

This work was completed on behalf of the European Food Information Resource (EuroFIR) Consortium and funded under the EU 6th Framework Food Quality and Safety thematic priority. Contract FOOD – CT – 2005-513944.



Synthesis report No 5: Nutrition and Health Claims: the Facts on your Food

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Acknowledgements

This report was compiled by Bridget Aisbitt, with the assistance of Professor Judy Buttriss, Dr Rachel Thompson (W.P 3.2) and Paul Finglas (project coordinator).

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1. Introduction

European consumers are increasingly exposed to a wide variety of messages about the relationship between diet and health and there is widespread interest in the nutritional content of food. Information about nutrition and health in the press can appear complex or conflicting and it may not be clear to many consumers what the healthiest choice is when deciding which foods to buy. Helping consumers to choose a healthy diet is increasingly important in the European Union (EU) as the prevalence of obesity and other related conditions such as type 2 diabetes, high blood pressure and cardiovascular disease are rising. Accurate and informative food labelling can play an important part in helping consumers to select the most appropriate foods when shopping to provide a healthy balanced diet. However, unclear or misleading information on food products can increase confusion and lead to mistrust of healthy eating messages.



1.1 The role of food composition data

A growing number of foods now carry nutrition and health claims and the European Commission (EC) has recently introduced a new regulation to harmonise the way these are made across the EU. An essential part of being able to make and verify these claims is access to accurate, up to date food composition data. EuroFIR (European Food Information Resource Network) is a world-leading European Network of Excellence on food composition databank systems, which aims to provide an internet portal which will allow

access to the most up to date food composition data from all online food composition databases (FCDBs) available across Europe and internationally. The project is a partnership between 48 universities, research institutes and small-to-medium sized enterprises (SMEs) from 26 European countries.

This Synthesis Report will outline the scope of the new EC regulation and will provide some information about other guidelines on health claims, and approaches used in countries both within the EU and around the world. It will also highlight the importance of good quality food composition data for making health claims on food, and the role that the EuroFIR project, including 26 national food database compilers, will play in supporting this regulation in the future.

2. New EU regulation on nutrition and health claims made on foods (1924/2006/EC)

Basic food labelling guidelines were first introduced in the EU in 1979 (79/112/EC). These were updated a number of times before being consolidated in 2000 (Council Directive 2000/13/EC). This regulation banned medicinal claims on foodstuffs, that is, foods must not carry a claim to treat, cure or prevent disease. However, there was no specific regulation introduced for health



claims apart from statutory legislation covering food safety and labelling, in that any claim made must be truthful, sufficient and not misleading.

The new regulation on nutrition and health claims was agreed in December 2006 and is intended to complement the general principles laid down in the previous directive on labelling, 2000/13/EC, and to work alongside other directives on foods for particular nutritional uses, the quality of drinking and mineral water and on supplements. It applies to all nutrition and health claims made in commercial communications, i.e. labelling, presentation or advertising of foods and supplements, and aims to provide a high level of consumer protection whilst allowing the EU market to function effectively.

The regulation outlined below, which applies from the 1st of July 2007, describes how nutrition and health claims should be used, and the procedure to apply for the authorisation of a claim by the European Commission (referred to below as 'the Commission'). The aim of this regulation is to put together a list of permitted nutrition and health claims that can be used by manufacturers across the EU by January 2010. Ultimately, only health claims that are on this list will be permitted for use in the EU, although there are interim measures in place to give manufacturers time to adapt to the new rules.

Box 1: Definitions

The following definitions are provided in the regulation:

- **Claim** – any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics.
- **Nutrient** – protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in the Annex to Directive 90/496/EEC and substances which belong to or are constituents of one of those categories.
- **Other substance** – a substance other than a nutrient that has a nutritional or physiological effect.
- **Nutrition claim** – any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:
 - the energy (calorific value) it
 - provides
 - provides at a reduced or increased rate, or
 - does not provide and/or
 - the nutrients or other substances it
 - contains
 - contains in reduced or increased proportions, or
 - does not contain.
- **Health claim** – any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.
- **Reduction of disease risk claim** – any health claim that states, suggests or implies 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.

2.1 The scope of the regulation

The regulation covers nutrition and health claims on labels, in advertising and other media. It applies to all foods, drinks and dietary supplements. Some foods are already covered by existing regulations, such as mineral water, foods for particular nutritional uses (e.g. dietetic foods) and genetically modified (GM) foods and this new regulation will work in conjunction with these. A new regulation has also recently come into force on the addition of vitamins and minerals to foods (EC/1925/2006). This will control the voluntary fortification of foods and will work alongside the regulation on nutrition and health claims.

Overall, any claim made should be truthful and should not attempt to mislead consumers. Nor should it call into question the safety or nutritional content of other foods or the adequacy of a balanced diet. The claim itself must apply to the food as eaten, prepared according to the manufacturers instructions, and the effects described in the claim must be understandable to consumers. There must be full nutritional labelling on the product for both nutrition and health claims. If information about the level of the food constituent in question does not normally appear on a food label, the level of that constituent should also be stated alongside the other nutritional information.

Box 2. Claims that will not be permitted

- Medicinal claims, about preventing, treating or curing a disease.
- Claims on alcoholic beverages (more than 1.2% alcohol), other than low/reduced alcohol or energy.
- Claims that suggest health could be affected by not consuming the food.
- Claims that make reference to a rate or amount of weight loss.
- Claims that make reference to recommendations of individual doctors and health professionals.

To make a nutrition or health claim, foods must have a healthy profile of nutrients. A system for assessing the nutrient content of foods is currently being developed and this is discussed in section 2.8 on nutrient profiling.

In order to make a health claim, the food must not exceed any of the limits set by the nutrient profile. In the case of nutrition claims, the product may exceed the limits for one nutrient, but this must be highlighted alongside the nutrition claim. Products exceeding the limits for two or more nutrients will not be permitted to make a nutrition claim. An exception to this rule exists for products making 'reduced' claims i.e. reduced in fat, saturated fatty acids, *trans* fatty acids, sugars, sodium or salt. These nutrition claims can be made, regardless of the nutrient profile of the product.

2.2 Nutrition claims

For a company to make a nutrition claim on their product, the specific claim must be listed in the Annex to the regulation. Examples listed in the Annex include 'low fat', 'no added sugars', 'high fibre' and 'source of calcium. In each case, conditions are specified for each claim, for example, foods claiming to be 'low fat' must have no more than 3g fat per 100g.

In order to make nutrition claims that comply with the conditions in the Annex it is essential to know the amount of the nutrient in question in the food. This highlights the necessity of accurate food composition data and the importance of the EuroFIR project that aims to provide this across the EU.

2.3 Health claims

To make a health claim, the product must display a message on the importance of a varied, balanced diet and healthy lifestyle, and provide information about the amount and frequency of consumption required to get the claimed health benefit. There should be information about any population

groups that should avoid eating the food (for example, pregnant women) and any risks from excess consumption.

A list of permitted health claims will be available from January 2010. The way in which claims get onto this list depends on the type of claim, as shown in figure 1. In the regulation health claims are divided into article 13 claims, functional claims that do not refer to either reduction of disease risk or children's development and health, and article 14 claims which do refer to one of these things. Article 13 claims comprise those that are based on 'generally accepted scientific evidence' and those based on emerging evidence. A list of those based on generally accepted evidence is being compiled by each Member State and will be submitted to the Commission by the end of January 2008. More details are provided below.

2.3.1 Article 13 health claims: claims other than those referring to the reduction of disease risk and to children's development and health

Health claims under this article can describe or refer to:

- The role of a nutrient or other substance in growth, development and the functions of the body
- Behavioural or psychological functions
- Slimming, weight control, an increased sensation of satiety or the reduction in available energy from the diet.

If these claims are supported by generally accepted scientific evidence and are considered to be well understood by the majority of consumers, it will not be necessary to compile a full dossier to gain authorisation. Instead, the food business operator can submit the claim and supporting scientific substantiation in the form of scientific papers, to the competent authority in their country, who will add this to their national Member State's list. This work is already taking place and each Member State will send a list of such claims

to the Commission by 31st January 2008 along with references providing scientific justification. These claims will form part of the EU-wide list of permitted claims which will be published by the Commission by 31st January 2010 (see section 2.5). The Member State lists will include information on the food constituent in question, the relevant health relationship, the suggested conditions of use (e.g. that the product must contain at least 15% of the recommended daily allowance), the nature of evidence (e.g. a report from an expert committee), references and an example of the wording of the claim.

In addition to the individual Member State lists, the CIAA (Confédération des Industries Agro-Alimentaires de l'UE / Confederation of the Food and Drink Industries of the EU) which represents the food industry in Europe, is compiling a similar list for submission to the Commission with claims submitted from food business operators across the EU.

Box 3. Examples of health claims based on generally accepted scientific evidence from the UK list:

'Folate is necessary for the normal structure of the neural tube in developing embryos.'

'Calcium helps maintain strong bones and teeth.'

'Iron helps make red blood cells, which carry oxygen around the body.'

Article 13 claims that are based on emerging scientific evidence must seek authorisation from the Commission and will involve the submission of a substantiation dossier.

2.3.2 Article 14 health claims: reduction of disease risk claims and claims referring to children's development and health

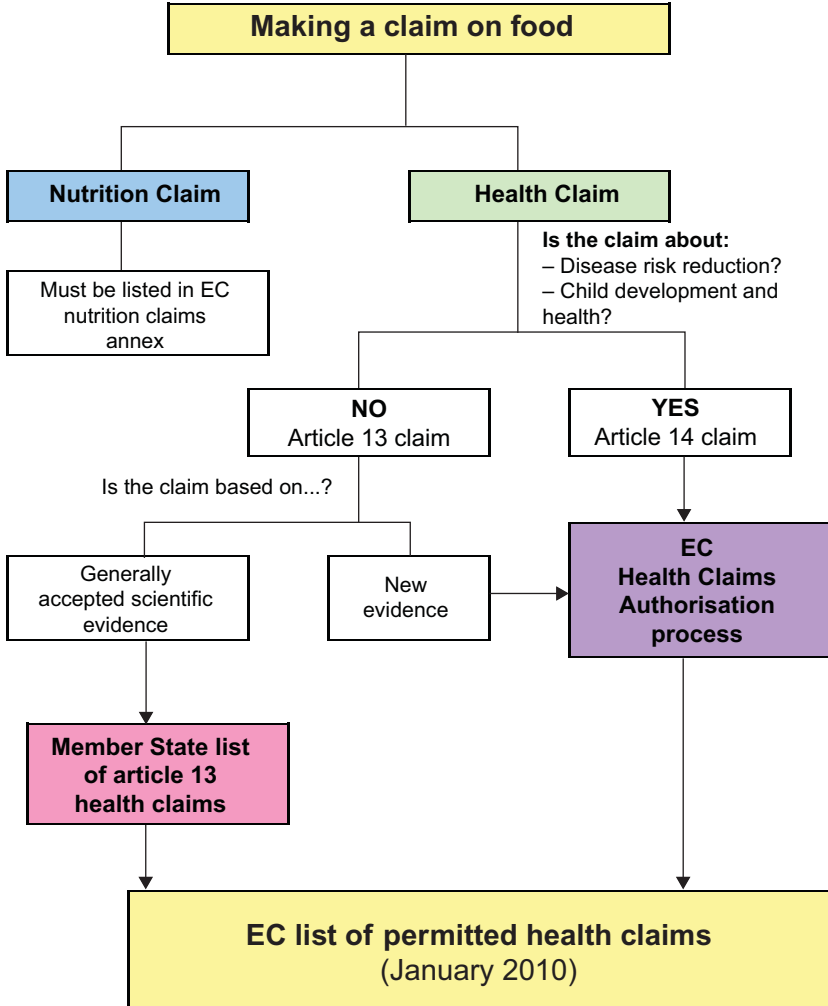
Following the submission of a dossier of evidence supporting the claim, article 14 health claims will go through an authorisation process by the Commission (see section 2.4). In addition to the requirement for full nutritional labelling on foods carrying health claims, reduction of disease risk claims must carry a statement that the disease referred to has multiple risk factors and that altering one of these may or may not have a beneficial effect. Some examples of article 14 claims could include:

- 'Eating 3g of long chain omega 3 fatty acids a week may help to reduce the risk of heart disease'
- 'Calcium is important for developing strong bones in childhood'

If the health claim (either under article 13 or 14) is based on new data provided by the food business operator, it will be authorised on the basis of proprietary data i.e. the claim is owned by the company and cannot be used by other companies unless they can provide their own data to substantiate the claim.

If proprietary scientific data and other information have been used to apply for authorisation of a health claim, these data cannot be used for a health claim application by another applicant until five years after the claim has been authorised. This effectively means that the claim cannot be used by other food business operators for at least five years following its authorisation.

Figure 1. The process of authorising a nutrition or health claim under the new EC regulation



2.4 Authorising a claim

As outlined in figure 1, in order to authorise a health claim under articles 13 or 14 (unless it is based, under article 13, on generally accepted scientific evidence) the food business operator must compile a dossier containing their details, the substance in question, the evidence for its relationship with health and a proposal for the wording of the claim. This is sent to the competent authority in their Member State. The competent authority then passes the information on to EFSA, who notify the Commission and the other Member States.

EFSA will verify whether or not the claim is sufficiently substantiated by the scientific evidence provided, and whether the wording of the claim complies with regulations. Various frameworks for the assessment of scientific evidence for health claims have been devised, for example the International Life Sciences Institute (ILSI) Europe project PASSCLAIM, which is discussed in section 3.2, the approach used for a number of years by the Joint Health Claims Initiative (JHCI) in the UK (section 4.4) and the 'significant scientific agreement standard' in the US (section 5.1). These and other approaches have provided a useful starting point for EFSA in deliberations about the detail of the approach to be adopted for the regulation of health claims. A draft document from EFSA providing guidance on the preparation and presentation of applications for the authorisation of article 14 health claims is currently out for consultation and should be published later in 2007. Guidance for applications under article 13 will be produced in due course.

EFSA's recommendations on each dossier of evidence are passed on to the Commission, who then take a decision as to whether the claim should be included on the community register of permitted health claims.

2.5 The community register of nutrition and health claims

Once this community register is established (January 2010) it will be made public and will include:

- Nutrition claims and the conditions applying to them (see Annex to Regulation 1924/2006/EC)
- Authorised health claims and the conditions applying to them
- Rejected health claims and the reasons for their rejection.

Health claims based on proprietary data will be listed separately as the use of these is restricted.

The claims on the list will then be available for manufacturers to use across the EU, apart from those claims based on proprietary data. Once these health claims begin to be used, Member States may decide to monitor their use by asking companies using health claims to submit a model of their product label.

In the context of rising levels of obesity and other non-communicable diseases in Europe, it is important to determine whether the harmonised use of health claims actually changes behaviour and encourages consumers to choose a healthier diet. With this in mind, three years after the list of permitted claims has been published, in 2013, the Commission will submit a report on the application of the regulations on nutrition and health claims to the European Parliament and the Council. This will cover the evolution of the market for foods bearing nutrition and health claims, consumer understanding of these claims and the impact they are having on dietary choice.

2.6 Transitional measures

Although this regulation applies from July 2007, it will obviously take some time for claims to be assessed and published. With this in mind, transitional measures have been adopted as part of the regulation to help manufacturers phase in changes to the packaging and advertising of their products. Foods that were on the market before this legislation and do not comply may be marketed until their expiry date, but not later than 31st July 2009. Products that do not comply with the nutrient profiling model due to be adopted in the EU in January 2009, may be marketed for up to 24 months following the adoption of this model. If a food bears a name or trademark that doesn't meet the standards of the regulation, this may continue to be used until 19th January 2022, after which it must be changed.

Some Member States may have previously allowed nutrition claims that are not included in the Annex to the EC regulations. If they were in use before 1st January 2006, they may continue to be used until 19th January 2010. If these appear as a picture, graph or symbol, the Member States involved should submit these to the Commission by 31st January 2008, along with the relevant scientific substantiation. The Commission will then take a decision as to whether they should be included in the Annex. If the pictorial, graphical or symbolic nutrition claim is not authorised by the Commission, it may continue to be used for a further 12 months, after which it must be discontinued.

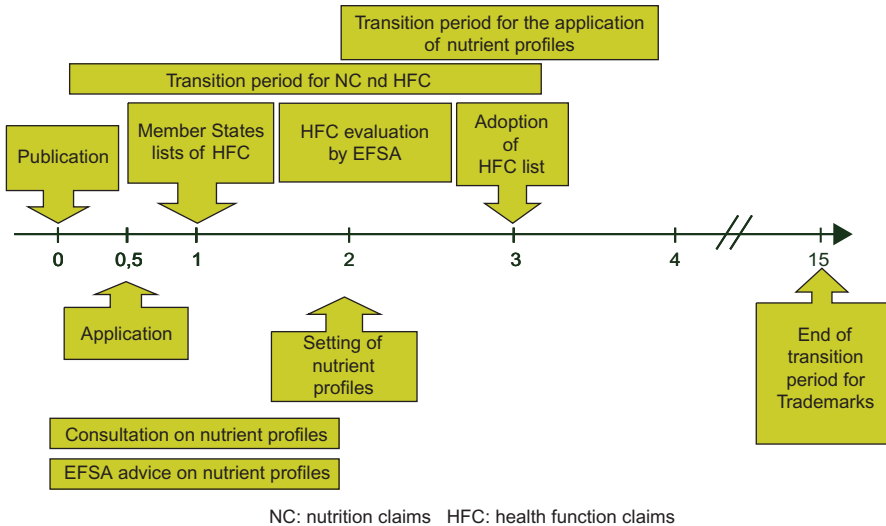
Health claims that refer to the role of a nutrient or other substance in growth, development or the functions of the body may be made from July 2007, when these regulations come into force, until the list of permitted claims is established in 2010. If the health claim fails to be incorporated into the list its further use will become illegal. In the interim, it is the responsibility of the manufacturer to make sure these claims comply with this regulation and with other relevant national provisions.

Health claims under articles 13 and 14, other than the type referred to above, can be used under existing national guidelines provided that each Member State sends these claims to the Commission, accompanied by supporting scientific data, by 31st January 2008.

Health claims that have been used without support from a Member State can be used until January 2008, the deadline for the user to apply for authorisation. Whether their use can be continued will be determined by the Commission.

An outline of the time frame for the legislation and the transitional periods built into this is shown in figure 2

Figure 2. Time frame for implementation of the new nutrition and health claims legislation



Source: presentation by Dr Robert Vanhoorde at an EFSA health claims conference, Bologna, November 2006. Reproduced with permission.

2.7 Effect of new legislation

This new regulation builds on previous guidelines that existed within EU Member States and those published by organisations such as ILSI, the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) (discussed in section 3). However, the move from guidelines to regulation should ensure the harmonisation of the way health claims are made across the EU. This will make diet and health messages on food clearer to consumers and provide food manufacturers with a greater incentive to innovate to produce healthy products. Furthermore, those who provide their own data for an emerging health claim will have their data and claim protected as part of the regulation.

It will take some time to compile the accepted list of claims, which will not be available until 2010. In the mean time, the competent authorities in respective Member States should be able to assist those wishing to make claims on products. It will also take a period of some months for a new claim to be authorised, but time limits have been placed on each stage of authorisation, which should prevent this from becoming an excessively long process.

In the context of this regulation it will become increasingly important for food business operators to have an accurate knowledge of the composition of their products. For both nutrition and health claims the constituent of interest must have been characterised and its level in the product established. As laboratory analysis of food composition is unfeasible for many companies, food composition databases are relied upon for this data. The work of the EuroFIR project to improve the quality and accessibility of food composition data in the EU is thus essential for this regulation to be implemented successfully.

2.8 Nutrient profiling for the new regulation on nutrition and health claims

A system of nutrient profiling will be used in conjunction with this regulation to ensure that claims do not mask the overall nutrient content of a product. It is hoped that this will encourage manufacturers to improve the nutritional characteristics of their products, making it easier for consumers to choose a healthy balanced diet. This profiling approach must balance the complex relationships between diet and health whilst being user friendly for stakeholders, such as food business operators and regulators.

EFSA has been asked by the Commission to provide scientific advice on how this approach should be constructed. In doing so, they will consider both the relationships between diet, nutrition and health and the commercial, cultural and culinary aspects of food.

There are five particular areas of nutrient profiling on which the Commission has sought advice. The first of these is whether the profile should be set for all foods across the board or whether it should be applied differently to different categories of food. The huge variety of foods eaten across the EU makes it difficult to identify a single model that can be applied to all. However, creating too many different profiles would make the process excessively complex. Initially there may be a single model for which there are a number of exemptions or adjustments for particular categories of food.

The second area raised for consideration is the selection of nutrients to be taken into account. Again, the challenge is to set levels for enough nutrients to take account of their health effects, without using so many that the approach becomes too complex. Total fat, saturated and trans fatty acids, sugars and salt/sodium are highlighted as being of concern in the regulation, but unsaturated fatty acids, fibre, vitamins and minerals may also be taken into account.

The quantity of a product on which the profile should be based on is also under consideration. Obviously, portion sizes vary greatly, from a spread where a portion would be only a few grams, to a ready meal that could be 500g, and it is difficult to apply one profile across these food categories. EFSA have been asked to advise the Commission on this issue. They have also been asked to look at how the profile of nutrients should be quantified. Threshold values could be used for the nutrients in question. Another way of doing this is to have a scoring system, where levels of different nutrients may have a positive or negative value, depending on their health effects, which gives an overall score for the food. In their request to EFSA for advice, the Commission referenced the WHO technical report 'Diet, nutrition and chronic diseases' (WHO 2003). This report made some recommendations that the Commission suggest could be used as a basis for setting levels in the nutrient profiling model:

- Saturated fatty acids make up no more than 10% of dietary energy
- 'Added sugars'* also make up no more than 10% of dietary energy
- No more than 2g of sodium, (5g of salt) per day

*Added sugars refers to all mono and disaccharides added to foods by the manufacturer, cook or consumer plus sugars naturally present in honey, syrups and fruit juices.

The Commission will also consult with stakeholders before adopting a particular nutrient profiling system.

Obviously, in order to determine whether a food fits with the specified nutrient profile, the composition of nutrients in the food must be known. The EuroFIR project will be instrumental in improving the data available on food composition. Table 1 shows the nutrients that have been made a priority to be available via the EuroFIR internet portal.

Table 1: EuroFIR priority nutrients (2006)

Macronutrients	
Energy (kJ)	Water
Total fat	Total protein
Available carbohydrate	Alcohol
Total sugar	Total starch
Total dietary fibre	Cholesterol
Fatty acids	
Total saturated fatty acids	Total monounsaturated fatty acids
Total polyunsaturated fatty acids	Total trans fatty acids
Total <i>n</i> -3 fatty acids	Total <i>n</i> -6 fatty acids
Linolenic acid	Linoleic acid
Fat soluble vitamins	
Vitamin A	
Retinol	Carotene
Vitamin D	Vitamin E
Water soluble vitamins	
Vitamin C	Total folate
Riboflavin	Thiamin
Preformed niacin	Niacin equivalents
Vitamin B6	Vitamin B12
Minerals	
Sodium	Potassium
Calcium	Magnesium
Iron	Zinc
Copper	Phosphorus
Selenium	Iodine

2.9 Nutrient profiling systems already in use in the EU

A number of nutrient profiling systems have been developed to meet a variety of purposes and are already in use across the EU. In the Netherlands five categories are considered separately; starchy carbohydrates (bread, pasta, rice etc); fruit and vegetables; meat, dairy products and substitutes; fats and oils; and drinks. Foods are given a classification of:

- A. Preferable
- B. Middle course
- C. Exceptional

This is done using the Dutch nutrient recommendations and dietary goals relevant to that category. For example, fibre is particularly relevant for starchy carbohydrates and saturated fatty acids are an important consideration for meat, dairy products and substitutes. This system is used for education, health advice and product development. These categories are not currently shown on food labels.

The UK has a nutrient profiling system in use for deciding which foods can be advertised to children on television. This uses a scoring system where points gained from 'positive nutrients' like protein and fibre are subtracted from points from 'negative nutrients' like saturated fatty acids and salt. Only foods with a score below a certain threshold can be advertised during television programmes that are watched by children.

In Sweden the keyhole labelling scheme is used for the nutrient profiling of products. The keyhole symbol is shown on foods that comply with the criteria. There are a number of nutritional criteria that allow foods to bear the keyhole symbol, these are:

- Low in fat
- Low in saturated and trans fatty acids
- Low in salt (sodium)
- Low in sugars
- High in dietary fibre

In addition there are a number of product categories that have their own specific criteria allowing them to bear the keyhole symbol.

3. Previous guidelines on health claims used in the EU

In advising the Commission on the way forward with regards to producing rules for making nutrition and health claims, nutrient profiling and the substantiation of evidence for claims, EFSA has not started from scratch. Much work has already been done in this area, which has influenced the form of the new regulation, some of which is discussed below.

Before the new EC regulation on nutrition and health claims that came into force in 2007 there was no specific legislation on this in the EU, and a number of countries and organisations created rules or guidelines for claims on food.

It is important to note that in the EU, any other guidelines on nutrition and health claims will be superseded once the new EC Regulation applies on the 1st July 2007.

3.1. FAO/WHO: *Codex Alimentarius*

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 to protect the health of consumers, ensure fair trade practices in the food trade, and promote coordination of all food standards work undertaken by international governmental and non-governmental organisations.

Guidelines for nutrition claims initially adopted by the Codex Alimentarius Commission in 1997 were amended in 2001, and provisions for health claims were inserted in 2004. These guidelines were intended to cover the use of nutrition and health claims in food labelling and in advertising where

appropriate. Overall, the Codex Alimentarius guidelines provided useful advice on good practice, but relied on legislation and action by the national competent authorities in each country to ensure that they were followed. The new EU regulation on nutrition and health claims, means that these guidelines no longer apply to the EU and, as the new regulation is legally binding, enforcement should not be a problem.

The Codex guidelines stated that nutrition and health claims should be consistent with national health and nutrition policies and should support them where possible. Also, that health claims should be supported by a sound and sufficient body of scientific evidence and should provide truthful, clear information to help consumers to choose a healthy diet. They recommended that nutrition and health claims should not be permitted for foods for infants and young children, except where specifically provided for by Codex standards or national legislation. In addition, it was recommended that the impact of health claims on consumers' eating behaviours and dietary patterns should be monitored by the competent authorities of each country.

Codex provided the following guidelines on the use of health claims: there must be a regulatory framework provided by the competent authority in each country that prevents health claims being made on foods that could potentially increase the risk of disease or an adverse health related condition. This should also ensure that health claims on products do not encourage excessive consumption or disparage good dietary practices. The claimed benefit must result from consumption of a reasonable amount of the food or food constituent in the context of a healthy, balanced diet. Any health claim made must be acceptable to the competent authorities of the country where it is sold.

Health claims must be supported by a substantial body of scientific evidence, sufficient to prove the claimed effect and the relationship to health in the relevant population. The claim should be made in two parts:

- 1. Information on the physiological role of the nutrient or an accepted diet-health relationship, then;*
- 2. Information on the composition of the product relevant to the effect described in 1.*

For example:

- 1. Dietary fibre helps to maintain normal bowel function;*
- 2. Product X contains dietary fibre.*

If the claim referred to a constituent of the food for which a nutrient reference value (NRV) has been established, the food should be a source of or high in that nutrient if increased consumption is recommended, or low in, reduced in or free from the constituent if reduced consumption is recommended. For any constituent that is the basis of a health claim there must be a validated method for its quantification. Only nutrients that have an established NRV in the Codex guidelines on nutrient labelling, or that are mentioned in officially recognised dietary guidelines in that country should be used in a nutrient function claim.

If a health claim is made on a product, the following information should appear on the label:

- The quantity of the nutrient or other constituent of the food that is the subject of the claim;
- The target group, if appropriate;
- How to use the food to gain the claimed benefit, with details of other lifestyle factors or dietary sources where appropriate;

- Where necessary, advice to vulnerable groups (e.g. pregnant women) on how to use the food and if certain groups should avoid it;
- The maximum safe intake of the food or constituent if appropriate;
- How the food or food constituent fits into the context of the whole diet;
- A statement on the importance of maintaining a healthy diet.

Guidelines about dietary advice and healthy eating should be consistent with the pattern of eating recommended by the appropriate national authority. The nutrient profile of the food as it is eaten should fit into these guidelines, not just selective consideration of certain aspects of the food. It should not be implied that the food itself, rather than a healthy, balanced diet imparts health and the label should carry a statement relating the food to national healthy eating guidelines.

The Codex guidelines on nutrition and health claims have been an important starting point for the development of the EU regulation. However, it is useful that the EU regulation provides a legal framework for nutrition and health claims that will be controlled, rather than relying on guidelines that may or may not be used.

3.2 PASSCLAIM – a framework for assessing the evidence for health claims

Although it is clear that health claims on foods need to be supported by scientific evidence, before this project was established there was no agreed way that this was assessed at a European level. The lack of consensus on how to assess evidence for health claims meant that different Member States were applying various approaches. There was concern that the resulting fragmentation of how claims were regulated could lead to different and even conflicting messages about diet and health, confusing consumers and causing uncertainty for the food industry.

The project 'Process for the Assessment of Scientific Support for Claims on Foods' or PASSCLAIM was set up in 2000 by ILSI Europe and funded by the EU, in order to produce consensus on the criteria for the scientific substantiation of health claims on foods in the EU. The project was completed and the document on these criteria was published in 2005 (Aggett et al. 2005). This has been used by EFSA in putting together guidance for those compiling evidence to support an application for an article 14 health claim. This EFSA document was circulated for comment in summer 2007 and should be published later in 2007.

More than 160 experts from academia, industry, public interest groups and the regulatory environment were involved in PASSCLAIM, and the criteria were established through discussions in a number of expert groups and workshops. The evidence for claims within seven scientific areas was reviewed. These were:

- Diet related cardiovascular disease
- Bone health and osteoporosis
- Physical performance and fitness
- Body weight regulation, insulin sensitivity and diabetes
- Diet related cancer
- Mental state and performance
- Gut health and immunity.

The consensus on criteria was published in 2005 (Aggett et al. 2005). Six criteria that should be fulfilled for the substantiation of a health claim were listed:

1. The food or food constituent to which the claimed effect is attributed should be characterised;

2. Substantiation of the claim should be based on human data, primarily from intervention studies;
3. When the true endpoint of a claimed benefit cannot be measured directly, studies should use markers
4. Markers should be
 - Biologically valid in that they have a known relationship to the final outcome and their variability within the target population is known
 - Methodologically valid with respect to their analytical characteristics
5. Within a study the target variable should change in a statistically significant way and the change should be biologically significant within the target group for the claim to be supported
6. A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing of the evidence.

The authors highlighted that it is important to see these as guidelines that must be applied on a case by case basis and that expert advice would often be required to do this.

3.3 National health claims guidelines

3.3.1 Sweden

In Sweden, existing regulation meant that food products were not allowed to display medicinal claims, however, in the absence of more specific legislation on health claims in the EU, the Swedish Nutrition Foundation (SNF) devised a voluntary code outlining how manufacturers should make health claims. This was first introduced in 1990, revised in 1997 and again 2004, and applied to foods rather than supplements.

According to the code, only products that 'with normal use, contribute to a nutritionally balanced diet' should bear health claims, and this was determined using the 'keyhole' criteria, established by the National Food Administration (NFA) which specifies levels of fat, sugar, salt and dietary fibre in food products.

There are two main types of health claim referred to in the code:

- Generic claims, including:
 - Nutrient function claims
 - Reduction of disease risk claims
- Product-specific physiological claims (abbreviated to PFP in Swedish)

Nutrient function claims were based on generally accepted physiological functions of nutrients and could be made in accordance with the Nordic Nutrition Recommendations. Companies were not expected to provide evidence from human intervention studies for nutrient function claims. For claims involving vitamins and minerals, the product had to contain a 'significant amount', that is, a minimum of 15% of the recommended daily intake (RDI) per 100g, or per serving where products were packaged as a single serving. In addition, it had to be possible to gain at least 15% of the RDI from normal daily consumption of the product. The product in question also had to meet the criteria for the Swedish keyhole symbol (see section 2.9) and contribute to a healthy balanced diet, consistent with national recommendations.

One exception to this rule was for iron contained in meat, fish, shellfish and poultry products. Iron from these sources is in the form of haem-iron which is well absorbed from the gut, and nutrient function claims about iron in this case could be made if the product provided 10% of the RDI per 100g or per serving. Products that made nutrient function claims about dietary fibre had to contain 2.5g per 1000kJ and normal daily consumption of the product had

to provide at least 3.75g of dietary fibre. All nutrient function claims made had to be relevant to Swedish consumers, for example a claim about the importance of vitamin A in night vision was deemed to be true, but not relevant to the Swedish population.

Some examples of nutrient functions that were approved for use in Sweden:

- Iron is essential for (a) making blood cells and (b) production of haemoglobin. Product X contains iron.
- Vitamin D helps build bones. Product Y contains vitamin D.

Reduction of disease risk claims were based on official Swedish Nutrition Recommendations and again, human intervention studies were not required in order to make the claims. Nine relationships were approved as the basis for health claims in Sweden:

1. **Overweight/obesity** – energy
2. **Cardiovascular disease** – blood cholesterol levels and:
 - a. saturated and *trans* fatty acids
 - b. certain types of dietary fibre
3. **Cardiovascular disease** – blood pressure – salt
4. **Cardiovascular disease** – omega 3 fatty acids from fish
5. **Constipation** – dietary fibre
6. **Osteoporosis** – calcium and/or vitamin D
7. **Dental caries** – sugar/fermentable carbohydrates



8. **Iron deficiency** – iron

9. **Coronary heart disease** – whole grain

As in the Codex guidelines, to prevent consumers interpreting a disease risk reduction health claim as being specific to a particular product, the claim had to be made in two parts; first the link between the nutrient and the disease, then the fact that the product contains the nutrient in question. For example: 'a nutritionally balanced diet high in calcium reduces the risk of osteoporosis. [Product name] is high in calcium. If the product has been processed, documentation could be required to show that the effect in question is retained in the final product. For example, a claim could be made about the cholesterol lowering effects of fibre in oats without documentation, but if the oats were processed and incorporated into a final product, evidence that the cholesterol lowering effect still exists had to be provided.

Product-specific physiological claims in Sweden had to be substantiated by human intervention studies that showed the claimed effect. The evidence was evaluated by a panel of experts, and if approved the claim could be used and the products could display text stating that the health benefits of the product had been evaluated in accordance with the food sectors code of practice. Some examples of products that had already gained product-specific physiological health claims in Sweden are Becel proactive spreads and drinks ('lowers total and LDL cholesterol') and ProViva fruit drinks ('reduces flatulence').

Products wishing to make a low glycaemic index (GI) claim had a simplified evaluation procedure, provided that they had at least 15g of carbohydrates per portion and two independent GI determinations, both showing a GI lower than 55. These did not bear a claim linking low GI to health but said 'gives a low and slow increase of blood sugar' and 'has a scientifically documented low glycaemic index (GI)'. Products bearing this claim included breads, ready meals, mueslis and snacks.

3.3.2 The Netherlands

The Netherlands had a voluntary code of practice for the assessment of health claims that was initiated in 1998 by the Netherlands Nutrition Commission (NNC). This aimed to provide manufacturers with an efficient means to assess the scientific evidence for a health claim and to boost consumer confidence in the information provided by health claims on food.

The code dealt with evidence regarding specific products on a case by case basis rather than providing generically approved claims. The data provided had to apply to a product or product group and had to be based on human data. The evidence had to be reproducible, concern normal product use and be relevant to the target population. Knowledge of the mechanism could be provided but was not essential. In addition, use of the product should not clash with dietary guidelines.

The evidence regarding the health benefits of a given product was considered by a panel of at least three independent experts appointed by the NNC, who made a decision within three months.

Some examples of products with approved health claims included:

- Phytosterol-enriched margarine and cholesterol lowering.
- Bread with added long chain omega 3 fatty acids and lower risk of fatal coronary heart disease.
- Yoghurt with probiotic and bowel function.



3.3.3 Finland

The previous legislation in Finland that applied to health claims was based on the corresponding EU directive (2000/13/EC) and generally stated that information about food on packaging, in advertising or other marketing must

be truthful, sufficient and not misleading. Also, claims must not imply that the food can prevent, treat or cure disease.

More specifically there was a guide for the control of health claims that were permitted:

- Information on nutrition and a healthy diet;
- Nutritional claims;
- Claims referring to physiological functions;
- Claims referring to a reduced risk of disease.

If claims were based on commonly known, well established effects then no additional substantiation was required, except to prove that the compound in question is absorbed from the gut. Scientific evidence was required for new claims and the claim was rejected if this was not deemed to be sufficient by the Finnish Food Safety Authority (Evira). Some examples of claims that were rejected include one on a colostrum powder stating that that it 'improves physical function and recovery' where the levels tested in the submitted

studies were higher than would be consumed from the product. A claim that a fortified fruit juice could lower blood homocysteine levels was rejected as the relevance of homocysteine to health was not thought to be clear enough, and one on the beneficial effects of haem iron added to an oatmeal cereal was disallowed as no data were provided on its bioavailability.



However, there was no system to prevent unsubstantiated health claims being devised, as substantiation by Evira had to be requested by the company, and once these appeared on packaging or other media, municipal authorities rarely took action to ban them.

In preparation for the new EU legislation on health claims, Evira did a survey on the use of health claims in Finland in 2006. A total of 625 responses were received, referring to 269 substances, foods or combinations of substances. The majority of claims were related to cardiovascular health, carbohydrate metabolism and weight control, and gut health and immunity. The scientific evidence for these claims varied from, for example, clinical trials conducted on the product (22%) and research evidence carried out on the constituent of interest (65%) to a few that reported no knowledge of research to support the claim (0.6%). About 250 types of food constituent or mixture were used as the basis of claims, including nutrients, antioxidants, flavonoids and probiotics. These claims have not yet been evaluated.

3.3.4 The UK

The Joint Health Claims Initiative (JHCI) was a voluntary body that was set up in the United Kingdom (UK) in 1997 in order to set common standards within the UK for all claims on food relating to the health of the consumer, in the absence of Community legislation at that time. It comprised of a collaboration between representatives of the consumer movement, the food industry and the food law enforcement officers. Each of the three groups mentioned had equal representation on the controlling body. It was financed by contributions from member organisations from the food industry and decisions on the scientific substantiation of claims were made by an expert committee comprising academics from a variety of public health backgrounds. The JHCI is now no longer active, since the publication of the new regulation.

A code of practice and a list of approved health claims were developed by JHCI. The general principle of the code was that the overriding aim of a health claim should be to help consumers make informed choices and that consumer perception of a health claim is paramount. As well as being accurate, the health claim should be presented in language that is understandable by the majority of consumers. The code also made it clear

that in addition to the wording of the claim, the overall effect of a consumer taking a quick glance at this, or looking at imagery on the product must be taken into account.

The claim itself must be truthful and must not mislead, exaggerate or deceive, either directly or by implication. Medicinal claims were not allowed as part of the JHCI code and they recommended that direct references to diseases were not used so that the impression of a medicinal effect is avoided. However, references to risk factors for diseases and to the maintenance of good health or a specific organ or system were acceptable, provided they made it clear that this is in the context of a healthy, balanced diet.

Similarly to many of the regulations and recommendations described in this report, according to the JHCI code, a health claim must not condone or encourage excessive consumption of any food, criticise good dietary habits or imply that a balanced diet cannot supply everything the body needs. The claimed benefit must be fulfilled by the food in the form and quantity consumed.

4. Nutrition and health claims outside the EU

Many other countries outside the EU have developed guidelines or regulation to control nutrition and health claims. Those in the US, Australia, New Zealand and Japan are discussed below.

4.1. USA

In the United States, health claims are covered by the Nutrition Labelling and Education Act (NLEA) which was passed in 1990. The NLEA provides for health claims that characterise the relationship between a food, food constituent or dietary supplement and the risk of a disease, e.g. 'diets high in calcium may reduce the risk of osteoporosis'. In order for a health claim to be authorised under this act, a 'health claims petition' is usually submitted by a company and the Food and Drug Administration (FDA) reviews the evidence for the claim. A set of criteria for assessing the strength of the evidence for a diet-disease relationship has been developed, known as the 'significant scientific agreement standard' and the data supporting the claim must meet this standard in order to gain authorisation under the NLEA.

The Food and Drug Administration Modernisation Act (FDAMA) of 1997 provides another way to have a health claim authorised. This allows a health claim to be made on the basis of an 'authoritative statement' from a scientific body of the US government or the National Academy of Sciences. This route cannot be used for dietary supplements.

In 2003, the FDA's 'Consumer health information for better nutrition' initiative allowed the use of 'qualified health claims' where there is emerging evidence of a relationship between a food, food constituent or dietary supplement and reduced risk of disease or health condition. In this case the evidence is not sufficient to meet the 'significant scientific agreement standard' described above and claims are authorised at the FDA's discretion using qualifying

statements to highlight the uncertain nature of the claim. Some examples of qualified health claims accepted in the USA include:

- Selenium and cancer: *Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive.*
- Walnuts and heart disease: *Supportive, but not conclusive research, shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet, and not resulting in increased caloric intake, may reduce the risk of coronary heart disease.*



This legislation is different to that in the EU and Codex guidelines as it allows a more direct connection to be made between diet and disease. It also allows claims on the basis of less firm evidence, although this must be made clear as a qualifying statement. This is a more flexible approach which perhaps allows more innovation within the food industry but also has the potential to confuse consumers who may find it difficult to weigh up the emphasis of the different statements on products. It will be interesting to monitor the EU and US approaches in the coming years and to see how they influence consumer behaviour and product development.

4.2. Australia/New Zealand

Food Standards Australia New Zealand (FSANZ) is currently consulting on new regulations for nutrition and health claims. The current regulation on nutrition and health claims in Australia and New Zealand is relatively restrictive. Nutrition content and function claims are allowed, but references to health, disease and slimming, or weight reduction, are not.

New FSANZ regulations on nutrition and health claims would allow a wider variety of claims to be made, including reduction of disease risk claims. This would provide more information for consumers and give a greater incentive to food manufacturers to formulate healthier products. Medicinal claims will still be prohibited, as will claims on alcoholic beverages, kava or infant formula.

Claims are divided into 'general' and 'high level' according to the extent of the benefit to consumers they identify. General level claims include:

- Nutrient content claims that describe or indicate the presence or absence of a constituent in food. For example *'This food is high in calcium'*.
- Nutrient function claims describing a constituent and its function in the body. For example *'Calcium is good for strong bones and teeth'*.
- Claims that refer to the maintenance of good health. For example *'helps keep you regular as part of a high fibre diet'*.
- Claims that refer to specific benefits for performance and well being in relation to foods. For example *'gives you energy'*.
- Claims describing how a diet, food or constituent can modify a function beyond its role in normal growth and development. For example *'exercise and a diet high in calcium help build stronger bones'*.
- Those that refer to the potential for a food or constituent to assist in reducing the risk of or helping to control a non-serious disease or condition. For example *'Yoghurt high in X and Y as part of a healthy diet may reduce your risk of stomach upsets'*.

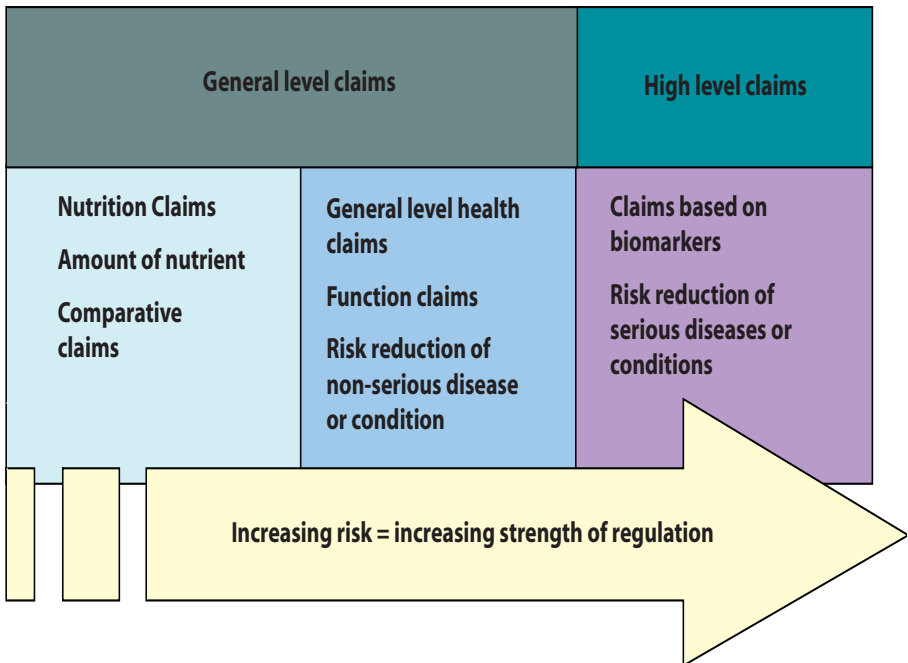
High level claims are those that:

- Refer to the potential for a food or constituent to assist in controlling a serious disease or condition by either reducing risk factors or improving health. For example: *'This food is high in calcium. Diets high in calcium may increase bone mineral density.'*

- Refer to the potential for a food or constituent to assist in reducing the risk of a serious disease or condition. For example: *'This food is low in sodium. Diets low in sodium may reduce the risk of elevated blood pressure.'*

As the possible level of risk increases, so does the level of regulation required for the claim as shown in figure 3 below:

Figure 3. The FSANZ framework for the regulation of nutrition and health claims (currently out for consultation)



Adapted from a presentation by Dr. Bob Boyd of FSANZ at an EFSA conference on nutrition and health claims, Bologna, November 2006.

As the level of the claim increases, so does the quality of the evidence required to substantiate the claim. A framework for the substantiation of claims has been developed in Australia and New Zealand, which is similar to the 'significant scientific agreement standard' in the US as described in section 4.1.

For general level claims there must be current generally accepted scientific evidence to support the relationship. There must also be evidence that the food constituent in question is contained in the product in a sufficient quantity to produce the claimed effect.

High level claims must be substantiated by well-designed experimental and observational studies, preferably in humans. Caution will be exercised when the available evidence is drawn solely from observational studies, even those with established biological plausibility, and in the absence of experimental human data. Evaluation of claims will be based on an assessment of the totality of the available evidence, with consistent and convincing findings likely to be required across study types. These studies must also be relevant to Australian and New Zealand populations.

A nutrient profiling model has been developed by FSANZ and products must comply with this to make a claim. This is based on the UK model that was developed to distinguish which foods are allowed to be advertised to children on television, with some modifications. The model works by having positive scores for nutrients with adverse effects when consumed in excess i.e. saturated fatty acids, salt and sugar, which can be offset by the product containing protein, fibre and fruit and vegetables. Foods that score too highly are not allowed to bear a claim, but exceptions are made for cheeses containing more than 320mg of calcium and for edible oils and spreads, for which a higher points threshold has been introduced. In addition, milk is classified as a food rather than a beverage, due to its important contribution of nutrients to the diet as a whole.

The new FSANZ regulation on nutrition and health claims is currently out for consultation and should be published later in 2007.

4.3 Japan

The Ministry of Health, Labour and Welfare (MHLW) in Japan, is responsible for controlling health claims on foods. These are divided into two groups; foods with nutrient function claims (FNFC) and foods for specified health uses (FOSHU).

FNFC allows food products to highlight the content of a number of vitamins and minerals and their health benefits, provided the amount is within a specified range and that they display a warning if applicable. Some examples are shown below:

Table 2. Examples of nutrient function claims approved in Japan

Nutritional Ingredient	Specified Range	Function Claims	Warning Indication
Vitamin A	135 ~ 600 µg	Vitamin A helps to maintain vision in the dark and helps to maintain healthy skin and mucosa.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the recommended daily intake. Women within the first three months of pregnancy or women considering becoming pregnant should be careful of over consumption.
Vitamin E	2.4 ~ 150 mg	Helps to protect fat in the body from being oxidized and to maintain cell health.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the recommended daily intake.

Table 2. Examples of nutrient function claims approved in Japan – *continued*

Nutritional Ingredient	Specified Range	Function Claims	Warning Indication
Zinc	2.1 ~ 25 mg	Necessary to maintain normal taste and helps to maintain healthy skin and mucous membranes. It is involved in the metabolism of protein and nucleic acids and is helpful in maintaining health.	Increased intake of this product will not result in curing diseases nor promoting health. Too much zinc can inhibit absorption of copper. Please comply with the recommended daily intake. Infants and young children should avoid use of this product.

The concept of FOSHU began in the 1970s when the Japanese government saw the benefit of controlling non communicable diseases through the addition of functional ingredients to foods, rather than using pharmaceuticals. FOSHU claims are those that refer to a health benefit of a constituent that is added to food and are intended for use by consumers who wish to promote health or control conditions such as hypertension or high cholesterol levels. FOSHU foods carry the symbol of FOSHU approval and must be approved by the MHLW.

In order to obtain FOSHU approval for a substance, its effect on health must be proven by high quality scientific studies, and there must be no safety issues, for example, instances of toxicity with excess consumption. There should not be excessive levels of salt, fat or sugar in the product, and there must be a sufficient level of the food constituent in question to produce the claimed effect, as verified by established quality control methods. The applicant for FOSHU approval first submits their dossier to the MLHW, who then consult the Council on Pharmaceutical Affairs and Food Sanitation on its efficacy and the Food Safety Commission on its safety.

Some examples of substances that are FOSHU approved include soybean isoflavones for osteogenesis (formation of bones), guava tea polyphenols for control of blood sugar levels and oligosaccharides to promote gut health. As in the US, qualified health claims can be made on the basis of emerging evidence, provided this is highlighted as part of the claim.

Standardised FOSHU ingredients are those that have accumulated enough evidence and been used for a sufficient time to warrant a more simple approval procedure for products that contain them. Substances in this category will have been used in more than 100 products and will have had FOSHU approval for at least six years. Reduction of disease risk claims for calcium and osteoporosis and for folic acid and neural tube defects have also been approved by the MHLW.

FOSHU claims have a different emphasis to those found in Europe, the US, Australia and New Zealand, in that they are focused on the properties of isolated functional ingredients, rather than whole foods or their constituents. The Japanese also appear to have gone further than many other countries in allowing claims for plant bioactives and other substances that would not normally be found in the diet such as chitosan, a substance extracted from the exoskeleton of crustaceans that has been claimed to help control blood cholesterol levels. As the market for FOSHU products grows and expands it will be interesting to observe whether demand for similar products will increase outside Japan. However, legislative differences might prevent FOSHU ingredients being marketed in other countries.

5. Food composition data, health claims and the role of EuroFIR

Before any nutrition or health claim can be made on a food, it is essential to know its nutritional composition in order to verify that the constituent in question is present in sufficient quantities to make the claim relevant. Because many food manufacturers calculate composition from FCDBs, these must be accurate, comprehensive and up-to-date. It is also possible that, in the future, health claims in the EU may expand to cover substances such as polyphenols from tea or lycopene in tomatoes, so data will also be needed on these. In this case, specialised datasets, such as the BASIS database on bioactive



compounds in plants, that is being developed as part of EuroFIR, will be invaluable, as data on these are currently sparse. Indeed, this database will not only provide compositional information but will also give details of evidence for the health benefits of these compounds.

EuroFIR is working closely with EFSA on the potential uses of the EuroFIR-BASIS bioactives database (on both compositional and biological effects) to support a number of tasks. The database may be used in the evaluation of GM foods, as bioactive compounds in plants can be key in determining whether a GM plant is substantially different from the non-GM version, and whether any differences have the potential to be harmful. It could also be used to evaluate novel food applications and the evaluation of natural plant compounds used as ingredients or additives in foods. As mentioned above, the database may be used by EFSA in the consideration of evidence for health claims involving plant bioactives and also in making new diet and health recommendations.

In addition, if, as it is hoped, the incentive of being able to display a nutrition or health claim on a product drives reformulation of foods, either to increase the content of beneficial constituents or to comply with a specified nutrient profile, there may be substantial changes in the



composition of foods. The links that the EuroFIR network is building with the food industry to share food composition data with FCDB compilers will help to ensure that the data available keeps up with these changes. EuroFIR is also working closely with CIAA to find ways to improve the flow of food composition data from industry to FCDBs.

Again, the availability of this information will be essential to EFSA in order to support their work on food nutritional profiles, health claims, and exposure assessment. In order to deepen our understanding of the relationship between diet and health, we must be able to characterise the composition of the foods we eat and tease out the associations between dietary constituents and physiological changes.

6. Conclusions

The new nutrition and health claims regulation in the EU should help to harmonise and simplify the process of making a nutrition or health claim. It should also make it easier for consumers to understand and interpret these messages on foods as they will be more consistent, and encourage manufacturers to develop healthier products, as their health benefits may be displayed and advertised. Importantly, monitoring is built into the regulation, and in 2013, preliminary results will be published on the development of the health claims market, consumer understanding of claims and the effect this may have on the prevalence of chronic disease.

The European approach is somewhat more restrictive than in countries such as the USA and Japan, where 'qualified' health claims can be made on the basis of emerging evidence. It remains to be seen whether Europe will ever go down this route.

Accurate and comprehensive food composition data will be required for every aspect of the decision process of making a nutrition or health claim, for example: identifying possible claims, complying with the specified nutrition profile, making an application to the EC, EFSA's role in forming an opinion, and being able to comply with labelling requirements. A huge variety of foods are consumed in Europe and new products and formulations are constantly coming onto the market. In this context, it is a challenge to provide composition data to keep up with developments. The EuroFIR project has a central role in providing access to authoritative data on food consumption in Europe and will be an indispensable support for the success of this new regulation on nutrition and health claims in the EU.

References

Aggett P, Antoine JM, Asp NG et al. (2005) PASSCLAIM: consensus on criteria. *European Journal of Clinical Nutrition* **44** (Suppl 1): i5-31

WHO (2003) Diet, nutrition and the prevention of chronic diseases. Report of the joint WHO/FAO expert consultation. WHO Technical Report Series, No. 916 (TRS 916)

Useful links for further information

A full copy of the new EC regulation on nutrition and health claims

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_012/l_01220070118en00030018.pdf

FAO/WHO Codex Alimentarius

http://www.codexalimentarius.net/web/index_en.jsp

PASSCLAIM (ILSI)

<http://europe.ilsa.org/activities/ecprojects/PASSCLAIM/>

Swedish Nutrition Foundation

<http://www.snf.ideon.se/snf/en/index.htm>

The Netherlands Nutrition Commission

<http://www.voedingscentrum.nl/voedingscentrum/Public/Statisch/English+summary/>

The Finnish Food Safety Authority (Evira)

<http://www.evira.fi/portal/en/>

The UK Joint Health Claims Initiative

<http://www.jhci.org.uk/>

Nutrition and Health Claims: the Facts on your Food

FDA labelling information

<http://www.cfsan.fda.gov/~dms/lab-hlth.html>

Food Standards Australia New Zealand

<http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2006/nutritionhealthandre3396.cfm>

The Japanese Ministry of Health, Labour and Welfare

<http://www.mhlw.go.jp/english/topics/foodsafety/fhc/index.html>

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ISBN 0 907667 538