



The Legal Department informs ...

New Developments in Food Law



Date: January 24, 2007

From: Armin Behringer

Re: 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



On December 30, 2006, the 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 was published in the Official Journal of the European Union. A short overview of this so-called Health Claims Regulation shall be given in the following.

This Regulation applies to all nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final customer.

“Nutrition claim” means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the energy (calorific value) it provides, provides at a reduced or increased rate, or does not provide; and/or the nutrients or other substances it contains, contains in reduced or increased proportions, or does not contain. Examples of nutrition claims are “low energy”, “sugar-free” or “source of fibre”.

“Health claim” means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. For a health claim, it is sufficient that a relationship exists between a certain product and human health. An example of a health claim is “Calcium improves bone health”.

The Health Claims Regulation brings a fundamental change in food law. Up to now, every statement could be used if it was correct, not misleading for the consumer and provable. Now every claim is forbidden, apart from the claims which are explicitly allowed. This applies as well to nutrition as to health claims.

According to this fundamental principle nutrition claims can only be made if they were mentioned in the Annex of the Regulation and fulfil the defined requirements. This Annex is also enclosed to this document. Apart from the statements literally mentioned in the Annex, similar statements can be used as well. Therefore, it is still allowed to use the claim “low calorie” instead of “low energy”.

Health claims may only be made if they were permitted and published in a Community List. This list is in progress at the moment and should be ready by January 31, 2010.

In order to define certain conditions which must be fulfilled to make nutrition or health claims, nutrition profiles shall be established based on scientific advice given by the European Food Safety Authority (EFSA). The application of nutrient profiles as a criterion would aim at avoiding a situation where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet. They should be based on generally accepted scientific evidence relative to the relationship between diet and health. However, profiles should also allow for product innovations and should take into account the variability of dietary habits and traditions, and the fact that individual products may have an important role in the context of an overall diet.



The establishment of nutrient profiles should take into account the content of different nutrients and substances with a nutritional or physiological effect, in particular such as fat, saturated fat, trans-fatty acids, salt/sodium and sugars, excessive intakes of which in the overall diet are not recommended. Even if not officially mentioned in the Regulation, nutrient profiles shall give the basis for a differentiation between "good" and "bad" foodstuffs.

If a certain food does not meet its nutrient profile, no nutrition or health claims can be made as a general rule. However, by way of derogation from this principle, nutrition (but not health) claims shall be allowed where a single nutrient exceeds the nutrient profile provided that a statement about the specific nutrient appears in close proximity to, on the same side and with the same prominence as the claim. This statement shall read as follows "High [*name of nutrient exceeding the nutrient profile*] content". Assuming that the nutrient profile for a soft drink is exceeded for sugar, the following claim could be made: "Enriched with vitamin C; high sugar content".

When a nutrition claim is made in commercial communications, nutrition labelling is required according to the EC Nutrition Labelling Directive as already in the past. The obligation and the modalities for providing such information shall apply *mutatis mutandis* where a health claim is made. However, in such a case the so-called Big 8 shall be mentioned, i.e. energy value, protein, carbohydrates, sugars, fat, saturates, fibre and sodium. In addition and as the case may be, the amount(s) of the substance(s) to which a nutrition or health claim relates that does not appear in the nutrition labelling shall also be stated in the same field of vision as the nutrition information and be expressed in accordance with the Nutrition Labelling Directive. For example, if a soy product bears the claim "rich in soy isoflavones", the content of isoflavones must be mentioned at the end of the nutrition table.

Regarding nutrition labelling the REGULATION (EC) NO. 1925/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 20 DECEMBER 2006 ON THE ADDITION OF VITAMINS AND MINERALS AND OF CERTAIN OTHER SUBSTANCES TO FOODS has to be considered as well. In case of claims on vitamins and minerals the "Big 8" always become mandatory.

The Health Claims Regulation entered into force on **19 January 2007**. It shall apply from **1 July 2007**.

The date of entry into force is decisive for a number of quite complicated transitional measures.

Foods placed on the market or labelled prior to 1 July 2007 which do not comply with this regulation may be marketed until their expiry date, but not later than **31 July 2009**. That means that foods not complying with the Health Claims Regulation can be manufactured until 30 June 2007 and then be sold off until their best before date. The final date of 31 July 2009 is only relevant for products with a shelf life of more than 24 months.

Foods that do not comply with the nutrient profiles and therefore may no longer bear nutrition or health claims may be marketed until **twenty-four months** following adoption of the relevant nutrient profiles and their conditions of use.



Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this regulation may continue to be marketed until **19 January 2022** after which time the provisions of this Regulation shall apply.

Nutrition claims which have been used in a Member State before 1 January 2006 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**. An example of such a claim is "free of cholesterol" in Germany. However, if such a claim is used on products which came on the market after 1 January 2006, then the general transitional rule applies, i.e. such products may be sold off after 1 July 2007 until their expiry date.

Health claims may be made from the date of entry into force of this Regulation until the adoption of the community list under the responsibility of food business operators provided that they comply with this Regulation and with existing national provisions applicable to them. There are some additional transitional periods for health claims which, however, shall not be mentioned here in more detail.

The complete text of the Health Claims Regulation can be handed over by the legal department in German, English and French language as well as in all other official languages of the EC.

A handwritten signature in blue ink, appearing to read "Armin Behringer".

Armin Behringer



Annex

Nutrition claims and conditions applying on 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 one teaspoon of sucrose), applies.

Remark: In Germany up to now the energy value for low calorie beverages and soups is mentioned as 20 kcal resp. 84 kJ!

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.

Remark: Mandatory explanation of energy reduction is new!

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 one 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 fat per 100 ml for semi-skimmed milk).

FAT-FREE

A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where 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

A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made if 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

A claim that a food does not contain saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the sum of saturated fat and trans-fatty acids does not exceed 0,1 g of saturated fat per 100 g or 100 ml.

LOW SUGAR

A claim that a food is low in sugar, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 5 g of sugar per 100 g for solids or 2,5 g of sugar per 100 ml for liquids.

SUGAR-FREE

A claim that a food is sugar-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of sugar per 100 g or 100 ml.

WITH NO ADDED SUGAR

A claim stating that sugars have not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where 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'.

Remark: It is our understanding that the claim mentioned in the second sentence is not mandatory because of the wording "...should also appear..".



LOW SODIUM/SALT

A claim that a food is low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where 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

A claim that a food is very low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,04 g of sodium, or the equivalent value for salt, per 100 g or 100 ml. This claim shall not be used for natural mineral waters and other waters.

SODIUM-FREE or SALT-FREE

A claim that a food is sodium-free or salt-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,005 g of sodium, or the equivalent value for salt, per 100 g.

SOURCE OF FIBRE

A claim that a food is a source of fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 3 g of fibre per 100 g or at least 1,5 g fibre per 100 kcal.

HIGH FIBRE

A claim that a food is high in fibre, and any claim likely to have the same meaning for the consumer, may only be made where 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

A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 12 % of the energy value of the food is provided by protein.



HIGH PROTEIN

A claim that a food is high in protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 20 % of the energy value of the food is provided by protein.

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

A claim that a food is a source of vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least a significant amount as defined in the Annex to Directive 90/496/EEC or an amount provided for by derogations granted according to Article 7 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and or certain other substances to foods.

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

A claim that a food is high in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least twice the value of 'source of (NAME OF VITAMIN/S) and/or (NAME OF MINERAL/S)'.

CONTAINS (NAME OF THE NUTRIENT OR OTHER SUBSTANCE)

A claim that a food contains a nutrient or another substance, for which specific conditions are not laid down in this Regulation, or any claims likely to have the same meaning for the consumer, may only be made where 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.

Remark: Article 5 mentions especially the following conditions:

- a) The presence, absence or reduced content in a food or category of food 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;*
- b) the nutrient or other substance for which the claim is made:
 - i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claims as established by generally accepted scientific evidence; or**



- ii) *is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claims as established by generally accepted scientific evidence.*
- c) *where applicable, the nutrient or other substance for which the claim is made is in a form that is available to be used by the body.*
- d) *the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claims as established by generally accepted scientific evidence.*

The use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.

INCREASED (NAME OF THE NUTRIENT)

A claim stating that the content in one or more nutrients, other than vitamins and minerals, has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim 'source of' and the increase in content is at least 30 % compared to a similar product.

REDUCED (NAME OF THE NUTRIENT)

A claim stating that the content in one or more nutrients has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least 30 % compared to a similar product, except for micronutrients where a 10 % difference in the reference value as set in Council Directive 90/497/EEC shall be acceptable and for sodium, or the equivalent value for salt, where a 25 % difference shall be acceptable.

LIGHT/LITE

A claim stating that a product is 'light' or 'lite', and any claim likely to have the same meaning for the consumer, shall follow the 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'.

Remark: An explanation for the claim "Light" is mandatory.



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.
