at least 20 % of the energy value of the food is provided by protein.

Nutrition claims

SOURCE OF (NAME OF VITAMIN/S) AND/OR (NAME OF MINERAL/S)

the product contains at least 15% of the Nutrient Reference Values.

HIGH (NAME OF VITAMIN/S) AND/OR (NAME OF MINERAL/S)

the product contains at least 30% of the Nutrient Reference Values.

CONTAINS (NAME OF THE NUTRIENT OR OTHER SUBSTANCE)

the product complies with all the applicable provisions of this Regulation, and in particular Article 5. For vitamins and minerals the conditions of the claim 'source of' shall apply.

NATURALLY/NATURAL

Where a food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term 'naturally/ natural' may be used as a prefix to the claim.

Nutrition claims

INCREASED (NAME OF THE NUTRIENT)

the product meets the conditions for the claim 'source of and the increase in content is at least 30 % compared to a similar product.

LIGHT/LITE

same conditions as those set for the term 'reduced'; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food 'light' or 'lite'.

Nutrition claims

REDUCED (NAME OF THE NUTRIENT)

the reduction in content is at least 30 % compared to a similar product, except for micronutrients where a 10 % difference in the reference values as set in Council Directive 90/496/EEC shall be acceptable and for sodium, or the equivalent value for salt, where a 25 % difference shall be acceptable.

The claim 'reduced saturated fat' may only be made:

- (a) if the sum of saturated fatty acids and of trans fatty acids is at least 30 % less than in a similar product; and
- (b) if the content in trans fatty acids is equal to or less than in a similar product.

The claim "reduced sugars" may only be made if the amount of energy is equal to or less than the amount of energy in a similar product.

NOW CONTAINS X % LESS ...

Reformulated products where the reduction in content is at least 15 % for energy, fat, saturated fat, salt/sodium or sugars may bear the claim "now contains X % less [energy, fat, saturated fat, sodium/salt, sugars]".

+ statement indicating the content prior to reformulation of the nutrient or energy for which the claim is made, expressed per 100 g or 100 ml.

May be used for a maximum of one year following the placing on the market of the reformulated product (+ exhaustion of stocks for products placed on the market and labelled before the end of this period).

The claim 'now contains X % less of saturated fat' may only be made:

- (a) if the sum of saturated fatty acids and of trans fatty acids is at least 15% less than in the original product prior to the reduction; and
- (b) if the content in trans fatty acids is equal to or less than in the original product.

The claim 'now contains X % less of sugars' may only be made if the amount of energy is equal to or less than the amount of energy in the original product."

Nutrition claims

"SOURCE OF OMEGA-3 FATTY ACIDS

- minimum 0,3g ALA per 100g and per 100kcal, or
- minimum 30mg of the sum EPA and DHA per 100g and per 100kcal.

HIGH OMEGA-3 FATTY ACIDS

- minimum 0,6g ALA per 100g and per 100kcal, or
- minimum 60mg of the sum EPA and DHA per 100g and per 100kcal.

HIGH MONO UNSATURATED FAT

at least 45% of the fatty acids present in the product derive from MUFA under the condition that MUFA provides more than 20% of energy of the product.

HIGH POLY UNSATURATED FAT

at least 45% of the fatty acids present in the product derive from PUFA under the condition that PUFA provides more than 20% of energy of the product.

HIGH UNSATURATED FAT

the amount of unsaturated fat is 70% of the total fat content in the product under the condition that unsaturated fat provides more than 20% of energy of the product.

Nutrition claims: transitional measures

- Foods placed on the market or labelled prior to the date of application of this Regulation which do not comply with this Regulation may be marketed until their expiry date, but not later than 31 July 2009.
- Nutrition claims which have been used in a Member State before 1 January 2009 in compliance with national provisions applicable to them and which are not included in the Annex, may continue to be used until 19 January 2010 under the responsibility of food business operators.



Art. 28.1 & 3



General provisions



Nutrient profiles



Nutrition claims



Health claims



Scientific substantiation

Health claims

- Positive list of health claims each with its relevant condition of use in to be adopted after scientific evaluation by EFSA



Helpt de spieropbouw
Aident à la construction
des muscles

Geeft energie
Apportent
de l'énergie

Energiereserve
Sont une réserve
d'énergie

Noodzakelijk voor een
goede darmfunctie
Nécessaire au bon
fonctionnement
du transit intestinal



Health claims: 3 categories

- Article 13 - "function" health claims:

Ex: *Calcium is needed for strong bones*
Helps to maintain normal cholesterol levels
Helps to improve concentration
Contributes to weight loss

Generic list

Individual
dossiers

Article 14 – development and health of children claims:

Health claims solely referring to the development and health of children:

Ex: *Calcium is needed for normal growth and development of bone*
Essential fatty acids are needed for normal growth and development

+ all claims used on products intended exclusively to children

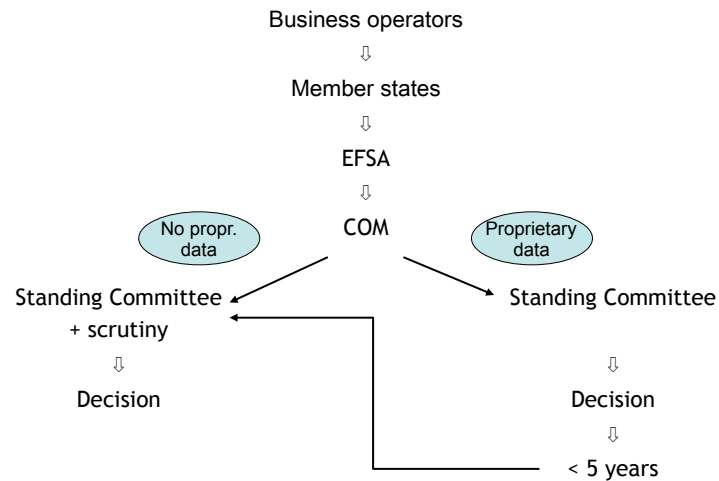
Article 14 – disease risk reduction claims:

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

Individual
dossiers

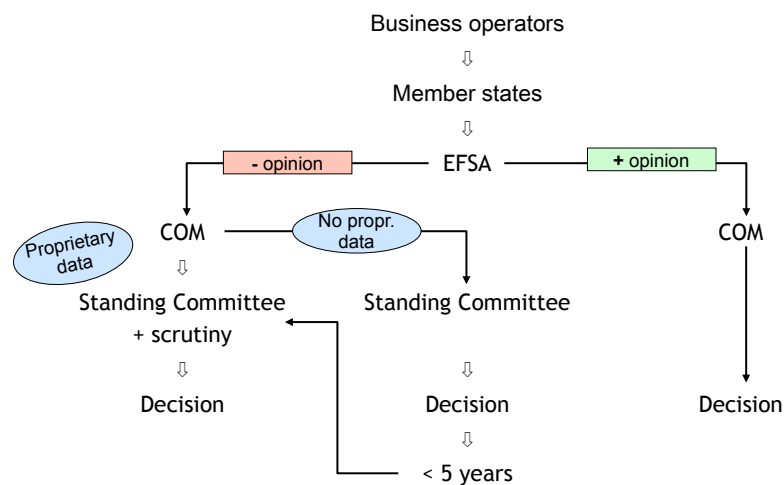
41

Procedure: Article 14 health claims



42

Procedure: Article 13.5 health claims



Individual dossiers

- Article 13.5 and Article 14 claims
- Continuous process:

→ submission → evaluation → adoption/rejection

See: European Union register of nutrition and health claims

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



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

EUROPA > European Commission > DG Health and Consumers > Overview > Food and Feed Safety

General Food Law Animal Nutrition Labelling & Nutrition Biotechnology Novel Food Chemical Safety Biological Safety Official controls

European Union Register of nutrition and health claims made on food - Authorized health claims

Authorised health claims and the conditions applying to them provided for in Articles 13(3) and (5), 14(1), 19(2), 21, 24(2), and 28(6) of Regulation (EC) No 1924/2006 and the national measures referred to in Article 23(3)

Authorised health claims

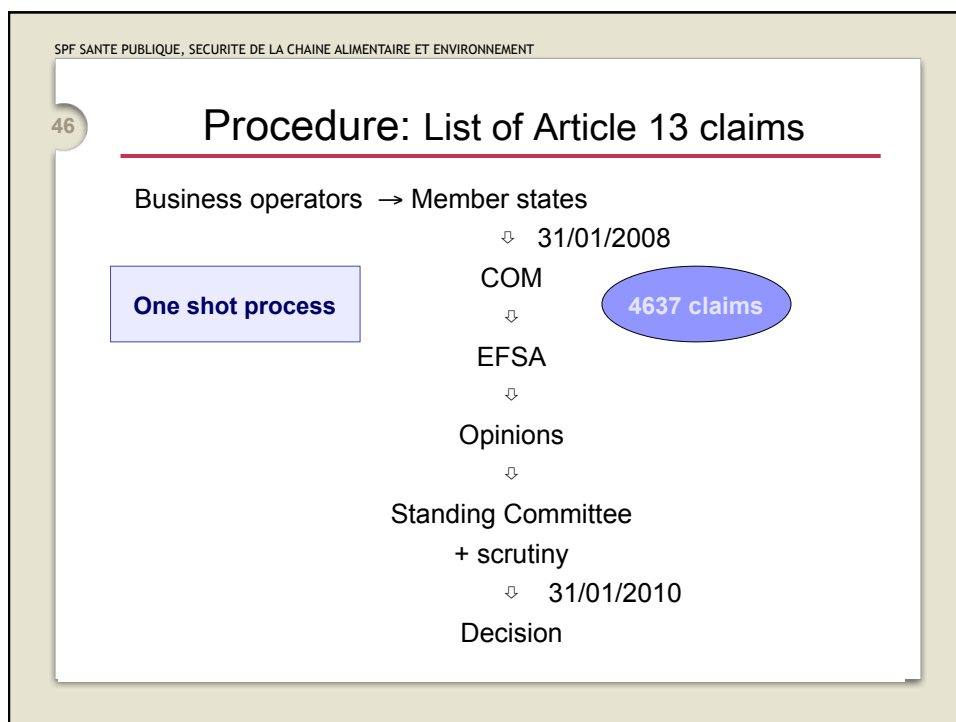
Authorised health claims that can be used by all food business operators provided that they comply with the particular conditions of use of the authorised claim and with the principles and requirements of Regulation (EC) No 1924/2006

- [Article 14\(1\)\(a\) health claims referring to the reduction of a risk factor in the development of a disease](#)
- [Article 14\(1\)\(b\) health claims referring to children's development and health](#)
- [Article 13\(5\) health claims based on newly developed scientific evidence and/or including a request for the protection of proprietary data](#)

➤ **Article 14(1)(a) health claims referring to the reduction of a risk factor in the development of a disease**

Nutrient, substance, food or food category	Claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference	Commission Regulation
Plant sterols/Plant stanol esters	Plant sterols and 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 1.5-2.4 g plant sterols/stanolols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the	Q-2008-779	Commission Regulation (EC) No 384/2010 of 5/05/2010

Individual submissions - Authorized health claims	
Art. 14.1 a Disease risk reduction	
<u>Plant sterols and plant stanol</u> esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	
<u>Sugar-free chewing gum</u> helps neutralise plaque acids. Plaque acids are a risk factor in the development of dental caries	
<u>Sugar-free chewing gum</u> helps reduce tooth demineralisation. Tooth demineralisation is a risk factor in the development of dental caries	
<u>Chewing gum sweetened with 100% xylitol</u> has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries in children	
Art. 14.1 b Children	
<u>LA & ALA</u> are needed for normal growth and development of children	
<u>DHA</u> intake contributes to the normal visual development of infants up to 12 months of age	
<u>DHA</u> maternal intake contributes to the normal devlpt of the eye of the foetus and breastfed infants	
<u>DHA</u> maternal intake contributes to the normal brain devlpt of the foetus and breastfed infants	
<u>Protein/Ca/vit D/P</u> are needed for normal growth and development of bone in children.	
<u>Fe</u> contributes to normal cognitive development of children	
Art. 13.5 – Proprietary data	
<u>Water-Soluble Tomato Concentrate I and II</u> helps maintain normal platelet aggregation, which contributes to healthy blood flow	



List of Article 13 claims

- Claims on botanicals will be addressed at a later stage.
(~ 1500 claims)
- All other claims have been evaluated by EFSA.
- Adoption by Commission and Member States of 'non-botanical' claims at the beginning of 2012 ???




Health claims: transitional measures

When the list is adopted:

- Claims adopted → have to comply with the conditions of use
- Claims submitted but not adopted → out of the market after x months
- Claims not submitted → out of the market directly
- Claims on botanical → status quo until an approach is chosen.



EFSA health claims evaluation status					
10 october 2011					
					
Claim type	received	withdrawn	adopted	In progress	Under validation
Art. 13.5 - New science/ proprietary	57	14	35	7	1
Art. 14.1 a - Disease risk reduction	55	12	27	6	10
Art. 14.1 b - Children	219	106	60	2	51
Total individual submissions	331	132	122	15	62
Art. 13.1 list of health claims	4637	331	2758		1548

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

EUROPA > European Commission > DG Health and Consumers > Overview > Food and Feed Safety

General Food Law Animal Nutrition Labelling & Nutrition Biotechnology Novel Food Chemical Safety Biological Safety Official controls

Site Map | W

European Union Register of nutrition and health claims made on food - Authorized health claims

Authorised health claims and the conditions applying to them provided for in Articles 13(3) and (5), 14(1), 19(2), 21, 24(2), and 28(6) 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 particular conditions of use of the authorised claim and with the principles and requirements of Regulation (EC) No 1924/2006

- Article 14(1)(a) health claims referring to the reduction of a risk factor in the development of a disease
- Article 14(1)(b) health claims referring to children's development and health
- Article 13(5) health claims based on newly developed scientific evidence and/or including a request for the protection of proprietary data

➤ Article 14(1)(a) health claims referring to the reduction of a risk factor in the development of a disease

Nutrient, substance, food or food category	Claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference	Commission Regulation
Plant sterols/Plant stanol esters	Plant sterols and 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 1.5-2.4 g plant sterols/stanolols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the	Q-2008-779	Commission Regulation (EC) No 384/2010 of 5/05/2010 



General provisions



Nutrient profiles



Nutrition claims



Health claims



Scientific substantiation

Scientific substantiation

« the presence, absence or reduced content of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by

generally accepted scientific evidence »

Regulation 1924/2006 - Article 5



Scientific substantiation

In assessing each specific food/health relationship that forms the basis of a health claim EFSA considers the extent to which:

- the food/constituent is defined and characterised ;
- the claimed effect is defined and is a beneficial nutritional or physiological effect (“beneficial to human health”) ;
- a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use) ;



EFSA - Briefing document for Member States and
European Commission on Article 13.1 health claims list

.be

Scientific substantiation

The outcome of each assessment is one of three possible conclusions:

1. A cause and effect relationship has been established between the consumption of the food/constituent and the claimed effect.
2. The evidence provided is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect.
3. A cause and effect relationship is not established between the consumption of the food/constituent and the claimed effect.



EFSA - Briefing document for Member States and
European Commission on Article 13.1 health claims list

.be

Dairy and dental health

Scientific substantiation of a health claim pursuant related to dairy products (milk and cheese) and dental health to Article 14 of Regulation (EC) No 1924/2006¹

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-112)

Adopted on 12 August 2008 by written procedure

In the present application the food category dairy foods is defined as including milk and cheese. The Panel considers that the foods for which the claim is made (milk and cheese) are not sufficiently characterised, e.g. nutritional composition and its variability between products were not provided.

regulat®.pro.kid IMMUN and immune system of children

Scientific substantiation of a health claim related to regulat®.pro.kid IMMUN and immune system of children during growth pursuant to Article 14 of Regulation (EC) No 1924/2006¹

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

On the basis of the data presented, the Panel concludes the following:

- The food for which the claim is made, “regulat®.pro.kid IMMUN”, has not been sufficiently characterised, e.g. sufficient information has not been provided on the lactic acid bacteria strains used for the fermentation of the fruit and vegetable base.
- While a well functioning immune system is important for maintaining physiological integrity and thus health and growth, the claimed effect (support/modulate/improve the immune system in children) is not sufficiently defined and can not be verified from the data provided.
- A cause and effect relationship has not been established between the consumption of regulat®.pro.kid IMMUN and the claimed effect.

Dairy foods and healthy body weight

Scientific substantiation of a health claim related to dairy foods and healthy body weight pursuant to Article 14 of Regulation (EC) No 1924/2006¹

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-110)

Adopted on 08 August 2008 by written procedure

The Panel noted that cross-sectional studies only provide an association and do not provide sufficient evidence of a cause and effect relationship. The two prospective studies included only a small sample size (53 and 92 subjects) and covered a limited age range (2 to 13 years). However, there are no intervention studies to specifically examine any causal relationship, and there are insufficient data to establish a specific level or frequency of consumption of dairy foods associated with any specific effect on body weight.

SCIENTIFIC OPINION

Ocean Spray Cranberry Products[®] and urinary tract infection in women

Scientific substantiation of a health claim related to Ocean Spray Cranberry Products[®] and urinary tract infection in women pursuant to Article 14 of Regulation (EC) No 1924/2006¹

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-117)

The Panel noted that in the other 3 pertinent human studies there were significant limitations, including use of different cranberry formulations from that in the application, poor study design e.g. small numbers of subjects, the lack of a control group, short duration of study, as well as high drop-out rate in some of the studies, that considerably limit their value as a source of evidence to substantiate the claimed effect.

SCIENTIFIC OPINION

Follow-on formulae with bioactive constituents and intestinal ailments

Scientific substantiation of a health claim related to “Follow-on formulae with fixed combination of short-chain galacto-oligosaccharides (GOS), acidified milk, nucleotides and beta-palmitate” and intestinal ailments pursuant to Article 14 of Regulation (EC) No 1924/2006¹

Most studies were performed in infants younger than 6 months of age. Indeed, 4 interventions were carried out between 0 and 3 months of age (Quinlan *et al.*, 1995; Carnielli *et al.*, 1996; Moro *et al.*, 2002, 2003; Costalos *et al.*, 2008) and 11 between 0 and 6 months of age (Brunser *et al.*, 1994; Kennedy *et al.*, 1999; Savino *et al.*, 2003, 2005, 2006; Schmelzle *et al.*, 2003; Xiao-Ming *et al.*, 2004; Bongers *et al.*, 2007; Ziegler *et al.*, 2007; Singhal *et al.*, 2008; Castellazzi *et al.*, unpublished). Thus, 15 studies have been carried out in infants younger (0-6 months) than the target population (6-12 months) of the proposed claim.

Data from younger infants (0-6 months) cannot be generalised to older infants or young children because these populations differ by the level of maturation of digestive functions and the introduction of solid foods in children over 6 months.

Plant Sterols and Blood Cholesterol

Scientific substantiation of a health claim related to plant sterols and lower/reduced blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006¹

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-085)

Adopted on 11 July 2008

The Panel discussed the wording proposed by the applicant and considers that the following wording reflects the available scientific evidence: “Plant sterols have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of coronary heart disease”.



General provisions



Nutrient profiles



Nutrition claims



Health claims



Scientific substantiation

In conclusion

A totally different approach...

- Nutrition and health claims have to be scientifically evaluated and authorized before being used
- Specific conditions of use apply
- Compliance with nutrient profiles will be required





service public fédéral
**SANTE PUBLIQUE,
SECURITE DE LA CHAINE ALIMENTAIRE
ET ENVIRONNEMENT**

JEAN POTTIER

FPS Health, Food Chain Safety and Environment

Tel.: +32 (0)2 / 524 73 62

jean.pottier@health.fgov.be

