



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Brussels, 13 February 2009

**WORKING DOCUMENT ON
THE SETTING OF NUTRIENT PROFILES**

**Preliminary draft
Legal proposal**

Prepared by the Commission services

- (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 for the use of nutrition or health claims for foods or categories of foods with respect 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.
- (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; Nutrient profiles should be based on scientific knowledge about diet and nutrition, and their relation to health.
- (5) 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, in the same time, of the protection of the interests of consumers.
- (6) In accordance with Article 4 (1) of Regulation (EC) No 1924/2006, certain foods or categories of food should be exempted from the requirement to comply with established nutrient profiles, depending on their role and importance in the diet of the population.
- (7) Furthermore, 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; from that

consultation, 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 that have important dietary roles; such food categories have been identified by the Authority on the basis of their importance on the overall diet and are non-alcoholic beverages, cereals and cereal products, vegetable oils and spreadable fats, meat and meat products, fruits and vegetables, and their products, fish and fish products, and dairy products.

- (8) It is appropriate to set conditions of uses for foods and/or categories of foods covered by these exemptions, and/or adapted nutrient profiles for certain of them; in particular, specific nutrient profiles should apply to the products covered by Regulation (EC) No 2991/94 of 5 December 1994 laying down standards for spreadable fats¹, while composition criteria should be established for other food categories for which specific nutrient profile applies.
- (9) 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.
- (10) However, setting a single maximum level of saturated fatty acids appears to be sufficient, as such level takes into account the total fat and monounsaturated fatty acids content of the food, allowing nutrition and health claims on low saturated fat foods, which can be important sources of unsaturated fatty acids.
- (11) Recent reformulation initiatives aiming at lowering trans fatty acid amounts have resulted in the reduction of their overall intake in the diet although some products may still have a high trans fatty acid content; However, many of these products could not bear claims because of other nutritional characteristics, such as a high content of saturated fat or sugars; Under these circumstances, taking trans fatty acid into account in setting nutrient profiles would impose an unnecessary burden on economic operators and controlling authorities without significant benefit for consumers and, therefore, would be disproportionate.
- (12) Consequently, maximum levels of sodium (salt), saturated fat and sugars should be set for foods in general and certain food categories that have an important role in the diet, while specific requirements should be established for ready meals, soups and sandwiches, which would not otherwise qualify for any adapted nutrient profile; those

¹ OJ L 316, 9.12.1994, p. 2.

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.

- (13) Such maximum levels 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.
- (14) Cereals and cereal products are important providers of fibre and carbohydrates other than sugars; the overall nutritional benefits of that food category is taken into account more appropriately through an adapted nutrient profile, rather than by setting a minimum fibre content, which would only favour the products rich in natural or added fibre.
- (15) Nutrient profiles should take account of reformulation initiatives promoted at national and Community levels; reformulation with respect to salt content is an ongoing initiative; Bread, which is a major contributor of sodium intake, but at the same time plays an important role in the diet of the population in general, should be accorded particular attention. A higher threshold for sodium level in bread containing fibre, such as certain traditional brown breads and crisp breads should be set for a limited period in the context of nutrient profiles.
- (16) In the case of soy based products, which do not fall under specific categories as listed in Annex 1, the Authority should be consulted with regard to the setting of specific nutrient profiles, so that, if appropriate, specific measures, based on the Authority's opinion, could be put forward at the latest two years after the adoption of this Regulation.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

Article 1

The nutrient profiles and their conditions of uses established in accordance with Article 4 (1) of Regulation (EC) No 1924/2006, are listed per food category in Annex 1.

For the purpose of the use of the nutrient profiles, the definitions of 'sugars' and 'saturates' set out in Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs² shall apply.

² OJ L 276, 6.10.1990, p. 40. Directive as last amended by Commission Directive 2003/120/EC (OJ L 333, 20.12.2003, p. 51).

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:
- (a) Fruits, vegetables and their products, presented fresh, frozen, dried, or under any other form in so far as they contain no added sugars, salt or fat, except vegetable oils;
 - (b) Honey, as defined in Council Directive 2001/110/EC³;
 - (c) Food supplements as defined in Article 2(a) of Directive 2002/46/EC⁴;
 - (d) Table top sweeteners as defined by Article 3(g) of Regulation (EC) N° 1333/2008⁵.
- (2) The following dietetic foods are exempted to comply with the nutrient profiles with regard to their nutrients for which levels are already regulated:
- Cereal-based foods and baby foods intended for infants and young children covered by Commission Directive 2006/125/EC⁶;
- (a) Foods intended for use in energy-restricted diets for weight reduction covered by Commission Directive 96/8/EC⁷;
 - (b) Infant formulae and follow-on formulae covered by Commission Directive 2006/141/EC⁸;
 - (c) Dietary foods for special medical purposes covered Commission Directive 1999/21/EC⁹.

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 syrup, nutrient profiles shall apply to the food as reconstituted following manufacturer instructions.

³ OJ L 10, 12.1.2002, p. 47–52.

⁴ OJ L 183, 12.7.2002, p. 51. Directive as amended by Commission Directive 2006/37/EC (OJ L 94, 1.4.2006, p. 32).

⁵ OJ L 354 31.12.2008, p. 16

⁶ OJ L 339, 6.12.2006, p. 16

⁷ OJ L 139, 31.5.2007, p.22

⁸ OJ L 401, 30.12.2006, p.130.

⁹ OJ L 91, 7.4. 1999, p.29.

Article 3

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 applies from [date of publication + 2 years]

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

ANNEX 1: 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		Specific conditions*	Thresholds		
			Sodium (mg/100g or 100ml)	Saturates (g/100g or 100ml except when specified otherwise)	Sugars (g/100g or 100ml)
Vegetable oils and spreadable fats as defined in Council Regulation (EC) No 2991/94		-	500	30 kcal /100g	-
Fruits, vegetables, seeds, and their products, except oils	Fruits, vegetables, and their products, except oils**	Minimum 50g of fruit and/or vegetable per 100g of finished products	400	5	15
	Seeds*** and their products, except oils	Minimum 50g of nuts per 100g of finished products	400	10	15
Meat or meat based products		Minimum 50g of meat per 100g of finished products	700	5	-
Fish, fishery products, crustaceans, and molluscs		Minimum 50g of fish per 100g of finished products	700	10	-
Dairy based products	Dairy based products, except cheeses	Minimum 50g of dairy constituents per 100g of finished products	300	2,5	15
	Cheeses	Minimum 50g of dairy constituents per 100g of finished products	600	10	15

Food category		Specific conditions*	Thresholds		
			Sodium (mg/100g or 100ml)	Saturates (g/100g or 100ml except when specified otherwise)	Sugars (g/100g or 100ml)
Cereal and cereal products	Breads containing at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal.	Minimum 50g of cereals per 100g of finished products	700 until [date of adoption + 6 years] 400 from [date of adoption + 6 years]	5	15
	Cereal and cereal products except breakfast cereals	Minimum 50g of cereals per 100g of finished products	400	5	15
	Breakfast cereals	Minimum 50g of cereals per 100g of finished products	500	5	25
Ready meals, soups and sandwiches		Minimum 200g per serving size Minimum 2 of the following for ready meals and sandwiches: - 30g fruits, vegetables and/or nuts, 30g cereals, 30g meat, 30g fish and/or 30g milk	400	5	10
Non alcoholic beverages		Liquid foods, insofar as they do not qualify for one of the above mentioned food categories	-	-	8
Other foods		Solid foods, insofar as they do not qualify for one of the above mentioned food categories	300	2	10

* the minimum quantity required should be calculated on the basis of the ingredients entering into the recipe.

** vegetables include potatoes, beans, and pulses.

*** seeds include seeds, kernels, nuts. Nuts include peanuts and tree nuts.