National Food Institute

Technical University of Denmark DTU

Health claims on foods and food supplements

Existing practice in Nordic and Baltic countries

Health claims on foods and food supplements

Existing practice in Nordic and Baltic countries

Prepared by:

Heddie Mejborn

National Food Institute, DTU

Department of Nutrition

Health Claims on foods and food supplements. Existing practice in Nordic and Baltic countries

1st edition, 1st circulation, November 2007
Number printet: 50

ISBN: 978-87-92158-13-0

This report is available at www.food.dtu.dk

National Food Institute
Technical University of Denmark
Moerkhoej Bygade 19
DK-2860 Soeborg
Denmark

Tel: +45 72 34 70 00
Fax: +45 72 34 70 01

Contents

Preface

Nordic Innovation Centre (NICe) is the Nordic Council of Minister's operating instrument for promoting an innovative, competitive and knowledge-intensive Nordic business sector. In 2006 NICe decided to make functional foods a focus area. Six projects, including ACCLAIM, were launched with the aim of helping Nordic businesses succeed in the global market for functional foods.

This report was prepared as part of the ACCLAIM "Consumer acceptance and trust: recommendation for using health-related claims in marketing" – project (grant no. P06045). The project aims to develop a shared Nordic View among stakeholders on how the claims should be used in marketing. As a basis of this work, consumer surveys on perception of claims have been carried out in all Nordic countries, and these surveys will be followed by a series of national and Nordic workshops, where marketing principles are discussed between food industry, authorities, consumer organisations, retailers and other actors in the food chain. The project is coordinated by Dr. Liisa Lähteenmäki, VTT Technical Research Centre of Finland, and has altogether 20 partners from the Nordic countries. In addition to National Food Institute DTU, MAPP University of Aarhus, Matforsk, Matis, National Consumer Research Centre in Finland and SIK are research partners. EVIRA from Finland and SLV from Sweden represent authorities, and Arlafoods Amba, Bama Gruppen AS, Danish Meat Research Institute, Fazer Bakeries Oy, MøllerCollet AS, MS Iceland Dairies, Norgesmøllene AS, Sinebrychoff Oy, Tine BA, Vaasan & Vaasan Oy,Valio Oy are industry partners. The project started in June 2006 and is planned to run to the end of May 2008.

The report summarizes how authorities in all Nordic countries (and to some extend in the Baltic countries) handled the use of health claims on foods prior to the adoption of the EU regulation of nutrition and health claims made on foods (EC No 1924/2006).

The report was presented to participants from all six functional food projects at a seminar arranged by NICe, September 5-7, 2007 in Hanaholmen, Helsinki, Finland.

Introduction

Increasing knowledge about the influence of diet, foods, food ingredients or nutrients/substances present in foods on health and well-being have been accumulating during the previous years. Consumers have access to much of this information, and relations between foods or components of food and health is the subject of articles in women's magazines, newspapers or the like. Also, many food producers want to improve their products in accordance with the obtained knowledge about diet-health relations. Such products are often sold at a premium price. To justify the price difference, it is important for the food producers to communicate the healthy qualities of their products to the consumers. Thus, many food manufactures or retailers are interested in marketing their products with information about beneficial health effects, health claims. Health claims are defined as any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health[1].

Until recently no specific regulation for use of health claims on foods existed in the EU. Therefore, health claims on foods and food supplements were administered significantly different in different European countries. These differences caused problems, mainly for small and medium size enterprises, for who it was difficult to survey the legislation in foreign countries.

EU regulation on nutrition and health claims made on foods, Regulation (EC) No 1924/2006 of the European Parliament and of the Council was adopted 20 December 2006 and published 18 January 2007 (Corrigenda). It came into force from 19 January 2007 and applies from 1 July 2007. Until lists of authorised health claims are established by the Commission and the Parliament, existing practises can be expected to continue in Member States. Therefore, knowledge about Member States' individual handling of health claims is useful for food producers, importers and retailers (hereafter named "operators").

The objective of this report is to describe how health claims have been regulated and governed in Nordic and Baltic countries before the EU Regulation came into force. Existing practice is described for the individual countries. Examples of claims given in the text are almost exclusively found in national guidelines for use of health claims. Please note there may be exceptions from the examples of acceptable claims given below, depending on the specific product and context. At the end of this report, references are given to important legislation, guidelines and internet sites relevant for use of health claims.

Norway and Iceland are not members of the EU, but associated through the EEA agreement. Both countries are expected to revise their food act in order to implement the new EU regulation.

[1] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

Existing practice

Finland
According to Section 6 of the Food Act (361/1995) Amendment 737/2001 and new Food Act (23/2007) that entered into force 1 March 2007, the information provided on the packaging of the foodstuff, in a brochure, in advertising or by any other means, shall be true and sufficient. It is prohibited to attribute to any foodstuff the property of preventing, treating or curing a human disease, or to refer to such properties, unless otherwise stipulated by a statutory order.

Besides, the regulations of the Decree on Foodstuff Labelling (794/1991) and of the Ministry of Trade and Industry's Decision on Labelling (795/1991) shall also be considered. Pursuant to Section 5 of the Decree on Labelling, labelling may not mislead the consumer about the properties of the product. Misleading claims include claims that make an indirect reference to the effects of the product, such as 'Research shows that substance X can/may/possibly…' Such claims imply that there is no proof of such effects. Examples of claims that were found to be un-substantiated, and therefore misleading are: 'Promotes burning of fat', 'Improves mental health', and 'Tones muscles'.

Health claims can be used on foods and food supplements if they comply with the legislation mentioned above. A guide for the control of health claims, including conditions for use of claims and documentation can be found on the internet (in Finnish and English). Special guidelines exist for use of claims related to blood cholesterol level (in Finnish only), and a guidebook for consumers "Humbug or not?" can be found on the internet as well.

Claims referring to the *effect of a nutrient or one of its ingredients on vital body functions* are permitted. For example claims referring to digestion, the functioning of the stomach and the bowel, fat balance, maintenance of normal blood pressure level and blood cholesterol are permitted, provided that information on what the claimed effect is based on and the prerequisites that are necessary for the claimed effect to be realized are given too. For example, if the effect of a substance is based on absorption, this shall be substantiated by sufficient proof. If the effect is commonly known, commonly accepted research information is sufficient proof. If the claim refers to an effect not commonly attributed to an ingredient of the food, the claim shall be substantiated by sufficient scientific proof, including human studies. The proof and its sufficiency shall be assessed separately in each case. The significance of a diverse diet shall be emphasized, unless there is specific proof that diet has no effect on the claimed effect.

Claims referring to a *reduced risk of disease* are permitted as well, if certain general principles including diet, realization of the claimed effect and proof are considered. Information shall be provided in connection with the claim on the significance of the diet to health, as well as information about the composition of the product to the extent that is relevant to the claim. Besides, the required intake to obtain the effect must be described. It is recommended also to provide information on other risk factors connected with the disease in question. The claimed effect shall be based on repeated and independent research results, including human studies that meet scientific quality requirements. Results must be based on foodstuff-specific studies carried out on the product in question, for which the influence of the risk factor of the disease is established. For example it is possible to claim 'Regular use of 100% xylitol chewing gum reduces the risk of caries'.

If a given risk factor is known to be generally linked with the outcome of a disease, and if scientific studies show that the food influences this particular risk factor, the claim of a reduced risk of the

disease can be made in a two-tier form such as ‘An increased cholesterol level is a risk factor for coronary heart disease. Ingredient Y in product X helps reduce blood cholesterol.’

Reduced risk of disease claims about effect on blood cholesterol can be made on all types of foods, provided there is sufficient data supporting the claims. For products with cholesterol claims there are demand for nutrient profiles (saturated fat, as mentioned below).

In Finland the National Food Safety Authority, EVIRA, is an authority for planning, steering, developing and undertaking food control nationally. Practical control is taken at local level by municipal authorities that undertake food control in their own areas. However, only EVIRA can make national marketing bans on misleading or medicinal marketing of foods. Neither health claim nor documentation can be pre-approved by the Authority. The scientific truth is the responsibility of the operator, and documentation must be at hand, when the food is marketed, so it can be shown to the control authority upon request. EVIRA has since 2003 had an expert group for evaluating health claims, and about 20-25 claims have been evaluated to date. Evaluations are publicly available. EVIRA can issue a marketing ban against specific claims, or they can send remarks to the food companies. A reason for control activities is if experiments are done with products that are different from products on the marked (different amount of active nutrient or higher frequency of use). Observe: product names/trademarks can include a claim, and so can pictures.

Placing on the market of pharmaceuticals and herbal remedies, on the other hand, requires a marketing authorisation of the National Agency for Medicines. When using claims referring to vital body functions attention shall be paid to the requirements specified in legislation concerning pharmaceuticals. Marketing a special product with a claim that it can be used to restore, prevent, repair or *modify a person’s vital functions* may lead to the product being considered a medicine.

Nutrient profiles have not been developed by the National Food Agency for products that are allowed to carry health claims in general. However, products carrying health claims related to blood cholesterol must not exceed certain levels of saturated fat, depending on product group. Also, the private organization Finnish Heart Association has developed principles for use of the Heart Symbol (considered a nutritional claim). Included in these principles are nutrient profiles (total and saturated fat, sodium, cholesterol, fibres and sugars).

Sweden

The labeling and marketing of foods shall be designed such that it observes National Food Administration labeling regulations, and National Food Administration and Swedish Consumer Agency directives and practice (Government bill 1985/86:121, Marketing Act SFS 1995:450, and report of the Committee on Consumer Policy SOU 1994:14). According to National Food Administration labeling regulations (SLVFS 1993:19 §6) it is not allowed to make claims that a food prevents, treats or cures disease.

However, according to a voluntary Code of Practice, supported by the competent authority, health claims, including claims related to health, performance and well-being are allowed on regular foods, but not on food supplements. The allowed claims can be divided in two main groups: General health claims and Product-specific physiological claims (Produktspecifika fysiologiska påståenden, PFP). The latter include claims for a subgroup of products with a documented low glycemic index (GI).

When a health claim is used, nutrient declaration is compulsory.

The voluntary Code of Practice was developed in 1990 by the Swedish food sector (the Swedish Cooperative Union, the Federation of Swedish Farmers, the Swedish Food Federation, the Swedish Federation of Trade, and the Swedish Food Retail Association). The Code is administered by the non-governmental organization Swedish Nutrition Foundation (SNF). The Code was revised in 1996 and in 2004. The present principals of the Code are the Swedish Food Federation (Livsmedelsföretagen) and the Swedish Food Retailers Federation (Svensk Dagligvarehandel). SNF's research committee and the National Food Administration's expert group on diet and health are consulted on an ongoing basis regarding the current scientific situation as a basis for allowed claims.

Although the Code is not officially adopted by the Swedish National Food Administration (Livsmedelsverket), claims according to the Code are regarded as acceptable in practice and can be used without interference from the authorities. However, consumer organizations, food operators, and others can contact the Assessment Board for Diet-Health Information (Bedömningsnämnden för kost-hälsainformation, BKH, belonging to the Code but separated from SNF) if they think the Code is violated. Statements from the Board (BHK) are in written form and made public through press releases and posting on the Code's web-site hp-info.nu. The Board has no authority to make sanctions to those violating the Code, but by informing the National Food Administration, the Board can make sure that action is taken.

Generic health claims are claims about generally accepted relations between diet and health or well-being. Two types of generic health claims are considered: Nutrient function claims and Reduction of disease risk claims. No application or pre-approval is necessary, but the company marketing the product must be able to prove that the nutrient or dietary substance, which the claim is about, is present in the food in the quantities specified by the Code, and that the food fulfils the specified compositional criteria, i.e. specific nutrient profiles.

Nutrient function claims may only be made for generally accepted nutritional physiological functions, i.e. such as those listed in a current version of the Nordic Nutrition Recommendations, the National Food Administration book on diet, exercise and health, or other recognized textbooks on nutrition. The function shall also be *relevant for Swedish consumers*.

One of the main rules for nutrient function claims is that they must not be worded such that it may be interpreted that the product as such has a particular effect. For this type of claim, producers are referred instead to the option of applying to have the documentation evaluated for product-specific physiological claims (see below). For nutrient function claims regarding dietary fibres, vitamins and minerals, general requirements are described in relation to content of the actual nutrient (as a rule for vitamins/minerals the food must contain at least 15% of the recommended daily intake per 100 g or 100 mL). Besides, where applicable, products making nutrient function claims must meet the criteria for using the Swedish Keyhole Symbol (nutrient profiles). Neither health claim nor documentation need pre-approval. The scientific truth is the responsibility of the operator, and documentation must be at hand, when the food is marketed. The guidelines include a list of health claims (examples) that are allowed on foods, but the list is not a positive list.

Nutrient function claims can preferably be given in two parts (två steg), that is, a nutrition claim combined with information about a certain generally accepted physiological role of the nutrient in question. Examples of approved nutrient function claims, relevant under Swedish conditions, are 'Vitamin C enhances iron absorption. Product X contains vitamin C', and 'Dietary fibre helps to maintain normal bowel function. Product Y contains dietary fibres.'

A claim that is true, but regarded *irrelevant for Swedish conditions* is: ‘Vitamin A is found in visual pigments and is important for night vision. Product Z contains vitamin A.’ The claim can therefore not be used. For claims not specified by the Code, SNF can be consulted to discuss the relevance. In case of a conflict it might be a task for the Assessment Board for Diet-Health Information to decide.

For generic *reduction of disease risk claims*, the basic principle is that claims must be consistent with official Swedish Nutrition Recommendations, and only relate to in Sweden generally recognized and scientifically well-documented connections between diet and a reduced risk of diet related disease. The claim must not be worded such that it may be interpreted that the product as such has a particular effect. For this type of claim, producers are referred instead to the option of applying to have the documentation evaluated for product-specific physiological claims (see below).

Generic reduction of disease risk claims must be given in two separate parts (två steg), that is, information on the product’s composition and the generally accepted connection between diet and a reduced risk of disease. The wording must take into account the requirements for the composition of a balanced diet that provide all of the different nutrients. Generic reduction of disease risk claims can only be used on products that under normal use, contributes to a nutritionally balanced diet, and the criteria for the Keyhole Symbol (nutrient profiles) must be met where applicable.

The following connections between disease, and their risk factors, and diet are considered well-established, and can therefore constitute the basis for generic reduction of disease risk claims:

- Overweight/obesity – Energy
- Cardiovascular disease/atherosclerosis – Blood cholesterol levels – Hard fats/Certain types of dietary fibre
- Cardiovascular disease/atherosclerosis – Blood pressure – Salt
- Cardiovascular disease/atherosclerosis/hardening of the arteries – Omega-3 fatty acids
- Constipation – Dietary fibre
- Osteoporosis – Calcium and/or Vitamin D
- Caries – Sugar/Fermentable carbohydrates
- Iron deficiency – Iron
- Coronary heart disease – Whole grain

Examples of acceptable claims are: ‘A nutritional balanced diet with a low saturated fat content contributes to lower cholesterol levels in the blood and can thereby reduce the risk of cardiovascular disease/atherosclerosis. Product X has a low saturated fat content.’ or ‘a nutritionally balanced diet high in long omega 3 fatty acids from fish and fish products reduces the risk of cardiovascular disease/atherosclerosis. Product Y is high in long omega 3 fatty acids.’ or ‘A nutritional balanced diet with low sodium/salt content can contribute to lower blood pressure and thereby to a reduced the risk of cardiovascular disease/atherosclerosis. Product Z has a lower sodium/salt content than corresponding normal products.’ The exact wording of the claims are flexible, except for connection number 9, where the claim must sound: ‘A healthy lifestyle and well-balanced diet high in whole grain products (a) reduces the risk of coronary heart disease, (b) reduces the risk of heart disease. Product X has a high whole grain content (Y% whole grain).’ The responsibility for the appropriateness of the final wording used in labeling and marketing rests upon the company marketing the product.

Since 2001, the Code of Practice was extended to *Product-specific physiological claims (PFP)*. The scientific documentation behind PFP-claims must go through a pre-market evaluation. PFP-claims must be substantiated by studies that demonstrate the claimed effect using scientifically sound methods. The company marketing the product must be able to provide documentation of these studies, and the Swedish Nutrition Foundation Research Committee is responsible for ensuring that the evaluation is carried out by the appropriate experts. A positive evaluation allows the operator to use a label (hp-info label) that states the product has undergone evaluation of the scientific documentation according to the Code.

PFP-claims can be used on foods intended for consumption as a part of a nutritionally balanced diet. The studies must be conducted on humans, and the trial group used should be representative of the product's target group. The studies must represent intake levels that correspond to normal use of the food for the trial period, and be of sufficient duration to demonstrate the intended effect. The necessary number of studies will be decided from case to case, depending on how well established the physiological effect is considered to be. Background information such as animal studies may be used, when relevant, as supportive documentation, but is not considered conclusive in themselves.

For the PFP-claims it is most desirable but not demanded that they meet the profiles from the Keyhole Symbol.

Currently, (February 2007) PFP-claims are accepted for five main products and four equivalent products, i.e. altogether nine products:

- Benecol spreads and yoghurt drink can claim 'Decreases cholesterol' (Sänker kolesterolvärden)
- Hjärtans Lust cheese based on rapeseed oil can claim 'As a substitute for regular cheese, Hjärtens Lust helps to decrease the blood cholesterol level' (Som ersättning för vanlig ost bidrar Hjärtans Lust till sänkta kolesterolvärden)
- ProViva fruit drink and shot with *Lactobacillus plantarum 299v* can claim 'ProViva decreases the gas production in the stomach' (ProViva minskar gasbildning i magen)
- Becel pro.activ yoghurt drink, milk drink and spread can claim 'Becel pro.activ yoghurt drink/milk drink/spread decreases total and LDL cholesterol' (Becel pro.activ yoghurtdryck/mjölkdryck/matfett sänker total- och LDL-kolesterol)
- Primaliv yoghurt with müsli can claim 'Primaliv levels out the blood sugar level after a meal' (Primaliv utjämnar blodsockernivån efter en måltid)

Operators that are interested in PFP-claims should contact SNF for more information about the application procedure. An application form is available on the home page of SNF. NOTE: With respect to the EU regulation SNF is no longer accepting applications within the Code. How the Code will be administered in the future is presently not clear.

Claims regarding effects on the postprandial blood glucose level, *GI-claims*, are considered PFP-claims, except for pasta products, for which a nutrient function claim about low blood sugar response can be given. According to the Code of Practice, a pre-marked evaluation of the documentation supporting any PFP is required. Applications regarding GI-claims may be evaluated according to a simplified procedure, described at the SNF home-page, provided the product complies with criteria given i.e. on the method used and on (digestible) carbohydrate content of the product. The GI-value must be determined by studies in humans, using the actual food product, and results from at least two independent laboratories are required to show a GI of less than 55

(glucose = 100), which is considered a low GI. The product must contain at least 15 g (preferably 20 g) digestible carbohydrate per normal amount consumed at one eating-occasion.

At the moment (February 2007), fifteen products can use the hp-info label and the information that the product has a low glycemic index (GI) compared to similar products.

According to the simplified evaluation procedure, the documentation will be evaluated by SNF's secretariat, in consultation with SNF's Research Committee. If the criteria are not fulfilled, the application will be handed according to the full procedure for PFP-applications (see above).

Denmark

In Denmark health claims are defined as any statement that state or gives the impression that a connection exists between a food or part of a food (e.g. a nutrient) and disease or a health related condition. According to Danish legislation, §76 in Departmental Order on labelling of foods, it is not allowed in marketing of foods, including food supplements, to state or indicate that a food can prevent, alleviate or have a beneficial effect on disease or disease related symptoms. This is an implementation of the EU Labelling Directive 2000/13/EC article 2. The Danish legislation also forbid claims, which can cause or take advantage of fear, or give reference foods being recommended by doctors. According to the Danish regulatory practice "functional claims" like 'Calcium aids in the development of strong bones' have been interpreted as having relation to disease, and therefore included in the ban.

The ban against health claims has the purpose of protecting the consumers against misleading marketing, especially by arousing anxiety or fear, for instance by telling that foods can cure or prevent disease. The ban is valid, even though documentation exists to substantiate the claim, and it includes a ban on nutrient functional claims. The reason for the ban is that even though the health claims might be true, they can still lead to an inappropriate food use due to uncertainty or fear for symptoms of disease. Claims, which are interpreted not to have a specific connection to a disease or disease related symptoms, for instance claims like 'Increased well-being' are regulated by the labelling rules, which generally prohibits the use of information that could mislead the consumers, in agreement with article 16 in the EU Regulation 178/2002/EC.

Guidelines from 1993 on *health claims on foods* exist (in Danish). The guidelines include examples of claims that were found to violate the general prohibition against disease related health claims, and also includes examples of "health claims" that were found not to be directly related to disease and therefore accepted. Examples of claims that were not allowed, as they were considered to cause uncertainty or fear, are: 'Dare you refrain from…' (Tør du lade være med…), 'I will like to see my grandchildren grow up' (Jeg vil gerne se mine børnebørn vokse op). Examples of other health claims not allowed: 'Gives strength to muscles' (Styrker musklerne), and 'Improve the defence mechanism' (Styrker forsvarsmekanismen). Also brand names are sometimes viewed as health claims: 'Heart Bran Bread' (Hjerte Klidbrød), 'Heart Good' (Hjertegodt) were not allowed. Examples of claims that are not violating the current §76, and thus can be used, are: 'Increased endurance' (Øget udholdenhed) and 'Better well-being' (Bedre velbefindende).

By the end of the 1990th the Danish Food Administration established a scientific expert group that prepared guidelines on scientific evaluation of health claims and suggestions for general conditions for use of health claims on foods. The guidelines were published in a report (in Danish; a corresponding scientific article in English is available too). These guidelines, however, have not been used. The report includes suggestions for nutrient profiles that must be observed. The profiles

state maximum levels for fat, sugar and salt, and minimum levels for essential micronutrients to ensure that only foods of a certain nutritional value can carry a health claim.

In the previous years, Denmark (unlike all other Nordic and Baltic countries except Sweden) has handled *health claims on food supplements* slightly different from claims on foods. Food supplements are now allowed to carry some health claims ("function claims"), provided the claims can be substantiated, and provided that the claims do not violate the general prohibition of disease related claims.

In July 2003, a Departmental Order on food supplements went into force, implementing the EU Directive on food supplements (2002/46/EF). In the Departmental Order, food supplements are defined as foods that:

- have the purpose of supplementing the normal diet
- are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or combined, and
- are marketed in doses, for example capsules, tablets, pills, liquid ampoules, and the like, intended for intake in measured amounts

Neither health claim nor documentation can be pre-approved by the Danish Veterinary and Food Administration (Fødevarestyrelsen). The scientific truth is the responsibility of the operator, and documentation must be at hand, when the food supplement is marketed. According to the Departmental Order, all food supplements must be notified to one of the Regional Food Control Centres. The notification must include a description of the purpose of the supplement, and an example of the labelling that will be used on the product including any claim. The notification is *not* an approval of the product or the claim. In Guidelines on Food Supplements, all procedures related to food supplements are described.

In the guidelines it is stated that food supplements may be sold, accompanied by a description indicating the nutritional or physiological effect, but the description must not relate to diseases. Several types of claims are defined in the guidelines:

- Functional health claims based on generally accepted scientific data, typically describing knowledge from textbooks, e.g. 'Calcium helps build and maintain bones', 'Folic acid contributes to normal growth of the foetus', are allowed
- Functional health claims *not* based on generally accepted scientific data, e.g. 'Impede snoring', 'Prevent hangovers'[2], are allowed if they can be substantiated
- Claims related to reduced risk of disease, e.g. 'Reduce the risk of osteoporoses'; such claims are not allowed
- Claims stating that the product has the effect to prevent, relieve, or cure, e.g. 'Prevent osteoporoses'; such claims are not allowed
- Unspecific claims, e.g. 'Good for the stomach' are allowed if they can be substantiated, and if they are not suitable to mislead the consumers. The documentation must not indicate a medicinal effect
- Claims specifying a target group, e.g. 'Women of childbearing age are recommended to get 400 microgram folic acid per day', are allowed only if they refer to official nutrient recommendations

[2] As hangover is not defined as a disease in Denmark. Thus, it is allowed to claim a product has the ability to *prevent* hangovers.

The guidelines describe demands on scientific documentation for health claims including a definition of scientific level. The documentation must be based on a systematic review of all relevant literature, both supporting and not supporting the effect. In general, one reference on ”moderate scientific level” plus at least two references on “low scientific level” all pointing in the same direction will be accepted as documentation for a claim, but if the documentation is on “high scientific level”, just one reference will be acceptable. Human studies are required, while references to traditional use, or to *in vitro* studies are not considered sufficient. Besides, the company must verify that the desired effect can be obtained through the recommended daily dose.

Norway

Norway is not a member of the EU but is associated through the EEA agreement. As the EU has agreed on a nutrition and health claim regulation, the regulation will be implemented in the EEA agreement simultaneously. Until further notice, nutrition and health claims are regulated by “Forskrift 21. desember 1993 nr. 1385, Merkeforskriften” about labelling of foods, and by “Forskrift 21. desember 1993 nr. 1386, Næringsdeklarasjonsforskriften” about labelling of nutrient content.

In principle, it is not allowed to label foods in a way that can mislead the consumers, and it is not allowed to claim or give the impression that a food can prevent, cure or treat disease, symptoms or pain, affect physiological functions, or diagnose disease. Such claims, including reduction of disease risk claims, are considered medicinal claims. Medicinal claims are not allowed in Norway. However, claims indicating a relation between foods and health are allowed on foods and food supplements, provided they are true, not misleading, and can be scientifically substantiated.

When a claim describing the effect of a nutrient or other active substances on growth, development and normal functions of the body is used, nutrient declaration is compulsory.

Guidelines (in Norwegian) for documentation of nutrition and health claims were approved in November 2005. The guidelines are provisional until the EU regulation can be implemented. Neither health claim nor documentation need pre-approval from the Norwegian Food Safety Authority (Mattilsynet). The scientific truth is the responsibility of the operator, and documentation must be at hand, when the food is marketed. The guidelines include a list of health claims (examples) that are allowed on foods.

In 2003 Ministry of Health and Care Services (Helse og Omsorgsdepartementet) set up a committee, who evaluated a list of medicinal claims administered by the Norwegian Medicines Agency (Legemiddelverket). In the resulting report (Syse-rapporten), classification (A, B, or C) of several hundred claims within many health conditions is described. The report can be found at http://www.odin.dep.no/filarkiv/108029/Syseutredningen.pdf. The report also discusses the problems related to the part of the Norwegian definition of medicine that relates to “substances that affects physiological functions”.

Category A: Medicinal claims that are not allowed on foods. If an operator intents to use a health claim and doubt whether the claim is medicinal, he can consult the Norwegian Medicines Agency (Legemiddelverket). Examples of medicinal claims are claims including the words High/low blood pressure (Høyt/lavt blodtryk), Osteoporosis (Benskjørhet), Increase power of resistance (Øker modstandskraften), Cholesterol-reducing (Kolesterolreduserende/senkende/nedsettende), and Constipation (Forstoppelse) – but “Slight constipation” (Lettere forstoppelse) is a legal health claim.

Category B: Claims that were not considered medicinal claims, but health claims. A list of acceptable claims of this category are included in the guidelines describes above and in Syse-

rapporten. They can be used on foods if they can be documented and if they fulfil the demand from 'forskrift om merking med mer av mat'. The lists are not exhaustive; they just show examples. No special wording is required, but the framing "can help" is most often used. The acceptable claims mainly describe slight improvements in health conditions (and diseases?). Claims describing a more profound improvement are considered medicinal claims, and are not allowed. From the list of acceptable claims can be mentioned: 'Can work against varicose veins' (Kan virke mot åreknuter), 'Can help against slightly increased blood pressure' (Kan hjelpe mot lett forhøyet blodtryk), 'Can help against slight depression' (Kan hjelpe mot lett nedtrykthet).

Category C: Medicinal claims that are considered irrational or diffuse to the average, sensible consumer and therefore cannot be substantiated, are not allowed. Examples are claims containing the words 'Stress','Increases life quality' (Øker livskvaliteten), 'Gives better sleeping quality' (Gir bedre søvnkvalitet), and 'Immune-stimulating' (Immunstimulerende).

In order to ensure that labelling a food with a claim is not misleading to the consumers, the operator must be in possession of sufficient documentation to verify the claim. In general, it is considered appropriate that differences in documentation level are reflected in the wording of the claim. Three alternatives are possible:

Generic claims require documentation based on general knowledge about nutrients and other active components' effect on growth, development and normal body functions. Descriptions from scientific monographs are sufficient documentation, provided it describes the same active ingredient and the same way of use including form, strength and dose.

Claims on single products based on generic documentation can be expressed in two sentences (tostegsprinsippet): the first sentence describes the general knowledge about the connection between the active component and its physiological effect, and the next sentence describes information about the actual content of the component.

Health claims on individual products require documentation based on scientific studies at product level. Mainly human studies performed after approved scientific methods form the basis for the claim. Animal studies or *in vitro* studies can be used to support the results. The studies must be reproducible (meaning you must perform at least two studies), involve a sufficiently big (target) population, and last so long that eventual long-term effects are revealed. The suggested dose must be relevant, it shall mainly be tested in the actual matrix, and it must be documented that the effect can be obtained through usual intake of the food as part of the usual, daily diet. If the claim refers to specific, active components, it must be substantiated that the component is present in sufficient amount and that it is bio-available. The biological effect must be statistical significant, and of a magnitude that is biological, physiological or epidemiological important. The results must be published in peer reviewed scientific journals or electronic databases. All relevant literature must be taken into consideration, both supportive and non-supportive.

Claims referring to "traditional use" of foods/ingredients in folk medicine (folkemedisin) are considered valid, if the products have been used traditionally in Europe or North America for at least 30 years with a likely/probable effect. The documentation must be related to the actual product and describe the traditional use of that particular product, and also prove that the product has been legally for sale for at least 30 years. Documentation based on traditional use is not considered prove of an effect, but instead an assumed effect. Examples of this kind of products are herbal medicine, botanicals, and drugs (droger).

Nutrient profiles have not been developed for products that are allowed to carry health claims.

Iceland
Iceland is not a member of the EU but is associated through the EEA agreement. As the EU has agreed on the nutrition and health claim regulation, the regulation will be implemented in the EEA agreement simultaneously.

Until further notice, nutrition and health claims are regulated according to the regulation on labelling, advertising and presentation of foods, Regulation 588 from 1993. According to Regulation 588 it is not allowed in labelling, presentation or advertising to indicate that a specific food is healthy or has health-promoting characteristics. However, such characteristics may be cited if it is specifically noted that the food should be consumed as part of a healthy and wholesome diet. According to regulation 588/1993 it is possible to apply for use of nutrient function claims. These claims are only permitted if they are true, not misleading for the consumer and can be scientifically substantiated. Products bearing claims must carry both ingredient list and nutrition labelling.

A health claim is defined as any representation that states, suggests or implies that consumption of a food or a constituent of that food will improve health. *Health claims, including reduction of disease risk claim*s, are not allowed on foods or food supplements, but *nutrient function claims* are allowed, provided they can be substantiated. The Authority does not distinguish between maintaining, controlling, and improving good health or reducing (risk of) bad health, when they decide what is a health claim. The importance is if the name of a disease is mentioned. If the name of a disease is mentioned, the claim is not allowed. However, elevated blood cholesterol is not considered a disease. Therefore, claims such as ‘Maintain (low) cholesterol’, ‘Control cholesterol’, and ‘Reduce cholesterol’ all are nutrient function claims that have been allowed to use.

Regulation 588 includes a list of allowed claims. Guidelines on nutrient function claims are not available in English. A list of nutrient function claims that are allowed can be found on The Environment and Food Agency of Iceland’s homepage (in Icelandic). The list includes 4 product specific nutrient function claims that have been approved (not authoritative translation):

- ‘LH milk-drink contains IPP and VPP peptides, and The peptides can help to control blood pressure’
- ‘Natural way to help control blood pressure’
- ‘Benecol contains plant sterol esters that lower cholesterol’
- ‘Clinically proven to lower cholesterol. Spreads from Flora Pro Active contains plant sterols that lower cholesterol in the body’

Besides, claims like ‘Contain folic acid which is important for normal development of the foetus’, ‘Calcium is necessary for your bones’, and ‘Positive effect on triglycerides’ are considered nutrient function claims that can be applied for, while claims like ‘This product brings you better health’ and ‘Maintain a healthy heart’ are health claims and therefore not allowed. No special wording of the claims is required. However, the level of documentation must be reflected in the claim. For example experiments showing a 10% reduction in plasma LDL cholesterol do not qualify the claim ‘Dramatically lowering cholesterol’. The claim ‘Extraordinarily healthy’ was not allowed on another product either.

Thus, the Icelandic legislation describes both what is allowed and what is not allowed. Nutrient function claims need pre-approval from The Environment and Food Agency of Iceland. If an operator intents to use a nutrient function claim and doubt whether the claim is legal, he can

consult the Environment and Food Agency. Product specific claims must be approved by the Food Agency.

Guidelines on documentation of nutrient function claims have not been developed, and nutrient profiles have not been developed for products that are allowed to carry nutrient function claims.

Estonia

The Estonian legislation does not provide a definition for a health claim. According to the Food Act it is prohibited to refer to food properties that prevent, treat or cure disease (medicinal claims), and it is forbidden to mislead the consumers. In practice, it is allowed to use health claims that are in accordance with those rules, e.g. ‘Calcium strengthen bones’, ‘Fibres promote digestion’ (=nutrient function claims). Claims on food and food supplements are treated similar.

In general, reduction of disease risk claims are not allowed, because it is considered that these claims refer to properties that prevent disease. Claims about maintaining, controlling and improving health can be made if appropriate for the product, and if the wording is not misleading consumer.

The legislation describes what is not allowed in relation to use of health claims. There is no pre-marketing approval for food labelling, and the scientific truth of a claim is the responsibility of the operator. The operator must have the documentation verifying the claim at hand, so that it can be provided, if the competent authority asks for it during control. If the Authority finds the claim inappropriate for the product, the operator is asked to change the labelling to comply with the labelling rules. If an operator intents to use a health claim and doubt whether the claim is legal, he can consult the competent authority (Food and Veterinary Department).

If the health claim includes or is accompanied by a nutrition claim, nutrition labelling is compulsory.

No list with examples of acceptable claims exists, and no specified wording of the claims is preferred. However, the level of documentation must be reflected in the claim. Guidelines on documentation of health claims have not been developed, and nutrient profiles have not been developed for products that are allowed to carry health claims.

Latvia

All food products must comply with the requirements of Regulations regarding the Labelling of Food Products (Regulation No.964, adopted 23 November 2004). According to Article 11, the information indicated on the labelling of foods and food supplements as well as the methods used for labelling must not attribute to the food or food supplement any medicinal (curative) qualities or qualities of prevention of disease.

There are no specific regulation regarding health claims but health claims, including nutrient function claims, are not allowed. Claims including the name of a disease are considered reduction of disease risk claims. Claims such as ‘Maintain (low) cholesterol’, ‘Control cholesterol’, and ‘Reduce cholesterol’ all are considered health claims and not allowed.

In general, the Latvian legislation describes what is not allowed in relation to (health) claims, so no pre-market approval of claims can be obtained. If an operator intents to use a claim and doubt whether the claim is a health claim and thus illegal, he can consult the competent authority (Ministry of Economics is responsible for labelling of foods. Food supplements are the responsibility of the Food Centre of the Food and Veterinary Service).

If food supplements contain other substances than vitamins or minerals, and information in the technical documentation implies the food supplement might be a drug (medicine), the Food and Veterinary Service (who is in charge of the food law) shall ask for the State Agency of Medicine's opinion. If the latter confirms that the product is a pharmaceutical product, it cannot be registered as a food supplement.

Guidelines on documentation of health claims have not been developed, and nutrient profiles have not been developed for products that are allowed to carry health claims, as health claims are not allowed.

Lithuania

This paragraph is somewhat uncertain, as it was difficult to obtain information from Lithuania. An update will be provided if possible.

There is no specific national legislation relevant to health claims made on foods including food supplements. That means health claims (nutrient function claims and reduction of disease risk claims) in general are not allowed.

Whether some nutrient function claims are allowed is somewhat uncertain. Claims like 'Iron is important for formation of red blood cells' and 'Contain iron, which is important for transportation of oxygen in the blood' are considered health claims. Claims like 'Maintain (low) cholesterol' will probably be regarded as a health claim, while 'Control cholesterol', and 'Reduce cholesterol' probably will be regarded as medicinal claims.

Summary

The Competent Authorities in Nordic and Baltic countries handles health claims on foods in different ways. In many countries, health claims like the type described in Article 13(1)(a) in Regulation EC 1924/2006 (=nutrient function claims) are allowed on foods and/or food supplements, while reduction of disease risk claims (Article-14 claims) are only allowed in Finland and Sweden.

Most Nordic countries have guidelines for use of health claims including guidelines for documentation of the claims, but pre-approval of health claims on foods cannot be obtained, except in Sweden and Iceland. The scientific truth is the responsibility of the food retailer, and if a food is sold with a health claim, documentation must be at hand, when the food is marketed.

An overview of the present authority practice in Nordic and Baltic countries is shown in the table below.

Present practices for use of health claims on foods and food supplements in Nordic and Baltic countries.

Country	Health claims[#] on foods	Risk reduction claims on foods	Health claims[#] on food supplements	Risk reduction claims on food supplements	Guidelines for use of health claims	Guidelines for documenta-tion	Pre-approval of health claims	Nutrient profiles
Finland	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes[§]
Sweden	Yes	Yes	No	No	Yes	Yes	No (Yes for PFP-claims)	Yes*
Denmark	No	No	Yes	No	Yes	Yes	No	No
Norway	Yes	No	Yes	No	Yes	Yes	No	No
Iceland	Yes	No	Yes	No	Yes	No	No/Yes	No
Estonia	Yes	No	Yes	No	No	No	No	No
Latvia	No	No	No	No	No	No	No	No
Lithuania	No	No	No	No	No	No	No	No

Including nutrient function claims

§ Not for health claims in general, but for claims about effect on blood cholesterol, and for the Heart Symbol (self-regulated)

*Where applicable, products must meet the criteria for the Swedish Keyhole Symbol

Implications of the new EU legislation

On 20 December 2006 common legislation for the EU on use of nutrition and health claims was established, as Regulation (EC) No 1924/2006 was adopted. A Corrigendum was published on 18 January 2007. The Regulation came into force on 19 January 2007. The Regulation applies from 1 July 2007.

According to Article 20, the Commission shall establish and maintain a Community Register of all authorised health claims made on foods. Also, a list of rejected health claims and the reason for their rejection shall be established.

Transitional measures
The Regulation includes provisions about transitional measures that differ for different types of health claims. For Health claims other than those referring to the Reduction of disease risk and to Children's development and health (Article 13) a list of permitted claims will be established by 31 January 2010 at the latest.

According to article 28 (5) health claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body (Article 13(1)(a)) may be used from the date of entry into force until the adoption of the 'Article-13 list' under the responsibility of food business operators, provided that they comply with the Regulation and with existing national provisions.

For claims referred to in Article 13 (1)(b) and (c), the transitional period is described in Article 28 (6). These claims can be continued if they were evaluated and authorised by a national authority and in use before 19 January 2007, and if the Member State informs the Commission through an evaluation report at the latest 31 January 2008. Subsequently, the Commission consults the European Food Safety Authority (EFSA), and if the Commission turns down the health claim, the claim can still be used for six month after the rejection.

Claims referred to in Article 13 (1)(b) and (c), that were not evaluated and authorised by a Member State before 19 January 2007, can be continued provided an application is made before 19 January 2008. Health claims not being authorised under this procedure may continue to be used for six month after the rejection.

For Reduction of disease risk claims and Claims referring to children's development and health (Article 14) applications can be sent to the national competent authority of a Member State from 1 July 2007. The competent authority shall inform the Commission and the other Member States, and EFSA will be asked to perform the necessary evaluation of the scientific substantiation of the claim. Whether a claim will obtain Community authorisation will be decided through Committee procedure (Member State vote).

As claims referring to the reduction of disease risk have not previously been allowed in the EU, no transitional period is described in the Regulation for such claims. In spite hereof, few Member State did previously allow the use of Reduction of disease risk claims, and it is uncertain how health claims falling under Article 14, that are already in use, will be handled in the transitional period until an evaluation of the scientific data supporting such claims can been performed. For Reduction of disease risk claims already on the marked, it can be assumed that such claims can temporarily be used in the country, where they were used before 19 January 2007, but not in other countries.

For Claims referring to children's development and health, a transitional period was not described in the Regulation. To avoid withdrawal from the market of products which have legally used such claims, the Commission on 28 June 2007 proposed an amendment to Regulation 1924/2006 that put Claims referring to

children’s development and health on the same footing as claims described in Article 13 (1)(b) and (c) (se above). The proposal is not adopted yet.

Please observe that references to general, non-specific benefits of a nutrient or food for overall good health or health-related well-being (e.g. ‘Healthy stomach’ or ‘Healthy heart’) may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14. That means an unspecific health claim related to an Article-13 claim can only be used after the Article-13 list has been established, which will be on 31 January 2010 at the latest. Unspecific claims related to Article-14 claims can be used when the particular Article-14 claim enters the Article-14 list, which will be updated continuously.

According to Article 1 (3) a trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food, which is constructed as a nutrition or health claim may be used without undergoing authorisation procedures provided for in the Regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising, which complies with the provisions of the Regulation. Thus, the rules for such claims correspond to the rules for general unspecific claims referred to in Article 10 (3). Trademarks or brand names that were on the marked before 1 January 2005 but do not comply with the Regulation can be used until 19 January 2022 according to Article 28 (2). However, this transitional measure does not apply to fantasy names. They must comply with the Regulation from 1 July 2007.

According to Article 28 (1), foods placed on the market or labelled prior to 1 July 2007, which do not comply with the Regulation, may be marketed until their expiry date, but not later than 31 July 2009.

References to EU and individual countries' legislation, regulation or guidelines

Important EU legislation in relation to use of claims on foods and food supplements:
Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of feedstuffs.
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2000/l_109/l_10920000506en00290042.pdf

Regulation of the European Parliament and of the Council (EF) no. 178/2002 of 28th January 2002 on general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2002/l_031/l_03120020201en00010024.pdf

Directive 2002/46/EF of European Parliament and of the Council on 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2002/l_183/l_18320020712en00510057.pdf

Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_012/l_01220070118en00030018.pdf

Finland
Guide for the Control of Health Claims. National Food Agency Finland, 2002. In English only. http://www.palvelu.fi/evi/files/55_519_269.pdf (or find the document at the page "Guidebooks in English" http://www.palvelu.fi/evi/evi_material.php). The guide includes a description of proof of different types of (health) claims.

Valvonta 8/2000. Kolesteroliväitteiden valvontaopas. Elintarvikkeiden pakkausmerkinnöissä ja muussa markkinoinnissa käytettäviä veren kolesteroliin viittaavia väitteitä koskeva opas. Helsinki 2000. In Finnish only. Guidelines for health claims about cholesterol.

Misleading claims are discussed in detail in the National Food Agency's brochure "Humbug or not". www.elintarvikevirasto.fi/julkaisut.html

Homepage of Finnish Heart Association http://sydanmerkki.navigo.fi. In Finnish with Swedish and English summary. Guidelines for the use of the Heart Symbol: The Heart Symbol Food Certification Label, Principles of issue and use, December 2005, can be obtained from the Finnish Heart Association.

Sweden
Guidelines on all types of health claims can be found at the home-page of Swedish Nutrition Foundation www.snf.ideon.se in both Swedish and English version.
Link to front page in English from where you have access to guidelines on Nutrient function claims, Reduction of disease risk claims, and Product-specific physiological claims:
http://www.snf.ideon.se/snf/en/rh/Healh_claims_FF.htm

The website of the Code (in Swedish) http;//www.hp-info.nu

The following papers are central:
Health claims in the Labelling and Marketing of Food Products. The Food Sector's Code of Practice (pdf).

Reduction of disease risk claims, allowed connections:
http://www.snf.ideon.se/snf/en/rh/Generic_claims.htm

Asp N-G, Trossing M. The Swedish code on health-related claims in action – extended to product-specific physiological claims. Scan j Nutr 2001;45:189-92.
http://www.snf.ideon.se/snf/en/rh/PFP.htm

Asp N-G, Bryngelsson S. The Swedish Code on health claims for foods – revised version in action September 2004. Scand j Nutr 2004;48:188-189.

Glycaemic Index (GI). Simplified evaluation and criteria fro health claims referring to effect on postprandial blood glucose levels, determined as glycaemic index (GI).
http://www.snf.ideon.se/snf/en/rh/GI_en.htm

Denmark
Guidelines on health claims: Vejledning om sundhedsanprisninger. Levnedsmiddelstyrelsens vejledning af juni 1993, 01/06/93.

Departmental Order on Food Supplements: Bekendtgørelse om kosttilskud, bkg. nr. 683 af 21. juli 2003.

Guidelines on food supplements: Vejledning om kosttilskud. Fødevarestyrelsen, Oktober 2006
http://www.foedevarestyrelsen.dk/Ernaering/Kosttilskud/Vejledning_om_kosttilskud/forside.htm
Choose "Vejledning om kosttilskud" at the right side. In Danish.

Mejborn H, Ovesen L (eds.). Sundhedsanprisning af levnedsmidler – det faglige grundlag og forslag til vilkår for anvendelsen af sundhedsanprisninger. FødevareRapport 2000:24, Fødevaredirektoratet, Søborg. In Danish.
http://www.foedevarestyrelsen.dk/FDir/Publications/2000024/Rapport1.asp

A (shorter) version in English is:
Mejborn H, Dragsted LO, Dyerberg J, Koch B, Poulsen M, Trolle E, Ovesen L. Guidelines and conditions for use of health claims in Denmark. Scan J Nutr 2001;45:35-9.

Norway
Forskrift 21. desember 1993 nr. 1385, Merkeforskriften, §5.

Forskrift 21. Desember 1993 n. 1386, Næringsdeklarasjonsforskriften.

Guidelines for documentation of nutrition and health claims on foods.
Retningslinjer for dokumentasjon ved bruk av ernærings- og helsepåstander på næringsmidler.
Mattilsynet, November 2005. In Norwegian.
http://www.mattilsynet.no/regelverk/veiledere/mat/retningslinjer_for_dokumentasjon_ved_bruk_av_helsep_stander_p__matvarer_28872

Syse-rapporten, with classification (A, B, or C) of several hundred claims within many health conditions can be found at http://www.odin.dep.no/filarkiv/108029/Syseutredningen.pdf In Norwegian.

Report “Helsepåstander og matvarer” (Health claims and food) in Norwegian, can be found at http://www.tidsskriftet.no/lts-pdf/pdf2004/1251-2.pdf.

Iceland
Guidelines for use of nutrition claims and nutrient function claims. In Icelandic.
http://www.ust.is/matvaeli

Estonia
Food Act, available in Estonian at https://www.riigiteataja.ee/ert/act.jsp?id=12769928; can be found also in English at http://www.legaltext.ee/en/andmebaas/ava.asp?m=022, although the latest version might not be available.

Labelling is in general covered by Regulation of Government No 324 of 19 December 2003, available in Estonian at https://www.riigiteataja.ee/ert/act.jsp?id=966146.

Food supplements are covered by Regulation of Government No 165 of 30 April 2004, available in Estonian at https://www.riigiteataja.ee/ert/act.jsp?id=12756007.

Latvia
Lithuanian Agricultural and Food Products Market Regulation Agency www.litfood.lt.

State Food and Veterinary Services of the Republic of Lithuania www.vet.lt.

Database of the registered food supplements. In Latvian. http://www.pvd.gov.lv/?sadala=894&id=2875

Lithuania
No links have been found.

National Food Institute
Technical University of Denmark
Mørkhøj Bygade 19
DK - 2860 Søborg
Denmark

P: +45 72 34 70 00
F: +45 72 34 70 01
www.food.dtu.dk

ISBN: 978-87-92158-13-0