

# Functional Foods in Europe: A Focus on Health Claims

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## 1. Introduction

The functional foods concept started in Japan in the early 1980s with the launch of three large-scale government-funded research programs on *systematic analyses and development of functional foods*, *analyses of physiological regulation of the functional food* and *analyses of functional foods and molecular design* (Ashwell 2002; Pravst et al. 2010). In 1991, in an effort to reduce the escalating cost of health care, a category of foods with potential benefits was established (Foods for Specified Health Use - FOSHU) (Ashwell 2002). In the USA, evidence-based health or disease prevention claims have been allowed since 1990, when the *Nutrition Labelling and Education Act* was adopted; claims have to be approved by the Food and Drug Administration (FDA) (Arvanitoyannis and Houwelingen-Koukaliaroglou 2005). *Codex Alimentarius Guidelines for the use of nutrition and health claims* were accepted in 2004, and amended in 2008 and 2009, followed by *Recommendations on the scientific basis of health claims* (Grossklaus 2009). In the European Union, harmonisation was achieved in 2006 with *Regulation (EC) No 1924/2006 on nutrition and health claims made on foods*, which requires authorization of all health claims before entering the market.

The definition of functional foods is an ongoing issue and many variations have been suggested (Arvanitoyannis and Houwelingen-Koukaliaroglou 2005). A consensus on the functional foods concept was reached in the European Union in 1999, when a working definition was established whereby a food can be regarded as functional if it is satisfactorily demonstrated to beneficially affect one or more target functions in the body beyond adequate nutritional effects in a way that is relevant to either an improved state of health and well-being or a reduction of disease risk. Functional foods must remain foods and demonstrate their effects when consumed in daily amounts that can be normally expected (Ashwell 2002). In practice, a functional food can be: an unmodified natural food; a food in which a component has been enhanced through special growing conditions, breeding or biotechnological means; a food to which a component has been added to provide benefits; a food from which a component has been removed by technological or biotechnological means so that the food provides benefits not otherwise available; a food in which a component has been replaced by an alternative component with favourable properties; a food in which a component has been modified by enzymatic, chemical or technological means to provide a benefit; a food in which the bioavailability of a component has been modified; or a combination of any of the above (Ashwell 2002). Regardless of the various definitions, the main purpose of functional food should be clear - to improve human health

and well-being. However, health claims are a very convenient tool when it comes to marketing functional foods. The latest analyses show that in some European countries health claims are now used in over 15% of commonly eaten packaged foods (Lalor et al. 2010). Consumers are very sensitive to health-related communications and the use of health claims is unfortunately often connected with intentions to mislead them (Pravst 2011b). While this is clearly prohibited by law (Colombo 2010), companies are employing innovative strategies to avoid these rules so as to make a greater profit. Sophisticated regulation of this area is needed to provide consumers with high quality foods and non-misleading information. In this review the assessment of functional foods and their use in Europe will be critically discussed.

## **2. Consumer acceptance of functional foods and nutrition labelling**

Health-related information on food labels may play a crucial role in informing consumers and influence their purchase decisions (Pothoulaki and Chryssochoidis 2009). However, consumer acceptance is far from unconditional and depends on beliefs about functional foods being viewed as a marketing stunt, as well as on familiarity and perceptions related to the perceived fit of ingredients and carrier or base products rather than on classical demographic characteristics (Verbeke 2010). In addition, it is unlikely one can count on consumer willingness to compromise on the taste of functional foods for health (Verbeke 2006). Recent studies show that the consumer might have a stronger preference for simple health statements compared to the implied benefits that result from consuming a functional food product (Bitzios et al. 2011). Indeed, consumers' attitudes to functional foods and the use of nutrition information or claims on food labels have been studied extensively in recent years (Bitzios et al. 2011; Hoefkens et al. 2011; Krutulyte et al. 2011; Pothoulaki and Chryssochoidis 2009; Urala and Lahteenmaki 2004; Verbeke 2005; Verbeke 2006; Verbeke et al. 2009) and some useful reviews of these topics are available (Bech-Larsen and Scholderer 2007; Pothoulaki and Chryssochoidis 2009; Verbeke 2010; Wills et al. 2009).

A recent multi-country study confirmed that consumers perceive some nutrients as qualifying (fibre, vitamins and minerals) or disqualifying (energy, fat, saturated fat, salt, sugars) (Hoefkens et al. 2011) and only small differences are observed between countries. Overall, consumers perceive the nutritional value of foods as important when selecting foods, particularly when it comes to qualifying nutrients (Hoefkens et al. 2011). Such a finding is quite interesting since public health nutrition awareness campaigns across Europe mainly target disqualifying nutrients, i.e. salt (Celemin et al. 2011). The marketing campaigns of the food industry can obviously have very strong effects, particularly if consumers perceive them as trustworthy. It must be noted that the labelling of nutrition information on foods in the EU is currently not mandatory, except for foods with nutrition and health claims. This is about to change under the accepted *Regulation on the provision of food information to consumers*. However, most food labels already contain at least back-of-pack nutrition labelling or related information, although there are significant differences between various food categories and countries (Bonsmann et al. 2010).

## **3. Assessment of functionality**

The effects of particular functional foods on human health must be based on scientific evidence of the highest possible standard. However, because a direct measurement of the

effect a food has on health is not always possible, the key issue is to identify critical biomarkers that can be used to monitor how biological processes are being influenced (Howlett 2008). If appropriate biomarkers are chosen it is possible to study the effect of the food on the final endpoints by measuring the biomarkers. The markers could be chosen to reflect either some key biological function or a key stage in development that is clearly linked to the study endpoint (markers of an intermediate endpoint) (Fig. 1) (Howlett 2008). In such a way we can study the long-term effects in the shorter term. Nonetheless, the biomarkers must be very carefully selected.

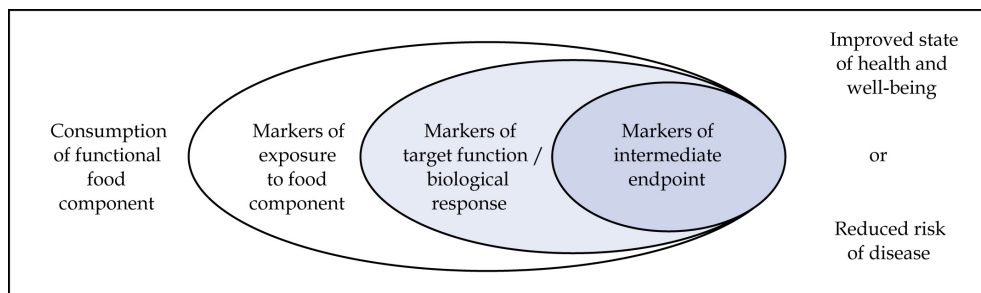


Fig. 1. The use of markers to link food consumption to health outcomes. Reproduced with permission of ILSI Europe (Howlett 2008).

In Europe the consensus on the criteria for the scientific support for claims on foods was reached in 2005 within PASSCLAIM – the Process for the Assessment of Scientific Support for Claims on Foods (Aggett et al. 2005). It delivered criteria to assess the scientific support for claims on foods. The set of criteria developed were derived through an iterative continuous improvement process that involved developing and evaluating criteria against key health claim areas of importance in Europe. These areas included diet-related cardiovascular disease, bone health, physical performance and fitness, body-weight regulation, insulin sensitivity and diabetes risk, diet-related cancer, mental state and performance and gut health and immunity. Expert groups reviewed the availability of indicators of health and disease states within their respective areas of expertise. They have demonstrated the limitations of existing biomarkers and have identified the need for better biomarkers (Aggett et al. 2005).

### 3.1 Food vs. medicine

In a time when the role of a healthy diet in preventing non-communicable diseases is well accepted, the borderline between foods and medicine is becoming very thin. The concept of foods should obviously go beyond providing basic nutritional needs. While products intended to cure diseases are classified as medicine, a healthy diet consisting of foods with functional properties can help promote well-being and even reduce the risk of developing certain diseases (Howlett 2008). However, a diet can only be healthy if the combination of individual foods is good. Limiting certain components (e.g. salt and saturated or trans fatty acids) or simply delivering an intake of nutrients cannot be regarded as a healthy diet. While it is easy to give advice on a *healthy diet*, it is much harder to define it for a particular need.

The borderline between food and medicine is shown in Table 1. As with traditional foods, functional foods should also not have serious side effects when consumed in reasonable

amounts, although some functional foods can be intended for specific populations. This is contrary to medicine, which is intended for curing a disease or treating its symptoms, and used in exactly defined quantities to minimize side effects and assure therapeutic action. Food legislation also defines *food supplements* and *foods for special medical purposes*. *Food supplements* are concentrated sources of nutrients or other substances with a nutritional or physiological effect and are meant for supplementing a normal diet. Supplements are usually marketed as capsules, pastilles, tablets, pills and other similar forms of liquids and powders designed to be taken in measured small unit quantities. In contrast, *foods for special medical purposes* are specifically formulated, processed and intended for the dietary management of diseases, disorders or medical conditions of individuals who are being treated under medical supervision. These foods are intended for the exclusive or partial feeding of people whose nutritional requirements cannot be met by normal foods.

	<b>Functional food</b>	<b>Medicinal food</b>	<b>Medicine</b>
Usage	Providing nutritional needs, weight management, supporting health of digestive system, skeleton, heart, reducing risk of development of certain diseases.	Food management of some diseases or certain medical conditions, in which there are specific nutritional needs (i.e. problems with swallowing, lost appetite, postoperative nutrition)	Curing disease or treating its symptoms
To be consumed:	As wanted	As needed	As prescribed

Table 1. The borderline between food and medicine (Raspor 2011)

#### 4. Functional foods in the context of regulation

To promote the use of any particular functional food its beneficial effects must be communicated to consumer. This is usually done through the use of nutrition and health claims in the labelling and advertising of foods. In this context, functional foods in Europe are probably most critically affected by the *Regulation (EC) No 1924/2006 on nutrition and health claims made on foods* (EC 2006). The regulation applies to all nutrition and health claims made in commercial communications, including trademarks and other brand names which could be construed as nutrition or health claims. The general principle is that claims should be substantiated by generally accepted scientific data, non-misleading and pre-approved on the EU level. Additionally, claims shall not give rise to doubt about the safety of other foods or encourage excessive consumption of a food.

##### 4.1 Nutrition claims

The regulation defines a *nutrition claim* as any claim stating, suggesting or implying that a food has particular beneficial nutritional properties due to the calorific value or composition with respect to the presence (or absence) of specific nutrients or other substances. Only nutrition claims which are listed in the regulation are allowed, providing they are in accordance with the set conditions of use. Some examples of authorised nutrition claims and the conditions applying to them are listed in Table 2.

Nutrition claim	Conditions of use
low energy	less than 170 kJ/100 g for solids or 80 kJ/100 ml for liquids
low sodium	less than 0.12 g of sodium per 100 g or per 100 ml (different limits for waters)
source of fibre	at least 3 g of fibre per 100 g or at least 1.5 g of fibre per 100 kcal
high fibre	at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal
source of vitamins or minerals	a significant amount <sup>1</sup> of vitamins or minerals
high in vitamins or minerals	at least twice the amount of 'source of vitamins or minerals'
source of omega-3 fatty acids	at least 0.3g alpha-linolenic acid per 100g and per 100kcal, or at least 40mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal.
high omega-3 fatty acids	at least 0.6g alpha-linolenic acid per 100g and per 100kcal, or at least 80mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal.

Note: <sup>1</sup>As a rule, 15 % of the recommended allowance specified in the Annex of Directive 90/496/EEC on nutrition labelling for foodstuffs supplied by 100 g or 100 ml (or per package if the package contains only a single portion) should be taken into consideration in deciding what constitutes a significant amount.

Table 2. Examples of nutrition claims and the conditions applying to them (EC 2006)

Labelling of the content of vitamins and minerals must also comply with the *Council Directive 90/496/EEC on nutrition labelling for foodstuffs*, which was amended in 2008. In this directive vitamins and minerals which may be declared on labels and their recommended daily allowances (RDAs) are set (Table 3).

Vitamins	RDA	D-A-CH RI/AI <sup>1</sup>	Minerals and trace elements	RDA	D-A-CH RI/AI <sup>1</sup>
Vitamin A (µg)	800	1,000	Potassium (mg)	2,000	2,000
Vitamin D (µg)	5	5	Chloride (mg)	800	830
Vitamin E (mg)	12	14	Calcium (mg)	800	1,000
Vitamin K (µg)	75	70	Phosphorus (mg)	700	700
Vitamin C (mg)	80	100	Magnesium (mg)	375	350
Thiamin (mg)	1.1	1.2	Iron (mg)	14	10
Riboflavin (mg)	1.4	1.4	Zinc (mg)	10	10
Niacin (mg)	16	16	Copper (mg)	1	2.0-5.0
Vitamin B6 (mg)	1.4	1.5	Manganese (mg)	2	1.0-1.5
Folic acid (µg)	200	400	Fluoride (mg)	3.5	3.8
Vitamin B12 (µg)	2.5	3	Selenium (µg)	55	30-70
Biotin (µg)	50	30-60	Chromium (µg)	40	30-100
Pantothenic acid (mg)	6	6	Molybdenum (µg)	50	50-100
			Iodine (µg)	150	150-200

Notes: <sup>1</sup>RI- Recommended intake, AI- Estimated value for adequate intake (provided value for adult men, 25-51 years).

Table 3. Vitamins and minerals which may be declared and their recommended daily allowances (RDAs) as set in Council Directive 90/496/EEC on nutrition labelling for foodstuffs (amended in 2008) in comparison to D-A-CH reference values (D-A-CH 2002)

## 4.2 Health claims

Regulation (EC) 1924/2006 defines *health claim* as any claim which states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. All health claims should be authorised and included in the list of authorised claims. The quantity of the food and pattern of consumption required to obtain the claimed beneficial effect should be included in the labelling and reasonably expected to be consumed in context of a varied and balanced diet. The claim must be specific, based on generally accepted scientific data and well understood by the average consumer. Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim (EC 2006). All authorised health claims are listed in a public *Community Register of nutrition and health claims made on food* which includes the wordings of claims and the conditions applying to them, together with any restrictions. Basically, the regulation distinguishes three categories of health claims (Table 4). General function claims describe the role of a food in body functions, including the sense of hunger or satiety and not referring to children, while disease risk reduction claims state that the consumption of a food or food constituent significantly reduces a risk factor in the development of a human disease. The regulation also mentions claims referring to children's development and health, for which no further definition is given.

General function health claims	Claims referring to children's development and health	Reduction of disease risk claims
Claims not referring to children and describing the role of a nutrient or other substance in growth, development and the functions of the body; or psychological and behavioural functions; or slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.	No further definition provided.	Claims that state, suggest or imply that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

Table 4. Types of health claims according to EC regulations (EC 2006)

## 5. Evaluation and authorisation of health claims

The regulation requires authorization of all health claims by the European Commission through the Comitology procedure, following scientific assessment and verification of a claim by the European Food Safety Authority (EFSA) (Pravst 2010). Claims referring to children's development and health, reduction of disease risk claims and general function claims which are based on newly developed scientific evidence are submitted directly by companies. In cases where health claim substantiation is based on (unpublished) proprietary data and if a claim cannot be substantiated without such data, the applicant can request 5 years of protection of such data.

In addition to the described procedure of health claims submission by applicants, all health claims which were on the market prior to 2006 were included in the so-called *Article 13 evaluation process*. Lists of general function claims on the market were provided by EU member states in collaboration with the industry and included in a consolidated list which formed the basis for the EFSA evaluation. In 2009 it became clear that the process of evaluating existing general function health claims would be much more demanding than expected. After examining over 44 000 claims supplied by the EU member states, the EFSA has received a consolidated list of over 4600 general function claims which entered the evaluation process. The evaluation of most claims was finished in 2011 with 341 published scientific opinions, and providing scientific advice for 2758 general function health claims, about 20% being favourable. While some claims were withdrawn, about 1500 claims on so-called *botanicals* have been placed on hold by the European Commission pending further consideration on how to proceed with these.

*Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim* (EFSA 2011c) and *General guidance for stakeholders on the evaluation of health claims* (EFSA 2011a) were prepared by the EFSA. Scientific substantiations of claims are performed by taking into account the totality of the available pertinent scientific data and by weighing up the evidence, in particular whether:

- the effect is relevant for human health;
- there is an established cause-and-effect relationship between the consumption of the food and the claimed effect in humans;
- the effect has been shown on a study group which is representative of the target population; and
- the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet.

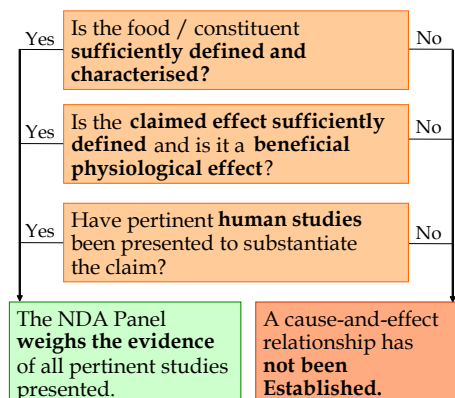


Fig. 2. Key questions addressed by the EFSA in the scientific evaluation of health claims (EFSA 2011a)

The process of the implementation of health claims legislation has involved a steep learning curve which is far from complete. While the EFSA has had to cope with an unprecedented and unforeseen workload, coupled with very short deadlines, the industry is financing expensive trials which are often still not being performed using standards that would enable successful substantiation. More specific guidance is therefore being released to help industry

to substantiate health claims, starting with *Guidance for health claims related to gut and immune function* (EFSA 2011b). Guidance for health claims related to (1) antioxidants, oxidative damage and cardiovascular health, (2) bone, joints and oral health, (3) appetite ratings, weight management and blood glucose concentrations, (4) physical performance, and (5) cognitive function is also being developed. The key questions addressed by the EFSA in the scientific evaluation of health claims are presented in Fig. 2.

### 5.1 The wording of a health claim

The wording of a health claim must be specific, it must reflect the scientific evidence and it must be well understood by the average consumer. In the process of the scientific evaluation the EFSA can propose changing the wording to reflect the scientific evidence, but such wording is sometimes hard to understand by the general population. An example of such a procedure can be shown with a health claim for specific water-soluble tomato concentrate and maintenance of a healthy blood flow (Table 5). The EFSA considered that the wording which was proposed by the applicant did not reflect the scientific evidence because only measures of platelet aggregation have been used, whereas blood flow and circulation also depend on many other factors. It changed the wording to reflect the scientific evidence, although the Commission later reworded it to be understood by consumers (Pravst 2010).

	<b>Claim wording</b>
Applicant proposal:	Helps to maintain a healthy blood flow and benefits circulation
EFSA's proposal:	Helps maintain normal platelet aggregation
Authorised by the EC:	Helps maintain normal platelet aggregation, which contributes to healthy blood flow

Table 5. The wording of a health claim for specific water-soluble tomato concentrate and maintenance of a healthy blood flow (EFSA 2009; Pravst 2010).

When discussing the wording of health claims it should also be noted that, for reduction of disease risk claims, the wording should refer to the specific risk factor for disease and not to disease alone.

### 5.2 Food characterisation

The sufficient characterisation of foods or food constituents is important for the proper scientific evaluation of a health claim application and must enable authorities to control the market. In the scientific evaluation process the characterisation is needed to identify the food or food constituent, to define the appropriate conditions of use, and to connect it with the provided scientific studies. These studies should be performed using the same food or food constituent (which should also be sufficiently characterised). The lack of characterisation was one of the most common reasons for the EFSA's non-favourable opinions regarding general function claims (Pravst 2010).

In relation to characterisation it is necessary to distinguish between a specific formulation, specific constituent and a combination of constituents. All combinations must be characterised in detail, particularly in relation to the active constituents. Beside the physical and chemical properties and the composition, the analytical methods must also be provided (EFSA 2011a). In cases where variations in composition could occur, variability from batch to batch should be addressed together with stability with respect to storage conditions

during shelf life (EFSA 2011a). Where applicable it is useful to show that a constituent is bioavailable and provide a rationale of how the constituent reaches the target site.

For microorganisms genetic typing should be performed at the strain level with internationally accepted molecular methods and the naming of strains according to the International Code of Nomenclature. Depositing samples in an internationally recognised culture collection for control purposes has been suggested (EFSA 2011a). The stability of the microorganisms and the influence of the food matrix on their activity should be studied.

For plant products the scientific name of the plant should be specified, together with the part of the plant used and details of the preparation used, including details of the extraction, drying etc. It is beneficial when the applicant can show that the composition of the plant-derived product can be controlled by analyses of specific chemical ingredients. For example, the above mentioned specific tomato concentrate was characterised on the basis of a clearly described production manufacturing process of tomatoes (*Lycopersicum esculentum*) together with a detailed chemical specification of the most important components and demonstrated batch-to-batch reproducibility (EFSA 2009). Chemical compounds which have been shown to have a beneficial effect *in vitro* were identified and quantified using the HPLC-MS technique, and the presence of unspecified constituents was limited. Several chemical and physical characteristics were assessed during stability testing, including breakdown products and the microbiological status. The bioactive components were shown to survive and to retain their activity *in vitro* over typical product shelf lives and when the product was included in specified matrixes.

Study population	Function
Subjects with untreated hypertension	maintaining normal blood pressure (for general population)
Overweight and obese subjects	weight reduction (for general population)
Patients with functional constipation	bowel function (for general population)
Irritable Bowel Syndrome (IBS) patients	bowel function (for general population)
Irritable Bowel Syndrome (IBS) patients	gastro-intestinal discomfort (for general population)
Subjects with immunosuppression	immune function (for population groups considered to be at risk of immunosuppression)

Table 6. Some specific study populations which were found as appropriate for scientific substantiation of health claims (EFSA 2011b; Pravst 2010)

### 5.3 Specific conditions of use

The quantity of the food or food constituent and pattern of consumption must be specified together with possible warnings, restrictions on use and directions for use. It is important that the consumer can consume enough food as part of a balanced diet to obtain the claimed effect (EFSA 2011a). The target population must be specified and in relation to this, it is critical that the specific study group in which the evidence was obtained is also

representative of the target population for which the claim is intended (Pravst 2010). A key question is whether the results of studies on patients can be extrapolated to the target population. A judgement on this is made on a case-by-case basis, but in most cases patients were not found to be an appropriate study group. Usually, such studies are not considered as pertinent. In cases where studies are not performed on a representative of the target population, evidence must be provided that the extrapolation can be performed. No scientific conclusions can be drawn from studies on patients with genetically and functionally different cells and tissues. Some examples of specific study populations which were found as appropriate for scientific substantiation of health claims are listed in Table 6.

#### **5.4 Relevance of the claimed effect**

The claimed effect should be clearly defined and relevant to human health (Pravst 2010). This can be demonstrated with the example of the *Caralluma fimbriata* extract, and its effect on one's waist circumference (EFSA 2010c). Studies showed a statistically significant reduction in waist circumferences, but a reduction in one's waist circumference is not a beneficial physiological effect if it is not accompanied by an improvement in the adverse health effects of excess abdominal fat. On the contrary, only a slight improvement in parameters which are widely accepted as important to human health can be recognised as key evidence, such as in the case of a general functional claim for the role of omega-3 in maintaining normal blood pressure (EFSA 2009i). The EFSA concluded that high doses (3 g per day) of docosahexaenoic (DHA) and eicosapentaenoic acid (EPA) may have smaller, but statistically significant, effects in normotensives of about 1 mmHg; better results were observed in subjects with untreated hypertension.

#### **5.5 Scientific substantiation of the claimed effect**

Human data are critical for substantiating a claim and particular attention is paid to whether such studies are pertinent to the claim. Studies need to be carried out with the subject product with similar conditions of use in a study group representative of the population group and using an appropriate outcome measure of the claimed effect (EFSA 2011a). Using appropriate outcome measures can be a challenge because a limited number of validated biomarkers is available (Cazaubiel and Bard 2008). Biomarkers are characteristics that are objectively measured and evaluated as indicators of normal biological processes, pathogenic processes or pharmacologic responses to therapeutic intervention. Well-performed human intervention trials are particularly important for successful substantiation. Double-blind, randomised, placebo-controlled trials are considered the *gold standard* not only for the substantiation of disease risk reduction claims but also for general function claims (Pravst 2010). During the scientific evaluation such trials are assessed critically to assure there are no weaknesses. A good study design, proper performance, well-defined statistics and appropriate statistical power (enough subjects) are key issues in this context. In some cases, non-blind studies are also acceptable, particularly in the case of non-processed foods where blinding is not possible. This was confirmed recently in the case of a general function claim application for dried plums and their laxative effect (EFSA 2010h) – a study in which subjects free of gastrointestinal and eating disorders were randomised to consume either dried plums or grape juice was

found to be pertinent. Nevertheless, taking the results of other studies into account there was insufficient evidence to establish a cause-and-effect relationship.

Human observational studies and data from studies in animals or model systems are considered only as supporting evidence.

## **6. Components of functional foods**

As already mentioned, limiting certain food components or simply delivering nutrient intake cannot be regarded as a healthy diet. However, the functional effects of foods are usually studied in relation to their composition and bioactive components (in some cases also with isolated components). In this chapter over 300 scientific opinions on general function health claims (for the ones which are currently present on the European market) were reviewed. On the basis of these opinions and discussion within member states the European Commission will prepare a list of substantiated health claims and their conditions of use.

### **6.1 Vitamins, minerals and trace elements**

When talking about essential nutrients we need to consider that there is a well-established consensus among scientists on many functions of such nutrients. In the evaluation of health claims we may rely on such a consensus and in such cases it may not be necessary to review the primary scientific studies on the claimed effect of the food (EFSA 2011a). On such bases many general function health claims for vitamins, minerals and trace elements received favourable opinions in the assessment process (Table 7). In most cases the proposed condition of use of such a claim is that the food is at least a source of the nutrient (15% of the RDA specified in Table 3 per 100 g or 100 ml, or per package if the package contains only a single portion).

Several essential nutrients were recognised to possess antioxidant activity, which is commonly communicated on functional foods. While the current evidence does not support the use of antioxidant supplements in the general population or in patients with certain diseases (Bjelakovic et al. 2008), some food components are indeed included in the antioxidant defence system of the human body, which is a complex network including endogenous antioxidants and dietary antioxidants, antioxidant enzymes, and repair mechanisms, with mutual interactions and synergetic effects among the various components (EFSA 2009). For example, vitamin C functions physiologically as a water-soluble antioxidant and plays a major role as a free radical scavenger. On such a basis a cause-and-effect relationship has been established between the dietary intake of vitamin C and the protection of DNA, proteins and lipids from oxidative damage. Other antioxidants include vitamin E, riboflavin, copper, manganese and selenium (Table 7).

A series of vitamins and trace elements is involved in the functioning of the human immune system, but their ability to promote immunity function is questionable, especially in populations with adequate intake. For example, zinc deficiency is associated with a decline in most aspects of immune function; lymphopaenia and thymic atrophy are observed, cell mediated and antibody mediated responses are reduced (EFSA 2009~). Additionally, zinc deficiency appears to induce apoptosis, resulting in a loss of B-cell and T-cell precursors within the bone marrow. Adequate zinc status is necessary for natural killer cell function

and zinc deficiency renders people more susceptible to infections. A cause-and-effect relationship has been established between the dietary intake of zinc and the normal function of the immune system but it was noted that there is no evidence for inadequate intake of zinc in the general EU population (EFSA 2009~). A function in the immune system was also recognised for copper, selenium and various vitamins (vitamins A, D, B6, B12, C and folate) (Table 7). In the case of vitamin D it was also concluded that it contributes to healthy inflammatory response (EFSA 2010f).

Health relationship <sup>1</sup>	Vitamins	Minerals and trace elements
Function as antioxidant	Vitamin E (EFSA 2010,,) Riboflavin (EFSA 2010) Vitamin C (EFSA 2009{)	Cu (EFSA 2009h) Mn (EFSA 2009r) Se (EFSA 2009v)
Function in immune system	Vitamin A (EFSA 2009x) Vitamin D (EFSA 2010f) Vitamin B6 (EFSA 2009z) Folate (EFSA 2009k) Vitamin B12 (EFSA 2009y) Vitamin C (EFSA 2009{)	Cu (EFSA 2009h) Fe (EFSA 2009n) Se (EFSA 2009v) Zn (EFSA 2009~)
Function in brain or nervous system	Thiamine (EFSA 2009c; EFSA 2010 ) Riboflavin (EFSA 2010) Niacin (EFSA 2009s; EFSA 2010w) Pantothenate (EFSA 2009t; EFSA 2010x) Vitamin B6 (EFSA 2009z; EFSA 2010) Folate (EFSA 2010j) Vitamin B12 (EFSA 2010€) Biotin (EFSA 2010d) Vitamin C (EFSA 2009{; EFSA 2010,.)	Cu (EFSA 2009h) Fe (EFSA 2009n; EFSA 2010n) I (EFSA 2010m) K (EFSA 2010{) Mg (EFSA 2009q; EFSA 2010r) Zn (EFSA 2009~)
Function in bone or teeth	Vitamin D (EFSA 2009g; EFSA 2009   ) Vitamin K (EFSA 2009{)	Ca (EFSA 2009f; EFSA 2009g) Mg (EFSA 2009q) P (EFSA 2009u) Cu (EFSA 2009h) K (EFSA 2010{) Mn (EFSA 2009r) Zn (EFSA 2009~) F- (EFSA 2009j)
Function in skin, hair or connective tissues	Vitamin A (EFSA 2009x) Riboflavin (EFSA 2010) Niacin (EFSA 2009s) Biotin (EFSA 2009e)	Cu (EFSA 2009h) I (EFSA 2009m) Se (EFSA 2009v; EFSA 2010~) Zn (EFSA 2010†)
Function in vision	Vitamin A (EFSA 2009x) Riboflavin (EFSA 2010)	Zn (EFSA 2009~)
Function in muscle	Vitamin D (EFSA 2010f)	Ca (EFSA 2009f) Cu (EFSA 2009h) K (EFSA 2010{) Mg (EFSA 2009q)

Health relationship <sup>1</sup>	Vitamins	Minerals and trace elements
Function in blood, haemoglobin and oxygen transport	Vitamin A (EFSA 2009x) Vitamin K (EFSA 2009j) Riboflavin (EFSA 2010j) Vitamin B6 (EFSA 2009z) Folate (EFSA 2009k) Vitamin B12 (EFSA 2009y) Vitamin C (EFSA 2009f)	Ca (EFSA 2009f) Cu (EFSA 2009h) Fe (EFSA 2009n)
Function in cell division & differentiation	Vitamin A (EFSA 2009x) Vitamin D (EFSA 2009l) Folate (EFSA 2009k) Vitamin B12 (EFSA 2009y)	Ca (EFSA 2010e) Fe (EFSA 2009n) Mg (EFSA 2009q) Zn (EFSA 2009~)
Function in regulation of hormones	Pantothenic acid (EFSA 2009t) Vitamin B6 (EFSA 2010)	I (EFSA 2009m) Se (EFSA 2009v) Zn (EFSA 2010†)
Function in metabolism of nutrients	Thiamine (EFSA 2009c) Riboflavin (EFSA 2010j) Niacin (EFSA 2009s) Pantothenate (EFSA 2009t) Vitamin B6 (EFSA 2009z; EFSA 2010) Vitamin B12 (EFSA 2009y) Biotin (EFSA 2009e) Vitamin C (EFSA 2009f)	Ca (EFSA 2009f) Cr (EFSA 2010f) Cu (EFSA 2009h) Fe (EFSA 2009n) I (EFSA 2009m) Mg (EFSA 2009q) Mn (EFSA 2009r) Mo (EFSA 2010v) P (EFSA 2009u) Zn (EFSA 2009~; EFSA 2010†)

Notes: <sup>1</sup> See references for details on specific health claims. A reference to general, non-specific benefits of the nutrient for overall good health or health-related well-being may only be made if accompanied by a specific health claim.

Table 7. Selection of general function health claims for vitamins, minerals and trace elements as assessed by the EFSA

According to a recent Irish study, brain function is most commonly communicated on soft drinks. In fact, all known water-soluble vitamins, and several minerals and essential elements (copper, iron, iodine, potassium, magnesium and zinc) are recognised as important in this context (Table 7). Functions which were favourably assessed by the EFSA include maintenance of normal function of the nervous system, cognitive function, psychological functions, neurological functions, and reduction of tiredness and fatigue (depending on the particular nutrient). The role of vitamin B6 in the maintenance of mental performance was also evaluated. Human studies have shown the effect of vitamin B6 on symptoms of depression, cognition, ageing, premenstrual syndrome and memory performance, however the daily doses for supplementation ranged from 40 - 600 mg (EFSA 2009z), well above the Tolerable Upper Intake Level (UL) (25 mg). Such a claim is not appropriate because it would encourage excess consumption of vitamin B6.

The effect of nutrition on bone health is well established. The maximum attainment of peak bone mass achieved during growth and the rate of bone loss with advancing age are the two principal factors affecting adult bone health. With increasing life expectancy the

epidemiology of bone-health related conditions is changing drastically and represents a major public health threat in the Western world. The careful formulation of functional foods represents an important step in the promotion of bone health and consequently on the quality of one's life, but to minimise health risks for consumers both the positive and the negative effects of active ingredients should be considered when developing such products. Calcium and vitamin D are considered the most important constituents of functional foods for the support of bone health (Earl et al. 2010; Palacios 2006) and received favourable opinions for maintaining normal bone and teeth. Additionally, the role of vitamin D in maintaining normal blood calcium concentrations and absorption and utilisation of Ca and P was confirmed (EFSA 2009j). In the last decade, the role of vitamin K in  $\gamma$ -carboxylation of osteocalcin has also been recognised (Ikeda et al. 2006; Katsuyama et al. 2004) as about 10-30% of osteocalcin in the healthy adult population is in an under-carboxylated (and therefore inactive) state (Vermeer et al. 2004). Other nutrients recognised in maintaining normal bone health are magnesium, zinc, manganese, potassium, copper and phosphorus (Table 7). However, the enrichment of (functional) foods or drinks with phosphorus is controversial as its intake can easily exceed the recommendations and a bigger intake might have adverse effects on bone health (Pravst 2011b). Therefore, both health and ethical concerns arise as to whether such claims should be allowed, even though science is not yet clear on this issue. A useful solution in such cases would be to authorise the claim with more specific conditions of use.

Most of the nutrients with a function in bone health were also recognised as important in the maintenance of normal teeth (vitamin D, calcium, magnesium and phosphorus). Additionally, the beneficial role of fluoride for tooth health (by counteracting hydroxyapatite demineralisation and supporting remineralisation) is widely accepted as fluoride can replace hydroxyl ions in the hydroxyapatite crystal lattice of a tooth's tissues and make it more resistant to acid exposure (EFSA 2009j).

Biotin is the only vitamin that has received a favourable opinion for its role in the maintenance of normal hair (EFSA 2009e). While there were no studies available in which improvement in hair loss and hair quality were studied using objective methods, it is known that the symptoms of biotin deficiency include thinning hair and progression to a loss of all hair, including eyebrows and lashes (EFSA 2009e). Copper, selenium and zinc were also recognised as important in the maintenance of normal hair (Table 7). Other functions of these nutrients include the maintenance of normal nails, skin or mucous membranes, while a role in the normal formation of connective tissue was determined only for manganese (EFSA 2010s) and copper (EFSA 2009h).

Vitamin A and compounds with pro-vitamin A activity (i.e. beta-carotene) are recognised to have a function in maintaining normal vision. Retinal is required by the eye for the transduction of light into neural signals which are necessary for vision and without an adequate level of vitamin A in the retina night blindness occurs (EFSA 2009x). In a different way vitamin A deficiency leads to a reduction in mucus production by the goblet cells of the conjunctival membranes and the cornea becomes dry. Riboflavin (EFSA 2010i) and zinc (EFSA 2009~) also received favourable opinions.

With muscle weakness being a major clinical syndrome of vitamin D deficiency, vitamin D is the only vitamin with a favourable opinion about its role in the maintenance of normal muscle function (EFSA 2010f). Clinical symptoms of the deficiency include proximal muscle weakness, diffuse muscle pain and gait impairments such as a waddling way of walking.

Dietary intake of calcium, magnesium, potassium and copper was also connected with muscle function (Table 7). In a similar manner the importance of sodium was confirmed; however, current sodium intake in the general EU population is more than adequate and directly associated with a greater likelihood of increased blood pressure, which in turn has been directly related to the development of cardiovascular and renal diseases (EFSA 2011y). Promoting sodium intake with the use of health claims is in obvious conflict with current targets for a reduction in dietary sodium intakes (Cappuccio and Pravst 2011).

Several nutrients have received favourable opinions for their function in blood, formation of haemoglobin or oxygen transport (Table 7). In haemoglobin, iron allows reversible binding of oxygen and its transport in the erythrocytes to the tissues. The most common consequence of iron deficiency is microcytic anaemia. The role of iron in oxygen transport, normal formation of red blood cells and haemoglobin is obviously well established (EFSA 2009n). Interestingly, there is still a significant prevalence of iron deficiency in Europe, especially among children and women of reproductive age and during pregnancy. Because dietary iron is absorbed as  $\text{Fe}^{2+}$  (and not as  $\text{Fe}^{3+}$ ), reducing agents, including vitamin C, promote non-haem iron absorption by keeping it reduced. The function of vitamin C and non-haem iron absorption therefore received a favourable opinion (EFSA 2009l). Other vitamins and minerals with a confirmed cause-and-effect relationship were vitamin A in the metabolism of iron, vitamin K and calcium in normal blood coagulation, folate in normal blood formation, copper in normal iron transport, and riboflavin, vitamin B6 and B12 in the normal formation of red blood cells.

Other specific functions of vitamins, minerals and trace elements which are rarely communicated on food labelling were also included in the evaluation process. The ones with favourable outcomes include a function in cell division & differentiation, regulation of hormones and metabolism of nutrients (Table 7). In addition, some of the following very specific health claims were assessed: selenium and the maintenance of normal spermatogenesis (EFSA 2009v); zinc and normal fertility and reproduction, normal DNA synthesis; normal vitamin A metabolism and normal acid-base metabolism (EFSA 2009~); vitamin C and normal collagen formation (EFSA 2009l) and regeneration of the reduced form of vitamin E (EFSA 2010,); vitamin B6 and normal glycogen metabolism (EFSA 2009z) and normal cysteine synthesis (EFSA 2010); folate and normal maternal tissue growth during pregnancy (EFSA 2009k); phosphorus and normal functioning of cell membranes (EFSA 2009u); magnesium and electrolyte balance (EFSA 2009q); and, calcium and normal functioning of digestive enzymes (EFSA 2009f).

Vitamin B6, B12 and folic acid were recognised as important for their contribution to normal homocysteine metabolism (EFSA 2009k; EFSA 2010e; EFSA 2010). Deficiencies in these vitamins lead to impaired homocysteine metabolism causing mild, moderate, or severe elevations in plasma homocysteine (depending on the severity of the deficiency) as well as the coexistence of genetic or other factors that interfere with homocysteine metabolism (EFSA 2010). In addition to these vitamins, a contribution to normal homocysteine metabolism has also been established for betaine (EFSA 2011g) and choline (EFSA 2011l). Choline can function as a precursor for the formation of betaine, which acts as a methyl donor in the remethylation of homocysteine in the liver by the enzyme betaine-homocysteine methyltransferase (EFSA 2011g). Choline can be biosynthesised in our liver and is therefore not a vitamin; however, most men and postmenopausal women need to consume it in their diets (Zeisel and Caudill 2010). The nutritional need for choline greatly

depends on gender, age and genetic polymorphisms. For this reason the EFSA was unable to propose conditions of use; however, it was noted that a nutrient content claim has been authorised in the US, based on the adequate intake for adult males (550 mg of choline per day). Furthermore, choline has also received a favourable opinion for the maintenance of normal liver function and its contribution to normal lipid metabolism (EFSA 2011). In relation to betaine it must be mentioned that the application for the use of betaine as a novel food ingredient in the EU was rejected, mainly due to concerns over the safety of betaine with long term use (EFSA 2005). Despite this, betaine as a constituent of traditional foods is not considered a novel food.

In practice, a functional food can also be a food from which a component has been removed to provide benefits not otherwise available (Ashwell 2002). Good examples of such foods are foods low or very low in sodium, whose consumption helps to maintain normal blood pressure (EFSA 2011p). In fact, sodium intake and blood pressure demonstrate a close and consistent direct relationship (Cappuccio and Pravst 2011) and there is extensive evidence to support this (He and MacGregor 2010). A 4.6g reduction in daily dietary salt intake decreases BP by about 5.0/2.7 mmHg in hypertensive individuals and by 2.0/1.0 mmHg in normotensive people. Dose-response effects have been consistently demonstrated in adults and children (He and MacGregor 2003). A 5g higher salt intake is associated with a 17% greater risk of total cardiovascular disease and a 23% greater risk of stroke (Strazzullo et al. 2009).

## 6.2 Fats, fatty acids and fatty acid composition

Fats are a major contributor to total energy intakes in most Western diets, supplying 35-40% of food energy through the consumption of 80-100g of fat per day (Geissler and Powers 2005). All fat sources contain mixtures of saturated, monounsaturated and polyunsaturated fatty acids, but the proportions vary significantly according to the source. Besides being a source of energy, fats also play other diverse roles in the human body. Two fatty acids, linoleic acid and  $\alpha$ -linolenic acid are essential in the human diet as they cannot be synthesised in mammalian tissues. The human body can synthesise eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) from  $\alpha$ -linolenic acid, but the synthesis is not very efficient.

The balance between saturated and unsaturated fats in the diet is known to influence circulating cholesterol concentrations (WHO 2003). Current dietary recommendations for adults in the EU are to limit intake of fats to 20-35 energy % (E%) and to keep the intake of saturated fatty acid (SFA) and trans fatty acid as low as possible (EFSA 2010b). The proposed adequate intakes are: 4 E% for linolenic acid; 0.5 E% for  $\alpha$ -linolenic acid (ALA); and 250 mg for EPA+DHA.

In Table 8 the proposed conditions of use of health claims related to fats, fatty acids and fatty acid composition are listed. Cholesterol related claims are one of the most common categories of health claims on the market (Lalor et al. 2010). The role of fatty acid composition in cholesterol management has been confirmed and the proposed conditions of use should stimulate a reduced intake of saturated fatty acids also through product reformulation (EFSA 2011o; EFSA 2011i). Such a product should contain at least 30% less saturated fatty acids compared to a similar product. The role of linolenic and  $\alpha$ -linolenic acid in cholesterol management also received favourable opinions, where a food contains at least 15% of the proposed labelling reference intake.

Food component <sup>1</sup>	Function	Conditions of use	Reference
Fat	Normal absorption of fat-soluble vitamins	no conditions of use can be defined	(EFSA 2011n)
Saturated fatty acids	Management of cholesterol	reduced amounts of saturated fatty acids by at least 30% compared to a similar product	(EFSA 2011j) (EFSA 2011o)
Linoleic acid	Management of cholesterol	15% of the proposed labelling reference intake values of 10g linoleic acid per day	(EFSA 2009p)
ALA	Management of cholesterol	15% of the proposed labelling reference intake value of 2g ALA per day	(EFSA 2009b)
Plant sterols	Management of cholesterol	0.8g per day	(EFSA 2010z)
DHA/EPA	Management of blood triglycerides	2-4g per day	(EFSA 2009i)
	Management of blood pressure	3g per day	(EFSA 2009i)
	Heart health	250mg per day	(EFSA 2010i)
DHA	Vision	250mg per day	(EFSA 2010g)
	Brain function	250mg per day	(EFSA 2010g)

Notes: <sup>1</sup>ALA -  $\alpha$ -linolenic acid; DHA - docosahexaenoic acid; EPA - eicosapentaenoic acid.

Table 8. Conditions of use health claims related to fats, fatty acids and fatty acid composition as assessed by the EFSA

Plant sterols have been known for several decades to cause reductions in plasma cholesterol concentrations (St Onge and Jones 2003). These are also well known by consumers and are one of the most well-known functional ingredients. Plant sterols are structurally very similar to cholesterol, except that they always contain a substituent at the C24 position on the sterol side chain (Ling and Jones 1995). It is generally assumed that cholesterol reduction results directly from the inhibition of cholesterol absorption through the displacement of cholesterol from micelles. Their concentrations in mammalian tissue are normally very low - primarily due to poor absorption from the intestine and faster excretion from the liver compared to cholesterol (Ling and Jones 1995). The LDL-cholesterol lowering effects of plant sterols and stanols have been reviewed several times, lately by Demonty and co-workers (Demonty et al. 2008). In the general health claim evaluation process plant sterols and stanols were confirmed to be helpful in maintaining normal blood cholesterol levels when the food provides at least 0.8g of plant sterols or stanols daily in one or more servings (EFSA 2010z). Such products may not be nutritionally appropriate for pregnant and breastfeeding women, or for children under the age of five (EFSA 2010z). It must be mentioned that the related reduction of disease risk claims were already authorised for both plant sterols and stanol esters. Lowering blood cholesterol and reference to cholesterol as a risk factor in the development of coronary heart disease can be communicated on foods which provide a daily intake of 1.5-2.4g plant sterols/stanols. Most studies of cholesterol lowering effects were conducted with plant sterols or stanols added to foods such as margarine-type spreads, mayonnaise, and dairy products. Studies are showing an increase in the

consumption of plant sterols in Europe. The consumption of foods enriched with plant sterols was recently studied in Belgium; the results indicate that plant sterol-enriched food products are also consumed by the non-target group and that efficient communication tools are needed to better inform consumers about the target group of enriched products, the advised dose per day and alternative dietary strategies to lower blood cholesterol level (Sioen et al. 2011). Although intakes of plant sterols have not produced significant adverse effects, it is not known whether constant consumption at high levels would have any toxic effects (St Onge and Jones 2003). It is therefore logical to advise the food industry to also formulate cholesterol-management foods with other effective functional ingredients, particularly with specific dietary fibres, being a more common constituent of the human diet (see chapter 6.3 *Carbohydrates and dietary fibre*).

Intervention studies have demonstrated the beneficial effects of preformed n-3 long-chain polyunsaturated fatty acids (DHA, EPA) on recognised cardiovascular risk factors, such as a reduction in plasma triacylglycerol concentrations and blood pressure, albeit in quite high daily dosages (EFSA 2010b). The proposed daily dose for the management of blood triglycerides and the management of blood pressure is 2-4g and 3g of DHA and EPA respectively (Table 8). The question remains, however, as to whether such claims will be authorised. Lower daily dosages of DHA and EPA are required to maintain normal cardiac function (250mg DHA/EPA), normal vision and brain function (250 mg DHA).

### **6.3 Carbohydrates and dietary fibre**

According to the degree of polymerisation we categorise carbohydrates into sugars (monosaccharides and disaccharides), oligosaccharides (3-9 residues), and polysaccharides with over 9 monomeric residues.

#### **6.3.1 Glycaemic carbohydrates**

Glycaemic carbohydrates are digested and absorbed in the human small intestine and provide glucose to body cells as a source of energy. According to their degree of polymerisation, these are sugars and some oligosaccharides and polysaccharides. The main glycaemic carbohydrates in the diet are glucose and fructose (monosaccharides), sucrose and lactose (disaccharides), malto-oligosaccharides and starch (polysaccharides) (EFSA 2010a). Glycaemic carbohydrates provide about 40% of energy intake in average Western diets, with a desirable level at around 55% (Geissler and Powers 2005). Far more glycaemic carbohydrates are consumed in developing countries.

Glucose is the preferred energy source for most body cells and the brain requires glucose for its energy needs. An intake of 130g of dietary glycaemic carbohydrates per day for adults is estimated to cover the glucose requirement of the brain (EFSA 2010a). In the health claim evaluation process a cause-and-effect relationship has been established between the consumption of glycaemic carbohydrates and the maintenance of normal brain function (EFSA 2011r). However, when talking about carbohydrates as constituents of functional foods we are usually discussing either lowering their amount or the functional properties of indigestible polysaccharides (dietary fibre).

Sugar replacement in foods or drinks with xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose was found to be efficient in the reduction of post-prandial blood glucose responses as compared to sugar-containing products (EFSA 2011 |). Lowering sugar levels is also considered beneficial in

maintaining the mineralisation of teeth (EFSA 2011s; EFSA 2011 |). However, excessive amounts of polyols may result in a laxative effect and this should be communicated to the consumer with an appropriate (and mandatory) advisory statement.

### 6.3.2 Dietary fibre

Dietary fibre is mostly derived from plants and is composed of complex, non-starch carbohydrates and lignin that are not digestible within the small intestine – since mammals do not produce enzymes capable of their hydrolyses into constituent monomers (Turner and Lupton 2011). Dietary fibre is considered a non-nutrient and contributes no calories to our diet as it reaches the colon intact. However, in the colon dietary fibres are available for fermentation by the resident bacteria, and the metabolites released can be used to meet some of the energy requirements.

Regulatory fibre is defined in *Council Directive 90/496/EEC on nutrition labelling for foodstuffs* as carbohydrate polymers with three or more monomeric units, which are neither digested nor absorbed in the human small intestine and belong to the following categories: (1) edible carbohydrate polymers naturally occurring in the food as consumed; (2) edible carbohydrate polymers which have been obtained from raw food material by physical, enzymatic or chemical means and which have a beneficial physiological effect demonstrated by generally accepted scientific evidence; (3) edible synthetic carbohydrate polymers which have a beneficial physiological effect demonstrated by generally accepted scientific evidence. The EFSA has evaluated several specific dietary fibres for their role in the management of cholesterol, glycaemic response and gut health (Table 9).

The beneficial health effects of water-soluble dietary fibre mainly relate to their ability to improve viscosity of the meal bolus in the small intestine and thus to delay the absorption of nutrients. A lowering of blood cholesterol was established for beta-glucans, chitosan, glucomannan, hydroxypropyl methylcellulose (HPMC), pectins and guar gum when at least 3-10g of fibre was consumed daily (Table 9). Among these, the lowest daily dosage (3g in one or more servings) is required for non-processed or minimally processed beta-glucans from specific sources (EFSA 2009d). The structural features of beta-glucans greatly influence their molecular shape (conformation) and the behaviour of the polysaccharide in a solution, including viscosity. The primary source of beta-glucans and the production processes therefore have a great impact on their functionality. Beta-glucans are widely distributed as non-cellulosic matrix phase polysaccharides in cell walls of the *Poaceae*, which consist of the grasses and commercially important cereal species (Burton and Fincher 2009). Chemically, these are (1,3;1,4)- $\beta$ -D-Glucans - as they consist of unbranched and unsubstituted chains of (1,3)- and (1,4)- $\beta$ -glucosyl residues. Their physicochemical and functional properties in cell walls are influenced by the ratio of (1,4)- $\beta$ -D-glucosyl residues to (1,3)- $\beta$ -D-glucosyl residues. An example of beta-glucans with a recognised cholesterol effect includes beta-glucans from barley (AbuMweis et al. 2010; Talati et al. 2009), a cereal grain derived from the *Hordeum vulgare*. The proportion between  $\beta$ -(1,3) and  $\beta$ -(1,4) linkages is 30 and 70%, respectively (Jadhav et al. 1998). In the polymer chain the blocks of 2 or 3 contiguous (1,4) linkages are separated by single (1,3) linkages; however, blocks of 2 or more adjacent (1,3) linkages are absent (Jadhav et al. 1998). Because the (1,3) linkages occur at irregular intervals the overall shape of the polysaccharide is irregular, which reduces its tendency to pack into stable, regular molecular aggregates and enable the formation of stable viscous solutions. It must be noted that beta-glucans are useful particularly in the production of hard functional

foods such as bread, toasts, pasta, extruded flakes, crisps etc. On the market there are also some beta-glucan-enriched liquid functional foods (i.e. yoghurts) and drinks with a labelled cholesterol management effect; however, the length of the polymeric chain of beta-glucans contained in such products is shortened with chemical or enzymatic procedures. Such an ingredient has a lower capacity to form viscous solutions, and consequently a lower efficiency. Thus, the use of a health claim is not allowed in these cases (EFSA 2009d).

Dietary fibre	Management of cholesterol	Management of glycaemic response	Gut health	Reference
Beta glucans	3g per day (non-processed beta-glucans)	4g for each 30g of available carbohydrate (oats and barley beta-glucans)	high in fibre <sup>2</sup>	(EFSA 2009d) (EFSA 2011f) (EFSA 2011u)
Chitosan	3g per day			(EFSA 2011k)
Glucomannan	4g per day			(EFSA 2009l)
HPMC <sup>1</sup>	5g per day	4g per meal		(EFSA 2010l)
Pectins	6g per day	10g per meal		(EFSA 2010y)
Guar gum	10g per day			(EFSA 2010k)
Arabinoxylan		8g of arabinoxylan-rich fibre per 100g of available carbohydrates		(EFSA 2011e)
Resistant starch		14% of total starch as resistant starch (high carbohydrate baked foods)		(EFSA 2011w)
Rye fibre			high in fibre <sup>4</sup>	(EFSA 2011x)
Wheat bran fibre			high in fibre <sup>2</sup> 10g per day <sup>3</sup>	(EFSA 2010...)

Notes: <sup>1</sup>HPMC - hydroxypropyl methylcellulose; <sup>2</sup>Increase in faecal bulk; <sup>3</sup>Reduction in intestinal transit time; <sup>4</sup>Changes in bowel function; Reference to general, non-specific benefits of the nutrient for overall good health or health-related well-being may only be made if accompanied by a specific health claim.

Table 9. Conditions of use for general function health claims of various dietary fibres as proposed by the EFSA

Decreasing the magnitude of elevated blood glucose concentrations after consuming carbohydrate-rich food is a critical target in the production of low glycaemic index (GI) foods. It is well established that the management of glycaemic responses is beneficial to human health, particularly for people with impaired glucose tolerance (which is common among the general population). Various specific dietary fibres were recognised as beneficial in the reduction of post-prandial glycaemic responses. In most cases, the rationale for such a function is, similar to cholesterol lowering, related to their ability to achieve improved viscosity of the meal bolus in the small intestine. This enables a delay in the absorption of sugars - which is considered beneficial as long as post-prandial insulinaemic responses are not disproportionately increased. In the evaluation process the EFSA found a cause-and-

effect relationship between the mentioned effect and the consumption of beta-glucans from oats and barley, HPMC, pectins, arabinoxylan produced from wheat endosperm and resistant starch. Various conditions of use were proposed (Table 9).

Both water-soluble and water-insoluble dietary fibres are also known to support gut health through changes in bowel function. Reduced transit time, more frequent bowel movements, increased faecal bulk or softer stools may be a beneficial physiological effect, provided these changes do not result in diarrhoea (EFSA 2011x). On the basis of such changes the functional role of rye fibre was confirmed to contribute to normal bowel function in foods providing at least 6g of such fibre per 100g (or at least 3g per 100kcal), being *high in fibre* (EFSA 2011x). The ability to increase faecal bulk has also been confirmed for wheat, oat and barley grain fibre (Table 9). Similar to the previous case, the proposed conditions of use are that the food is *high in fibre*. It is well established that the bulking effect of dietary fibre is closely related to the physico-chemical properties of the fibre, and in that way to the degree of fermentation by the gut microbiota in the large intestine (EFSA 2011u). The insoluble components of fibre are minimally degraded by colonic bacteria and thus remain to trap water, thereby increasing faecal bulk. In contrast, the bulking effects of soluble dietary fibre are determined by the higher extent of fermentation, and thus an increase in the bacterial mass in faeces (EFSA 2011u). A somewhat different support of gut health can be based on the ability of dietary fibre to reduce intestinal transit time. Such a function was found for wheat bran fibre, which increases the water holding capacity of the contents of the intestine, increases intestinal and pancreatic fluid secretion and thus increases the velocity of chyme displacement through the intestine if at least 10g per day is consumed (EFSA 2010...). A similar effect, but with a different mechanism of action, was also confirmed for lactulose – a synthetic sugar used in the treatment of constipation (EFSA 2010p). In the colon, lactulose is broken down to lactic acid and to small amounts of acetic and formic acids by the action of beta-galactosidases from colonic bacteria. This process leads to an increase in osmotic pressure and a slight acidification of the colonic content, causing an increase in stool water content and a softening of stools (EFSA 2010p). However, due to the medicinal use of lactulose in some EU countries the authorisation of such a health claim on foods is questionable.

### 6.3.3 Prebiotics

Prebiotics were defined as non-digestible food ingredients that beneficially affect the host by selectively stimulating the growth or activity of one or a limited number of bacterial species already resident in the colon, and thus attempt to improve host health (Gibson and Roberfroid 1995). An intake of prebiotics can modulate the colonic microbiota by increasing the number of specific bacteria and thus changing the composition of the microbiota.

Consumers perceive prebiotics as having health benefits. The *Guidance on the implementation of regulation No 1924/2006 on nutrition and health claims made on foods* specifies that a claim is a health claim if, in the naming of the substance or category of substances, there is a description or indication of functionality or an implied effect on health. The examples provided include the claim *contains prebiotic fibres*. Such claims should therefore only be used if the food contains prebiotic fibres with a scientifically proven effect and when such a claim is accompanied by a specific health claim. In practice, this is not yet the case and such claims are still very common on the market. Only a few (prebiotic) fibres have received

favourable opinions from the EFSA. One example is the already-mentioned oat and barley grain fibres - whose bulking effects are determined by the higher extent of fermentation and thus an increase in the bacterial mass in faeces. On such a basis their ability to increase faecal bulk has been confirmed (EFSA 2011u) (Table 9). Several fibres were evaluated for other functions, i.e. for their role in maintaining healthy gastro-intestinal function by increasing the number of bifidobacteria in the gut. In some cases the studies clearly demonstrated a significantly increased number of bifidobacteria in the gut; however, there was no direct evidence provided that changes in the number of bifidobacteria in the gut are beneficial for gut function (EFSA 2009a). For such claims the beneficial effect needs to be shown.

## **6.4 Other food or food constituents**

### **6.4.1 Antioxidants**

Numerous food constituents possess antioxidant activity, yet, in the health claim evaluation process, only a few of them were assessed with a favourable outcome. As in the prebiotics case, the claim *contains antioxidants* is considered a health benefit and should be accompanied by a specific health claim. However, apart from vitamins and trace elements (Table 7), until now only olive oil polyphenols have been recognised to possess antioxidant activity which is beneficial to human health, specifically in the protection of LDL particles from oxidative damage (Covas et al. 2006a; Covas et al. 2006b; EFSA 2011v; Marrugat et al. 2004; Weinbrenner et al. 2004). Hydroxytyrosol and its derivatives (e.g. oleuropein complex and tyrosol) are the key compounds with such activity, and to bear the claim olive oil it should contain enough of them to provide 5mg of these compounds daily. It was noted that the concentrations in some olive oils does not allow consumption of such an amount of polyphenols in the context of a balanced diet (EFSA 2011v). Many other known antioxidants (including flavonoids and flavonols, lycopene, lutein etc.) received unfavourable opinions, mostly because of poor characterisation, non-specific health effects or poor evidence for such effects. In a recent draft of the *Guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health* the EFSA noted that it is not established that changes in the overall antioxidant capacity of plasma exert a beneficial physiological effect in humans. A beneficial physiological effect will therefore need to be proven for any specific antioxidant for a successful substantiation.

### **6.4.2 Probiotics**

The claim *contains probiotics* is also considered a health benefit and should be accompanied by a specific health claim. However, the EFSA has not released a favourable opinion in relation to live organisms other than for live yoghurt cultures in yoghurt, which were shown to improve the digestion of lactose in yoghurt in individuals with lactose maldigestion (discussed below). The main reasons for the unfavourable opinion were that the microorganisms were not properly characterised (in either the health claim application or the supporting study of the claimed effect), or that there was poor evidence of the beneficial effect. However, many probiotics health claims were returned for re-evaluation and there has been a call to provide additional data for scientific evaluation. Discussion about the results of the re-evaluation has been very speculative, but it is clear that further research will be needed to support a beneficial physiological effect in humans in most (if not all) cases. The specific functions will need to be properly addressed.

### 6.4.3 Sport nutrition

A series of food constituents have been evaluated for sport related general function health claims. Caffeine was shown to contribute to increase in endurance performance, reduction in the rated perceived exertion during exercise and increased alertness (Table 10). However, it is noted that for children consumption of a dose of 5mg/kg body weight could result in transient behavioural changes, such as increased arousal, irritability, nervousness or anxiety. In relation to pregnancy and lactation, moderation of caffeine intake, from whatever source, is advisable (EFSA 2011i). The role of vitamin C in the maintenance of normal function of the immune system during and after intense physical exercise was also confirmed, but due to the high daily dosage (200mg vitamin C per day in addition to the usual diet) it remains a question if such a claim will be authorised. In some EU countries such a dosage of vitamin C is considered a medicinal use. Other health claims which received favourable opinions include protein and the maintenance of muscle mass, water and the maintenance of normal thermoregulation, and creatine and an increase in physical performance during short-term, high intensity, or repeated bouts of exercise. The proposed condition for use of these claims is presented in Table 10. The role of carbohydrate-electrolyte solutions in the enhancement of water absorption during exercise and in the maintenance of endurance performance was also evaluated. It was proposed that in order to bear the claim a carbohydrate-electrolyte solution should contain 80-350 kcal/L from carbohydrates, and at least 75 % of the energy should be derived from carbohydrates which induce a high glycaemic response, such as glucose, glucose polymers and sucrose. In addition, these beverages should contain between 460mg/L and 1150mg/L of sodium, and have an osmolality between 200-330mOsm/kg water (EFSA 2011j).

Food or ingredient	Function	Conditions of use	Reference
Vitamin C	Maintenance of normal function of the immune system during and after intense physical exercise	200mg vitamin C per day <sup>1</sup> (in addition to the usual diet)	(EFSA 2009{)
Protein	Maintenance of muscle mass	Source of protein	(EFSA 2010 )
Caffeine	Increase in endurance performance	3mg/kg body weight (one hour prior to exercise)	(EFSA 2011h)
	Increase in endurance capacity		(EFSA 2011h)
	Reduction in the rated perceived exertion during exercise	4mg/kg body weight (one hour prior to exercise)	(EFSA 2011h)
	Increased alertness	75mg caffeine per serving (adults)	(EFSA 2011i)
Creatine	Increase in physical performance during short-term exercise	3g per day	(EFSA 2011m)
Water	Maintenance of normal thermoregulation	2.0 L per day	(EFSA 2011~)

Food or ingredient	Function	Conditions of use	Reference
Carbohydrate-electrolyte solutions	Enhancement of water absorption during exercise	Energy: 80-350kcal/L from carbohydrates and at least 75 % from sugars; Sodium: 460-1,150mg /L Osmolality: 200-330mOsm/kg	(EFSA 2011j)
	Maintenance of endurance performance		(EFSA 2011j)

Notes: <sup>1</sup>In some countries 200mg of vitamin C daily is considered a medicinal use.

Table 10. Conditions of use for sport related general function health claims as proposed by the EFSA

#### 6.4.4 Weight management

For food producers weight-management products are appealing as these can be marketed successfully. Weight loss can be interpreted as the achievement of a normal body weight in previously overweight subjects. In this context, weight loss in overweight subjects without the achievement of a normal body weight is also considered beneficial to health (EFSA 2010t). However, only a few favourable opinions of the EFSA were published (EFSA 2010o; EFSA 2010t; EFSA 2011j). It was established that substituting two daily meals with meal replacements helps to lose weight in the context of energy restricted diets. In order to bear the claims, a food should contain a maximum of 250 kcal/serving and comply with specifications laid in legislation covering foods intended for use in energy-restricted diets for weight reduction (EFSA 2010t). Similarly, it was established that replacing the usual diet with a very low calorie diet (VLCD) helps to lose weight (EFSA 2011j). VLCDs are diets which contain energy levels between 450 and 800 kcal per day, and 100% of the recommended daily intakes for vitamins and minerals. They should contain not less than 50g of high-quality protein, should provide not less than 3g of linoleic acid and not less than 0.5g alpha-linolenic acid, with a linoleic acid/alpha-linolenic acid ratio between 5 and 15, and should provide not less than 50g of available carbohydrates (CODEX STAN 203-19956) (EFSA 2011j). VLCDs are typically used for 8-16 weeks.

#### 6.4.5 Foods for individuals with symptomatic lactose maldigestion

Lactose maldigestion is a common condition characterised by intestinal lactase deficiency. It is most prevalent in Asian, African, Hispanic and Indian populations, but is also common in Europe. Most people with primary lactose maldigestion are usually able to tolerate small amounts of lactose (EFSA 2009o). Ingested lactose is hydrolysed by an enzyme of the microvillus membrane of the enterocytes, called lactase. It is split into the monosaccharides glucose and galactose, which are rapidly and completely absorbed within the small intestine. In persons with lactose maldigestion, undigested lactose reaches the colon where it is degraded to lactic acid, acetic acid, water and carbon dioxide by intestinal bacteria (EFSA 2011q). In some lactose maldigesters this can elicit symptoms of lactose intolerance, which may develop one to three hours after the ingestion of lactose. These symptoms include abdominal pain, bloating, flatulence and diarrhoea. It was established that consumption of foods with reduced amounts of lactose may help to decrease gastro-intestinal discomfort caused by lactose intake in lactose intolerant individuals (EFSA 2011q). However, it was not possible to propose a single condition of use because of the great variation in the individual

tolerances of lactose intolerant individuals. Additionally, an improvement in lactose digestion may be of interest to lactose intolerant subjects (EFSA 2009o). A cause-and-effect relationship has been established between the externally administered lactase enzymes and breaking down lactose in individuals with symptomatic lactose maldigestion, which can alleviate lactose intolerance symptoms. The recommended dose was 4500 FCC (Food Chemicals Codex) units with each lactose-containing meal. It was noted that the dose may have to be adjusted to individual needs for lactase supplementation and consumption of lactose-containing products (EFSA 2009o). Live yoghurt cultures in yoghurt were also shown to improve the digestion of lactose in yoghurt in individuals with lactose maldigestion (EFSA 2010q). The effect has been confirmed in a number of human studies and is based on the ability of specific bacteria to produce active  $\beta$ -galactosidase enzymes in the digestive tract. It was proposed that in order to bear the claim, the yoghurt should contain at least  $10^8$  colony-forming units (CFU) live starter microorganisms (*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*) per gram (EFSA 2010q).

#### 6.4.6 Chewing gums

It was established that there is a cause-and-effect relationship between the consumption of sugar-free chewing gum and plaque acid neutralisation, the maintenance of tooth mineralisation, and a reduction of oral dryness (EFSA 2009w). The solubility of tooth hydroxyapatite crystals drops with the lowering of pH and buffering of acids, and limiting the duration of periods of pH drop can prevent demineralisation and promote remineralisation of the hydroxyapatite crystals. Acid is produced in plaque through the fermentation of carbohydrates by acid-producing bacteria and studies have shown that chewing a sugar-free chewing gum enhances saliva flow and counteracts pH drops upon sugar-induced acid production. Chewing for at least 20 minutes after meals may be needed to obtain the beneficial effect. In the absence of fermentable carbohydrates, no clinically relevant reduction on plaque pH may be expected by the consumption of sugar-free chewing gum (EFSA 2009w). In a separate opinion it was established that sugar-free chewing gum with carbamide contributes to plaque acid neutralisation over and above the effect achieved with sugar-free chewing gums without carbamide (EFSA 2011z). At least 20mg carbamide should be added per piece to communicate such claims.

#### 6.4.7 Borderline substances

In some cases the functionality of possible food ingredients enters the borderline between food and medicine. A series of such cases has also been revealed in the evaluation of general function health claims. The most obvious example is the evaluation of monacolin K from rice fermented with the red yeast *Monascus purpureus* (EFSA 2011t). Red yeast rice is a traditional Chinese food product which is still a dietary staple in many Asian countries. Depending on the *Monascus* strains used and the fermentation conditions, it may contain Monacolin K, in the form of hydroxy acid and lactone (also known as lovastatin), which received a favourable opinion for the maintenance of normal blood LDL-cholesterol concentrations (EFSA 2011t). On the EU market there are a number of lovastatin-containing medicinal products and it remains controversial if it is possible to set appropriate conditions of use that would put this product into a food category. In any case, red yeast rice has not been traditionally consumed as a food in Europe and must go through a novel food authorisation procedure. However, its use is already possible in some specific food

categories (i.e. in food supplements) in some EU countries. Somewhat similar is the case of melatonin. While in a number of EU countries this hormone is considered a medicinal product, in some countries it is sold as a food supplement. In the health claim evaluation process it was confirmed that melatonin helps to reduce the time taken to fall asleep (EFSA 2011d) and contributes to the alleviation of subjective feelings of jet lag (EFSA 2010u). It is proposed that 1mg of melatonin is consumed close to bedtime (EFSA 2011d).

## 7. Nutrient profiles

To exclude the use of nutrition and health claims on foods with overall poor nutritional status nutrient profiles should be established, including the exemptions which food or certain categories of food must comply with in order to bear the claims (EC 2006). Unfortunately, this part of the legislation has not yet been implemented, even though the scientific criteria for this were prepared on time (EFSA 2008). The stakeholders have obviously been quite effective in lobbying against the setting of nutrient profiles and there is little evidence of progress in this area since 2009. Currently, it is not even clear if nutrition profiles will be implemented at all (Cappuccio and Pravst 2011). Nevertheless, the producers of functional food must be aware that the overall composition of a final product should provide health benefits. Particular care should be directed towards those nutrients with the greatest public health importance for EU populations, such as saturated fatty acids, sodium and sugar, intakes of which generally do not comply with nutrient intake recommendations in many Member States (EFSA 2008).

## 8. Quality of functional foods

The quality and safety of functional foods is entirely the responsibility of the producer but can be controlled by national authorities. In practice, such controls mainly focus on assuring adequate safety by controlling for contaminants and additives (Pravst and Žmitek 2011). Nutritional composition is usually not considered a health risk and is therefore less controlled. In fact, while labelling requirements have been in existence in many countries for more than a decade, analyses of many food constituents are still challenging. The EU legislation currently concentrates on regulating the use of vitamins and minerals, while the use of other substances with a nutritional or physiological effect is not regulated in detail. When discussing the safety and quality control assessment of foods containing particular ingredients with biological activity we must distinguish products on the basis of their active ingredients; i.e. chemically stable dietary minerals, less stable vitamins, chemical compounds other than vitamins and minerals, living microorganisms (i.e. probiotics) etc. (Pravst and Žmitek 2011). The appropriate content of these ingredients in final products must be achieved using suitable production standards (including quality control of both raw materials and the final product) and stability during the manufacturing process and shelf life. The low content of an ingredient in a final product is often connected with either improper manufacturing (inappropriate purity or insufficient ingredients used in the production, uncontrolled manufacturing conditions, and inappropriate formulation) or its decomposition during shelf life. In situations where decomposition occurs either during manufacturing or shelf life this not only misleads the consumer but might also create increased health risks due to the possibility of the uncontrolled formation of by-products. In contrast, when not enough ingredients are used during manufacturing the primary concern

is about misleading the consumer. In some cases, such scenarios can also pose a risk to human health, i.e. in instances of adulteration.

A significant problem that arises in the evaluation of the quality of functional foods is that there are no generally accepted tolerances for the declaration of nutrients and other active ingredients in the EU (DG SANCO 2006), although guidelines on this issue have been accepted in some countries (Table 11). The task of setting tolerable margins was identified as a priority 10 years ago during the discussion that led to the adoption of Directive 2002/46/EC on food supplements, but this goal has not yet been achieved (Pravst and Žmitek 2011). Nevertheless, there is a general agreement that such tolerances should be defined at the Community level in order to avoid trade barriers and ensure consumer protection (DG SANCO 2006).

<i>Country</i>	<b>Tolerances for added nutrients <sup>1</sup></b>		
	<i>Minerals</i>	<i>Water-soluble vitamins</i>	<i>Fat-soluble vitamins</i>
Belgium	90% - 120%	90% - 120%	90% - 120%
Denmark	80% - 150%	80% - 150%	80% - 150%
France	80% - 200%	80% - 200% <sup>2</sup>	80% - 200% <sup>2</sup>
Italy	75% - 100%	80% - 130% <sup>2</sup>	80% - 130% <sup>2</sup>
Slovenia	80% - 150%	80% - 150% <sup>2</sup>	80% - 130%
Netherlands	80% - 150%	80% - 200%	80% - 200%
United Kingdom	50% - 200%	50% - 200%	70% - 130%

Notes: <sup>1</sup> if legislation prescribes minimum and maximum values for the addition of nutrients, the analysed amount must not exceed these limits; <sup>2</sup> with exceptions

Table 11. Tolerance values accepted or practiced in some EU member states (CIAA 2007; DG SANCO 2006; IVZ 2009).

## 9. Conclusions and future issues

In the last few years the regulation of nutrition and health claims has been one of the top food-related themes discussed in Europe. Regulation covering these areas was indeed required. Protecting consumers against misleading claims, along with the harmonisation of the European market, were the key issues that needed to be addressed. The regulation targets functional foods, a concept which emerged in Japan about 20 years ago to reduce the escalating health care costs with a category of foods offering potential health benefits, although from a different perspective. At the time, the USA and some EU-member states were also at the frontier of developments, but the European Union as a whole was lagging far behind. It was decided that the use of pre-approved evidence-based health claims on food labels would serve us best and in the ensuing time there has been a focus on creating a list of approved claims. In such a system, functional foods are basically defined by the limitations and the opportunities for the use of claims.

Essential nutrients are clearly the winner of the evaluation process. In cases where a well-established consensus among scientists exists on the biological role of a nutrient, the EFSA relied on that consensus and confirmed the cause-and-effect relationship without reviewing the primary scientific studies. In most cases, the proposed condition of use is to include at least 15% of the RDA of the nutrient per 100g of final product, to enable the use of health

claims for such a nutrient. This will enable products which are a source of at least one such nutrient to communicate health claims, even in cases where there is no deficiency in the population. The consumer will recognise such a nutrient as a health added value and there are concerns that such claims might flood the market and enable consumers to be legally misled. While the authorisation of such health claims may pose a risk of misleading the consumer, there are also cases where concerns related to public health arise. Such an example is the claim concerning phosphorus and its role in the maintenance of normal bones. The intake of phosphorus easily exceeds the recommendations and a bigger intake might have adverse effects on bone health (Pravst 2011b). Therefore, both health and ethical concerns arise as to whether such claims should be allowed, even though science is not yet clear on this issue. A useful solution in such cases would be to authorise claims with more specific conditions of use.

Foods promoted with claims may be perceived by consumers as having a health advantage over other foods and this may encourage consumers to make choices which directly influence their total intake of individual nutrients in a way which would run counter to scientific advice. The regulation aims to avoid a situation where claims mask the overall nutritional status of a food product and confuse consumers when trying to make healthy choices in the context of a balanced diet with the introduction of nutrient profiles. However, these profiles have not yet been established and it is not even clear if they will be implemented at all. In a situation in which food producers have the power to stimulate the consumption of foods with a poor nutritional status we must count on their commitment to serving consumers (Pravst 2011a).

All of the above issues suggest that we are still far from the target. The scientific substantiation of health claims for non-essential ingredients is very important and substantial additional research will be needed to get new claims approved. A detailed examination of all the concerns raised by the EFSA in its published opinions, together with some additional advice about expectations related to the scientific substantiation of health claims, should result in the improved quality of clinical testing for bioactive components and functional foods.

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