

Draft 17 March 2009

COMMISSION REGULATION (EC) No .../..

of [...]

establishing nutrient profiles provided for in Article 4(1) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods¹, and in particular Article 4(1),

Having consulted the European Food Safety Authority (the Authority),

Whereas:

- (1) Regulation (EC) No 1924/2006 lays down harmonized rules for the use of nutrition and health claims on the labelling, presentation and advertising of foods; such claims are intended to highlight a beneficial effect of a food category, a food, or one of its constituents, due to its nutritional properties or to its effect on health.
- (2) However, foods promoted with such claims may be perceived by consumers as having an overall nutritional, physiological or other health advantage over similar or other products; it is therefore necessary to avoid situations 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; to that end, Article 4 of Regulation (EC) No 1924/2006 provides for the setting up of nutrient profiles, including exemptions, which food or certain categories of food must comply with in order to bear nutrition or health claims; it also states that the conditions under which foods or categories of foods will be subject to the nutrient profiles shall be established.
- (3) Article 4 (1) of Regulation (EC) No 1924/2006 details the elements that shall be taken into account when establishing the nutrient profiles for food and/or certain categories of food, in particular the quantities of certain nutrients and other substances contained in the food, its role, importance and contribution to the diet, and its overall nutritional composition, including the presence of nutrients known as having an effect on health; it also requires that the nutrient profiles shall be based on scientific knowledge about diet and nutrition, and their relation to health.

¹ OJ L 404 30.12.2006 p. 9–25 [corrigendum : OJ L 12 18.01.2007 p. 3–18]

- (4) In accordance with Article 4 (1) of Regulation (EC) No 1924/2006, the Commission has requested the Authority to provide relevant scientific advice in view of establishing the nutrient profiles; on 31 January 2008, the Authority adopted its opinion, providing recommendations on the following: (i) whether profiles should be set for food in general and/or categories of food; (ii) the choice and balance of nutrients to be taken into account; (iii) the choice of reference quantity/basis for profiles (iv) the approach to be used for the calculation of the profiles; and (v) the feasibility and testing of a proposed system;
- (5) In accordance with Article 4 (1) of Regulation (EC) No 1924/2006, certain foods or categories of food may be exempted from the requirement to comply with established nutrient profiles, depending on their role and importance in the diet of the population. Certain foods are important basic elements of traditional diets across Europe and as such are important sources of essential nutrients for the population. It would be appropriate for such foods, mainly unprocessed, to be exempted from the scope of application of nutrient profiles in order to avoid potential conflict with efforts at national or Community level to encourage their inclusion in a balanced and diversified diet of the population. Further, when these basic foods are processed they still can give rise to products that are still, to a large extent, good sources of the essential nutrients in question. It would, therefore, be appropriate to set specific nutrient profiles for these categories of processed foods, which take into account these considerations. Other foods or food categories have no significant impact on dietary intakes of the nutrients that will be taken into account for the nutrient profiles and should also be excluded from the scope of application of nutrient profiles,
- (6) In addition to being scientifically based, nutrient profiles should also be established in a way that ensures proportionality with the objective to be reached, allows for product innovation and takes due account of the necessary feasibility and simplicity of use by all stakeholders and by controlling authorities as well as, at the same time, of the protection of consumer interests. In compliance with Article 4 (1) of Regulation (EC) No 1924/2006, Member States and stakeholders, in particular food business operators and consumers groups, were consulted by the Commission for setting the nutrient profiles; based on that consultation and the opinion of the Authority, it emerges that it is appropriate to set up a system of nutrient profiles for foods in general, from which adjustments and exemptions should be allowed for a limited number of categories of foods or of specific foods for reasons identified above;
- (7) For the sake of clarity, it is appropriate to set specific criteria and conditions with a view to determining which foods and/or categories of foods are covered by these exemptions, and/or by adapted nutrient profiles for certain of them; however, given that specific composition criteria apply to the products covered by Article 115 and annex XV of Regulation (EC) No 1234/2007 of 22 October 2007 laying down standards for spreadable fats, no further conditions are needed for these products to benefit from specific nutrient profiles, while composition criteria should be established for other food categories for which specific nutrient profile applies.

- (8) Following Article 4 (1) Regulation (EC) No 1924/2006, nutrient profiles should be established taking into account nutrients that have been scientifically recognised as having an effect on health; the Authority recommended to select nutrients for which there is evidence of a dietary imbalance in European populations that might influence the development of overweight and obesity or diet-related diseases such as cardiovascular disease, or other disorders; they include nutrients that might be consumed in excess, as well as those for which intakes might be inadequate; it therefore advised that nutrient profiles should take into account nutrients consumed in excess, such as fat, saturated fatty acids, trans-fatty acids, sugars, salt/sodium, but also possibly monounsaturated fatty acids, and fibre, whose intakes are often lower than recommended.
- (9) Nutrient profile schemes can be very elaborated by taking into account many such nutrients, combining nutrients whose excessive consumption would be detrimental to health and those which would be good to consume at higher amounts. Such elaborated nutrient profile scheme could result in a more refined selection of products that would be allowed to bear claims or not. But the burden imposed to economic operators and to controlling authorities would be disproportionate to the benefits expected from such refinement, as resulted through the testing of the various options on the testing basket of foods devised for this purpose.
- (10) Consequently, and for the purpose of better regulation only threshold levels for sodium (salt), saturated fat and sugars should be taken into account for setting of nutrient profiles. Those maximum levels should be set per 100g/ml, which is an efficient, simple and practical reference basis for a category based system limited to nutrients that are consumed in excess.
- (11) Such threshold levels should allow nutrition and health claims on the healthier products within each category of the nutrient profiles system, in line with dietary advice developed and promoted by Member States, allowing for product innovation when reformulation opportunities to reduce the exceeding nutrient(s) exist for products exceeding the maximum levels. In some cases, as for food in dried form, such as milk powder and preparations for instant drinks to be reconstituted with water or milk and for foods in concentrated forms such as fruit concentrate, it is appropriate that maximum level for nutrient profiles should apply only to the food as reconstituted, ready for consumption, following manufacturers' instructions.
- (12) The monitoring of use and the impact of nutrition and health claims is necessary to identify and measure the nutritional impact of nutrient profiles in the diet, potential distortion on competition, such as higher or lower market share, and potential distortion on consumption patterns, such as a lower consumption due to the prohibition of making a claim.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

1. The nutrient profiles which food or certain categories of food must comply with in order to bear nutrition or health claims, as referred to in Article 4 (1) of Regulation (EC) No 1924/2006, are set out in the Annex.
2. For food in dried form, and for foods in concentrated forms, nutrient profiles referred to in paragraph 1 shall apply to the food as reconstituted following manufacturer instructions.

Article 2

- (1) The following foods or food categories are exempted from complying with the nutrient profiles referred to in Article 1 where they bear nutrition or health claims in accordance with Regulation 1924/2006:
 - (a) Fruits, vegetables, seeds and their products, except vegetable oils, presented fresh, frozen, dried, or under any other form in so far as they contain no added sugars, salt or fat;
 - (b) Meats and edible meat offal falling within CN code 02;
 - (c) Fishes and crustaceans, molluscs and other aquatic invertebrates falling within CN codes 03;
 - (d) Milks falling within CN code 0401 20;
 - (e) Eggs falling within CN code 0407;
 - (f) Breads falling within CN code 1905 90 30 and containing at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal;
 - (g) Honey, as defined in Annex I to Council Directive 2001/110/EC of 20 December 2001 relating to honey²;
 - (h) Food supplements as defined in Article 2(a) of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements³;
 - (i) Table top sweeteners as defined by Article 3(2)(g) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives⁴;

² OJ L 10, 12.1.2002, p. 47.

³ OJ L 183, 12.7.2002, p. 51.

⁴ OJ L 354 31.12.2008, p. 16.

- (j) Cough drops falling within CN code 1704 90 55, chewing gum falling under CN code 1704 10 10, and dextrose tablets.
- (2) The following dietetic foods are exempted from complying with the nutrient profiles referred to in Article 1:
 - (a) Cereal-based foods and baby foods intended for infants and young children covered by Commission Directive 2006/125/EC of 5 December on processed cereal-based foods and baby foods for infants and young children⁵;
 - (b) Foods intended for use in energy-restricted diets for weight reduction covered by Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction⁶;
 - (c) Infant formulae and follow-on formulae covered by Commission Directive 2006/141/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction⁷;
 - (d) Dietary foods for special medical purposes covered by Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes⁸.
- (3) Salt is exempted from complying with the nutrient profiles referred to in Article 1 where they bear nutrition or health claims related to the addition of iodine and / or fluorine.

Article 3

Member States, in collaboration with interested parties, in particular food business operators and consumer groups, shall monitor foods bearing nutrition and health claims on the Community market. The monitoring shall be aimed to identify and measure the nutritional impact of nutrient profiles in the diet and any distortion of competition between different food sectors. It shall be in place when nutrient profiles will apply, in order to provide results for reviewing nutrient profiles after the 3 first years of application.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

In accordance to Article 28 (1) of Regulation (EC) No1924/2006, it shall apply from [date of adoption + 2 years]

⁵ OJ L 339, 6.12.2006, p. 16

⁶ OJ L 139, 31.5.2007, p.22

⁷ OJ L 401, 30.12.2006, p.130.

⁸ OJ L 91, 7.4. 1999, p.29.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

ANNEX: specific nutrient profiles and conditions of use, which food or certain categories of food must comply with in order to bear nutrition or health claims

Food category and specific conditions ⁽¹⁾		Thresholds		
		Sodium (mg/100g or 100ml)	Saturates ⁽²⁾ (g/100g or 100ml)	Sugars ⁽²⁾ (g/100g or 100ml)
Vegetable oils, butter and spreadable fats as defined in Article 115 and Annex XV of Council Regulation (EC) No 1234/2007		500	30	10
Products of fruits, vegetables, and seeds, except oils	Products of fruits and vegetables products ⁽⁴⁾ , except oils Minimum 50g of fruit and/or vegetable per 100g of finished products, except for nectars covered by Directive (EC) No 112/2001	400	5	15
	Seeds ⁽⁴⁾ products, except oils Minimum 50g of nuts per 100g of finished products	400	10	15
Meat based products Minimum 50g of meat per 100g of finished products		800	8	10
Fishery products, crustaceans, and molluscs Minimum 50g of fish, crustaceans, and/or molluscs per 100g of finished products		800	10	10
Dairy products as defined in Council Regulation (EC) No 1234/2007, Annex XII	Dairy products, except cheeses Minimum 50g of dairy constituents per 100g of finished products, except for drinks based on fermented milks Minimum 40g per 100g for drinks based on fermented milks	300	2,6	15
	Cheeses Minimum 50g of dairy constituents per 100g of finished products	900	20	15

(1) the minimum quantity required should be calculated on the basis of the ingredients entering into the recipe.

(2) as defined in Council Directive 90/496/EEC.

(3) vegetables include potatoes, beans, and pulses.

(4) seeds include seeds, kernels, nuts. Nuts include peanuts and tree nuts.

Food category and specific conditions		Thresholds		
		Sodium (mg/100g or 100ml)	Saturates (g/100g or 100ml)	Sugars (g/100g or 100ml)
Cereal and cereal products	Cereal and cereal products except breakfast cereals and fine bakery wares Minimum 50g of cereals per 100g of finished products	400	5	15
	Biscuits and other fine bakery wares Minimum 30g of cereals per 100g of finished products for fine bakery wares	500	8	25
	Breakfast cereals Minimum 50g of cereals per 100g of finished products	500	5	25
Ready meals, soups and sandwiches	Soups Minimum 200g per serving size	400	5	10
	Ready meals and sandwiches Minimum 200g per serving size Minimum 2 of the following for: - 30g fruits, vegetables and/or nuts, 30g cereals, 30g meat, 30g fish and/or 30g milk			
Soy based products	Soy based products containing between 3 and 10% soy protein	300	2,6	15
	Soy based products containing more than 10% soy protein	800	8	10
Non alcoholic beverages, insofar as they do not qualify for one of the above mentioned food categories		300	2	8
Other foods, insofar as they do not qualify for one of the above mentioned food categories		300	2	10