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# THE SETTING OF NUTRIENT PROFILES FOR FOODS BEARING NUTRITION AND HEALTH CLAIMS PURSUANT TO ARTICLE 4 OF THE REGULATION (EC) ° No 1924/2006

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

**(Request N° EFSA-Q-2007-058)**

**Adopted on 31 January 2008**

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| **EFSA consultation event (EFSA Conference on Nutrition and Health Claims)** | 8-10 November 2006 |
| **Receipt of request letter and terms of reference from the European Commission** | 19 February 2007 |
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| **EFSA additional consultation event (EFSA 9th Scientific Colloquium on Nutrient Profiling for foods bearing nutrition and health claims)** | 11-12 October 2007 |
| **Adoption of the Opinion by the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA Panel)** | 31 January 2008 |

European Food Safety Authority

*The EFSA Journal* (2008) 644, 1-44

# The setting of nutrient profiles for foods bearing nutrition and health claims pursuant to Article 4 of the Regulation (EC) No 1924/2006

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

**(Request Nº EFSA-Q-2007-058)**

**Adopted on 31 January 2008**

**SUMMARY**

The European Commission has requested the European Food Safety Authority (EFSA) to provide relevant scientific advice for the setting of nutrient profiles.

Article 4 of Regulation 1924/2006 on Nutrition and Health Claims on Foods foresees that the European Commission shall establish (by 19th January, 2009) specific nutrient profiles that foods or certain groups of foods must respect in order to bear nutrition and health claims. Foods promoted with claims might be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products without claims. The use of nutrient profiles aims to avoid a situation where nutrition or health claims could mislead consumers as to the overall nutritional quality of a food product when trying to make healthy choices in the context of a balanced diet.

In preparing its scientific advice to the Commission, the Panel reviewed a wide range of reports and papers on nutrient profiles and considered views from stakeholders.

In addition to this Opinion, EFSA will continue to assist the European Commission in establishing a nutrient profile scheme, by developing a suitable food composition database and providing advice on its use in testing any proposed system.

*General Principles* - The term 'nutrient profile' refers to the nutrient composition of a food or diet. 'Nutrient profiling' is the classification of foods for specific purposes based on their nutrient composition. In this opinion, the purpose is solely for the regulation of nutrition and health claims made on foods.

The nutrient profile of the overall (habitual) diet is an important determinant of health and the nutrient profile of a 'balanced' diet is defined by science based recommendations for intakes of energy and nutrients. Because diets are composed of multiple foods, overall dietary balance may be achieved through complementation of foods with different nutrient profiles so that it is not necessary for individual foods to match the nutrient profile of a 'balanced' diet. Nevertheless, individual foods might influence the nutrient profile of the overall diet, depending on the nutrient profile of the particular food and its intake. Thus, when classifying

food products as eligible to bear claims, the potential of the food to adversely affect the overall dietary balance is the main scientific consideration.

This consideration relates in particular to nutrients for which there is evidence of a dietary imbalance in EU 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 to excess, as well as those for which intake might be inadequate.

The Regulation requires that the setting of nutrient profiles should take into account the dietary role and importance of food groups and their contribution of nutrients to the overall diet of the population (or specific population groups). Food groups with important dietary roles include vegetable oils, spreadable fats, dairy products, cereals and cereal products, fruits and vegetables and their products, meat and meat products, fish and fish products, and non-alcoholic beverages. The different dietary roles of such food groups are related to differences in their nutrient composition, as well as their (habitual) intake, and are recognised in food based dietary guidelines in Member States. Such guidelines also make distinctions between different products within these food groups based on their potential to influence, beneficially or adversely, the overall dietary balance for certain nutrients. The dietary roles of these food groups might differ across Member States owing to the variability of dietary habits and traditions and the Regulation requires that this variability be taken into account in establishing nutrient profiles.

Experience with nutrient profile schemes has shown that such schemes need to be adaptable in order to provide for issues that might arise from time to time in their use for the classification of food products.

*Nutrient profiles for food in general and/or categories of food* – For a category-based scheme, food groups, such as dairy products (including e.g. milk, yoghurt, cheese) or cereal products (including e.g. bread, breakfast cereals, bakery products, rice, pasta) could have specific nutrient profiles related to the potential of food products in those groups to adversely affect overall dietary balance. Such a scheme could have a simple nutrient profile for each food group and could be easily adapted. The main disadvantage would be the complexity of defining and managing a large number of food groups. A scheme for food in general could have a single nutrient profile for all foods. While this approach would avoid the need to define and manage food groups, the need to account for large differences in the nutritional composition of different food groups could lead to a more complex nutrient profile scheme that might be less easy to adapt than a category-based scheme.

The Panel considers that a nutrient profile for food in general with exemptions from the general profile, if necessary, for a limited number of food groups that have important dietary roles (one option outlined in the Terms of Reference) might overcome the main disadvantages of these two types of schemes. Such exemptions would ensure that some food products in these food groups might be eligible to bear claims. Exemptions for some food groups from the requirement to comply with the nutrient profile for food in general might be based on the use of different nutrients, thresholds or scores.

*Choice of nutrients* - The Panel recommends that the choice of nutrients to be included in nutrient profiles should be driven by their public health importance for EU populations. These nutrients include saturated fatty acids, sodium, dietary fibre and unsaturated fatty acids, intakes of which generally do not comply with nutrient intake recommendations in many Member States. Unsaturated fatty acids might not be needed if saturated fatty acids are

included. The use of dietary fibre might be limited to certain food groups that are important dietary fibre sources and for which the use of dietary fibre to discriminate between food products would be most relevant, e.g. cereal products. Trans fatty acids might be included for some food groups but are of decreasing public health importance as intakes in the EU have declined considerably. Total sugar content might be included for particular food groups, e.g. beverages, and foods, such as confectionery products, that might be consumed with a high frequency. Depending on the scheme adopted, energy density or total fat, as well as other nutrients, might also be considered. However, the total number of nutrients included would have to be limited to avoid overly complex nutrient profiles.

*Reference quantity* – Nutrient profiles are related to a reference quantity of food, expressed per portion, by weight/volume (e.g. per 100g or 100ml), or on an energy basis (e.g. per 100 kcal or 100kJ). The Panel recommends that selection of a suitable reference quantity should be based on pragmatic considerations related to the needs of the particular nutrient profile scheme.

*Threshold/scoring* – A nutrient profiling scheme could be based on threshold or scoring systems. A threshold is a nutrient concentration value that must be complied with for the food to be eligible to bear a claim. The Regulation allows derogation for one nutrient in the case of nutrition claims, whereas all the thresholds must be met for health claims. Scores for food products could be based on their content of the nutrients that are in the nutrient profile scheme. The Panel recommends that the choice of threshold or scoring system should be based on pragmatic considerations related to the needs of the particular scheme, while threshold or score values should be selected to ensure the appropriate classification of food products.

*Feasibility/testing* - Testing the suitability of a nutrient profile scheme to classify foods appropriately as being eligible to bear nutrition and/or health claims requires a database of energy and nutrient contents of a range of foods (as purchased) on the EU market. The database is interrogated to identify foods that are (i) eligible to bear health claims (comply in full with the nutrient profile), (ii) eligible to bear nutrition claims (comply with the nutrient profile except for one nutrient) or (iii) ineligible to bear a nutrition or health claim.

The main scientific consideration for judging whether food products are classified appropriately is the potential of the food products to adversely affect the overall dietary balance for nutrients of public health importance. In practice, it is easier to assess the classification of a food in relation to other foods in the same group, i.e. whether a food is more or less likely to adversely affect the overall dietary balance than other foods in the same food group.

The dietary role and importance of the food group, allowing for the variability in dietary habits and traditions across different Member States, must also be taken into account in order to ensure that some products in food groups that have important dietary roles can bear claims.

The classification of foods as being eligible to bear nutrition and/or health claims should be consistent with food based dietary guidelines established in Member States, albeit it is recognised that such guidelines are not uniform across countries.

In addition to scientific considerations, other issues that must be taken into account by the European Commission include the need to allow for product innovation and the feasibility and ease of use of the nutrient profile scheme.

*Limitations* – The Panel recognises the scientific limitations intrinsic in the use of nutrient profiles to classify foods as eligible to bear claims and the need for expert judgement to be applied. There is an inherent difficulty in seeking to apply to individual food products nutrient intake recommendations that are established for the overall diet. Furthermore, the potential of food products (as purchased) to adversely affect the overall dietary balance does not take into account changes in nutrient content that occur during cooking or preparation, such as addition of fat, sugar or salt, nor does it take into account the habitual intake of the food or the pattern of consumption. In addition, the lack of uniform data for food composition and food consumption across the EU, as well as differences in nutrient intake recommendations and food based dietary guidelines between Member States, makes it more difficult to set nutrient profiles at EU level than at national level. The basis for expert judgements needed to address such limitations should be transparent in order to avoid variable outcomes.

**KEY WORDS**

Nutrients, food groups, nutrient intake recommendations, dietary recommendations, food based dietary guidelines, balanced diet, nutrition claims, health claims, nutrient profiles, nutrient profiling, across the board scheme, category-based scheme, reference quantity

## BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[1] entered into force on 19th January 2007.

Article 4 of the Regulation foresees that the Commission shall establish specific nutrient profiles, including exemptions, which foods or certain categories of foods must respect in order to bear nutrition or health claims. These nutrient profiles shall be established through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

The adoption of nutrient profiles as a criterion for permitting products to make claims is an innovative step that aims to benefit both the consumers and the food manufacturers by ensuring that claims do not mask the overall nutrient content of the products and encouraging manufacturers to improve the nutritional quality of their products. This should favour the development of products whose composition helps consumers to follow current scientific advice, as to the overall nutrient balance to be aimed at day by day. This in turn is expected to help stem the increasing levels of obesity and of non-communicable diseases that today are of major public health concerns.

The setting of nutrient profiles is an exercise that should take into account dietary recommendations, public health considerations, generally accepted scientific evidence relative to the relationship between diet, nutrition and health as well as other considerations of an industrial/commercial, cultural and dietary/culinary nature. Profiles should also, however, permit product innovation and should take into account the variability of dietary habits and traditions and the fact that dietary changes take time.

The setting of nutrient profiles should be undertaken bearing in mind the concept of better regulation. As such the exercise should meet a number of criteria such as feasibility, simplicity, ease of use by all the stakeholders and by the controlling authorities while protecting at the same time the interests of the consumers.

## TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 29 (1) (a) of Regulation (EC) N° 178/2002, the European Commission requests the European Food Safety Authority to provide relevant scientific advice for the setting of nutrient profiles focusing in particular on:

(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 the calculation of the profiles, and

[1] European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

(v) the feasibility and testing of a proposed system.

In addition the Authority is requested to provide scientific advice on thresholds that should be used for triggering the derogation foreseen in Article 4(2)(b) of the Regulation. In providing scientific advice, EFSA is asked to consider to following:

**Profiles to be set for food in general and/or categories of food**

The first point to be considered is whether a single set of nutrient profiles should be set for all foods across the board, whether nutrient profiles should be set by categories of foods or whether there should be a combination of the two approaches.

A single set of nutrient profiles may be too rigid for taking into account the variety of products that are currently eaten as part of a varied diet across the EU. On the other hand setting profiles for an excessive number of categories of foods could be rather unmanageable both for the interested operators and for the controlling authorities. Finally, it should also be noted that the Regulation foresees the adoption of exemptions.

A system could combine both advantages of setting profiles in general and for a limited number of food categories or individual foods. An overall nutrient profile would be set from which derogations, adjustments and exemptions may be decided for a limited number of categories of foods or individual foods. These could be identified by taking account of the provision of Article 4(1):

"(b) the role and importance of the food (or of categories of food) and the contribution to the diet of the population in general or, as appropriate, of certain risk groups including children;

(c) the overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health."

Categories could be, for example, some or all of:

- Vegetable oils
- Spreadable fats
- Dairy products
- Cereal products (bread, breakfast cereals)
- Fruit products

The number of such categories, should be limited above all in the starting period, but may be able to evolve over time. The coverage of such categories should be based on scientific opinion and will help to avoid borderline issues. For example, when fruits are concerned, the limit of the category may be established by taking into account criteria such as of the presence of vitamins and the sugar added. This will concern manufactured products, such as fruits salads in light / heavy sugar syrup, fruits juices, fruits and vegetable juices, compote, compotes with added sugar, compotes with fruit juice concentrates (apple juice concentrate) and jams.

Specific conditions could also be discussed. Total exemption, or specific nutrient profiles could be proposed, depending on the characteristics of the product and its role in the diet. For example, should the saturated fat level for some dairy products (full fat milk, cheeses), vegetable oils and spreadable fats be considered as the only criterion to be taken into account to set specific nutrient profiles. Should sugar levels be adapted for breakfast cereals if those contain high levels of fibre.

Other foods or categories of foods may have a micronutrient content and bioavailability of particular interest for the intake of that nutrient, such as iron in meat products and may also be considered.

### Choice and balance of nutrients to be taken into account

Secondly, consideration should be given to the selection of the nutrients to be taken into account in setting the nutrient profiles. A number of important points should be given consideration here such as the ease of use of the model, its robustness, its cost effectiveness, avoiding undue distorting effects for the market and current scientific opinion about the role of nutrients in health, and the availability of data on composition of products that will allow the effective control of compliance.

In selecting such nutrients note should be taken of the provision of Article 4(1)(a):

"(a) the quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium"

and of recital 12 which states that "the establishment of nutrient profiles should take into account the content of different nutrients and substances with a nutritional or physiological effect, in particular those such as fat, saturated fatty acids, trans-fatty acids, salt/sodium and sugars, excessive intakes of which in the overall diet are not recommended, as well as poly- and mono-unsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre."

A key consideration in the choice of nutrients to take into account is whether a wide range of them should be used in the formulation of the overall nutrient profiles or some few pertinent ones, and depending, as the case may be, on the food category. Again the virtues of nutrient profiles based on a large number of nutrients should be weighted against the burden that such complexity would constitute.

The question of maintaining total fat, as a criterion for nutrient profiles could be considered, taking into account that total fat could include saturated fat, for which intake among the European population is too high, and fats such as mono and poly-unsaturated fatty acids, which are nutritionally preferable according to scientific evidence.

Trans-fatty acids, like saturated fat, are also among the fats whose consumption can be detrimental to health and therefore being among the nutrients to be taken into account. The alternative to consider would be to have the sum of trans fatty acids and saturated fat as a single criterion. Finally, an energy criterion could be taken into consideration as an alternative to fat, as its level is well reflected in the food energy density. However, it should be taken into account that calories are already part of nutrition labelling that is compulsory when a claim is made.

Concerning the other nutrients listed in article 4 of the Regulation, i.e. sodium and sugars, it is crucial that they are covered overall, but also in the context of some food categories as already mentioned above.

Positive nutrients (one or more) could be considered for overall profiles or limited for some food categories. For example, the level of fibre in cereal products could be taken into account or the calcium level for some dairy products.

### The choice of reference quantity/basis for profiles

The basis on which to base the nutrient profiles is important. Such basis is usually the energy or the weight/volume of the foods. However, with the increasing offer of products in portions, the basis of portion may merit consideration. The lack of uniformity in the portion sizes across the EU may, however, constitute a serious handicap for that basis. In any case, the choice of the basis should be adapted to the objectives of the exercise and should be the one that minimises any undue anomalies in the market.

### The approach to the calculation of the profiles

An important piece in the puzzle of setting the nutrient profiles will be the mode or approach for calculating/setting those. One approach can be by setting specific thresholds for the nutrients chosen. Otherwise the nutrients chosen may be attributed a weighting according to the nutrient and its quantity present in the food which will result in a scoring system for calculating the profiles.

It should be noted that Article 4(2)(b) provides for a derogation according to which a claim may be made for a product where a single nutrient is exceeding the profiles provided a relevant statement appears in close proximity to the claim. If the nutrient profiles are set by a scoring system, then a threshold will need to be set for the triggering of the above-mentioned derogation.

In its technical report entitled “Diet, nutrition and the prevention of chronic diseases” that WHO published in 2003, some Population Nutrient Intake goals for preventing diet-related chronic diseases are proposed and could serve as a starting point to develop a nutrient profiles system.

In this report, it is proposed that saturated fatty acid should not bring more than 10% of energy of the total diet. The same percentage is proposed for added sugars, defined as all monosaccharides and disaccharides added to foods by the manufacturer, cook or consumer, plus sugars naturally present in honey, syrups and fruit juices.

An intake of 2g of sodium per day is also proposed, which would correspond to a level of 100mg/100kcal for an intake of 2000 kcal per day.

### The feasibility and testing of a proposed system

Finally, it would be desirable that potential nutrient profile models are tested for their feasibility and effects on a range of foods currently existing on the market. This would permit to minimise undue effects and, as the case may be, adjust the models accordingly. In fact, this should allow to examine the effect of varying the parameters of the model on a test sample and identify different variants for the final model, as well as the resulting consequences for the products of the test sample.

Testing and adequate corrections can only be performed with given models. Before such tentative models begin to emerge the Commission services intend to provide further guidance on the sample of foods to be used for the testing. Contacts are taken with stakeholders and Member States in order to elaborate this test sample.

# 1. INTRODUCTION

Nutrient profiling has been defined as "the science of categorizing foods according to their nutritional composition" (Rayner *et al*., 2004), or as "categorization of foods for specific purposes on the basis of their nutrient composition according to scientific principles" (Tetens *et al*., 2007). In the context of the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods[2] (hereafter "**the Regulation**"), nutrient profiling is intended for the sole purpose of governing the circumstances in which nutrition and health claims may be made.

EFSA has been asked by the Commission to provide scientific advice on the setting of nutrient profiles as indicated in Article 4 of the Regulation. This Regulation foresees that the European Commission shall establish (by 19th January, 2009) specific nutrient profiles with which foods or certain groups of foods must comply in order to bear nutrition and health claims. Foods promoted with claims might be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products without claims. The use of nutrient profiles would aim to avoid a situation where nutrition or health claims could mislead consumers as to the overall nutritional quality of a food product when trying to make healthy choices in the context of a balanced diet.

According to the Regulation, such profiles should take into account dietary recommendations and public health implications, consider the role and importance of foods in the diet, and the variability of dietary habits and traditions across Europe, and also allow for product innovation by food manufacturers. All nutrients and other substances with a nutritional or physiological effect, in particular those for which excessive intakes are not recommended, such as fat, saturated fatty acids (SFA), trans fatty acids (TFA), salt/sodium, and sugars could be considered in the setting of profiles.

In preparing its scientific advice to the Commission, the Panel reviewed a wide range of reports and papers on nutrient profiles, including existing national and private schemes for nutrient profiling. The Panel also considered views from stakeholders resulting from two consultation events, i.e. the EFSA Conference on Nutrition and Health Claims (EFSA, 2006), and the EFSA Scientific Colloquium on Nutrient Profiles (EFSA, 2007).

Although the Panel has tried to answer each question individually, it is mindful that the questions posed in the Terms of Reference are inter-related and answers for each question will necessarily be inter-dependent.

In addition to this Opinion, EFSA will continue to assist the European Commission in establishing a nutrient profile scheme by developing a suitable food composition database and providing advice for its use in testing any proposed scheme.

[2] European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

## 2. GENERAL PRINCIPLES

- The term 'nutrient profile' refers to the nutrient composition of a food or diet. 'Nutrient profiling' refers to the classification of foods based on their nutrient composition for specific purposes. In this Opinion, the purpose is solely for the regulation of nutrition and health claims made on foods[3].
- The nutrient profile of the overall (habitual) diet is an important determinant of health and the nutrient profile of a 'balanced' diet is defined by science based recommendations for intakes of energy and nutrients. Because diets are composed of multiple foods, overall dietary balance may be achieved through complementation of foods with different nutrient profiles so that it is not necessary for individual foods to match the nutrient profile of a 'balanced' diet. Nevertheless, individual foods might influence the nutrient profile of the overall diet, depending on the nutrient profile of the particular food and its intake. Thus, when classifying food products as eligible to bear nutrition and/or health claims, the potential of the food to adversely affect the overall dietary balance is the main scientific consideration.
- This consideration relates in particular to **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 to excess, as well as those for which intakes might be inadequate (**Section 4**).
- The setting of nutrient profiles should take into account **the dietary role and importance of food groups and their contribution of nutrients to the overall diet of the population (or specific population groups)** in order to ensure that some food products in food groups with an important dietary role might be eligible to bear claims. Some food groups are recognized as having important roles in the diets of different population groups. The particular dietary roles of such food groups are related to differences in their nutrient composition, as well as their (habitual) intake, and are recognised in food based dietary guidelines in Member States. Such guidelines also make distinctions between different products within these food groups based on their potential to influence, beneficially or adversely, the overall dietary balance for certain nutrients (**Section 5**). The dietary roles of these food groups might differ across Member States owing to the variability of dietary habits and traditions. The Regulation requires that this variability be taken into account in establishing nutrient profiles.
- Experience with nutrient profile schemes has shown that they need to be adaptable in order to provide for issues that may arise from time to time in their use in the classification of particular food products.

[3] European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

## 3. OVERVIEW OF NUTRIENT PROFILES SCHEMES

Nutrient profiling has been used for different purposes, e.g.: for nutritional classification of foods, product development purposes, or for the regulation of claims. Reviews of existing schemes for nutrient profiling, including comparisons and critical discussions, are available (Stockley, 2003; Tetens *et al*., 2007; Garsetti *et al*., 2007; BEUC, 2006; Azais-Braesco *et al*., 2006; Scarborough *et al*., 2007a) and are summarised in the **Annex** as are those schemes intended for nutrition education, product labelling and product development.

Nutrient profiling for other purposes than regulation of claims is available, such as nutrition education by health professionals, and as guidance to help consumers to make 'healthy' choices from the wide range of available food products. Nutrient profiling schemes are also increasingly used as a (voluntary or private) basis for product labelling by food producers and retailers who use graphic or symbolic representations (logos) on food products to communicate nutrition information to the consumer and/or to mark products as "healthy" food choices. Such classifications are also applied in product development and (re)formulation by serving as a tool to evaluate and improve the overall nutritional quality of a producer's product portfolio (Nijman *et al*., 2007; Labouze *et al*., 2007). In the UK, a nutrient profile was established by the Food Standards Agency (Rayner *et al.*, 2004) to regulate the promotion of food to children, i.e. to restrict (broadcast) advertisements to children of products high in fat, saturated fatty acid, salt, and/or sugar.

Only those nutrient profiling schemes which have been used for the regulation of claims will be discussed here. A short description of schemes, that have been used for the purpose of permitting products to bear claims is provided in **Table 1** and given in the **Annex**.

According to regulations in the US, Canada, Australia/New Zealand and Sweden, foods must comply with general or specific criteria for nutrient composition to bear a nutrition or health claim. Such regulatory schemes are not intended to convey direct messages to purchasers, but aim to ensure that claims on foods will not mislead the consumer by masking the overall nutrient composition of the product.

Nutrient profiling schemes generally used (or proposed) for regulatory purposes are based upon general ('across the board) or category-based nutrient criteria. Rather than using one nutrient profiling scheme for all claims and covering all foods, nutrient profiles and conditions in the US and Sweden are set for individual claims, or certain types of claims.

**Table 1: Examples of nutrient profiling schemes developed for the purpose of permitting products to bear nutrition and/or health claims**

| Country/Authority | Type of scheme | Approach to the calculation of the profile | Reference quantity | Nutrients subject to a maximum level in the food | Nutrients subject to a minimum level in the food | Comments (see also the Annex) |
|---|---|---|---|---|---|---|
| USA (FDA; 2002) http://www.cfsan.fda.gov | Across the board | Threshold | Per serving | Total fat (<13 g) SFA (<4 g) Cholesterol (< 60 mg) Sodium (<480 mg) Per serving | >10% of 'daily value' for at least one of the following nutrients: Vitamin A (500IU) or C (6 mg) or Calcium (100 mg) or Iron (1,8 mg) or Protein (5 g) or Dietary fibre (2,5 g) per serving | Except for dietary supplements. In addition to the nutrients subject to a maximum or minimum level, other criteria specific for an approved health claim can apply. |
| Canada (Health Canada; 2001) http://www.hc-sc.gc.ca | Category-based | Threshold | | SFA | >10% of recommended amount for at least one of the vitamins/minerals | No general requirement for the nutrient composition of food bearing claims. Instead, food falling under the "other foods" category of Canada's Food Guide to Healthy Eating are excluded, e.g. foods high in salt, sugar, fat, and beverages |
| Australia/New Zealand (ANZFA; 2001) http://www.foodstandards.gov.au/ (replaced by renewed scheme under construction) | Across the board | Threshold | Per serving [for some specific products per 100 g or 100 kJ] | Total fat (<14 g) SFA (<5 g) Sodium (<500 mg) | >10% of RDI of all nutrients other than sodium or potassium | Nutrient profiling (scoring) system under construction, taking into account level of total sugar, sodium, SFA, total energy, dietary fibre, protein and fruit and vegetable contents (modified from UK FSA model) (FSANZ, 2007) |
| Sweden (SNF, 2005) | Category-based | Threshold | 100 g (weight %) | Total fat, [Sodium], [added sugar] | Dietary fibre | Criteria linked to green 'keyhole' symbol |
| France (Afssa, 2008) | Across the board | Scoring | Energy (SAIN), Weight (LIM) | LIM: Saturated fatty acid, trans fatty acids, total sugars | SAIN: Protein, dietary fibre, iron Vitamin C, and fat soluble nutrients | Based upon two independent scores: a limited nutrient score (LIM) and a nutrition density score (SAIN) |
| Belgium (NHFP, 2007) | Category-based | Threshold | Serving size | Energy | | Criteria based on the energy content of food products. |

# 4 NUTRIENTS OF PUBLIC HEALTH IMPORTANCE FOR EUROPEAN POPULATIONS

There is evidence that, for a number of nutrients and food groups, a dietary imbalance can increase the risk of obesity and diet-related diseases (e.g. cardiovascular disease, cancer, diabetes mellitus, osteoporosis and dental disease) that are of importance for public health in the EU.

In its report on Diet, Nutrition and the Prevention of Chronic Disease, the WHO has ranked the relationships between nutrients or foods and chronic disease according to the strength of the evidence (WHO, 2003). The report indicated that there was convincing evidence for causal links between the intake of energy dense foods (positive), dietary fibre and fruits and vegetables (negative) and obesity, between the intake of saturated and trans fatty acids and sodium (positive) and linoleic acid (PUFA), n-3 long-chain polyunsaturated fatty acids, potassium and fruits and vegetables (negative) and cardiovascular disease, and between the intake of vitamin D and calcium (negative) and osteoporosis. Convincing evidence was also identified in the report between the intake of free sugars (positive) and dental disease. This relationship with dental caries is related more to the frequency than to the quantity of sugar consumption (Moynihan and Petersen, 2004; DoH, 1991; IOM, 2005).

The public health importance of these nutrients and foods for European populations has also been identified in science based nutrient intake recommendations and food based dietary guidelines from national and international agencies (e.g. Nordic Nutrition Recommendations (Becker *et al*. 2004); Health Council of The Netherlands, 2006; Eurodiet report, 2000; WHO, 2006). For a number of nutrients and foods (total fat, saturated, unsaturated and trans fatty acids, protein, carbohydrates, sugars, dietary fibre, salt, fruit and vegetables), population intake goals that have been established in a number of Member States are generally consistent (but not uniform), and aimed at the prevention of major diet-related public health problems in Europe.

For some of these nutrients, habitual dietary intakes often exceed recommended levels and should be reduced (e.g. saturated fatty acid and sodium) while for others (e.g. dietary fibre) habitual intakes are frequently lower than recommended levels and should be increased in order to promote health.

Data on dietary intakes of children, adults and older people in 12 European Member States are available from the European Nutrition and Health Report (Elmadfa and Weichselbaum, 2005). The methods used for estimating dietary intake varied among Member States and even within countries.

**Nutrients for which intakes might exceed recommended levels include**:

- **Energy density -** Diets high in energy density (energy content per unit weight) tend to be high in fat and low in water content. Evidence suggests that consuming diets of high energy density can undermine normal appetite regulation leading to increased overall energy intake through 'passive overconsumption' of food and can result in weight gain (WHO, 2003; IOM, 2005).
- **Total fat** - Diets high in fat generally have a high energy density, can contribute to excessive energy intake and energy imbalance and thus might promote weight gain. However, no causal relationship has been established between total fat intake and obesity or chronic disease risk (IOM, 2005). According to the European Nutrition and Health report, the average contribution of fat to the total energy intake in Europe

varies between 28 and 48 E% in adults (Elmadfa and Weichselbaum, 2005). This contribution is higher than recommended maximum intakes for adults in the various EU countries, which vary between 30 and 40 E% (IOM, 2005; EFSA, 2005b). In addition to total fat intake, fat quality is important, i.e. the type of fatty acids that are present (Section 7).

- **Saturated fatty acids** (SFA) – Diets high in SFA increase serum LDL-cholesterol which has been associated with an increased risk of cardiovascular disease (IOM, 2005; EFSA, 2004). The average intake of SFA in adults in many EU Member States (Elmadfa and Weichselbaum, 2005) exceeds the recommended maximum levels (about 10 E%; WHO, 2003; Eurodiet, 2000).

- **Trans fatty acids** (TFA) - Diets high in TFA increase serum LDL-cholesterol, reduce HDL-cholesterol and increase the total cholesterol to HDL-cholesterol ratio, all of which have been associated with an increased risk of cardiovascular disease (IOM, 2005; EFSA, 2004). Evidence from a number of countries indicates that the intake of TFA in the EU has decreased considerably over recent years, owing to reformulation of food products, especially fat spreads. More recent reported intakes in some EU Member States are close to the recommended maximum intake levels of 1-2 E% (EFSA, 2004). For example, in the UK the average intake of TFA has been halved to less than 1 E% (SACN, 2007*).* However in some countries, the amounts of TFA are still high in some foods, such as in some snacks (e.g. popcorn), fast-foods (e.g. beefburgers; French fries), and bakery products (e.g. cookies/pies; croissants) (Stender and Dyerberg, 2003; Lehner, 2005; Stender *et al*., 2006).

- **Sugars** - Increased risk of dental caries in children is associated with a high frequency (more than about 4 times daily) of intake of cariogenic sugars (mainly sucrose, glucose, and fructose) rather than with the total amount of dietary sugars; the evidence indicates that frequent consumption of sweets and confectionery products and sugar-containing drinks is associated with a higher risk of caries (Moynihan and Petersen, 2004; DoH, 1991; IOM, 2005). The evidence relating high intake of sugars (mainly as added sugars), compared to high intakes of starch, to weight gain is inconsistent (IOM, 2005; van Dam and Seidell, 2007). However, there is some evidence that sugar-sweetened beverages do not induce satiety to the same extent as solid forms of carbohydrate, and that high intakes of sugars in the form of sugar-sweetened beverages might contribute to weight gain (van Dam and Seidell, 2007; Mann *et al*., 2007). There is some evidence that high intakes of added sugars, particularly from low nutrient density foods, might be associated with a decrease in the nutrient density of the diet ('nutrient dilution') due to displacement of nutrient rich foods (van Dam and Seidell, 2007). However, a systematic review concluded that the evidence for an association of micronutrient dilution with added sugar intake is limited and inconsistent (Rennie and Livingstone, 2007). Average intake for sugar (sucrose) in Europe varies between 7-18 E% in adults (Elmadfa and Weichselbaum, 2005).

- **Sodium** - The major adverse effect of high dietary sodium intake is elevated blood pressure. High blood pressure is an acknowledged risk factor for ischaemic heart disease, stroke and renal disease (IOM, 2004; EFSA, 2005a). Mean daily sodium intakes of populations in Europe range from about 3-5 g (about 8-11 g salt) and are well in excess of recommended intakes. The main source of sodium in the diet is processed foods (about 70-75% of the total intake), with about 10-15% from naturally occurring sodium in unprocessed foods and about 10-15% from discretionary sodium

added during cooking and at the table (EFSA, 2005a). The evidence suggests that current levels of sodium consumption in Europe contribute to increased blood pressure in the population, and a consequent higher risk of cardiovascular and renal disease (EFSA, 2005a).

**Nutrients for which intakes might be inadequate in relation to recommended levels include:**

- **Dietary fibre** - High dietary fibre consumption is related to optimal bowel function and reduction of cardiovascular disease risk. An adequate dietary fibre intake is also associated with weight maintenance and sustained weight reduction in overweight subjects, because of its satiating effect (WHO, 2003; van Dam and Seidell, 2007; IOM, 2005). Average intake for dietary fibre in Europe varies between 16-26 g/day in adults and is generally lower than the recommended intake of about 25 g/day (Elmadfa and Weichselbaum, 2005).
- **Unsaturated fatty acids** – In contrast to SFA and TFA, mono- and polyunsaturated fatty acids (MUFA and PUFA, respectively) have beneficial effects on the serum lipid profile. Average intakes of unsaturated fatty acids vary widely across EU Member States, i.e. between 11-23 E% for MUFA and between 4-7 E% for PUFA in adults (Elmadfa and Weichselbaum, 2005). The ratio of intake of unsaturated fatty acids to SFA is considered to be too low in many Member States and food based dietary guidelines generally recommend an increase in unsaturated fatty acids at the expense of SFA (EFSA, 2005b). There is evidence that long chain omega-3 PUFA (n-3 LCPUFA) from fish and fish oils (EPA/DHA) might reduce the risk of cardiovascular disease (EFSA, 2005b). Current average intakes of n-3 LCPUFA in Europe are generally considered to be lower than the recommended intakes of about 200-500mg/day (EFSA, 2005b).
- **Vitamins/minerals** – For a number of vitamins and minerals there is evidence that deficiencies can occur among some population groups in the EU that can adversely affect health.

  A role for calcium and vitamin D in the prevention of osteoporosis in older populations (> 50 years) with a high fracture incidence was indicated in the WHO report (WHO, 2003). There is a significant prevalence of low status for vitamin D in many EU countries, particularly among older people and adolescents, and migrant populations (Ovesen *et al*., 2003; Andersen *et al*., 2005). In general, average calcium intakes in adults in Europe appear to be above recommended levels, but intakes appear to be below recommended levels in some countries (e.g. Austria, UK and Hungary) and particularly among women and older people (Elmadfa and Weichselbaum, 2005).

  Adequate dietary intake of potassium helps to maintain lower blood pressure levels and to reduce the adverse effects of high sodium intake on blood pressure that can increase the risk of cardiovascular disease (IOM, 2004; WHO, 2003). Intakes of fruits and vegetables, which are among the main dietary sources of potassium, are lower than recommended in many EU countries (WHO, 2003; WHO, 2006).

  Iron deficiency anaemia has detrimental health implications, particularly for mothers and young children and there is evidence of low intake and status for iron in young

children and in women of child-bearing age in some EU countries (Elmadfa and Weichselbaum, 2005; WHO, 2002).

Low maternal folate intake in early pregnancy is a causal factor for neural tube defects in infants and many EU countries recommend that women planning a pregnancy should supplement their diet with 400µg/day of folic acid (SACN, 2006).

Iodine deficiency, of mild to moderate severity, which is an important determinant of foetal and child development, is recognised in a number of EU Member States. National salt iodisation programmes have been implemented in some EU countries to address this problem (WHO, 2002).

# 5 FOOD GROUPS WHICH HAVE IMPORTANT ROLES IN THE DIETS OF EUROPEAN POPULATIONS

A number of food groups are recognized as having important roles in the diets of population groups in EU countries.

The important dietary roles of selected food groups (including those indicated in the **Terms of Reference)**, and their contribution to the intake of the nutrients of public health importance for European populations (identified in Section 4) are summarised in **Table 2**. Food based dietary guidelines in Member States generally encourage increased consumption of these food groups while making distinctions between different products within these food groups based on their potential to influence, beneficially or adversely, the overall dietary balance for nutrients of public health importance.

- **Vegetable oils** (including e.g. seed, olive and palm oils) are important contributors of unsaturated fatty acids including MUFA, and PUFA, and vitamin E. However, some oils, such as coconut and palm oil, have a higher SFA content than most of the others, such as olive, rapeseed or sunflower oil. Except for those that are (partially) hydrogenated, vegetable oils contain low levels of TFA (< 2 E%) and contribute little TFA to the diet.
- **Spreadable fats** (including e.g. fat spreads, margarine, butter) are also important contributors of unsaturated fatty acids including MUFA, and PUFA, and of fat soluble vitamins (E, A, and D (added)), depending on the constituent fats and oils. Some products, especially those containing animal fats, are relatively high in SFA. In the past, this food group was a significant source of dietary TFA, owing to the use of (partially) hydrogenated (hardened) oils. However, the contribution of fat spreads to TFA intake has decreased considerably in many Member States owing to technical improvements and reformulation (EFSA, 2004; SACN, 2007).
- Most **dairy products** (including e.g. milk, yoghurt, cheese) are important contributors of calcium and protein, vitamins ($B_2$, $B_{12}$, and D if added), and trace elements (Zn, iodine). Some of these products also contribute to intakes of SFA, sodium (added) and sugar (added). The content of SFA is dependent on the content of total fat. TFA are naturally present in the fat containing products, but generally in low amounts.
- **Cereals and cereal products** (including e.g. bread, breakfast cereals, bakery products, rice, pasta) are important contributors of digestible carbohydrates and dietary fibre, B-vitamins, minerals, and trace elements. Some of these products also contribute to SFA,

sodium (added) and sugar (added) intakes in certain population groups. In some countries, the TFA content of bakery products (e.g. cookies/pies; croissants) is reported to be high (Stender and Dyerberg, 2003; Lehner, 2005; Stender *et al*., 2006).

- **Fruits and vegetables, and their products** (including e.g. fresh fruits and vegetables, fruit juices, fruit salads, vegetable juices) are important low-energy density foods and at the same time are important contributors of vitamins (C, folate), minerals (potassium, magnesium) and dietary fibre to the overall diet. A higher consumption of foods from the fruit and vegetable group has been associated with a lower risk of some chronic diseases (Eurodiet, 2000; WHO, 2003), an effect that cannot be easily explained on the basis of their nutrient content. Food based dietary guidelines from Member States and international agencies generally recommend an increase in the consumption of fruits and vegetables as part of a balanced diet (WHO, 2003; WCRF, 2007). However, some (processed) products can contribute appreciable amounts of sugar (added) or sodium (added) to the overall diet.
- **Meat and meat products** (including e.g. fresh meat, sausages, cured meat, offals) contribute significantly to the dietary intake of high quality protein, iron, vitamins (A, $B_{12}$, folate, and D) and monounsaturated fatty acids. Some products can also contribute to SFA, and added salt (processed meats) to the overall diet.
- **Fish and fish products** (including e.g. fresh fish, salted and smoked fish), are principal contributors of n-3 polyunsaturated long chain fatty acids (EPA/DHA). They are also good contributors of protein, vitamins (A and D) and iodine. Some fish also contribute SFA, and (added) salt (some processed fish products) to the overall diet.
- **Beverages (non-alcoholic)** (including e.g. water, powdered drinks, soft drinks) are important for hydration. Some products, e.g. sugar-sweetened beverages, can contribute to (added) sugar (mono- and disaccharides) content of the overall diet.

The role and contribution of each group and of individual foods within these food groups to diets vary between the various Member States because of differences in dietary/cultural habits and the availability of food products. For example, potatoes are an important source of dietary carbohydrates in most northern-European countries and are recommended as such by some national dietary guidelines, while rice and/or pasta products have that role in the southern EU countries. Also the amount and type of dairy products (milk versus yoghurt and cheeses) as contributors of dietary calcium and protein vary between countries, as well as the relative dietary importance of certain foods and food groups.

The Regulation requires that the variability of dietary habits and traditions in the EU be taken into account in establishing nutrient profiles.

**Table 2: Role and dietary contribution of selected food groups including those identified in the Terms of Reference**

| Food or food group | Nutrients for which intakes might exceed recommendations [1-5] | Overall dietary role[1-5] | Dietary habits and consumption patterns in different Member States (MS)[1,2,5] |
|---|---|---|---|
| **Vegetable oils:** | SFA | Unsaturated fatty acids acid (MUFA & PUFA) and vitamin E | Differences in consumption patterns across MS such as Mediterranean use of olive oil versus Nordic use of rapeseed oil. |
| **Spreadable fats:** | SFA (fats of animal origin) and TFA (hardened fat). | Unsaturated fatty acids (MUFA, PUFA), vitamins E, and A and D (if added) | Differences in consumption patterns across MS. |
| **Dairy products:** | SFA, Na (cheese), sugar (added) | Calcium, Vitamin D (added), protein, and vitamins $B_{12}$, $B_{2,}$. iodine, Zn | Consumption of cheese and (fermented) dairy products vary across MS. |
| **Cereal and cereal products:** | SFA, TFA, Na (added) and sugar (added) | Dietary fibre,<br>Digestible carbohydrates,<br>Minerals, B-vitamins, trace elements | Differences in consumption patterns of refined and wholegrain and breakfast cereal products between MS. |
| **Fruits and vegetables, and their products:** | Na (added), Sugar (added) | Related to individual product (vitamins and minerals, folate, potassium and dietary fibre).<br>Low energy density | Large inter-country differences; low consumption especially in new MS and in most socio-economically disadvantaged groups. |
| **Meat and meat products:** | SFA and<br>Na (added) | High quality protein, Fe, vitamins and minerals, and MUFA.. | Differences (socio-economic and geographical) in consumption of lean versus fattier products. |
| **Fish and fish products** | Na (added), SFA | n-3 LC-PUFA (EPA/DHA), vitamins A and D, and iodine | Differences in pattern of consumption between MS. |
| **Beverage (non-alcoholic)** | Sugar (added) | Hydration | Differences in pattern of consumption, |

1 Eurodiet, 2000
2 WHO report 916, 2003
3 National dietary surveys (e.g. Finnriski, 2007)
4 Elmadfa and Weichselbaum, 2005
5 FAO Food Balance sheets and country profiles (www.fao.org)

## 6 NUTRIENT PROFILES FOR FOOD IN GENERAL AND/OR FOR CATEGORIES OF FOOD-

For the purpose of the Regulation, foods may be grouped on the basis of their role in the diet, such as dairy products (including e.g. milk, yoghurt, cheese) as a source of calcium, B-vitamins and protein or cereal products (including e.g. bread, breakfast cereals, bakery products, rice, pasta) as a source of digestible carbohydrate, dietary fibre, B-vitamins and minerals. Grouping of foods in this way provides a basis for a **category-based scheme for nutrient profiles where each food group with an important dietary role (or sub- groups within it) has a specific nutrient profile** related to its potential to adversely affect the overall dietary balance for nutrients of public health importance. The Swedish green 'keyhole' logo scheme (SNF, 2005), and the proposed Belgian NFHP (2007), are typical category-based schemes (**Table 1**).

Thus, category-based schemes take into account the role of food groups in the overall diet, as required by the Regulation. **An advantage** of category-based schemes is that the general comparability of portion size, frequency of intake and pattern of consumption of products within a food group facilitates application of a single nutrient profile. Furthermore, because of similarity of nutrient composition within food groups, nutrient profiles can be simple for each food group (with few nutrients required to discriminate between products) and are easily adapted. For example in the Swedish green 'keyhole' scheme the nutrient profile for low fat milks is based on total fat content only (SNF, 2005). Such a system is flexible allowing ready amendment of nutrient profiles for specific food groups.

However, there are no EU-standardised food groups that are based on their nutrient contribution to the overall diet and, given the increasing complexity of the food supply in the EU, a relatively large number of food groups might be needed to allow the inclusion of all food products. The main disadvantage is the potential complexity of defining and managing a large number of food groups across Europe with each food product assigned to one food group.

A **nutrient profile scheme for food in general has a single nutrient profile for all foods**. While this approach overcomes the problem of defining and managing food groups, the need to account for large inherent differences in the nutritional composition of different food groups can lead to more complex nutrient profile schemes that are less easy to adapt than category-based schemes.

The FSA (Rayner *et al*., 2005) and proposed FSANZ (2007) and Afssa (2008) profiling models are typical of such schemes (**Table 1**). Once established, such schemes are easy to apply. Such schemes do not directly take into account the different roles of food groups in the overall diet. However, these differences can be taken into account indirectly, e.g. by inclusion of additional nutrients (sometimes optional: FDA, 2002; Labouze, 2007) which discriminate in favour of certain food groups such as protein or calcium for dairy products (Rayner *et al*., 2005). Indeed, in the development of such schemes, the appropriateness of the classification of individual food products is typically assessed in relation to the food groups to which they belong (Rayner *et al*., 2005; FSANZ, 2007). Such schemes also need to take into account the large inherent differences in the **nutrient composition** of different food groups, e.g. the differences in water content between foods and particularly between foods and beverages. While this approach overcomes the problem of defining food groups, it can lead to more complex nutrient profile schemes that are less easy to adapt than category-based schemes because changing one parameter in the profile might affect the outcome for many food groups.-

The Panel considers that **a nutrient profile for food in general with exemptions from the general profile**, if necessary, **for a limited number of food groups** that have important dietary roles (one option outlined in the Terms of Reference) might overcome the main disadvantages of these two types of schemes and would ensure that some food products in these food groups might be eligible to bear claims.

In principle, total exemption of a food group from the requirement to comply with the nutrient profile for food in general might be made based on the role and importance of the food group in the diet, e.g. all fresh or minimally processed fruits and vegetables.

Alternatively, nutrient profiles specific to particular food groups might be established based on the use of different nutrients, thresholds or scores.

In setting specific nutrient profiles for such food groups other considerations might also be taken into account such as:

- the potential for product reformulation;
- the number of foods eligible to bear claims in a specific group, while allowing sufficient consumer choice of foods with claims;
- the availability of good quality data on the food composition, and the range of nutrient contents in the group.

## 7 CHOICE OF NUTRIENTS IN SETTING NUTRIENT PROFILES

The choice of nutrients to be included in nutrient profiles should be driven by their public health importance for EU populations. Nutrients of public health importance for EU populations are discussed in Section 4**.**

Based on their public health importance, **saturated fatty acids, sodium, dietary fibre** and **unsaturated fatty acids**, intakes of which do not comply with nutrient intake recommendations in many Member States, could be included in the nutrient profile. As either saturated or unsaturated fatty acids could be used to discriminate between foods with respect to the nutritional quality of their fat content, there might not be a need to include unsaturated fatty acids in the profile if saturated fatty acids are included. The use of dietary fibre might be limited to certain food groups which are important dietary sources and for which its ability to discriminate between food products would be most relevant, e.g. cereal products.

**Trans fatty acids** (TFA) might be included; however, TFA are of decreasing public health importance as intakes in the EU have declined considerably (Section 4). For some product groups, such as some snack and bakery products that might have a high content of TFA, the inclusion of TFA might discriminate better between foods with respect to the nutritional quality of their fat content. However, there might not be a need to include TFA in the profile if SFA are included. The data available in published food composition databases on TFA contents of food products are of variable quality, due partly to ongoing reformulation of foods, which might present practical difficulties for inclusion of TFA (e.g. for testing the scheme) (EFSA, 2007).

The public health importance of **sugars** relates in particular to increased risk of dental caries in children associated with a high frequency of intake of cariogenic sugars and the possible risk of weight gain associated with high intakes of sugars in the form of sugar-sweetened

beverages (Section 4). Food composition data for sugars are generally available only for 'total sugars' and not for 'added' or 'cariogenic' sugars. Thus, total sugar content might be included for particular food groups, e.g. beverages, and foods,, such as confectionery products, that might be consumed with a high frequency.

**Energy density** might be considered because of the association of high energy density diets with increased risk of weight gain. However, energy density of foods is influenced by both water and fat content and differences in their water content might confound comparisons between foods**.** This confounding is a greater disadvantage for schemes devised for food in general than for category-based schemes, because the water content is more variable between food groups than within food groups. Nevertheless, energy density might be a suitable criterion for specific food groups, e.g. if the water content is relatively consistent between food products in the group.

The use of **total fat** might be considered because of its association with higher energy density in foods. However, unlike SFA, total fat would not discriminate between food products on the basis of the nutritional quality of their fat content. As foods high in SFA are mostly also high in total fat content, total fat might not be needed if SFA were included. Nevertheless, total fat might be a suitable criterion (instead of SFA) for specific food groups, e.g. if the fat quality was consistent between food products in the group.

The inclusion of some of the **vitamins and minerals** of public health importance (Section 4) might be considered. In addition, depending on the type of scheme adopted, nutrients might be included in the setting of nutrient profiles for reasons other than their public health importance. For example, nutrients might be included that better discriminate between food products within a food group, or that could serve as markers for particular food groups (e.g. iron for meat, calcium or protein for dairy products (Rayner *et al.*, 2005). However, the total number of nutrients included would have to be limited to avoid overly complex nutrient profiles. Overall, the selection of nutrients for inclusion in any scheme should be such as to give appropriate classification of food products in the different food groups (Section 10.2).

In conclusion, the Panel recommends that the choice of nutrients to be included in nutrient profiles should be driven by their public health importance for EU populations. These nutrients include saturated fatty acids, sodium, dietary fibre and unsaturated fatty acids, intakes of which do not comply with nutrient intake recommendations in many Member States. Unsaturated fatty acids might not be needed if saturated fatty acids are included. The use of dietary fibre might be limited to certain food groups that are important dietary sources and for which its ability to discriminate between food products would be most relevant, e.g. cereal products. Trans fatty acids might be included for some food groups but are of decreasing public health importance as intakes in the EU have declined considerably. Total sugar content might be included for particular food groups, e.g. beverages, and foods, such as confectionery products, that might be consumed with a high frequency. Depending on the scheme adopted, energy density or total fat, as well as other nutrients, might also be considered. However, the total number of nutrients included would have to be limited to avoid overly complex nutrient profiles.

## 8 REFERENCE QUANTITY

In expressing the nutrient content of foods there are three different approaches that could be considered individually:

- serving size or portion
- weight/volume, e.g. per 100 g/100 ml
- energy, e.g. amount per 100 kcal/100 kJ, or, for macronutrients, as percentage of energy content (E%).

Alternatively, a combination of these approaches might be considered in order to limit the disadvantages of each.

Expressing nutrient content on a per **serving basis** is the only approach that is directly related to the quantity of food typically consumed, which is an important determinant of the potential of the food to adversely affect the overall dietary balance. This approach has been used in the USA for regulating health claims, and servings (Reference Amounts Customarily Consumed Per Eating Occasion, RACC) are legally defined for a wide range of food product groups (e-CFR, 2008). Currently, EU nutrition labelling allows for nutrient content to be presented per serving (as defined by individual food manufacturers), in addition to nutrient content per 100g or 100ml. Although many food products are labelled in this way, the lack of standardised serving sizes for different groups of food products at EU level is a disadvantage of this approach.

Using **weight or volume** (e.g. per 100g or per 100ml) would be consistent with current EU nutrition labelling regulations. Many foods already indicate the contents of key nutrients per 100g or 100 ml on labels. However, the quantity of a food typically consumed might differ significantly from 100g or 100ml. It might be less than 100g per serving, for example, for fat spreads and oils, cheeses, and dry breakfast cereals or greater than 100 ml per serving for beverages. In addition, differences in the water content of foods can greatly influence the nutrient content expressed on a weight/volume basis and can confound comparisons between foods, e.g. the fat content of cheese compared to milk. This confounding is a greater disadvantage for schemes devised for food in general than for category-based schemes, because the water content is more variable between food groups than within food groups. In schemes for food in general, however, this disadvantage can be partly overcome if beverages are considered separately from solid foods (e.g. in the schemes from UK (Rayner *et al.*, 2005) and Australia/New Zealand (FSANZ, 2007)).

Expressing nutrient content in relation to the **energy content** can be done either as amount per 100 kcal/100 kJ, or, for macronutrients, as percentage of the total energy content (E%). These expressions facilitate the comparison between foods of different water contents. Relating nutrient content to energy content also allows ready comparison of the nutrient content of a food with nutrient recommendations expressed on an energy basis for the overall diet or labelling reference values derived from such recommendations. However, the nutrient contents of foods or beverages with a low energy content might appear high on an energy basis while being low when expressed as the amount in the quantity typically consumed, e.g. dietary fibre in fruits and vegetables with a high water content.

The Panel recommends that selection of a suitable reference quantity should be based on pragmatic considerations related to the needs of the particular nutrient profile scheme.

# 9 THRESHOLD AND SCORING SYSTEMS

## 9.1 General considerations

Whatever the method for calculating nutrient profiles, it results in a threshold separating the foods which are eligible to bear a claim from other foods. The methods can be classified into two main types, depending on the use of a threshold for each nutrient included in the scheme or on the use of one or two thresholds for the score(s) calculated from a combination of individual thresholds for each nutrient. These two principles have been applied to across the board schemes as well as to category-based schemes. The reference values, on which the threshold criteria are based, are those of the country in which the system has been developed. Comparative testing of different profiling systems should be done on the same food basket and use the same nutrient reference values.

In this Section, the terms "**qualifying**" and "**disqualifying**" are used in connection with nutrients only for the purpose of scoring systems.

### *9.1.1 Thresholds*

A threshold is defined as a single value for each nutrient that must not be exceeded (**upper limit**) or that must be reached (**lower limit**) in a food to be eligible to bear a claim. The regulation allows derogation for one nutrient in the case of nutrition claims, whereas all the thresholds must be met for health claims. In some across the board schemes (FDA, 2002) with lower limits for several nutrients, at least one threshold should be met. Several methodologies have been proposed to derive thresholds:

- Thresholds can be derived for a specific food product from the recommendations for the nutrient intake in the total diet. Such an approach could lead to very unrealistic thresholds for some food groups and exclude them from any possibility to bear a claim. This approach also implies that foods bearing a claim should have a composition corresponding to dietary recommendations. Such an approach is easier to apply to across the board schemes.
- Using food composition data, a threshold could be fixed for example at the average or median value of the nutrient content of foods in a given food group. This threshold could be changed with the evolution of product composition. Such an approach is easier to apply to category-based schemes. Alternatively, when starting from a selection of products, which have been identified by experts as eligible for bearing claims, statistical approaches could be used to derive the thresholds (Afssa, 2008).
- Using nutrient consumption data, e.g. in the Dutch tripartite system (NNC, 2006), desirable changes in the population nutrient intake could be used to set thresholds for food groups.

Depending on the choices made for other issues, more complex threshold systems could be proposed. As an example, exceeding the threshold for total fat (e.g. 10 E%) might lead to the consideration of a second threshold, which could take into account the quality of fatty acids.

### *9.1.2 Scores*

Points are attributed to a food for fulfilling the criteria for the content of each of the nutrients that are part of the nutrient profile, and the points are combined into a total score. The scoring systems may be distinguished as follows:

- *According to the method of calculation of the points*: points can be given according to the position of the value in predefined reference intervals or, alternatively, according to the position on a continuous reference scale. In some systems the ratio of the nutrient amount in the food to the reference value or the position of the nutrient value in the food compared to two references, nutrient recommendation and average consumption, determine the number of scoring points.
- *According to the method of calculation of the final score*: some systems allow for a compensation between qualifying and disqualifying nutrients, while others do not and result in two separate scores. When a single score is used, some additional rules might be necessary, because very different foods can have the same score. For example, for a food with a high content of a qualifying nutrient and a moderate content of a disqualifying nutrient, and for a food with a low content of a qualifying nutrient and no disqualifying nutrient the score could be the same, while the two foods might not have the same importance for the balance of the total diet.

### 9.2 Examples from threshold and scoring systems

A more detailed description of some examples from threshold and scoring systems are given in the **Annex**.

A system based on thresholds has been applied in several nutrient profiling schemes, e.g. Food and Drug Administration of the United States (FDA, 2002), The tripartite system proposed by the Netherlands Nutrition Centre (NNC 2006), the green 'keyhole' in Sweden (SNF, 2005) and The Nutrition Score proposed by Unilever (Nijman *et al*., 2007).

Scoring systems have been applied e.g. in the Nutritious Food Index (NFI) (Gazibarich and Ricci, 1998), the model RRR (Scheidt and Daniel, 2004), the model developed by the Food Standards Agency (FSA) of the United Kingdom (Scarborough *et al*., 2007a), TheFoodProfiler (Labouze *et al*., 2008), and French Food Safety Agency (Afssa, 2008).

### 9.3 Advantages, disadvantages of each approach

In the actual absence of a gold standard methodology to evaluate nutrient profiles, advantages and drawbacks can only be analysed from a theoretical point of view. This is demonstrated by various working groups who compared the use of different systems on the same food panel and demonstrated that they lead to discrepancies.

The advantage of **threshold** systems are their simplicity and practicability: they can be easily explained and used by manufacturers, as an immediate target for reformulation, and by control organizations. The application of derogations for nutritional claims is easy.

A disadvantage is that they might be too simplistic and would need food group specific thresholds.

**Scoring systems** might reflect better the global quality of a food and might be more appropriate for products which are good sources of qualifying nutrients while having also high levels of disqualifying nutrients. Their apparent complexity does not preclude ease of use, especially if there are a limited number of nutrients.

The Terms of Reference indicates that if the nutrient profiles are set by a scoring system, then a threshold will need to be set for the triggering of the derogation, in the case of regulation of

nutrition claims. A **derogation** for nutrition claims is easy in scoring systems, without the need to define separately some thresholds: if, e.g. the removal of a single disqualifying nutrient from the calculation of the score for a food group leads to an improvement of the total score. As an example using the FSA scheme (**Annex - Table 4**), consider a food with 1 point for energy, 6 points for salt, 3 points for sugars and 2 points for saturated fatty acids and 6 points for the qualifying nutrients. Because the total of negative points (12) does not permit any subtraction of positive points, the food would not be allowed to bear a claim. The removal of the sodium criterion results in a total of 8 points for disqualifying nutrients and permits subtraction of the points for the qualifying nutrients. The total score would be 2, the food could bear a nutrition claim and would need to be labelled with the high content of sodium. Theoretically, scoring systems could leave more room for the evolution of products. Scoring systems, particularly with points calculated in a continuous way, are less sensitive to threshold effects.

Manufacturers already use either scoring or threshold systems, with apparently the same efficiency and satisfaction. A scoring system may be more or less strict than a threshold system, depending on the thresholds used for the total score.

One possible concern might be the balance between qualifying and disqualifying nutrients. However, this concern has been taken into account in the proposed scoring systems, either by introducing additional rules (FSA, FSANZ) or by the absence of compensation between qualifying and disqualifying nutrients (The FoodProfiler, Afssa). Absence of compensation might be better suited to avoid the situation where the simple addition of a nutrient to a food which has been classified to be not eligible to bear a claim could make it eligible without changing its overall unfavourable composition.

The Panel recommends that the choice of threshold or scoring system should be based on pragmatic considerations related to the needs of the particular scheme, while threshold or score values should be selected to ensure the appropriate classification of food products.

# 10 TESTING OF NUTRIENT PROFILE SCHEMES

## 10.1 General considerations

The objective of testing a nutrient profile scheme is to determine its suitability to classify foods appropriately as being eligible to bear nutrition and/or health claims. Testing requires a database of energy and nutrient contents of a range of foods to be delivered as such to the final consumer (as purchased) foods on the EU market. The database is interrogated to identify foods which are (i) eligible to bear both nutrition and health claims (comply in full with the nutrient profile), (ii) eligible to bear nutrition claims only (comply with the nutrient profile except for 1 nutrient) and iii) ineligible to bear either a nutrition or health claim. It is then necessary to evaluate the outcome of the testing to establish whether individual food products are classified appropriately.

Testing of any or several nutrient profiling scheme(s) should be planned to go through several iterative steps including: 1) testing, 2) evaluating results by comparison to the classification obtained by expert judgement, 3) refining the model(s) with respect to both foods, nutrients and possibly reference quantity, 4) retesting. The outcome of the testing will lead to a final decision on the number and combination of nutrients and on separate thresholds or combined

thresholds in an overall score. Some examples of testing (Azais-Braesco *et al*., 2006; Rayner *et al*., 2005; Scarborough *et al*., 2007b; Volatier *et al*., 2007; Quinio *et al*., 2007) are outlined in the **Annex**.

### 10.2 Criteria for assessment of food classification

The main scientific consideration for assessing whether a food is classified appropriately with regard to its eligibility to bear nutrition and/or health claims is the potential of the food to adversely affect the overall dietary balance for nutrients of public health importance. In practice, it is easier to assess the classification of a food in relation to other foods in the same group, i.e. whether a food is more or less likely to adversely affect the overall dietary balance than other foods in the same food group. This approach is generally used in both category-based schemes and in schemes for food in general.

The dietary role and importance of the food must also be taken into account, allowing for the variability in dietary habits and traditions across different EU countries. This is to ensure that some products in food groups that have important dietary roles can bear claims. The classification of foods as being eligible to bear nutrition and/or health claims should be consistent with food based dietary guidelines established in Member States, although it is recognised that such guidelines are not uniform across countries.

Such assessment requires **expert judgement** based on scientific knowledge about diet and nutrition, and their relation to health.

In addition to scientific considerations, other issues that must be taken into account by the European Commission include the need to allow for product innovation and the feasibility and ease of use of the nutrient profile scheme.

### 10.3 Database

Testing requires a database of energy and nutrient contents of a range of foods to be delivered as such to the final consumer. Possible sources of data on food composition include national databases, food industry or nutrition labels on food products. The following should be considered when compiling the necessary database:

***Foods:*** As far as possible, the foods should be standardized and representative of all food groups across Member States. The database should include foods to be delivered as such to the final consumer (i.e. foods that are on the market), including non-pre-packaged foodstuffs (including fresh products such as fruit, vegetables or bread) and ready-to-eat meals put up for sale to the final consumer or to mass caterers) and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale. Foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers should also be included. For each food group the range of contents for those nutrients that might be included in nutrient profiles of food products on the market should be represented.

***Nutrients:*** The database should include energy and nutrients of public health importance for European populations, including nutrients for which intakes might exceed recommendations: e.g. total fat, saturated fatty acids, trans fatty acids, sugar, sodium, and nutrients for which intakes might be inadequate in relation to recommended levels: e.g. unsaturated fatty acids, dietary fibre, as well as other nutrients, e.g. some vitamins and minerals (Section 4). In addition, consideration should be given to including nutrients that might be used to

distinguish between foods in specific food groups or that might be used as markers for particular food groups (e.g. iron for meat and calcium or protein for dairy products). The absence of values for some nutrients in the database might be a limitation on which nutrients could be included in the nutrient profiles (e.g. for testing the scheme).

***Reference quantity:*** 100g (or 100ml) is the most common basis used for tables of nutrient contents of food; energy content is generally available for foods and may be used to calculate nutrient content on an energy basis (e.g. per 100 kcal or, for macronutrients, as E%). Nutrient contents per portion are usually not available in food tables; however, they may be calculated if the portion size is known. Nutrition labels on foods frequently contain data on energy and selected nutrients per portion in addition to data per 100g or 100 ml.

## 11 LIMITATIONS

There are **limitations in the use of nutrient profiles** based on the composition of foods as purchased to classify foods as eligible to bear claims. There is an inherent difficulty in seeking to apply to individual food products nutrient intake recommendations that are established for the overall diet. Furthermore, the potential of food products as purchased to adversely affect the overall dietary balance does not take into account changes in nutrient content that occur during cooking or preparation, such as addition of fat, sugar or salt nor does it take into account the usual intake of the food (based on portion size and the frequency of intake or the pattern of consumption) or particular combinations of foods that are purchased separately but usually consumed together (such as dry cereals consumed with milk). In addition, the lack of uniform data for food composition and food consumption across the EU, as well as differences in nutrient intake recommendations and food based dietary guidelines between Member States, makes it more difficult to set nutrient profiles at EU level than at national level. The basis for expert judgements needed to address such limitations should be transparent in order to avoid variable outcomes.

## CONCLUSIONS

'Nutrient profiling' is the classification of foods for specific purposes based on their nutrient composition. In this opinion, the purpose is solely for the regulation of nutrition and health claims made on foods.

When classifying food products as eligible to bear claims, the potential of the food to adversely affect the overall dietary balance is the main scientific consideration.

This consideration relates in particular to nutrients for which there is evidence of a dietary imbalance in EU 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 to excess, as well as those for which intake might be inadequate.

The Regulation requires that the setting of nutrient profiles should take into account the dietary role and importance of food groups and their contribution of nutrients to the overall diet of the population (or specific population groups). Food groups with important dietary roles include vegetable oils, spreadable fats, dairy products, cereals and cereal products, fruits

and vegetables and their products, meat and meat products, fish and fish products, and non-alcoholic beverages. The different dietary roles of such food groups are recognised in food based dietary guidelines in Member States, which also make distinctions between different products within these food groups based on their potential to influence, beneficially or adversely, the overall dietary balance for certain nutrients. The dietary roles of these food groups might differ across Member States owing to the variability of dietary habits and traditions and the Regulation requires that this variability be taken into account in establishing nutrient profiles.

Nutrient profile schemes for food in general and category-based schemes each have advantages and disadvantages. The Panel considers that a nutrient profile for food in general with exemptions from this general profile, if necessary, for a limited number of food groups that have important dietary roles (one option outlined in the Terms of Reference) might overcome the main disadvantages of these two types of schemes. Such exemptions would ensure that some food products in these food groups may be eligible to bear claims. Such exemptions might be based on the use of different nutrients, thresholds or scores.

The Panel recommends that the choice of nutrients to be included in nutrient profiles should be driven by their public health importance for EU populations. These nutrients include saturated fatty acids, sodium, dietary fibre and unsaturated fatty acids, intakes of which generally do not comply with nutrient intake recommendations in many Member States. Unsaturated fatty acids might not be needed if saturated fatty acids are included. The use of dietary fibre might be limited to certain food groups that are important dietary fibre sources and for which the use of dietary fibre to discriminate between food products would be most relevant, e.g. cereal products. Trans fatty acids might be included for some food groups but are of decreasing public health importance as intakes in the EU have declined considerably. Total sugar content might be included for particular food groups, e.g. beverages, and foods that might be consumed with a high frequency, such as confectionery products. Depending on the scheme adopted, energy density or total fat, as well as other nutrients, might also be considered. However, the total number of nutrients included would have to be limited to avoid overly complex nutrient profiles.

For the use of different reference quantities as well as the choice of threshold or scoring system, the Panel has outlined the advantages and disadvantages of each, and has recommended that these should be based on pragmatic considerations related to the needs of the particular nutrient profile scheme.

The testing of the suitability of a nutrient profile scheme to classify foods appropriately as being eligible to bear nutrition and/or health claims requires a database of energy and nutrient contents of a range of foods (as purchased) on the EU market. The main scientific consideration for judging whether food products are classified appropriately is their potential to adversely affect the overall dietary balance for nutrients of public health importance. In practice, it is easier to assess the classification of a food in relation to other foods in the same group, i.e. whether a food is more or less likely to adversely affect the overall dietary balance than other foods in the same food group. The dietary role and importance of the food group, allowing for the variability in dietary habits and traditions across different Member States, must also be taken into account in order to ensure that some products in food groups that have important dietary roles can bear nutrition and/or health claims. In addition, the classification of foods as being eligible to bear nutrition and/or health claims should be consistent with food based dietary guidelines established in Member States, albeit it is recognised that such guidelines are not uniform across countries. In addition to scientific considerations, other

issues that must be taken into account by the European Commission include the need to allow for product innovation and the feasibility and ease of use of the nutrient profile scheme.

The Panel recognises the scientific limitations intrinsic in the use of nutrient profiles to classify foods as eligible to bear claims and the need for expert judgement to be applied. There is an inherent difficulty in seeking to apply to individual food products nutrient intake recommendations that are established for the overall diet. Furthermore, the potential of food products (as purchased) to affect adversely the overall dietary balance does not take into account changes in nutrient content that occur during cooking or preparation, such as addition of fat, sugar or salt, nor does it take into account the habitual intake of the food or the pattern of consumption. In addition, the lack of uniform data for food composition and food consumption across the EU, as well as differences in nutrient recommendations and food based dietary guidelines between Member States, makes it more difficult to set nutrient profiles at EU level than at national level. The basis for expert judgements needed to address such limitations should be transparent in order to avoid variable outcomes.

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| **Afssa** | French Food Safety Agency |
| **ANZFA** | Australia New Zealand Food Authority (since renamed FSANZ) |
| **AOAC** | Association of Analytical Communities |
| **ALA** | Alpha-linolenic acid |
| **BEUC** | The European Consumers' Organisation |
| **DFC** | Desirable food components |
| **DHA** | Docosahexaenoic acid |
| **DRV** | Dietary Reference Values |

| | |
|---|---|
| **EC** | European Commission |
| **EFSA** | European Food Safety Authority |
| **E%** | Energy percentage |
| **EPA** | Eicosapentaenoic acid |
| **EU** | European Union |
| **FAO** | Food and Agriculture Organisation |
| **FDA** | Food and Drug Administration (US) |
| **FNB** | Food and Nutritional Board |
| **FSANZ** | Food Standards Australia New Zealand |
| **FSA** | Food Standards Agency (UK) |
| **HDL** | High density lipoprotein |
| **IoM** | Institute of Medicine |
| **LC-PUFA** | Long chain polyunsaturated fatty acid |
| **LDFC** | Less desirable food components |
| **LDL** | Low density lipoprotein |
| **LIM** | Limited nutrient score |
| **MUFA** | Monounsaturated fatty acid |
| **MS** | Member State |
| **NDA** | Scientific Panel on Dietetic Products, Nutrition and Allergies |
| **NFI** | Nutrition Food Index |
| **NHFP** | Belgian National Food and Health Plan |
| **NLEA** | Nutrition Labelling and Education Act |
| **NNC** | Netherlands Nutrition Centre |
| **NSP** | Non-starch polysaccharides |
| **PUFA** | Polyunsaturated fatty acid |
| **RACC** | Reference Amounts Customarily Consumed Per Eating Occasion |
| **RDA** | Recommended Dietary Allowance |
| **RDI** | Recommended Daily Intake |
| **RRR** | Ratio of Recommended to Restricted Food Components |
| **SAIN** | Nutrient density score |
| **SFA** | Saturated fatty acid |
| **SNF** | Swedish Nutrition Foundation |
| **TFA** | *trans* fatty acid |
| **UK** | The United Kingdom |

| | |
|---|---|
| **UL** | Upper Level |
| **US** | The United States |
| **WCRF** | World Cancer Research Fund |
| **WHO** | World Health Organisation |

# ANNEX:

## Examples of different nutrient profiling schemes, the approaches to the calculation and testing

### 1 Nutrient profiling schemes applied in the regulation of claims

A short description of schemes applied for the purpose of permitting products to make nutrition and/or health claims is also tabulated in **Table 1 of the Opinion**.

**In the US**, the Food and Drug Administration (FDA) established specific requirements for each of the (12) health claims approved under the nutrition labelling and education act (NLEA) (FDA Code of Federal regulations, 2002). For a number of 'disqualifying' nutrients that might have a negative impact on health, general threshold levels are set per serving with separate figures for main dishes and meal products. To maintain an adequate intake of (micro-)nutrients, all products bearing health claims, except dietary supplements, must contain 10% of the recommended amounts (as daily values) of at least one of six 'qualifying' nutrients.

Additional criteria govern the use of a claim for a reduced risk of dental caries on products with sugar alcohols. The product must be free of sugar or the plaque pH must not fall below 5.7.

For products containing folate (at least 40 mcg folate per serving), a claim is allowed for a reduced risk of neural tube defects only if the product does not contain more than 100% of the RDI for vitamin A and D.

**In Canada,** the 2002 amendment of the Food and Drugs Act and Regulations allows diet-related health claims on foods. Permitted health claims include relationships of diet or foods with reduced risk of hypertension, osteoporosis, heart disease, cancer and dental caries, but also claims on the biological role of nutrients. For the food to qualify for the claim, compositional criteria apply. For claims, referring to sodium and potassium, additional compositional criteria apply for saturated fatty acid content and the presence of vitamins and minerals (at least 10% of recommended intake). Diet-related health claims are not permitted on foods that are intended solely to be consumed by children less than two years of age, nor on foods presented for use in very low energy diets (Canadian Food Inspection Agency, 2003: http://www.inspection.gc.ca/english/fssa/labeti/guide/ch8e.shtml#8.3).

**In Australia and New-Zealand**, a regulatory framework was adopted in 2001 for approval of 'reduction of disease risk' and 'enhanced function' claims for food products fulfilling certain criteria related to their nutritional composition. A 'new' scoring system, taking into account the contribution of both 'disqualifying' nutrients (SFA, total sugars and sodium content relative to energy content) and 'qualifying' nutrients (fibre, protein and fruit/vegetable/nuts content), adapted from the UK FSA profiling system for use in the proposed health claim regulation system, is currently under construction (FSANZ, 2007).

**In Sweden**, products bearing nutrient function claims and some of the allowed health claims, have to meet he criteria for the green 'keyhole' symbol, if applicable. The green 'keyhole' symbol is used on food labels and in advertisements to help consumers identify lower fat and higher dietary fibre options within food groups. This voluntary system is based upon a food group based nutrient profiling scheme, developed by the Swedish National Food administration. Food groups included in the scheme are dairy products, edible fats, meat

products, ready-to-eat foods and cereal products (in total 26 product (sub-)groups). Naturally lean foods such as pure meat, poultry and fish and naturally fibre-rich foods such as vegetables, fruits, potatoes and other root vegetables may not bear the keyhole symbol. The threshold values for the total fat and dietary fibre content vary according to food group (SNF, 2005).

Added sugar and sodium content are additional criteria for some claims. Products making claims on the relationship between salt and reduced risk of cardiovascular disease /high blood pressure have to comply with the maximum levels specified for the various food groups. Cereal products making a claim on fibre content and blood cholesterol level may contain only limited amounts of (added) sugar. The criteria are based upon the Nordic Nutrition Recommendations (Becker *et al*. 2004).

**In France**, the French Food Safety Authority (Afssa, 2008) recently proposed a scheme for setting nutrient profiles: the SAIN-LIM model, an across the board system based on the calculation of 2 independent scores, i.e. a nutrient density score (SAIN) and a 'limited nutrient' score (LIM). Nutrients included in the SAIN score are protein, fibre, iron, vitamin C and one or two fat soluble nutrients (vitamins D, E or ALA), depending on the lipid contribution of the product. Nutrients included in the LIM score are saturated fatty acids, sodium, and added sugars (see also www.thefoodprofiler.com; Labouze *et al*., 2008).

**In Belgium**, a nutrient profiling scheme has been proposed as part of the Belgian National Food and Health Plan (NFHP, 2007). If products meet the criteria set in the scheme, a reference can be made to one of seven objectives of the NFHP for labelling and/or advertising purposes (e.g. "to maintain good health it is necessary to increase the intake of dietary fibre. This is a NFHP recommendation. This product is rich in dietary fibre").

The system is category-based with the energy content per standardized serving size as the main criterion. Additional criteria are based upon the other nutritional objectives of the NFHP, such as fat-, carbohydrate and micro-nutrient content, salt, water etc., but are secondary to the energy criterion. In total 47 groups are proposed, plus 11 ready-made meal product groups and meal components, based on their constituents.

## 2 Nutrient profiling schemes for other purposes than regulation of claims

**In the UK**, a nutrient profile was established by the Food Standards Agency (FSA) to regulate the promotion of food to children, i.e. to avoid (broadcast) advertisements to children of products high in fat, SFA, salt, and/or sugar. For this purpose a nutrient profiling scheme was developed in which points are attributed to each product for each of the following 'non-desirable' nutrients (saturated fatty acids, non-milk extrinsic sugars and sodium) and energy, as well as points for 'desirable' nutrients (protein, fibre), and the fruit/vegetable/nut content. The number of points given depends on the actual nutrient (food) composition. A score is then calculated for each product by subtracting the points given for the 'desirable' nutrients from those for 'non-desirable' nutrients to allow differentiation between 'healthier' and 'less healthy' products (Rayner *et al*., 2005)..

**In the Netherlands**, the Netherlands Nutrition Centre (NNC) developed a category-based nutrient profiling scheme, intended for nutrition education (The 'tripartite classification model'; Hammink *et al*., 2005). Food products that contribute in realising the dietary guidelines, e.g. products low in saturated fatty acids, and/or high in dietary fibre, and/or low energy content, are considered as 'preferable' food choices and up to 2005 food producers were allowed to make such a statement on the food label. The NNC tripartite model is currently under revision and will include sodium as an additional criterion

**In Denmark,** the Danish Food Administration has introduced a category-based nutrient profiling scheme (Departmental Order on Nutritional Mark Order, No. 330 of 3rd April 2007. Ministry of Family and Consumer Affairs). The scheme, based on nutrient profiles evolved by the National Food Institute, comprises 13 food groups that are ranked into 3 categories (1=eat most; 2=eat less; 3=eat least) based on their content of selected nutrients: fat, saturated fatty acids, sugar, salt and dietary fibre. It has, however, never been implemented

An increasing number of **private schemes** from food industries or retailers used as the basis for nutrition labelling and nutrition symbols (logo's) are currently in place, such as:

- Tesco Supermarkets, United Kingdom (www.tesco.com/health/food/food_labelling/labelling.html) - In addition to the total amount of sugar, fat, saturated fatty acids and salt per serving, the label provides the percentage of the Guideline Daily Amount (GDA).
- 'My Choice' (http://www.ikkiesbewust.nl/home.php) – A 'front of pack' logo initiated by Dutch food industries and supported by the Netherlands Ministry of Health. The criteria were established by a board of independent scientists and based upon WHO recommendations. It is a mixed (hybrid) scheme with both general criteria and product group specific criteria. Saturated and trans fatty acids, sodium and added sugar were selected as the key nutrients for which intake should be limited. Dietary fibre was included in the system as a positive key nutrient. In total, 16 'basic' food groups and 6 'non-basic' food groups were identified, including all food products available for the consumer. At least 20% of the basic foods and 10% of the non-basic food products on the market should comply with the criteria.
- Albert Hein (Ahold) adopted a 'healthy choice' (clover) logo for their home-brand products. It is a category-based scheme (23 food groups), using product criteria from the Netherlands Nutrition Centre, and the Swedish green 'keyhole' scheme (http://www.ah.nl/gezondekeuze/)
- Kraft Foods, Sensible Solutions (*www.kraftfoods.com/kf/HealthyLiving/SensibleSolutions)* - Front-pack labelling program. The nutrition criteria are category-based (12 food groups). Criteria for *Sensible Solution* products are derived from the 2005 *Dietary Guidelines for Americans*, as well as authoritative statements from the US Food and Drug Administration, National Academy of Sciences, nutrition and health experts and other public health authorities, and include calories, fat (including saturated and *trans* fatty acids), sodium and sugar.

## 3 Examples from threshold and scoring systems

### 3.1 Threshold systems

The system established by the US Food and Drug Administration considers four disqualifying nutrients (total fat, SFA, cholesterol, sodium) and at least one of six qualifying nutrients (vitamins A and C, calcium, iron, fibres, proteins) (Table 1 in the Opinion); thresholds are defined for a serving. The tripartite system proposed by the Voedingscentrum of the Netherlands (NNC, 2006) specifies for different groups (8 groups of basic foods and 7 groups of non basic foods) the nutrients and the thresholds which must be met (Table 3). The desirable changes in the population nutrient intake have been used to establish the thresholds, taking into account the contribution of the group to the total diet.

**Table 3 - Criteria of the tripartite classification model for foods**

| Basic food groups | A: 'preferable' | B: 'middle course' | C: 'exceptional' |
|---|---|---|---|
| Potatoes, rice, pasta, pulses | Fibre: min 3 g/100g<br>Saturated fat: max 1 g/100g | Fibre: 2-3 g/100g<br>Saturated fat: max 1 g/100g | Fibre: less than 2g/100g |
| Bread, bread substitutes, breakfast cereals | Fibre: min 6 g/100g<br>Saturated fat: max 1 g/100g | Fibre: 5-6 g/100g<br>or<br>Fibre: min 6 g/100g<br>Saturated fat: min 1 g/100g | Fibre: less than 5 g/100g |
| Vegetables, fruit and fruit juices | Vitamin C: min 1 mg/100g<br>Folate: min 1 mg/100g<br>Fibre: min 1 g/100g<br>Saturated fat: max 1 g/100g<br>Sugars: not added | Vitamin C: min 1 mg/100g<br>Folate: min 1 mg/100g | Vitamin C: not present |
| Milk and milk products | Saturated fat: max 0,5 g/100g<br>Sugars: max 6 g/100g | Saturated fat: 0,6-1 g/100g<br>or<br>Saturated fat: max 0,5 g/100g<br>Sugars: more than 6 g/100g | Saturated fat: more than 1 g/100g<br>or<br>Saturated fat: 0,6-1 g/100g<br>Sugars: more than 6 g/100g |
| Cheese | Saturated fat: max 12 g/100g<br>Energy: max 300 kcal/100g | Saturated fat: 13-18 g/100g<br>or<br>Saturated fat: max 12 g/100g<br>Energy: more than 300 kcal/100g | Saturated fat: more than 18 g/100g |
| Meat, prepared meat products, chicken, eggs | Saturated fat: max 4g/100g<br>Energy: max 200 kcal/100g | Saturated fat: 4-5 g/100g<br>or<br>Saturated fat: max 4 g/100g<br>Energy: more than 200 kcal/100g | Saturated fat: more than 5g/100g |
| Fish | Saturated fat: max 4 g/100g<br>n-3 fatty acids: max 2 portions for recommendation<br>energy: max 200 kcal | Saturated fat: 4-5 g/100g<br>n-3 fatty acids: 2-4 portions for recommendation | Saturated fat: more than 5 g/100g<br>n-3 fatty acids: more than 4 portions for recommendation |
| Spread and cooking fats | Saturated fat: max 16 g/100g | Saturated fat: 17-24 g/100g | Saturated fat: more than 24 g/100g |

'Saturated fat' is the sum of saturated and trans fatty acids; min: minimum; max: maximum.

| Other food groups | 'low' in SFA | 'high' in SFA | 'high' in fibre |
|---|---|---|---|
| Snacks, spicy filling | max 4 g/100g | > 5 g/100g | n.a. |
| Sauces | max 2 g/100g | >4 g/100g | n.a. |
| Cake, pastry, nuts, savoury snacks | max 6 g/100g | > 6 g/100g | ≥ 2 g/100g |
| Sweets, sweet filling | max 3 g/100g | > 4 g/100g | ≥ 1 g/100g |
| Cream | max 12 g/100g | > 18 g/100g | n.a. |
| Evaporated milk | max 1 g/100g | > 3 g/100 g | n.a. |

## 3.2 Scoring systems

In the **nutritious food index (NFI)** (Gazibarich and Ricci, 1998), ratios are calculated by dividing the amount of nutrient (p, q, z,…) in the food under consideration by the nutrient recommendation (Rec) for 13 qualifying nutrients (desirable food components or DFC): calcium, iron, zinc, fibres, folic acid, magnesium, potassium, thiamin, riboflavin, niacin, vitamin C, vitamin A and phosphorus) and 4 disqualifying nutrients (less desirable food components or LDFC): total fat, saturated fatty acids, sodium and cholesterol. The sum of the ratios of disqualifying nutrients is subtracted from the sum of the ratios of qualifying nutrients. The weights (w) of the different nutrients in each group are not the same, but the total weights of qualifying and disqualifying nutrients are the same. Since this system has not been developed specifically for claims, no threshold has been proposed. However, this

example is mentioned because it illustrates the fact that the importance of each included nutrient may be weighted, especially when there are many nutrients included, which "dilutes" the effect of each nutrient; the objective definition of the weight of each nutrient might be a difficult task.

$$NFI = \{ LDFC(p)w(p)/Rec(p) + LDFC(q)w(q)/Rec(q) + \ldots + LDFC(z)w(z)/Rec(z) \} - \{DFC(a)w(a)/rec(a) + \ldots. + DFC(n)w(n)/Rec(n) \}$$

The **model RRR** (Scheidt and Daniel, 2004) aims at providing consumers with a synthesis of the nutrition information but has not been specifically built for the purpose of nutrient profiles. However, it is mentioned to illustrate another way to perform compensation between qualifying and disqualifying nutrients (ratio instead of subtraction). It calculates a "Ratio of Recommended to Restricted" nutrients. Each ratio is a composite score of the percentages of the daily values (DV) used in nutrition labelling for recommended nutrients (protein, fibre, calcium, iron, vitamin A, vitamin C) and for nutrients to be restricted (calories, sugars, cholesterol, saturated fatty acids, sodium). The differential effect on the final result of using a ratio or a subtraction has not been explored.

$$\frac{(\%DV\text{protein} + \%\ DV\ \text{dietary fibre} + \%DV\ \text{calcium} + \%DV\ \text{iron} + \%DV\ \text{vit. A} + \%DV\ \text{vit C})/6}{(\%DV\ \text{calories} + \%DV\ \text{sugars} + \%DV\ \text{cholesterol} + \%DV\ \text{saturated fatty acids} + \%DV\ \text{sodium})/5}$$

The **model developed by the Food Standards Agency (FSA)** of the United Kingdom (Scarborough *et al.*, 2007a) has been initially developed for the regulation of food TV advertising to children and considers four disqualifying nutrients (calories, sodium, total fat, non-milk extrinsic sugars) and three qualifying nutrients (proteins, fibres, fruits or vegetables or nuts) (Table 4). Points ranging from 0 to 10 are attributed according to the amount in 100 g food in one of ten intervals predefined between zero and the nutritional recommendation for children. The global score is obtained by adding the points for qualifying nutrients and subtracting the points for disqualifying nutrients. A score of 4 or more for solid foods and of 0 or more for beverages does not allow TV advertising. An additional rule does not allow compensation of disqualifying nutrients by qualifying nutrients if the sum of disqualifying nutrients is equal or above 11. These thresholds have been set by comparison with the classification of test foods by a panel of experts.

**Table 4 - Criteria for the scoring system of FSA**

**Disqualifying nutrients per 100g**

| Points | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Energy (kJ) | ≤335 | >335 | >670 | >1005 | >1340 | >1675 | >2010 | >2345 | >2680 | >3015 | >3350 |
| Sat Fat (g) | ≤1 | >1 | >2 | >3 | >4 | >5 | >6 | >7 | >8 | >9 | >10 |
| Total sugar (g) | ≤4.5 | >4.5 | >9 | >13.5 | >18 | >22.5 | >27 | >31 | >36 | >40 | >45 |
| Sodium (mg) | ≤90 | >90 | >180 | >270 | >360 | >450 | >540 | >630 | >720 | >810 | >900 |

**Qualifying nutrients per 100g**

| Points | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Fruit, Vegetable and Nuts (weight %) | ≤40 | >40 | >60 | - | - | >80 |
| NSP fibre (g) | ≤0.7 | >0.7 | >1.4 | >2.1 | >2.8 | >3.5 |
| Or AOAC fibre (g)* | ≤0.9 | >0.9 | >1.9 | >2.8 | >3.7 | >4.7 |
| Protein (g) | ≤1.6 | >1.6 | >3.2 | >4.8 | >6.4 | >8 |

* Use of the alternative AOAC definition of fibre is allowed so long as a conversion factor is used (Garsetti *et al.*, 2007)

The system under scrutiny by Food Standards Australia New Zealand is derived from the FSA system, using some modifications: an uncapped score (possibility of points above 10) for fats and a threshold of 28 for the access to claims for oils and edible fats. The FSA system also constitutes the basis of a more complex system recently published (Visioli *et al*., 2007).

**TheFoodProfiler** (Labouze *et al*., 2008) is derived from the Nutrimap model (Labouze *et al*., 2007). The points for a nutrient depend on the position of the amount in the food as compared to two references, the recommendation and the average consumption in the population. For a qualifying nutrient (polyunsaturated fatty acids, calcium, iron or fibres), the point is -1 if the amount per 100 kcal is below the recommendation, between -1 and +1 in a continuous way if the amount is between the recommendation and the average consumption and +1 if the amount is higher than the average consumption. The same principle, in the reverse way, is applied for disqualifying nutrients (total fat, saturated and trans fatty acids, added sugars, added sodium). Two independent scores (maximum = ± 5) are defined, with no compensation of disqualifying nutrients by qualifying nutrients. It is proposed that a food is eligible to bear a claim when the negative score is higher than -2.5 and the positive score higher than +2.5, and when the positive score is higher than the negative score. This system attributes a positive score even to disqualifying nutrients, if the low content in the food contributes to re-balance the diet for this nutrient. Added sugars are used as an additional filter, taking into account the recommendations of the Eurodiet report (up to 4 consumption occasions per day and 10 % of energy, i.e. 50 g/d): a food is not allowed to bear a claim if a portion (assuming that a consumption occasion corresponds to a portion) provides more than 12.5 g of added sugars.

The **French Food Safety Agency** (Afssa, 2008) has proposed a nutrient density score, assessing separately qualifying and disqualifying nutrients (Maillot *et al*., 2007). It calculates and sums the ratios of the amount in the food to the nutrient recommendations. The reference basis is the energy content for qualifying nutrients and the weight for disqualifying nutrients.

$$\text{Disqualifying score} = \frac{\frac{\text{Na}}{3153} + \frac{\text{SFA}}{22} + \frac{\text{Added sugars}}{50}}{3} \times 100$$

It is proposed that this score alone be used to decide on nutrition claims; to apply a derogation, the disqualifying score is obtained by dividing by 2 instead of 3

$$\text{Qualifying score} = \frac{\frac{\text{Proteins}}{65} + \frac{\text{Fibres}}{30} + \frac{\text{Calcium}}{900} + \frac{\text{Iron}}{12.5} + \frac{\text{Vitamin C}}{110}}{5} \times 100 \quad \text{x } 100 \text{ kcal}$$

For a food to bear a claim, it is proposed that the score of qualifying nutrients should be ≥ 5 for and the score of disqualifying nutrients should be < 7.5: if 2000 kcal provides 100 % of the nutrient recommendation, then 100 kcal should provide at least 5 %; if 1330 g of food (average consumption of French adults) provides 100 % of the recommendation, then 100 g should provide no more than 7.5 %.

One of the qualifying nutrients might be optional: it has been shown for example that the possible use of vitamin D, instead of vitamin C, allows fatty fish to comply with the profile, without the need to define a specific category (fatty fish, products and mixed dishes derived from them).

## 4. Different schemes for testing

**Expert judgement** has been used to test selected existing nutrient profiling schemes. In France, 4 different nutrient profiling across the board schemes were tested in a panel of 12 expert nutritionists who ranked 125 foods chosen from various food groups to represent most of the foods regularly consumed in European countries (Azais-Braesco *et al*., 2006). The experts were provided with nutritional information only on the fat and/or sugar content of fresh dairy products and visible fat products of serving size to help discriminate between closely related foods before ranking each food along a 5-point scale ranging from 'healthier' to 'less healthy' foods. The expert ranking was compared with the scores of the 4 selected nutrient profile schemes. The ranking of the 4 nutrient profiling schemes gave similar results but several discrepancies existed in every system, mainly related to the choice of nutrients and thresholds. In particular, sugar seemed to be a critical nutrient for some systems. It was concluded that foods that contribute positively to the diet are rated better in both the nutrient profiling schemes and by the expert nutritionists.

In the UK, a panel of 702 nutritionists and dieticians responded to an online questionnaire to assess their perception of the relative 'healthiness' of individual foods (Rayner *et al*., 2005; Scarborough *et al*., 2007b). The experts ranked 40 foods, randomly selected from a master list of 120 foods, on a 6-point group scale from 'less healthy' to 'more healthy'. The 120 foods tested were selected to be representative of the UK diet. To assist in the classification, information on the contents of 10 nutrients per 100 g of food was provided. The subjective ranking from the nutrition experts was correlated with the nutrient profile scores for the same 120 foods, obtained by using 8 different nutrient profiling schemes (6 across the board schemes and 2 mix of across the board and category-based schemes). Considerable differences were obtained between ranking of the experts and the ranking of the models. In the continuous schemes the ranking of foods seemed to be strongly modified by changing only one nutrient.

The advantage of using expert judgements is that a panel of qualified nutrition experts has the knowledge and expertise in the area, and that the method is relatively simple and inexpensive. To avoid the risk of bias the approach with an expert judgement panel should ensure a high degree of transparency with regard to the criteria used. A pre-testing could be applied to rank the foods from the food database to be tested in order to identify foods that would adversely affect the dietary balance. This procedure can be used to evaluate the expert judgement of the foods in the actual testing.

A different approach has been reported recently using a **statistical approach** in testing of foods (Volatier *et al*., 2007; Quinio *et al*., 2007). In this approach, 3 selected nutrient profile schemes were tested against a set of indicator foods obtained from dietary intake data from 5 European countries. Indicator foods were selected according to their positive or negative association with a "healthy diet", defined according to the Eurodiet criteria. The result from this approach was that more foods were positively associated with a healthy diet compared with the number of negatively associated foods. This finding is coherent with the basic nutrition principle that more diversified diets are more likely to be healthier diets. However, in this approach individual foods identified to be associated with the quality of diet might be linked rather to patterns of consumption and the association might be independent of the nutrient content. This possibility emphasises one of the limitations of nutrient profiling, i.e. that classifying foods based on their nutrient profiles does not always reflect the potential of a

food to adversely affect the overall dietary balance as it does not take into account patterns of consumption.

It has been recommended that **validation methods** for nutrient profiling schemes should be developed (Drewnowski and Fulgoni, 2008). Recently, Arambepola *et al.* (2007) introduced a new method of assessing the validity of a nutrient profiling model by assessing measures of convergent and discriminant validity by categorizing foods according to a national food guide. Further the construct validity was assessed by testing a hypothesis relating the constructs of 'healthiness' of foods as measured by the nutrient profiling scheme and the 'healthiness' of diets measured using a diet quality index and assessing whether this hypothesis was confirmed or refuted by using data on the dietary patterns of subjects of a national dietary survey. This approach needs further development.