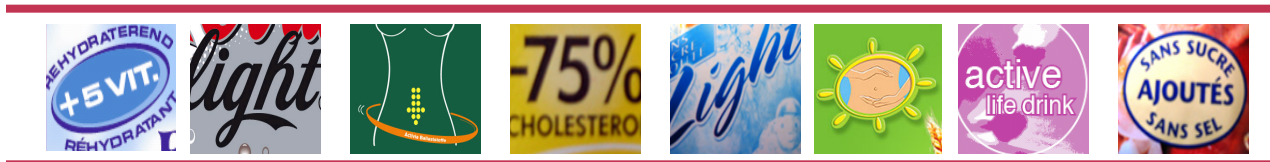


# Nutrition & Health Claims



## European Regulation 1924/2006

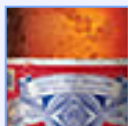


Jean Pottier

FPS Health, Food Chain Safety and Environment

Division Food, Feed and other consumption product





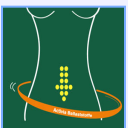
**General provisions**



**Nutrient profiles**



**Nutrition claims**



**Health claims**

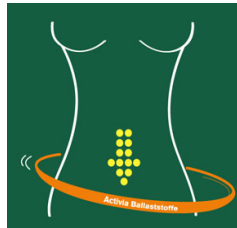


**Scientific substantiation**

## Definitions: Claim

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



## Definitions: Nutrition claim

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- 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**



## Definitions: Health claim

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

→ **Relates to the effect**



## Scope of the regulation

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- 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 !



## Scope of the regulation

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- 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 !



# 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



# 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



# 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



# Health claims: specific restrictions

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- 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;



## General provisions: transitional measures

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- 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

**Outdated**





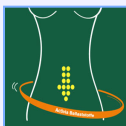
**General provisions**



**Nutrient profiles**



**Nutrition claims**



**Health claims**



**Scientific substantiation**

# Nutrient profiles

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- 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...



**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	/

20 **... is working**

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



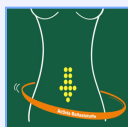
**General provisions**



**Nutrient profiles**



**Nutrition claims**



**Health claims**



**Scientific substantiation**

## Nutrition claims

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- 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 !



# Nutrition claims

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## 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

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### 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 per100 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

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### 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

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### 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

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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

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## 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

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**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

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### "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

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- 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.

**Outdated**





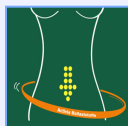
**General provisions**



**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



## 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:

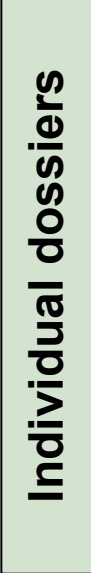
Health claims solely referring to the development and health of children:

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

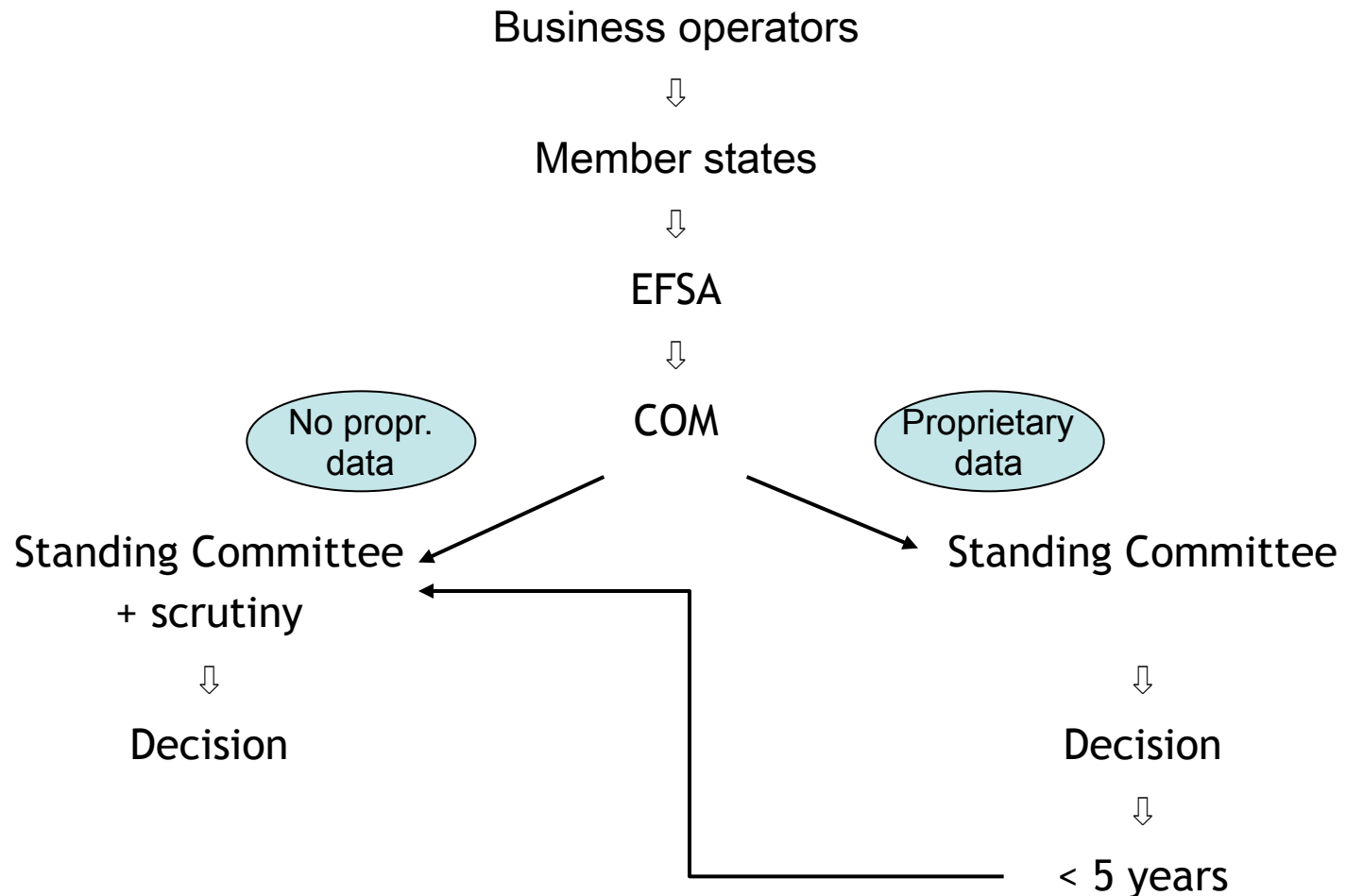
Article 14 – disease risk reduction claims:

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.*

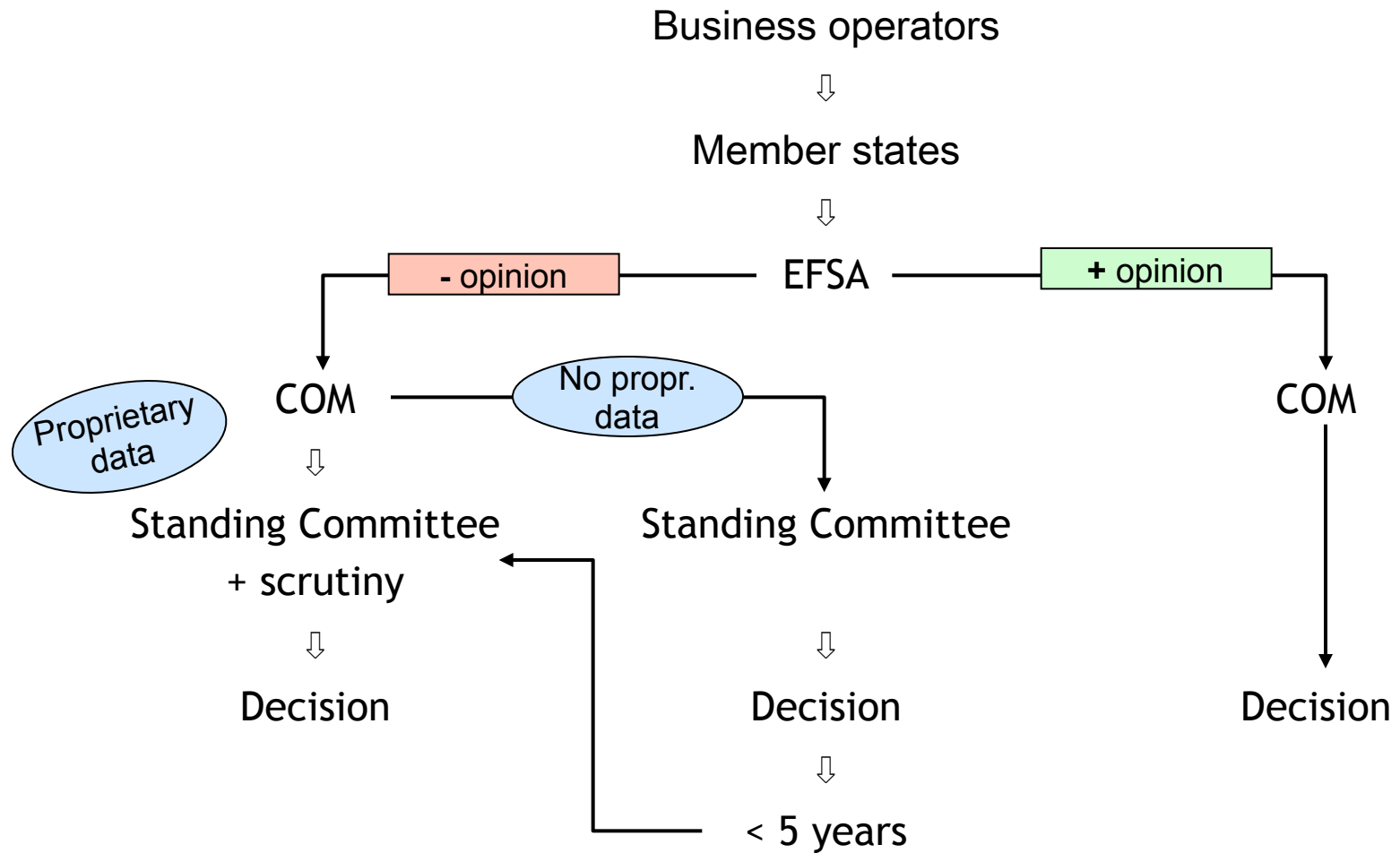


**Individual  
dossiers**

# Procedure: Article 14 health claims



# Procedure: Article 13.5 health claims



## Individual dossiers

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- 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)



# Individual submissions - Authorized health claims

## Art. 14.1 a Disease risk reduction

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

Sugar-free chewing gum helps neutralise plaque acids. Plaque acids are a risk factor in the development of dental caries

Sugar-free chewing gum helps reduce tooth demineralisation. Tooth demineralisation is a risk factor in the development of dental caries

Chewing gum sweetened with 100% xylitol 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

LA & ALA are needed for normal growth and development of children

DHA intake contributes to the normal visual development of infants up to 12 months of age

DHA maternal intake contributes to the normal devlpt of the eye of the foetus and breastfed infants

DHA maternal intake contributes to the normal brain devlpt of the foetus and breastfed infants

Protein/Ca/vit D/P are needed for normal growth and development of bone in children.

Fe contributes to normal cognitive development of children

## Art. 13.5 – Proprietary data

Water-Soluble Tomato Concentrate I and II helps maintain normal platelet aggregation, which contributes to healthy blood flow

# Procedure: List of Article 13 claims

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Business operators → Member states

↓ 31/01/2008

COM

↓

EFSA

↓

Opinions

↓

Standing Committee

+ scrutiny

↓ 31/01/2010

Decision

**One shot process**

**4637 claims**

## 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

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When the list is adopted:

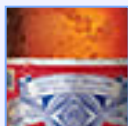
- Claims adopted → have to comply with the conditions of use
- Claims submitted but not adopted → out of the market after x months
- Claims not submitted → out of the market directly
- Claims on botanical → status quo until an approach is chosen.



# 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
<b>Total individual submissions</b>	<b>331</b>	<b>132</b>	<b>122</b>	<b>15</b>	<b>62</b>
<b>Art. 13.1 list of health claims</b>	<b>4637</b>	<b>331</b>	<b>2758</b>		<b>1548</b>



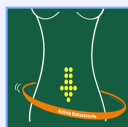
**General provisions**



**Nutrient profiles**



**Nutrition claims**



**Health claims**



**Scientific substantiation**

## Scientific substantiation

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« 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) ;



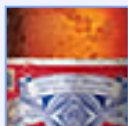
## Scientific substantiation

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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.





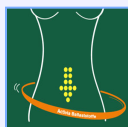
**General provisions**



**Nutrient profiles**



**Nutrition claims**



**Health claims**



**Scientific substantiation**

## In conclusion

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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**

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