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**Proposal for a Regulation on
Nutrition and Health Claims made on Foods.**

Briefing Note

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EXECUTIVE SUMMARY

In recognition of the growing need to protect and promote public health, the European Commission has recently adopted a draft proposal for a Regulation on nutrition and health claims, which will require that all health claims for food be approved before they are released on the market. This includes the adoption of a list of health claims based on well-established science although at this stage the Commission has not yet defined a process for identifying well-established health claims, or addressed the issue of how to handle existing health claims on the European market.

This briefing paper is trying to concisely explain the status quo in the European Union and other parts of the world with respect to the use of health claims in the labelling of the various food products by the industry.

The foreseen measures are to come up with new legislation as uniform as possible throughout the community with the objective to significantly improve the situation for the consumer, without creating too high barriers for the industry.

Legislation should be easily enforceable, fair versus industry and consumers and include certain flexibility for new products to be brought to market.

Some controversial issues such as the scientific substantiation of health claims, the application of nutrient profiles to foods allowed to bear such claims and consumer understanding are discussed.

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1 INTRODUCTION

To appreciate the importance of food bearing nutrition or health claims, it is helpful to put things into perspective and to understand how the science of nutrition has changed over the last century.

During the first half of the 20th century, nutrition scientists identified the essential nutrients and established nutritional standards, mainly, if not exclusively, with the aim of preventing deficiencies and supporting body growth, maintenance and development. Such advances are reflected today in:

- nutrients' reference values, such as the recommended daily allowances or reference nutrition intakes,
- dietary guidelines that give “advice on consumption of foods or food components for which there is a related public health concern”. These are expressed in relation to total diet, often in qualitative terms, based on consensus research findings relating to diet and health,
- food guides, such as food pyramids or food plates, that are “the translation of nutrition standards and dietary guidelines in terms of recommendations on daily food intake”. These forms of conceptual framework for selecting the kinds and amounts of foods that, together, provide a nutritionally satisfactory diet. They are based on nutrient reference values, composition of foods, food intake patterns and factors influencing food choice [1,2,3].

In the last third of the 20th century, nutritionists also recommended avoiding excessive consumption of certain nutrients after recognizing their potential roles in several (mostly chronic) diseases, such as coronary heart disease (CHD), type 2 diabetes, elevated blood pressure and cancer. This led to the recognition that some components of foods, when consumed in sufficient quantities, could have a negative impact on health. Development then followed of a wide range of food products with reduced amounts of certain nutrients, mainly fat, sugar and salt [4].

At the turn of the 21st century, the industrialized world faces new challenges, i.e. an enormous increase in the costs of health care, longer life expectancy, improved scientific knowledge, development of new technologies, and major changes in lifestyles. Nutrition scientists are now working on the idea of “optimal nutrition”, which focuses on optimizing the quality of the daily diet in terms of its content of nutrients and non-nutrients as well as other food properties that can favour the maintenance of health.

Whilst food provides us with energy and nutrients for growth and the maintenance of body functions, it is becoming clear that, in the context of the lifestyle of people in developed countries, it can offer much more. Through its capacity to contribute to and control many metabolic, physiological and psychological functions of the body, food has effects beyond what is traditionally accepted as nutrition. Food can play an important role in reducing the risk of disease and, equally importantly for a healthy population, can help to optimise and enhance normal functions and thereby improve quality of life. These new concepts have already stimulated health authorities, especially in Japan and the USA, to support research on physiological effects and health benefits of food components.

The current harmonized EU legislation on food labelling is only defining and allowing nutritional claims (Directive 2000/13/EC, as amended). This led to the proliferation of the number and type of claims made on food labels, resulting in non-uniform health and nutrition claims in the European Union. Some Member States have adopted legislation and other measures to regulate their use. This has resulted in different approaches and in numerous discrepancies both regarding the definition of the terms used and the conditions warranting the use of claims.

What can be claimed for a product in one country does not automatically mean that the same can be said in another member state. This, combined with the fact that the far majority of consumers has little knowledge with respect to Nutrition, requires an EU wide visible ruling in order to make it as clear as possible to the average consumer

New areas such as nutrient function claims, enhanced function claims and disease risk reduction claims are not taken into account today. The reason of the new proposed legislation is to take these new claims into consideration and develop a suitable legislative framework to allow these.

What's at least as important, is to avoid barriers to trade and to enable consumers to obtain identical claims throughout Europe and improve their understanding about the food and drinks they consume.

2 NUTRITION AND HEALTH CLAIMS: CURRENT DEFINITIONS

Table 1 below summarises the various types of claims under consideration and their definitions [5].

Table 1 Proposed draft guidelines for the use of health and nutrition claims (Codex Alimentarius 2005)

TYPE OF CLAIM	DEFINITION	EXAMPLE
<i>Nutrition claim</i>	<i>Any representation that states, suggests or implies that a food has specific nutritional properties including but not limited to the energy value and content of protein, fat and carbohydrates, as well as the content of vitamins and minerals</i>	
Nutrient content claim	A nutrition claim that refers to the level of a nutrient contained in a food	“Source of calcium”, “high in fibre”, “low in fat”
Comparative claim	A nutrition claim that compares the nutrient levels and/or energy value of two or more foods	“Reduced”, “less than”, “fewer”, “increased”, “more than”
<i>Health claim</i>	<i>Any representation that states, suggests or implies that a relationship exists between a food or constituent of that food and health</i>	
Nutrient function claim	A form of claim that refers to the physiological role of the nutrient in growth, development and normal functions of the body	“Food X is a good/excellent source of nutrient A, naming the physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development”
Enhanced function claim	Claims that concern specific beneficial effects of foods or their constituents in the context of the total diet on physiological or psychological functions or biological activities. Such claims relate to a positive contribution to health, improvement of a function, or modification or preservation of health	“Certain nondigestible oligosaccharides may improve the growth of a specific bacterial flora in the gut” “Caffeine can improve cognitive performance” “Folate can help maintain healthy plasma homocysteine levels”
Reduction of risk of disease	Claims relating to the consumption of a food or food constituent in the context of the total diet that may help reduce the risk of a specific disease or health-related condition. The claim must consist of two parts: (1) information on an accepted diet-health relationship, followed by (2) information on the composition of the product relevant to the relationship, unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food	“Folate may reduce a woman’s risk of having a child with neural tube defects” “Sufficient calcium intake may help to reduce the risk of osteoporosis in later life” “Intake of specific probiotics may help to reduce the risk of rotavirus infection in young children”

3 CURRENT USE OF NUTRITION AND HEALTH CLAIMS IN THE EU

In the absence of a European legislation on the use of health claims on foods, several European countries have developed self-regulatory frameworks and codes of practice for health claims.

- Sweden was the first country to develop a self-regulating programme, which originally allowed mention of eight diet-related diseases or risk factors in connection with the relevant nutrient or dietary fibre content of a food: see Table 2. The claims are in two steps: citation of one of these diet and health relationships, followed by a statement on the relevant composition of the product. A ninth claim was introduced later regarding wholegrain cereals and risk of (coronary) heart disease. Three of these claims refer to diseases (arteriosclerosis, osteoporosis and heart disease). Since 2001, product-specific health claims have also been permitted on food products, which, through their composition, contribute positively to a nutritionally adequate diet. The Code of Practice, Rules for Health Claims in the Labelling and Marketing of Food Products (1990, rev. 1997, 2001), is implemented by a coalition of farmers, food trade and retail organizations. The Swedish Nutrition Foundation plays an advisory role [6].
- In the Netherlands, the Dutch Nutrition Centre (a government-funded body) has drawn up a code for the use of health claims in conjunction with regulatory authorities, industry and consumer organizations, which was implemented in 1998 [7].
- Belgium, too, has a code of conduct driven mainly by the Federation of Food Industries [8].
- In Germany and France, health claims for foods are approved on a case-by-case basis. Denmark is drawing up a list of generic health claims along the lines of the US and Swedish models.
- In Finland, the National Food Administration has published guidelines for permissible health claims [9].
- In the United Kingdom, the Joint Health Claim Initiative (JHCI) was launched at the end of 2000 and has considered six generic health claims, three of which can be used on foods under existing law. The Code is the result of industry and consumer collaboration, and is monitored by the Joint Health Claims Initiative Council, made up of representatives from industry, consumer protection groups and enforcement agencies. The Joint Health Claims Initiative recommends that, in the absence of a legislative requirement for pre-approved claims, food manufacturers seek pre-market advice from the Initiative before making generic or product-specific claims as a means of ensuring that claims do not breach food law or mislead consumers. The process of seeking advice is voluntary; manufacturers can still make health claims without working through the Initiative, as long as they have evidence to support their claims [10].

The Confederation of the Food and Drink Industries of the European Union (CIAA) developed a code of practice on the use of health claims in 1999. Supported by representatives from 15 Member States, the CIAA code of practice lays down general principles for the substantiation and assessment of health claims with a view to influencing what evidence is requested to support a health claim by enforcement authorities [11].

These codes all contain guidelines and conditions for the use of health claims. Some encourage companies seeking to make innovative health claims to submit full documentation of the scientific evidence that forms the basis of the claim to an expert panel for guidance and approval.

Table 2 Some examples of health claims permitted by various countries

USA	UK	SWEDEN
<ul style="list-style-type: none"> - Calcium and reduced risk of osteoporosis - Dietary saturated fat and cholesterol and risk of coronary heart disease - Sodium and hypertension - Fibre containing grain products, fruit and vegetables and cancer - Fruits, vegetables and grain products that contain fibre, particularly soluble fibre, and the risk of coronary heart disease - Fruits and vegetables and cancer - Soy protein and heart disease - Plant sterols and plant stanol esters and risk of coronary heart disease - Folate and neural tube defects - Dietary sugar alcohols and dental caries - Dietary soluble fibre, such as that found in whole oats and psyllium seed husk, and risk of coronary heart disease - Dietary fat and reduced risk of cancer - Whole grain foods and risk of heart disease and certain cancers * - Potassium and the risk of high blood pressure and stroke* - Nuts and the risk of heart disease** 	<ul style="list-style-type: none"> - Saturated fat and blood cholesterol - Wholegrain foods and heart health - Whole oats and blood cholesterol - Long chain omega-3 polyunsaturated fatty acids and heart health - Soya protein and blood cholesterol - Fruits and vegetables and stomach cancer* - Fruit and lung cancer* - Vegetables and bowel cancer* 	<ul style="list-style-type: none"> - Obesity energy - Cholesterol level in the blood - saturated fatty acids and some types of dietary fibre - Blood pressure - salt - Atherosclerosis - factors affecting blood cholesterol and blood pressure, and omega-3-fatty acids - Constipation - dietary fibre - Osteoporosis - calcium - Caries - easily fermentable carbohydrates - Iron deficiency - iron - (Coronary) heart disease – wholegrain
<p>* authorized by the "authoritative statement" standard under the Food and Drug Administration Modernization Act</p> <p>** authorized as a "qualified health claim"</p>	<p>*These claims cannot currently be used in food labelling or advertising because of the EU prohibition on medicinal claims</p>	
<p>Sources: <i>A Food Labeling Guide-- Appendix C Food Labeling CFR References: Health Claims Summary of Qualified Health Claims Permitted.</i> Washington D.C., Food and Drug Administration Center for Food Safety and Applied Nutrition[12]</p>	<p>Source: Joint Health Claims Initiative (www.jhci.org.uk) [10]</p>	<p>Source: <i>Generic health claims.</i> Swedish Nutrition Foundation (http://www.snf.ideon.se/snf/en/) [6]</p>

Internationally and nationally, the regulatory framework for health claims is in a developmental stage. Although the evolving nature of the regulations makes it difficult to present a "snapshot" of the existing regulatory environment, this review shows that the regulation of health claims on foods varies widely between countries and areas. Many countries neither prohibit nor regulate health claims; others prohibit claims; while some permit claims. Even then, the details of the claims permitted may differ between countries. Table 3 illustrates the various approaches taken by different countries around the world.

Table 3 International comparison of regulatory approaches to health claims (✓ = yes sometimes still under development, X = no, - = not applicable)

Source: European Journal of Nutrition Vol. 42 Suppl 1, March 2003

	JHCI (UK)	Sweden	NL	Belgium	CIAA	Council of Europe	USA	Canada	Japan	Codex
Website	www.jhci.co.uk	www.snf.ieon.se	www.voedingscentrum.nl		www.ciaa.be	www.coe.fr/soc-sp	www.cfsan.fda.gov/~dms/hclai.ms.html	www.hc.gc.ca/food-aliment/english/subjects/healthclaims	Available in Japanese	www.codexalimentarius.net/reperts.asp
Voluntary/Mandatory	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary	Mandatory	Mandatory	Voluntary
Origin	Industry consumers, enforcement partnership	Industry (from primary production to retail organisations), supported by consumer organisations	Council of Europe	Industry	Food industry guidelines	Council of Europe	Federal scientific bodies e.g. NAS, NIH etc	Government	Government	Codex members
Definitions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Health claims	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Enhanced function	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Disease risk reduction	X	✓, for generic claims	✓	✓	✓	✓	✓	✓	X	✓
Generic claims	✓	✓	X	✓	X	X	✓	✓	✓	✓
Product specific	✓	✓	X	✓	X	✓	✓	✓	✓	✓
Communication guidelines	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Nutrition principles	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Amount and frequency specified	✓	✓	X	X	✓	✓	✓	✓	✓	✓
Safety	Refers to existing law	Refers to existing law	Refers to existing law	X	Refers to existing law	Refers to existing law	Refers to existing law	✓	Refers to existing law	Refers to existing law
Quality assurance	Refers to existing law	In general terms	X	X	Refers to existing law	✓	✓	✓	✓	✓
Guidelines for dossier	✓	X	X	X	✓	X	✓	✓	✓	✓
Process for substantiation	✓	✓	✓	✓	X	✓	✓	✓	✓	✓
Approval procedure	Level of data required	✓	✓	X	X	-	✓ (except medical food)	Outlined	✓	-
Administrative procedures	✓	✓	✓	X	X	X	✓	✓	✓	✓
Use of independent expert panel	✓ (7 experts)	At least 3 experts appointed case by case	✓	X	X	-	FDA, federal scientific bodies	✓ (Ministry)	✓	-
Defined wording of health claims	X	X	X	X	X	X	✓	✓ (6 months)	✓ (6 months)	X
Start date of code	2000	12 years generic <1 year product specific	1998	Draft 1998	-	-	1990 (NLEA authorised health claims 2000 (Qualified health claims)	Still evolving	Since 1991 Revised 2001	At step 5 of Codex procedure
Health claims approved (to Sept. 2002)	6	8 generic since 1990 1 product specific	2	X	-	-	12 generic since 1993 2 generic health claims since 1997	302 product specific claims	302 product specific claims	
Financial support	Mainly industry funding/project grants from FSA, moving to membership scheme in 2002	Principals of code basic funding for evaluation of product-specific claims	Fees for evaluation	X	-	-			Fees to be paid for evaluation	
Timescale for approval	X	✓ (4 months)	3 months	X	-	-	Yes (> 1 yr under NLEA)		✓ (6 months minimum)	

« Safety » in table 3 means that all food products placed on the market must comply with existing food safety rules, which is a prerequisite of the General Food Law (EC Regulation 178/2002).

Article 14 stipulates:

Food safety requirements

1. Food shall not be placed on the market if it is unsafe.
2. Food shall be deemed to be unsafe if it is considered to be:
 - (a) injurious to health;
 - (b) unfit for human consumption.

The question of safety is critical for all food products. This applies not least to health claims for products intended to be consumed regularly over an extended period of time to achieve a desired effect. A company producing or marketing food products is responsible for that product being safe. Supervision is the responsibility of the National Food Administration and local health protection authorities in every member state.

4 NEED FOR SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS

Health claims have proved controversial and difficult to regulate. Regulators must balance the potential to achieve public health objectives with the fact that health claims can deceive or mislead consumers if not based on scientific data clearly showing the link between a nutrient/food substance with health or disease. Even then, the form and words of a health claim may confuse consumers.

But there is a general consensus among regulators that benefits asserted in health claims must be substantiated by scientific evidence. However, the actual process and standard of substantiation remains a complex and controversial issue, as shown by Table 3 [13].

The proposed European law on nutrition and health claims anticipates that a list of approved claims will be compiled by Member States within a 12-month period, and that, within a three-year period, the European Food Safety Authority (EFSA) and the Commission will develop an “EU Register”. These permitted claims will be based on well established, generally accepted knowledge from evidence in the scientific literature – the so-called “generic claims”- and for all other “innovative” and “product-specific” health claims, an authorisation procedure will be developed that is based on substantiation by generally accepted scientific data.

A process for the scientific substantiation of health claims (PASSCLAIM) has been developed to underpin the EU regulatory developments on nutrition and health claims. Through an iterative process of discussion in expert groups and workshops, a set of criteria which define requirements for assessing the quality of scientific data reporting the impact of foods and food components on health and well-being have been proposed and progressively refined. As a basis for the development of the criteria, seven comprehensive reviews were produced covering examples of areas of diet, health and performance in which health claims are likely to be made. An eighth paper reviewed existing processes and regulations. Started in 2001 and completed in 2005, PASSCLAIM has involved more than 160 experts from academia, industry, public interest groups and the regulatory environment [13]. It has been supported by the Fifth European Community Framework Programme for Research and Technological Development and was co-ordinated by ILSI Europe [14].

One of the main objectives of PASSCLAIM was to identify common new ideas, definitions, best practice and methodology to underpin current and future regulatory developments. A key criterion for the scientific substantiation of a claim is to take into account the totality of the available data and the weighing of the evidence.

4.1 Setting the standard of substantiation

The context within which a claim and the case made in its support should be assessed, involves:

- considering existing legislation and dietary guidelines;
- the need for review in the light of evolving science; and
- the comprehensibility of the claims by consumers.

These aspects are not thought to be part of the scientific criteria reviewed by PASSCLAIM. They nevertheless provide the background against which the scientific validity of claims should be justified [15].

Once each scientific study has been evaluated, a further step is required to determine whether, cumulatively, the evidence substantiates the health claim. To facilitate this process, regulations usually define a standard of the degree of evidence required to substantiate a claim. Defining this standard has been a difficult and sometimes controversial issue. It involves two related standards: the base of scientific literature from which the evidence is drawn, and the degree of scientific agreement within that base of scientific literature.

Evidence in the scientific literature on the effects of food constituents on health is not always consistent. Results can conflict and vary with a wide array of factors, such as study design and population. To cope with this reality, some regulations - in Canada, the United Kingdom and the United States for example - require that substantiation be based on the “totality of the scientific evidence” (that is, as wider base of scientific literature as possible). The proposed guidelines developed by PASSCLAIM also include in the interim criteria the “totality of evidence”. The total evidence is thought to be necessary to ensure that “all evidence relating to the claim is considered and not just the evidence that supports the claim”. This implies that a systematic review is required i.e. a review to ensure that all the scientific evidence is considered and that studies included meet defined standards of methodological quality [13].

4.2 Grades of evidence:

A health claim must be based on a systematic and objective compilation of all the available scientific evidence. The compilation must be done in a balanced and unbiased way, and individual studies should be evaluated for rigour of design, appropriateness of methods and procedures, reliability of measures of intakes and outcomes, and sufficient statistical power etc. The conclusions should illustrate the weight of scientific evidence and the strength and consistency of the evidence will underpin the use of the term “generally accepted scientific data”. This assessment of the totality of the evidence should be sufficient to permit the conclusion that a change in the dietary intake of the food or food component will result in a health benefit.

The preamble of the proposed EU legislation states that health claims should only be authorised by EFSA after scientific assessment of the highest possible standard. Whilst no one would disagree with basic principles of scientific substantiation, there is a major concern on the part of the scientific community and industry about how to accommodate emerging science. The World Health Organisation (WHO 2004) and the World Cancer Research Fund (WCRF 1997) use four grades of evidence: “convincing”, “probable”, “possible” and “insufficient”: see table 4 as an example [15, 16].

There was a need to define “generally accepted scientific data” to take into account the overall concepts of grade of evidence as well as the use of appropriate qualifying language to communicate claims in terms that consumers can understand and trust. A process by which a health claim and reduction of disease claims could be made on a food category, a food or one of its components that is based on the totality of the available data, and by weighting the scientific evidence according to three major grades: “convincing”, “probable” and “possible” [15, 16].

The EU has not yet considered the concept of grades of evidence, but it is crucial to support scientific initiatives to find an approach where the term “generally accepted scientific data” includes not only generic or well-established linkages between a food or a food component and a health benefit but defines “generally accepted scientific data” to take into account the overall concept of the grades of evidence and the balance of probabilities that an association

between a food or a food component and a health benefit will be refined by subsequent scientific research (see Table 4). The academic community should have a key role in identifying suitable scientific criteria on which health claims can be based. For example, the provision of insufficient evidence to support a claim is clearly inappropriate and would be misleading to consumers. However, depending on the state of the science and history of use, there is a need to adopt a system that stimulates, not stifles, academic research, product innovation and communication of nutrition and health messages to the public.

Table 4 Summary of strength of evidence on foods and food components that give a health benefit (adapted from WHO 2004)

Condition	Factors leading to reduction of disease	Grade of evidence
Obesity/weight gain	Regular physical activity High dietary fibre intake Low GI food intake	Convincing Convincing Convincing
Diabetes (type 2)	Weight loss; regular physical activity	Convincing
Elevated blood sugar levels	High fibre intake (non-starch polysaccharides)	Probable
Decreased insulin sensitivitty	Low saturated fat intake n-3 fatty acid intake Low GI food intake Vitamin E, chromium, magnesium intake	Probable Possible Possible Insufficient
Cardiovascular disease	Regular physical activity Linoleic acid, eicosapentaenoic/docosahexaenoic acid intakes Fruit and vegetable intakes Potassium intake Low sodium intake, avoidance of trans fatty acids α -linolenic/oleic acid intakes Non-starch polysaccharides/dietary fibre intakes Whole grain cereal intake Nuts (unsalted) Plant sterols/stanols intakes Folate intake Flavonoids/soy intakes Calcium, magnesium, vitamins C and E intakes	Convincing Convincing Convincing Convincing Convincing Probable Probable Probable Probable Probable Probable Possible Insufficient
Cancer (oral cavity, oesophagus, stomach, colorectum)	Fruit and vegetable intakes Fibre, soy, n-3 fatty acids, carotenoids, folate, vitamins B ₂ /B ₆ , B ₁₂ , C, D, and E, calcium, zinc, selenium, allium compounds, flavonoids, isoflavones, lignans	Probable Possible/insufficient
Dental health	Good oral hygiene Fluoride, vitamin D (enamel defects) Hard cheese, sugar-free chewing gum Milk, dietary fibre and xylitol intakes	Convincing Convincing Probable Possible
Bone health	Regular physical activity Vitamin D, calcium intakes	Convincing Convincing

Table 5 Qualifying language for the four grades of evidence in support of a health claim (Richardson 2005)

Health claim	WHO/WCRF grade of evidence	US FDA category of health claim	Qualifying language
Yes	Convincing	A	Experts agree that scientific evidence supports → <i>Modal verb 'will'</i>
Yes	Probable	B	Although there is scientific evidence supporting the claim, the evidence is not conclusive → <i>Modal verb 'can'</i>
Yes	Possible	C	Some scientific evidence suggests...however, the evidence is limited and not conclusive → <i>Modal verb 'may'</i>
No	Insufficient	D	There is little scientific evidence supporting this claim

5 IMPLICATIONS OF HEALTH CLAIMS SUBSTANTIATION

PASSCLAIM [13] will have the following principal applications:

- it will offer a practical scientific framework and a generic tool for assessing the scientific support for health claims for foods and food components and preparing scientific dossiers supporting claims. This framework will ensure that all claims have a firm scientific base. The European food manufacturing industry, including SMEs, will benefit because of the competitive edge thus provided.
- it will enable the compilation of guidelines to prepare submissions for claims on foods. This will expedite and improve the efficiency of the regulatory review process.
- Consumers will benefit from an improved approach to the scientific support for claims on foods. This integrated strategy will generate more consumers confidence in the science base related to claims on foods and will better address the concerns of consumers.

Given that the science for a not insignificant part of the claims is lacking/not complete it is absolutely necessary to develop a reliable database and create more research cooperation between industry, academia and public research.

This will also significantly impact the way the food industry is developing and launching new products on the marketplace. Additional know-how with respect to food safety, nutrition and scientific justification of claims, conduct of clinical and/or human studies, etc. will be required.

Function claims (nutrient function claims and enhanced function claims) based on generally accepted scientific data will be listed in a Community list of permitted claims. They will be accessible to all types of food operators, including SMEs. Companies will be able to freely put products bearing such claims on the market, provided that products are eligible to the claims and fulfil necessary obligations.

Functions claims based on newly developed scientific data and disease risk reduction claims will require additional substantiation and be subject to a specific review process before they can be used and ultimately added to the EU Register. That is a much longer term process, which involves a long term commitment by industry to 1) develop the science in cooperation with the academic community, and 2) get approval for the anticipated claims. The suggested review process as of the submission of an application will more likely take more than one year. But one must keep in mind that developing the science will take far more time, that can be as much as ten years or even more in certain cases.

This has a direct impact on the time needed to develop and launch new products as well as on the budgets needed to do so. Only large corporations will have the resources needed to access such claims, which will restrict the feasibility of such claims. But once approved and added to the Register, all operators will have the opportunity to use them (provided that their products are eligible), which will contribute to the competitiveness of medium and small size enterprises.

6 TO WHICH FOODS CAN NUTRITION AND HEALTH CLAIMS APPLY (FOOD PROFILE)

Much more controversial, from a regulatory perspective, is the food-type or “nutritional profile” / “nutritional criteria” of foods with health claims. Concerns have been raised that placing nutrition or health claims on foods such as confectionary products, high-salt and high-fat snacks, or high-fat and sugary biscuits and cakes would encourage greater consumption of those products, and thus give mixed messages about healthy eating. It has thus been suggested that health claims should be prohibited on specific foods or products with a specific nutrition profile [7, 18, 25].

Health and nutrition education policies have consistently emphasised the need for a balanced diet, thus making the general public understand that they should select a varied diet favouring the consumption of fruit and vegetable and limiting fat (mainly saturated fat). But there is still a huge difference between consumer knowledge and understanding of nutrition and their daily food choices. One reason, among many others, is most probably related to the difficulty to translate a claim related to the overall diet into practical daily food selection. The concept of “food profile” or “nutrient profile” has been developed, aiming at positioning various foods as a function of their contribution to the overall balance of the diet [26].

The use of nutrition and health claims on foods has raised concern that claims may lead to the consumption of an unbalanced diet. Therefore nutrition profile has been included in the EU proposal for a regulation on nutrition and health claims made on foods as a means for restricting the use of nutrition and health claims on foods that do not have a “desirable” composition, mainly in terms of fat, salt and sugar content. It is feared that claims on such products, in association with advertising campaigns, could make consumers perceive these foods as “better” products, thereby increasing their consumption [25, 26].

6.1 Various approaches to the setting of nutrition profiles

The issue of nutritional profiles in relation to nutrition and health claims is a controversial and complex process and has far reaching implications. The setting of nutritional profiles should also allow for both product innovation and variability of dietary habits and traditions.

Various schemes have been developed to classify healthy or less healthy foods based on their nutritional characteristics. The development of such nutrition profiling systems for foods or certain food categories takes into account in particular:

- the quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans fatty acids sugars and salt;
- the role and importance of the food (or food categories) in the diet of the population in general or, as appropriate, of certain population sub-groups including children;
- the overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health.

Such schemes are typically used for different applications including:

- to help consumers to make informed choices
- to identify products eligible for health claims
- to evaluate nutritional quality of food products

The concept of differentiating between food products based on their nutrient quality/quantity and their presumed effects on health is not new. Examples include use of the food pyramid as

an educational model and also the voluntary (or mandatory) use of indications on food packaging of products meeting certain nutritional criteria. Proposed systems for classifying foods by their nutrient characteristics have been based on many different rationales and criteria, each having advantages and limitations. Table 6 provides an overview of existing schemes in various countries.

Many systems have been developed worldwide to categorise individual foods in terms of their nutritional characteristics, as an aid for consumers to make informed choices [18, 19, 20, 21, 22, 23]. For most, the underlying idea is that clearer discrimination between foods that should be consumed either more frequently, or eaten less often, would result in improved dietary quality. To categorise foods on the basis of their nutritional characteristics two main types of schemes have been proposed : 1) threshold models, and 2) scoring models.

All methods are composed of one or more elements of:

- a) International recommendations for every key nutrient or nutritional objective
- b) Intake data about key nutrients
- c) Market data: distribution of values for every key nutrient with the whole market or each category
- d) Food categories as defined by the market

There is no simple, scientifically justified method. Selected nutrients are basically the same. The only exception is added sugars, which are sometimes replaced by a criterion of nutritional density

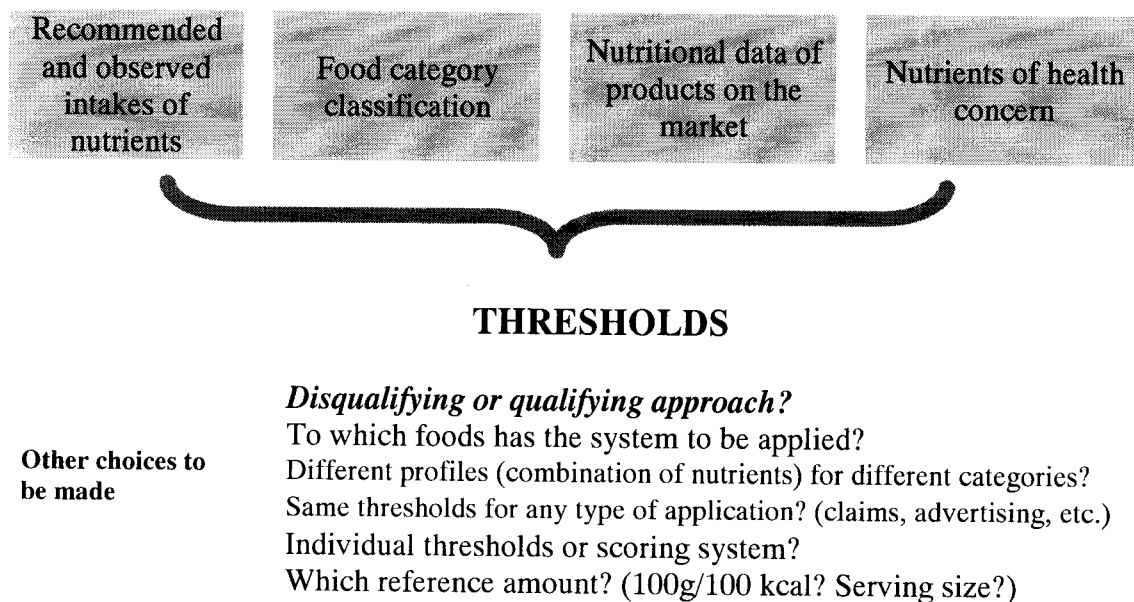
Table 6 Some existing approaches to foods categorisation in terms of their nutritional characteristics

SCHEME	RATIONALE	EXAMPLE
Type 1 Thresholds based on nutritional recommendations	Thresholds for selected nutrients correspond to x% (per serving or 100g) of the daily nutritional recommendation and diet recommendations applied directly to a product	Nutrient profile for health claims (Code of Federal Regulation, 2003, USA); A little a lot system (Healthy eating leaflets, 2002, UK); Guidelines for responsible food marketing to children (CSPI, 2005, USA)
Type 2 Thresholds based on objectives of nutritional policies	The objectives of the nutritional policy are applied directly to the products for selected nutrients chosen on the basis of the food category	Voedingscentrum (The Netherlands, 2005)
Type 3 Thresholds based regulatory definitions	Mix of nutrient recommendations and regulatory thresholds such as “low”, “reduced”, “rich”, “source”, ...	Key-hole (Swedish National Food Administration, 1989); Guidelines for tick approval (National Heart Foundation of Australia, 2004)
Type 4 Scores based on nutritional recommendations	Scores allocated for selected nutrients on the basis of the contribution to the daily nutrient recommendations. The final score includes the score from positive and negative nutrients	FSA Scoring system (2005); ratio of recommended to restricted food components (Douglas et al, 2004); The nutritious food index (Gazibarich & Ricci, 1998)

Dietary intake data are required to fully evaluate or validate schemes and models. Successful models need to be capable of being readily adapted to evolving nutritional knowledge. Nutritional profile parameters need to reflect both the requirements of the particular target population and the nutritional situation of the region. The potential effectiveness of new reference models can be optimised using computer based modelling, based on intake data from “reference population” with a satisfactory dietary pattern. Monitoring of actual changes in dietary habits is also highly desirable.

The following figure gives a global overview of the data needed and choices to be made in order to develop nutrition profiles.

Figure 1 Learning from existing methods: data and choices to be made to create a profiling scheme



A recent review of the existing literature allowed to identify, among the many different proposed systems, four systems based on a global food classification which seem to be sufficiently detailed and allow comparison. They are based on various methodologies. This recent analysis concludes that none of the proposed systems gives a totally coherent picture of the nutritional positioning of foods. This comparative approach confirms the difficulty to develop a reliable classification based on all foods. It is likely that different approaches by food categories, taking into consideration different nutrients and reference values, as an example, between dairy and cereal products, would lead to a more adequate evaluation of the nutritional profile against other products from the same category and would more easily demonstrate possible substitutions. It seems necessary to further investigate and develop more appropriate tools (Braesco et al., under publication).

Given the complexity of the issue, a pan-European group of experts in scientific areas related to health claims, including people from academia, regulatory bodies and industry, is currently reviewing all pertinent issues surrounding the setting of nutritional profiles. Initiated in February 2005, its findings will be debated in a scientific workshop at Spring 2006. This project is commissioned by the ILSI Europe Functional Foods Task Force.

Issues such as universal versus targeted nutritional profiling, beneficial elements of food, reference portion, population sub-groups with varying nutrient requirements, population impact, meal patterns, implications on consumption trends, strength of evidence of health claims and nutrition profiles, etc. will be discussed.

6.2 Various regulatory approaches to the use of Nutrition Profiles

In a recent report, the World Health Organisation (WHO) comments on the three possible regulatory models to restrict the foods on which claims can be made:

- (a) a specific list of foods or types of foods;

- (b) foods with a specific nutrition profiles/criteria per serving; or
- (c) foods with a specific nutrition profiles/criteria per 100g or per 100kJ.

The three approaches to restricting the foods on which claims can be made have been found to have different strengths and weaknesses. Using a few simple rules can be a practical advantage, while a greater number of precise criteria can prevent ambiguity on the inclusion or exclusion of certain food products. The model of nutrition profiling adopted can also have a significant effect on the foods that can bear health claims [26].

Draft Codex guidelines on health claims do not recommend any of these specific restrictions, but do allow countries to develop guidelines by stating:

“Health claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health-related condition”.

The United States has adopted the "nutrition criteria per serving" approach for health claims (not including structure/function claims). Referred to as the “Jelly Bean Rule”, products requiring pre-approval by the FDA are disqualified from bearing health claims if they contain in excess of (per serving) 13g fat, 4g saturated fat, 60mg cholesterol or 480mg sodium. The foods must not contain less than set amounts of vitamin A, vitamin C, calcium, protein or fibre (per serving). (Fruit and vegetables are exempt from the requirements.) Five years after the implementation of the regulations, health claims were no longer being made on sweet biscuit and margarines, with 21 of the 27 products carrying health claims being cereal products. FTC (Federal Trade Commission) research also suggests that health claims in advertising are now rarely made for carbonated soft drinks, desserts, sweets, doughnuts and salty snacks [12].

As part of the process of the development of a health claims regulation in Australia and New Zealand an analysis was carried out on the difference between the “per serve” and “per 100g” approach to nutrition profiling. It was found, for example, that white rice would qualify if the criteria were per serving, but not if the criteria were per 100g or 100kJ, and vice versa for brown rice.

Some eminent European nutritional scientists argue that from a practical point of view nutrient profiles based on the nutritional composition of foodstuffs will be extremely difficult to establish. This is mainly because the impact of foods on health is not determined by their nutritional composition, but by their use. The scientists argue that for the determination of nutrient profiles and their exemptions, clear and unambiguous criteria would need to be established on a scientific basis. Using basic nutritional facts and examples they show convincingly that this may prove an impossible task. They conclude that nutrient profiling is a radical new and complex model, the impact and scientific feasibility of which have not been properly assessed. In their view it cannot be done from a scientific point of view and would lead to arbitrary decisions, leading to incoherent and confusing nutritional messages for consumers [27, 28].

7 PRACTICAL EXAMPLES OF HEALTH CLAIMS

7.1 How are health claims approved in practical terms? Are nutritional profiles taken into consideration in the decision making process ?

Most existing schemes, as illustrated in Table 3 page 6, are based on voluntary approaches clearly defined in self-regulating codes of practice (UK, Sweden, Belgium, NL, etc).

Looking into the guiding principles of the various Codes, it is noteworthy to highlight that very similar guiding principles apply, whether or not claims must be subject to pre-market approval.

For example, three categories of health claims are covered by the Swedish Code: (1) *nutrient function claims*, (2) *generic reduction of disease risk claims*, and (3) *product-specific physiological claims*. These claims may be applied to food products included in a normal diet, and whose nutritional composition does not conflict with official dietary recommendations.

Table 7 gives illustrative examples of the difference between a nutrition claim and the different categories of health claims, as covered in the Code.

Table 7: Examples of nutrition claims and health claims

Nutrition claim	Contains calcium
Nutrient function claim	Calcium helps to build bones. Product X contains calcium
Generic reduction of disease risk claim	A nutritionally balanced diet high in calcium and vitamin D helps reduce the risk of osteoporosis. Product Y is high in calcium.
Product-specific physiological claim	Product Z helps to increase calcium absorption, and thereby to improved building of bones.

Health claims should only be employed in the labelling and marketing of products that with normal use contribute to a nutritionally balanced diet. The nutritional composition of products must not clash with official dietary recommendations. A product's nutritional composition at normal consumption levels must be such that it has a significant effect on the composition of the diet as a whole.

The amount of the food product normally consumed must be such that it has appreciable significance for a balanced diet, and the product's composition such that it is relevant to the claim. Criteria regarding the product's nutritional composition must be followed.

Examples from the Swedish Code:

Overweight/obesity – Energy

A high energy intake can lead to overweight/obesity. A diet with a low or reduced energy content can therefore reduce the risk for overweight/obesity. Reduced fat content and increased dietary fibre content lower a product's energy content. Depending on the nature of the product, reduced sugar content can also contribute to a lower energy content.

Criteria: Only products with significant relevance to the total energy intake are appropriate for claims regarding overweight/obesity. Products carrying this claim must contain at least 30% less energy per 100 g than a comparable normal product.

Cardiovascular disease/atherosclerosis – Blood cholesterol levels

(a) Hard fat (primarily saturated fat)

(b) Certain types of dietary fibre

High cholesterol levels in the blood represent a diet-related risk factor for atherosclerosis/hardening of the arteries and are thereby connected with cardiovascular disease.

Hard fats contribute to elevated blood cholesterol levels. A nutritionally balanced diet with a low intake of hard fats can therefore reduce the risk of cardiovascular disease/atherosclerosis. A reduced hard fat content can be achieved either by a total reduction in fat, or by substituting hard fats with mono- or polyunsaturated fats.

Certain types of dietary fibre help to reduce blood cholesterol levels. A nutritionally balanced diet rich in these types of fibre can thereby reduce the risk of cardiovascular disease/atherosclerosis.

Criteria: Only product groups with significant relevance for the total fat content of the diet are appropriate for claims regarding the connection between saturated fat and blood cholesterol levels.

In the British Joint Health Claims Initiative, similar principles apply:

“A health claim must not encourage or condone excessive consumption of any food or disparage good dietary practice. The health claim will need to be set in the context of the role of the food in relation to the overall diet or other lifestyle factors (e.g. "if eaten as part of a low fat diet") unless the evidence indicates that this is inappropriate or unnecessary, for example in the case of the effect of folic acid.

The health claim must be fulfilled in the target population when the food is consumed in the quantities, which can reasonably be expected to be consumed in one day or in quantities which make a reasonable contribution to the diet.

A food for which a health claim is made should, apart from the component(s) to which the claim refers, have a nutritional profile comparable to other similar foods. The making of a

health claim should not encourage an unreasonable intake of ingredients or components that are unlikely to make a significant overall contribution to a healthier diet.”

In France, health claims are subject to pre-market approval in all cases (except certain nutrient function claims); the same principles are followed by the AFSSA experts' group in nutrition before allowing any claim.

In summary, nutritional profiles may not be specifically mentioned in the various codes but the concept applies already in most cases. Nutritional profiles have been more argued and debated in the context of food labelling rather than as a tool to differentiate between products eligible to an health claim or not.

7.2 Where do health claims appear on food packaging in various EU countries?

There are no fixed rules but most food operators, if not all, **apply** the same principles.

The status of food labelling rules can help understand what current industry practices are. EC legislation on food labelling has been harmonised for a long time, first measures were adopted in 1979. Food labelling rules must follow the provisions of directive 2000/13/EC, as amended. Compulsory information on food labels is the following (Article 3):

- (1) The name under which the product is sold or product denomination;
- (2) The list of ingredients;
- (3) The quantity of certain ingredients or categories of ingredients as provided for in Article 7;
- (4) In the case of pre-packaged foodstuffs, the net quantity;
- (5) The date of minimum durability or the 'use by' date for highly perishable foodstuffs;
- (6) Any special storage conditions or conditions of use;
- (7) The name or business name and address of the manufacturer or packager, or of a seller established within the Community;
- (8) Particulars of the place of origin or provenance where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff;
- (9) Instructions for use when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions;
- (10) With respect to beverages containing more than 1,2 % by volume of alcohol, the actual alcoholic strength by volume.

The particulars listed under points 1, 4, 5 and 10 shall appear in the same field of vision (Article 13). Additional provisions about the legibility and marking are also laid down (Article 13).

That is applicable to nearly all pre-packaged foods, except those subject to other specific measures, like mineral waters.

Community provisions applicable to specified foodstuffs and not to foodstuffs in general may provide that other particulars in addition to those listed in Article 3 must appear on the labelling. Foods for particular nutritional uses are the most representative example (Ref: EC Directive 89/398).

Where there are no Community provisions, Member States may make provision for such particulars in accordance with the procedure laid down in Article 19.

Nutrition labelling of foods is governed by another Directive, namely Directive 90/496/EC on nutrition labelling for foodstuffs. Nutrition labelling is optional, except where a nutrition claim appears on labelling, in presentation or in advertising, with the exclusion of generic advertising. Then nutrition labelling becomes then compulsory.

1. Information shall be expressed per 100 g or per 100 ml. In addition, this information may be given per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated.
2. The information covered by this Directive must be presented together in one place in tabular form, with the numbers aligned if space permits. Where space does not permit, the information shall be presented in linear form. It shall be printed in legible and indelible characters in a conspicuous place.

This means:

Additional information such as trademarks, pictorials and claims is not compulsory. Nutrition labelling is compulsory only when a nutrition or health claim is made, but it is more and more frequently provided as voluntary additional information for consumers.

In practice, what most food operators do is the following:

1. To use the front size of the pack for trademarks, pictorials, claims, promotions, etc., all most appealing particulars of the product for consumer. Net weight is also very often mentioned there, the name of the product also.
2. Use the back of the pack to provide additional information about the claims they make, how to consume the product, whatever....
3. Because product denomination, net quantity and durability date must be in the same field of vision, this is most often put on the top or side of pack (when there is enough space) or in the back, some of this information may appear twice on large size packagings.

In summary, nutrition and health claims are always on the front size of the pack. Nutrition labelling always appears on the back or somewhere else, because this not the first information read by consumers. Explanations and comments about the claims and/or nutritional benefits of the product may often appear next to the nutrition labelling, but there is no fixed rule.

Industry needs flexibility to adapt because pack shapes and sizes may vary greatly depending on products.

8 CONSUMER UNDERSTANDING IN THE NEW REGULATORY CONTEXT

Nutrition labels can portray a wide range of information, which can, when clearly presented, be useful and easily interpretable. Some surveys suggest a high level of understanding. In Canada, for example, a survey found that 83% of respondents understand some of the information on nutrition labels, with 43% stating that they understood it very well. However, aspects of the label were confusing to consumers, or prone to being misunderstood. There was a lack of understanding about the difference between calories and energy, and about serving size information. Older people and those with lower levels of education or income were least likely to understand the label [25, 26, 27, 29 to 36].

A recent systematic review on consumer understanding of nutrition labelling concluded by the European Heart Network also found that consumers have some problems understanding nutrition labels: *“consumers generally regarded standard nutrition labelling as complex, especially the use of technical terms, and numerical information that required calculations. People also have difficulty in understanding the role that different nutrients mentioned on labels play in their diet”*. [29]

Provided that they are scientifically substantiated and not misleading to the consumer, nutrition and health related claims on food products can help facilitate well-informed food choices. An important aspect of the new proposed legislation is that, in addition to requirements for nutritional scientific substantiation, the proposal also takes the consumer perspective into account. Article 5.2. states that “the use of nutrition and health related claims (NHR) shall only be permitted if the average consumer can be expected to understand the beneficial effects expressed in the claim”.

ILSI-Europe is reflecting on the proposed EU legislation on consumer understanding of claims from a consumer science point of view. It focuses on the type of data and depth of evidence that could be needed to provide the necessary evidence that the average consumer indeed adequately understands a particular nutrition and health related claim and does not attach misleading interpretations to it.

Nutrition and health related (NHR) claims are potentially powerful tools in consumer communication as they convey information on food characteristics (e.g. “contains calcium”) and health-related food benefits (e.g. “contributes to a heart-healthy diet”) that might otherwise remain unknown to the consumer. As such, these NHR claims may provide a reason for consumer preference and facilitate well-informed food choices on the part of the consumer. The use of NHR claims is becoming widespread and if applied correctly, has the potential to enhance consumers’ nutritional knowledge and healthy eating patterns as well as to improve public health more generally. But NHR claims also have the potential to misinform and even mislead consumers toward food choices that may be against their own best interests.

Scientifically, this raises the following important question: What type of data and depth of evidence about consumer understanding are sufficient to provide evidence that the average consumer adequately understands a particular NHR claim and does not attach unwarranted interpretations to it? For example, the claim that “candy X is enriched with extra vitamins” seems readily understandable, but could be misinterpreted by consumers as meaning that nutritionally this is a desirable food. In contrast, the claim that “product X contains antioxidants which help to neutralise free radicals which cause oxidative damage to cells”, while scientifically accurate and precise, is unlikely to be understood by reasonably well-

informed and circumspect consumers. These two examples illustrate the range of problems faced when trying to show that the target consumer population will adequately understand a particular health claim.

This work focuses on the definition and measurement of consumer understanding of NHR claims and it complements the findings of the PASSCLAIM Concerted Action Project on the process for the assessment of scientific support for claims on foods.

After exploring several different methodologies, the ILSI experts group is likely to propose a case-by-case approach using a stepwise procedure for assessing consumer understanding of a NHR claim.

GLOSSARY

Claim: Any message or representation, including pictorial, graphic or symbolic representation, which states, suggests or implies that a food has particular characteristics.

Codex Alimentarius: Literally: 'Food Code'.

The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. Membership is open to all countries associated with the Food and Agricultural Organization of the United Nations and with the World Health Organization. At present (2005) Codex has 168 members and covers more than 98% of the world's countries. Also non-governmental organisations have input in Codex (www.codexalimentarius.net).

Dietary guidelines: The Dietary Guidelines are designed to help people choose diets that will meet nutrient requirements, promote health, support active lives, and reduce chronic disease risks. Research has shown that certain diets raise risks for chronic diseases. Such diets are high in fat, saturated fat, cholesterol, and salt and they contain more calories than the body uses. They are also low in grain products, vegetables, fruit, and fiber. Dietary guidelines are designed to help people foods, meals, and diets that can reduce chronic disease risks.

Disease risk reduction claim: A claim that states or implies that consumption of a product reduces the risk of occurrence of a certain disease. See also 'enhanced function claim', 'health claim', 'medical claim' and 'prevention of disease'.

Enhanced function claim: A claim that states or implies that the consumption of a product enhances a bodily function. 'Enhanced' aims to distinguish effects on functions other than the currently well-established effects of nutrients (so-called 'nutrient function claims'). As a result, a newly discovered effect on a function may initially give rise to an 'enhanced function claim', whereas once well established it would render a 'nutrient function claim'. See also 'disease risk reduction claim', 'health claim' and 'medical claim'.

Epidemiology: The study of health and the occurrence of diseases and their predictors and causes.

Food: 'Food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment (General Food Law Regulation EC/178/2002).

Food component: components such as ingredients and food additives intentionally added to foods, and also components inherently present as part of the essential composition of foods.

Generic claim: A claim based on knowledge from evidence generally available in the scientific literature and/or on recommendations from national or international public health bodies.

GI/Glycaemic index: The glycaemic index (GI) is a ranking of carbohydrates on a scale from 0 to 100 according to the extent to which they raise blood sugar levels after eating. Foods with a high GI are those which are rapidly digested and absorbed and result in marked fluctuations in blood sugar levels. Low-GI foods, by virtue of their slow digestion and absorption, produce gradual rises in blood sugar and insulin levels, and have proven benefits for health.

Health: a state of complete physical, mental and social well-being and not merely the absence of diseases or infirmity (WHO definition).

Health claim: Any representation that states, suggests, or implies that a relationship exists between a – constituent of a – food and health . See also ‘disease risk reduction claim’, ‘enhanced function claim’ and ‘medical claim’.

Medical/medicinal claim: A claim (see ‘claim’) that states or implies that a food or a food component has the property of treating, preventing or curing human disease or makes any reference to such property. ‘Human disease’ means any injury, ailment or adverse condition, whether body or mind. Such claims are prohibited on foods; this prohibition creates the legal separation between foods and medicines. See also ‘disease risk reduction claim’, ‘enhanced function claim’, ‘health claim’ and ‘prevention of disease’.

Nutrient function claim: A claim that describes the physiological role of a nutrient in growth, development and normal functions of the body.

Nutrients’ reference values: Quantitative estimates of nutrient intakes to be used for planning and assessing diets for healthy people. A reference value is the estimated amount of a nutrient which will be enough for almost everyone in the population. They are generally designed for various groups of the population (male, female, infants, children, adults, etc...)

Nutrition: The act or process of nourishing; the process by which foods are taken in and utilised by the body for growth, normal function and maintenance of health.

Prevention of disease: Hindrance of the onset of disease. This hindrance may reduce the probability or risk of a disease to zero, but in diet-related diseases it usually reduces the risk to a lesser degree. See also ‘disease risk reduction claim’ and ‘medical claim’.

Product-specific claim: A claim that a relationship exists between a specific food product, or a component of a specific food product, and health.

Risk: Probability or chance of meeting a certain – usually unwanted – event.

Well-being: A positive and sustainable state that allows individuals, groups or nations to thrive and flourish. At the level of an individual, well-being refers to psychological, physical and social states that are distinctively positive.

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ILSI Europe was established in 1986 to identify and evaluate scientific issues related to the above topics through symposia, workshops, expert groups, and resulting publications. The aim is to advance the understanding and resolution of scientific issues in these areas. ILSI Europe is funded primarily by its industry members. <http://europe.ilsii.org/>

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