

## Nutrient Profiles – The Precondition for Health Claims

Updated BfR Position Paper, 12 March 2007<sup>1</sup>

### Reasons and Background

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods was recently published in the Official Journal of the European Union. It has since entered into force and is valid from 1 July 2007.

Article 4 of the Regulation permits the use of nutrition and health claims on foods as long as the foods comply with a stipulated nutrient profile. What is meant by a nutrient profile is the characteristic composition of a food which, in future, according to the Regulation is to be used as the criterion for the fundamental decision whether a food may carry a nutrition or health claim. The definition of requirements for nutrient profiles for foods aims to ensure that foods bearing claims of positive effects on health do not, at the same time, contain amounts of nutrients associated with chronic diseases when consumed in excess. It also aims to protect consumers from being misled.

In 2005 the Federal Institute for Risk Assessment (BfR) was requested as part of its scientific policy advice for the Federal Government to formulate general proposals and principles for the elaboration of nutrient profiles.

This discussion paper is the result of intense co-operation and discussions between scientists from BfR and reputed national experts. Discussions focused on nutrient profiles as the basis for health claims on foods. According to the Regulation nutrient profiles are also to be the prerequisite for the admissibility of nutrition claims. Nutrient profile models that had already been developed internationally were taken into account.

### Resulting positions

1. Nutrient profiles should be formulated specifically for food categories.
2. The nutrients to be considered should be selected on the basis of scientifically accepted relationships between the consumption of certain nutrients and an increased or reduced risk of the manifestation of chronic diseases.
3. Nutrient deficiencies in the population could be considered as another important criterion.
4. The use of “disqualifying” nutrients is advocated for the elaboration of nutrient profiles. “Qualifying” nutrients could also be used as a criterion, provided they occur naturally in foods.
5. It is proposed that the following nutrients be considered:
  - disqualifying nutrients:  
total fat, saturated fatty acids, trans fatty acids, sugar and sodium/salt

<sup>1</sup> The updated position paper includes suggestions from the 3rd Consumer Protection Forum at which the original version was discussed.

- qualifying nutrients:  
fibre, folate, omega-3 fatty acids and calcium

This selection of nutrients is relevant for all age groups in the population independent of gender.

6. “100 g or 100 ml” of a food are proposed as the reference amounts.
7. A system based on thresholds is preferable to a scoring system.
8. a) Thresholds could be established in line with existing national and/or international dietary recommendations or guidelines.  
b) Alternatively, the thresholds for nutrition claims listed in the Annex to Regulation (EC) No 1924/2006 could be used to set maximum and minimum levels.  
c) Another alternative would be to set the thresholds according to a reference food from the corresponding food category.
9. Foods which are major sources of qualifying nutrients but which also contain disqualifying nutrients (e.g. full cream milk contains calcium and fat) should not be denied the possibility of bearing a claim.
10. From the scientific nutritional angle it may be appropriate to exclude certain foods from the possibility of bearing a claim.
11. It should be possible for unprocessed foods (primary agricultural products) to bear claims without having to specify nutrient profiles for them. This should help to counteract any shift in consumption from unprocessed foods to (highly) processed foods bearing claims.
12. Nutrient profiles should be viable and easy to apply by manufacturers and control authorities.

## Reasons

### Positions 1 and 11:

In order to decide whether nutrient profiles should be developed for all foods or for specific individual food categories, the advantages and disadvantages of these two alternatives were considered.

The advantages of a category-specific approach to nutrient profiles which argue against an across-the-board approach are:

- In principle all food categories are regarded as part of a healthy diet; within a category there are, however, differences in nutritional value.
- The contribution of each food category to total diet can be considered (frequency and amount of consumption, consumption patterns); this would not be possible if there were just one uniform nutrient profile for all foods.
- With this approach it is possible to consider the specific properties of individual food categories.
- This category-specific approach gives the opportunity to exclude individual foods in a category intentionally from bearing claims. By contrast, the application of one yardstick to

all foods could lead to the exclusion of food categories that make a major contribution to essential nutrient intake as part of a healthy diet (e.g. full cream milk, vegetable oils).

The working group identified the relevant food categories for the definition of nutrient profiles using the data from the German Food Code and Nutrient Database (BLS) and the typical dietary habits of the German population. As there is still no uniform European food classification, the food classification from Version II.3 of BLS was used. When establishing food categories the importance of the food and/or food category for overall diet should be considered. Based on frequently consumed foods in Germany a correlation emerged with food categories and products which are used as carrier foods for fortification or are placed on the market as "children's" foods. The working group, therefore, classified these foods in the following food categories:

- Cereal products
- Dairy products/mixed dairy products (except cheese)
- Convenience products/finished products
- Finished meat/sausage products
- Beverages/beverage powders/soft drinks/fruit juice drinks
- Sweets/confectionery

There is no need to elaborate nutrient profiles for food categories that only include primary agricultural products (e.g. fish, meat, fruit or vegetables). Nevertheless, it should be permissible to sell them with health claims (see Position 11).

#### Positions 2, 3, 4 and 5:

There are causal links between diet and health and there is also an impact of changes in lifestyle on physical activity. Excessive consumption of certain nutrients like fat, saturated fatty acids, trans fatty acids, sugar and salt/sodium is associated with a heightened risk of chronic diseases like arteriosclerosis, coronary heart disease, high blood pressure, obesity and secondary diseases as well as certain types of cancer, osteoporosis and caries. Table 1 presents the links between consumption of these nutrients and diseases and the strength of evidence to support this association according to WHO (2003).

**Table 1: Association between the consumption of nutrients and the risk of diseases with a rating of strength of evidence (according to WHO, 2003)\***

	Total fat	Saturated fatty acids	Trans fatty acids	Sugar	Salt/Sodium
Overweight/obesity	+++			++	
Type 2 Diabetes mellitus	+	++	+		
Cardiovascular diseases		+++	+++		+++
Caries				+++	
Osteoporosis					+

\* WHO distinguishes between four strengths of evidence for a causal link: convincing, probable, possible and insufficient. The first three categories are indicated by +++, ++ and +.

According to this, there is convincing scientific evidence of a causal relationship between the intake of the following nutrients and the onset of chronic diseases:

- |                                 |                         |
|---------------------------------|-------------------------|
| ➤ Energy content/energy density | Obesity                 |
| ➤ Total fat                     | Obesity                 |
| ➤ Saturated fatty acids         | Cardiovascular diseases |
| ➤ Sodium/salt                   | Cardiovascular diseases |
| ➤ Sugar                         | Caries                  |

In line with the requirements to be met by the respective nutrient profile, the presence of these nutrients in a food above a defined threshold may lead to positive claims for these foods not being permitted (disqualifying nutrients).

Besides nutrients which play a causal role in increasing the risk of disease, there are nutrients which are thought to have a favourable impact on reducing the risk of disease. These associations are presented in **Table 2**. Again, the WHO report (2003) served as the basis for this.

**Table 2: Association between the consumption of nutrients and reducing the risk of disease with a rating of strength of evidence (according to WHO, 2003)\***

	Fibre	n-3 fatty acids	PU-FA	EPA + DHA	Potassium	MUFA	Plant sterols/stanols	Folate	Secondary plant components	Fluoride	Vitamin D	Calcium
Overweight obesity	+++											
Type 2 Diabetes mellitus	++	+										
Cardio-vascular diseases	++		+++	+++	+++	++	++	++	+			
Caries	+									+++		
Osteoporosis											+++	+++

\* WHO distinguishes between four strengths of evidence for a causal link: convincing, probable, possible and insufficient. The first three categories are indicated by +++, ++ and +.

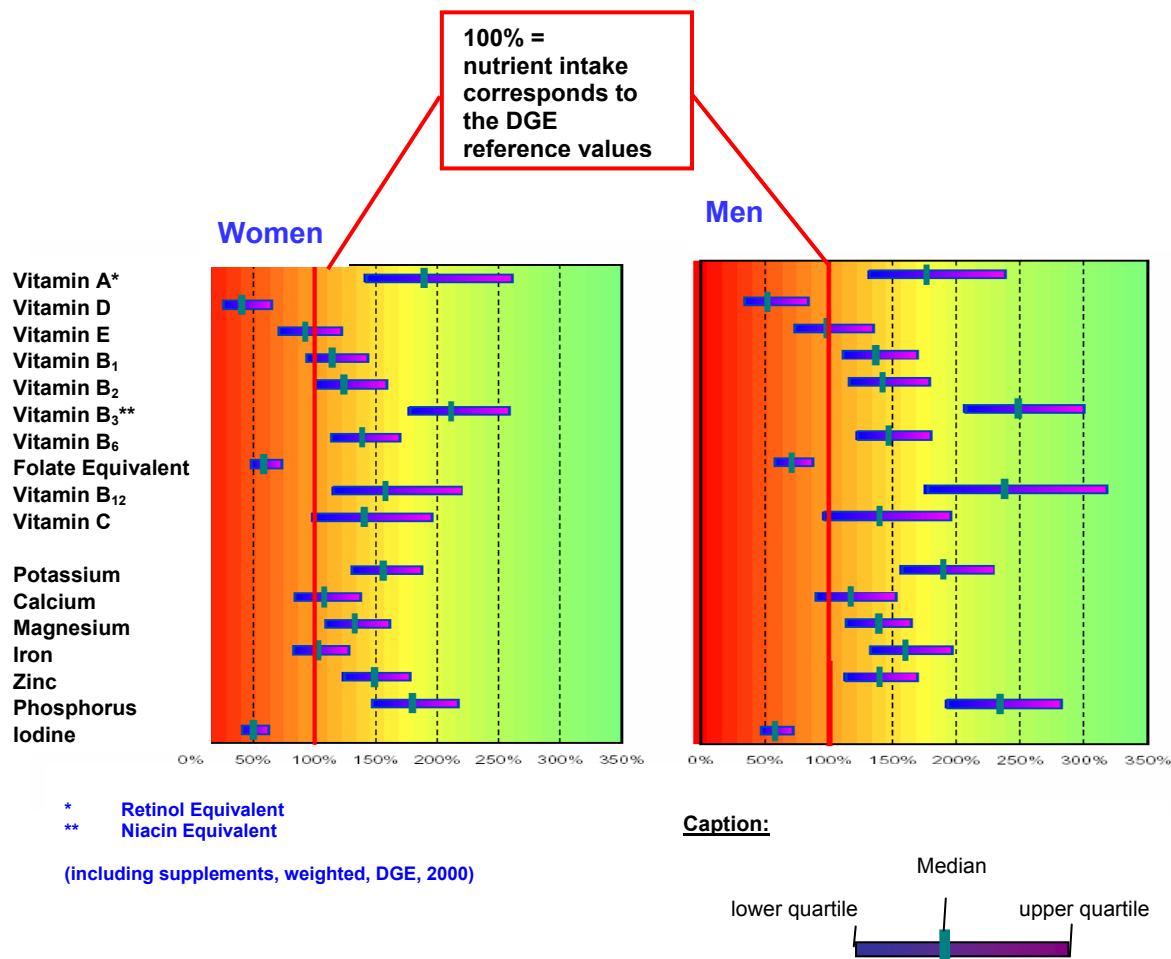
For the following nutrients sound scientific evidence is available about the reduction of the risk of disease:

- |                   |   |
|-------------------|---|
| ➤ Fibre (total)   | Increases colon motility                                    |
| ➤ Soluble fibre   | Reduces risk of cardiovascular disease                      |
| ➤ n-3 fatty acids | Reduces risk of cardiovascular disease                      |
| ➤ Calcium         | Favourable impact on bones (osteoporosis)                   |
| ➤ Folate          | Prevents neural tube defects, lowers the homocysteine level |

The presence of relevant amounts of these nutrients in a food can help – in line with the requirements to be met by the respective nutrient profile – to gain approval for positive claims for the food concerned (qualifying nutrients). In connection with qualifying nutrients discussions also focused on whether their nutritional-physiological value solely refers to intake from the natural matrix or whether a transfer of the positive properties to the respective isolated nutrient form is justified. The answer given to the latter question was no. Hence, the working group advocated that the qualifying substances required for a nutrient profile should occur naturally in the food.

Increased intake of the above-mentioned nutrients should also be recommended since not all groups in the population achieve the reference values for these nutrients in Germany. Hence the consumption data collected within the framework of the 1998 German Nutrition Survey (see Fig 1) reveals that an increase in folate/folic acid intake would be desirable. The fibre intake of almost all groups apart from men over the age of 65 is also on average lower than the D-A-CH reference value of 30 g per day (Deutsche Gesellschaft für Ernährung, 2004).

Fig 1: Overview of micronutrient intake by women and men in Germany (according to Mensink, 2001)



### Positions 6, 7, 8 and 12:

One alternative method is the development of a scoring system like the one proposed in the model of the British Food Standards Agency (FSA) the other the setting of thresholds for relevant nutrients. The FSA scoring system calculates the undesirable and desirable nutrients in a food in order to assess it. By selecting from the assessed foods, daily diet can be shaped in a more health-conscious manner. This kind of system lends itself to steering individual choices of foods but not, however, to defining the composition of foods which could then serve as the precondition for the admission of advertising claims. Furthermore, the scoring system would have to operate with many exemptions as otherwise its use in practice would lead, in some instances, to nonsensical results.

The simplest way of ensuring that foods have a healthy nutrient composition, for which health claims may be made, is to set thresholds for relevant nutrients bearing in mind the typical composition of products within a food category. The possible reference values are the energy or the mass/volume either as a common portion size or standardised to 100 g or 100 ml. One argument against using energy as the basis is, that numerous beverages do not contain any or only low levels of energy. Separate methods would then be needed for these foods. The choice of mass or volume as the reference parameter would, by contrast, permit a uniform system. Preference is given to standard amounts of 100 g or 100 ml. The common portion

sizes for individual foods vary considerably from region to region and from individual to individual and would, therefore, have to be standardised. It should be borne in mind that the nutrient profiles are not intended as information for end consumers but rather as a way of ensuring that health claims reflect the product composition.

The degree to which foods are a source of nutrients varies and this should be taken into account when drawing up nutrient profiles. This could be done by establishing the thresholds on the basis of existing national and/or international dietary recommendations. The thresholds for the products would then be established from a relevant share in daily intake. The concrete values would depend on which dietary recommendations are taken as the basis and how the “relevant part” is defined. The US Food and Drug Administration (FDA) chose, for example, for disqualifying nutrients 20% of the recommended daily intake per portion as the exclusion criterion and for qualifying nutrients 10% of the recommended daily intake per portion as the inclusion criterion. This procedure is dependent on the standardisation of portions consumed which makes it less easy to implement.

Alternatively, the thresholds laid down in the Annex to Regulation (EC) No 1924/2006 for nutrient claims (low in .... high in ....) could be used as exclusion or inclusion criteria for the nutrient profiles. This could be easily done. Nevertheless, a decision would have to be taken about the thresholds to be applied to each food category considered. A third option would be to establish thresholds using either a reference food from the corresponding food category or the distribution of nutrient concentrations between comparable products within a category. In both cases, the establishment of category-specific thresholds would be guaranteed. However, the contribution of foods to nutrient intake would not be taken into consideration in the nutrient profile.

## References

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