Functional Food, Nutrition and Health Claims:

Focusing on the EU Proposal for a Regulation on Nutrition and Health Claims made on Food
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Executive Summary

This report describes two subcategories of food – conventional food and dietary supplements – which contain nutrients that affect human health and may reduce the risk of diseases. This type of food is known as “functional food”. The paper presents functional food, nutrition and health claims made on them, and the problems occurring from introducing such food on the market, looking from two perspectives – marketing and law.

The paper shows the legal framework – regulations and directives – regarding functional food, nutrition, and food supplement. The main focus is placed on the proposal for a Regulation on nutrition and health claims made on food, and the likely outcome from implementing such proposal in the EU. Reviewed legal literature shows that there is two articles, which are mostly debating in the EU – article 4 “Nutrient profile” and article 11 “Restricted or implied claims”. Reviewed literature and interviewed law makers at the EU Institutions lead to the conclusion that article 4 of the proposed Regulation is likely to be kept, and article 11, if not deleted, it could be changed stating that even restricted health claims could be allowed if they are scientifically substantiated. Because proposed Regulation doesn’t have provision on marketing food directed at children, this could be included in article 11 “Restricted claims”, or it could be provided in a separate article.

For the practical presentation, the report shows few examples regarding functional food based on case law. Based on theory – legal framework – the paper evaluates the claims made on six different categories of food enriched with fish oil Omega-3: tuna salad, minced fish meat, bacon liver paste, whole grain bread, yoghurt drink, and muesli bar.

The nutrition claim: "The new (X food) with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis (X food) with Omega-3 in all cases is a good nutrition and it helps with good life” could be made for tuna salad, minced fish meat, bacon liver paste, and whole grain bread. However, some improvements are still needed.

The health claim: “The new (X food) with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. A high content of Omega-3 DHA fatty acids has a big influence on the brain” could be made for yoghurt drink. However, the claim has to be improved. Since muesli bar contains chocolate, it is not likely to bear a health claim.
1. Introduction

The interest of foods, which may be used as a part of a healthy diet, dates nearly 2500 years ago, when Hippocrates said “let food be the medicine and medicine be thy food”.¹ There are two subcategories of food – conventional food and dietary supplements. Conventional foods are consumed for their sensory appeal (e.g. smell, taste, aroma) and nutritional value. As a result of better science and innovative food products today can be used to achieve health benefits beyond basic nutrition. Dietary supplements are also used by consumers with the goal of achieving particular health benefits.

Unsurprisingly, the future of food will increasingly be about how it affects human health and well-being and the sorts of products and ingredients that will deliver such health benefits. This idea was termed “functional food”.² The following definition of functional foods is simple as: *Functional foods are foods or dietary components that may provide health benefit beyond basic nutrition.*³ The term itself was invented in Japan in the 1980s and the Japanese product “Fibe Mini” – a soft drink containing dietary fibre – was the world’s first functional food.⁴

As consumers become increasingly concerned about what is in the food they buy and eat, and the information contained on the label, it has become important for legislators and producers how to label food products in a legal and understandable way, what should be included on food label, etc. So far, there is no legislation in the EU that regulates such claims. Therefore the Commission has made a proposal for a Regulation on nutrition and health claims made on food⁵. The objective of proposed Regulation is two folds: to protect consumers’ interest, and to ensure fair trade within the Community. One knows that consumers make their choices based on labels on the products. However, not all consumers can comprehend with the information stated on the label; people vary in their ability to process information.⁶

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¹ Hasler, C.M., *Functional Foods: Their Role in Disease Prevention and Health Promotion*, June 1999 (the US Guidelines concerning nutrition issues, public health issues, food safety, etc. on-line: www.nutriwatch.org)
³ International Food Information Council (IFIC), *Background on Functional Foods*, May 2004.
⁵ COM (2003) 424 final
In September 2005 the European Consumers’ Organization, BEUC, has conducted a survey regarding consumers’ understanding of nutrition and food labelling. Consumer study finds that consumers make choices based on incomplete information. The survey results argue that most consumers pay more attention to and claim to understand better the marketing claims on the pack (“rich in calcium”, “sodium free”, “fat free”, and “light”) of the product than the basic nutritional tables show on some packs. In order to protect consumers’ interest and that they could make free and informative choice of a food product, it was necessary to have regulation that governs claims made on food.

Producers sometimes use claims, which cannot be scientifically substantiated or cannot be verified, or contain only a partial truth regarding the health effects on food products. For example, “purifies your organism” or “helps your body resist stress”. These claims may mislead consumers. In order to prevent such claims, the Commission has made a proposal for a regulation on nutrition and health claims.

Shortly, there are three major factors that gave necessity for the implementation of the proposal for the EU Regulation on Nutrition and Health Claims. Firstly, in the EU there is no harmonization of nutrition and health claims; they are dealt with at each national level. This Regulation would harmonize the market within the Community. Secondly, consumers are becoming more conscious about nutrition and health benefits. Proposed Regulation would allow consumers to make informative choice of a food product. Thirdly, producers provide nutrition information and claims on products’ labels. There are many unsubstantiated health claims on the labels; proposed Regulation could avoid such claims and ensure fair competition.

The objective of this paper – Master’s thesis – is two folds concerning marketing and legal issues: (1) to give better understanding about functional food – what it is, what the barriers are, and what to consider while introducing functional food on the market; (2) to present food legislation on nutrition and health claims, and on dietary supplements, mainly proposed Regulation on nutrition and health claims made on food – what are the outcomes of the implementation of proposed Regulation.

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7 BEUC press release: Consumers rely on marketing claims when buying food, 1 September, 2005 (News, Policy Positions & EU Actors online: www.euractiv.com), or Report on European Consumers’ Perception of Foodstuffs Labelling, 31 August, 2005 (BEUC/X/032/2005). Subtracted results are shown in Appendix 2 to this paper.  
8 Ibid.
The structure of the report is the following: Chapter 2 presents two main issues that EU nutritional policy covers, namely food safety and nutrition and foodstuff labelling. Nutritional and health claims definitions are included. Chapter 3 shows the Japanese and American markets as well as West European market. The main emphasis is placed on Danish market for functional food. The EU legislation on nutrition and health claims made on food is presented in Chapter 4. There is also shown the comparison between the EU proposed regulation and the US Scheme on nutrition and health claims. Chapter 5 describes the examples of functional food based on case-law. Chapter 6 presents and evaluates examples of fish oil Omega-3 PUFAs\(^9\) enriched food. Chapter 7 discuss the necessity of introducing functional food on the Danish market, as well as foods, for which health claims may be restricted. It tries to draw the line between substantiated-, partially substantiated- and un-permitted health claims. Chapter 8 sums up and gives recommendations.

Figure 1 shows the flow and structure of this paper.

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Figure 1: The structure of the report

- Problem statement
- Delimitations
- Methodology
- Concepts of nutrition and health claims
- Food Safety
- Nutrition and Foodstuff Labelling
- The US, Japan, and the EU
- Overview of the proposed Regulation
- Comparison between the EU and US legislations
- Danish national legislation on foods and claims made on foods
- Benecol, Kellogg, Novartis’s Aviva

- The outcomes of the implementation of proposed regulation on nutrition and health claims made on food
- For which foods the use of health claims will be restricted
- Secondary data – EU legislation, books, articles, web sites, research papers; and comparative analysis (EU and US food legislations); personal interview
- European Food Safety Authority
- Food Hygiene and Food Additives
1.1. Problem Statement

Nutrition and health claims can be made only for foods, which have health benefits to consumer. Since there is no legal definition regarding functional food in the EU legislation, some sources will be reviewed; thus, giving a better understanding:

- **What is “functional food”, nutrition and health claims? What does the EU nutrition policy cover?**

The need for functional food or nutrition in the EU becomes increasingly important in the food industry, since consumers are becoming more aware of what they eat, and the relationship between food and health effect. This is because of increase in elderly, obesity problem; consumers become more educated, are more open to innovation and new technology, have higher income and are concerned of reducing the risk of disease and to maintain in good health through improving the life style and eating habits. Thus, this paper will look closer at:
• What are the benefits of functional food (e.g. Omega-3 enriched foods) and why it is necessary to introduce it on the Danish market? What are the main barriers of introducing such food on the market and how to avoid it?

In July 2003 the Commission has proposed a regulation on nutrition and health claims. The paper will introduce to this proposal and will try to give an answer:

• What are the most likely outcomes of the implementation of proposed EU regulation on nutrition and health claims? Where is the line between substantiated-, partially substantiated- and un-permitted health claims?

However, not for all kinds of foods health claims can be made. Therefore, the report will show:

• For which foods the use of health claims will be restricted?

1.2. Delimitations
From legal perspective, the main focus is placed on EU legislation on functional food, nutrition and health claims: (1) proposed Regulation on nutrition and health claims made on food; (2) Labelling Directives, i.e. Directives on general labelling requirements of foodstuffs, on food supplements, and on nutrition; (3) Directives on food safety, i.e. Directives on food hygiene and on food additives. Any other legislation concerning food and nutrition are out of the scope of this paper.

From marketing perspective, the main focus is placed on the Danish market for functional food. Other Member States are excluded from the report. The US and Japan experiences are described, since Japan is the first country, which has defined functional food and its benefits on human health, and the US has issued regulations concerning the functional food.

For practical presentation, examples of claims for food enriched with fish oil Omega-3 are described, guiding the reader through those examples’ legal evaluation.

1.3. Methodology
There will mainly be used secondary data: (1) EU legislation (EC Treaty, regulations, directives, legal notes, etc.) regarding nutrition and health claims; (2) relevant articles, books, and press-releases concerning functional food / nutrition / health policy; (3) comparative analysis: between the
US legislation regarding nutrition and health claims, and the Proposal of EU Regulation on Nutrition and Health Claims made on Food. Also there will be used personal interviews via e-mail with members of the EU Institutions concerning nutrition and health issues.

2. EU Nutrition Policy

The fundamental principle in the EU policy on nutrition and health claims is the protection and promotion of public health. The EU Commission states that the objective of a nutrition policy is to improve the health and quality of life of the population, and to reduce the risk of diseases by promoting healthy diets and lifestyles.\textsuperscript{10} Thus, the Commission made the White Paper on Food Safety where the main issues with regards to the EU nutrition policy are presented.

There are two issues, which the EU Nutrition Policy covers and what should be considered by producers and food operators when introducing functional food on the market. The first aspect is safety food, meaning that the food purchased should not injure human health. The Commission has issued Regulation 178/2002 laying down the general principles and requirement of food law, establishing the European Food Safety Authority (EFSA). The primary task of EFSA is to assess the risk, and to communicate on food safety issues, including controlling and monitoring through out the food chain.\textsuperscript{11}

The second aspect is that claims made on food should be correct, true, and not misleading. Therefore the EU Commission laid down the provisions in Directives on nutrition labelling, and foodstuff labelling in order to promote a fair competition and give a freedom to consumers to make their informative buying decisions.

These two issues are described in the following sub-chapters. However, before turning into that, it is necessary to understand what functional food, nutrition and health claims is about.

\textsuperscript{10} The European Commission: \textit{Status report on the European Commission’s work in the field of nutrition in Europe}, 2003, p. 21
\textsuperscript{11} OJ L31, 01/02/2002
2.1. Concepts of Functional Food, Nutrition and Health Claims, and Food Supplements

Claims can be made only for foods, which are ready for consumption. Article 2 of Regulation 178/2002 defines food as any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by human. “Food” includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. The same article states that feed, live animals, plants prior to harvesting, medical products (…) should not be considered as food.

Functional foods have not yet been defined by legislation in the EU. The American Dietetic Association defines functional food as food that has health benefit beyond the nutrients it contains. The European Food Information Council suggests similar definition of functional foods: foods which are considered to be consumed as part of the normal diet and that contain components, which offer the potential of enhanced health or reduced risk of disease. “Functional food” can refer to whole foods, to fortified, enriched or enhanced foods, and dietary supplements that have the potential to improve mental and physical well being and reduce the risk of diseases. Examples are Omega-3 enriched bread, and yoghurt fortified with Omega-3, and others.

Any claim can also be made for food supplements. Article 2 of Directive 2002/46/EC laying down provisions on food supplements, defines food supplements as foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms (...) designed to be taken in measured small unit quantities. Because of the form of food supplements and their beneficial health effects, food supplements are similar to medical products. Since claims cannot be made for a medical product, it is necessary to find a boundary between food and medical product.

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12 The main concepts used in this paper are summarized in Appendix 1.
13 OJ L31, 01/02/2002
14 Ibid.
15 Ibid.
16 American Dietetic Association: [http://www.eatright.org/Public/index_22810.cfm](http://www.eatright.org/Public/index_22810.cfm)
17 The European Food Information Council: [Backgrounder on Functional Foods (www.eufic.org)](http://www.eufic.org)
18 Food information on-line: [www.food-info.net/uk/ff/intro.htm](http://www.food-info.net/uk/ff/intro.htm)
Article 1 of Directive 65/65/EEC relating to medical products, states that **medical product** is *any substance or combination of substances presented for treating or preventing disease in human beings or animals.*\(^{20}\) The main difference between food and medical product is that the food cannot treat, mitigate, or cure any human disease. Human disease has been interpreted as any ailment, injury or adverse condition, whether of body or mind.\(^{21}\)

There is no legal definition on nutrition and health claims. Different sources describe claims differently. For example, David Byrne, the former European Commissioner for Health and Consumer Protection, defines **health claims** which state, suggest or imply a relationship between a foodstuff (or one of its constituents) and health.\(^{22}\) These claims would fall into two categories: 1) those that describe the role of a nutrient, or other substance, based on long-established and non-controversial science.\(^{23}\) For example, “Calcium is an essential nutrient for the development of healthy teeth and bones”.\(^{24}\) In other words, these claims are called functional/nutrition claims, and don’t need pre-marketing approval. 2) Other claims including those signalling a reduction of the risk of disease.\(^{25}\) For example, “Whole grain may keep your heart healthy” or “Fruit and vegetables consumption may help to reduce the risk of cancer”.\(^{26}\) These claims are so-called health claims. They require scientific evaluation and pre-marketing approval.

It is worth noticing that health claims should be supplemented by a general statement indicating the importance of a balanced diet and healthy lifestyle. For example, “Whole grain may help to keep your heart healthy, as part of a balanced diet and healthy lifestyle”.\(^{27}\) Shortly, such a statement will bring a benefit to the consumer, if he or she eats a balanced diet. On the other hand, claim “Whole grain may help to keep your heart healthy” will not bring a positive health effect if the consumer eats a lot of fat food.

\(^{20}\) OJ L 22, 9.2.1965, p. 369  
\(^{21}\) The European Food Information Resource Network (EuroFIR): [www.eurofir.net](http://www.eurofir.net)  
\(^{22}\) Byrne, D., *Health, Nutrition and Labelling*, SPEECH/03/87, Brussels, 19 February, 2003  
\(^{23}\) *Ibid.*  
\(^{24}\) *Ibid.*  
\(^{26}\) *Ibid.*  
\(^{27}\) *Ibid.*
**Nutrition claim** refer to any statement, other than nutrition labelling declarations, which declares or implies that a food contains, or has a high or low amount, of one or more nutrients. The examples of nutrients are proteins, fat, sugar, sodium, dietary fibre, vitamins and minerals. The examples of nutrition claims are “low fat”, “rich in vitamin C”, “sugar free”, etc. Chapter 2.3.2 “Nutrition labelling” below elaborates more on this matter.

To conclude: functional food is a health product (but not a medical product!), which primary use is for consumption as part of a healthy diet and which is found in a form of a food product.

### 2.2. Food Safety

The main objective of food safety is consumer’s protection. The EU food safety policy encompasses the whole of the animal and human food chain. It provides extensive legislation and outlines the responsibility of producers and suppliers in helping to ensure a safe quality of the food supply.

The Commission has made White Paper on Food Safety, which establishes European Food Safety Authority (EFSA). The EFSA is an independent body that works in close cooperation with various scientific agencies and institutions in EU member states providing independent scientific advice on food safety. It covers all stages of food production and supply, from primary production right through to the supply of food to consumers.

Thus, EFSA objective is to protect and promote health of consumers through controlling and monitoring food industry. It has to make sure, that additives or substances used in the food products are safe and not harm the consumers.

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28 The European Food Information Resource Network (EuroFIR): [www.eurofir.net](http://www.eurofir.net)

29 The European Food Information Council: *Backgrounder on Food Safety* ([www.eufic.org](http://www.eufic.org))
2.2.1. Food Safety Instruments

Food safety can be achieved by three complementary instruments: risk analysis, the scientific opinions, control and inspection.\(^{30}\)

**Risk analysis** comprises scientific evaluation of risks, assessment of the measures that reduces risks, communication of the risks to other parties like consumers, producers, and the decision-makers. The primarily purpose of risk analysis is the protection of the health of consumers. Risk analysis must be informed by the precautionary principle. The Commission stresses that the precautionary principle may only be invoked in the event of a potential risk. Hence this principle may only be invoked when the three conditions are met: identification of adverse effects, evaluation of the scientific data available, and the extent of scientific uncertainty.\(^{31}\) For example, even though a food product lawfully produced and sold in a Member State X, but if it is exported to a Member State Y, the authorities of the country Y may apply precautionary principle, meaning that they will not let the product to be sold on its home market, if that product is likely to injure consumers’ health.

Article 6 of Regulation 178/2002 provides with the rules on risk analysis. It states that risk assessment shall be based on the scientific evidence and undertaken in an independent, objective and transparent manner.\(^{32}\) Article 7 of this Regulation gives rules that in specific circumstances where the possibility of harmful effects on health is identified but scientific uncertainty persists, the risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted. Measures adopted shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community.\(^{33}\)

**The scientific opinions** are delivered by the scientific committees, and must satisfy the principles of excellence, independence and transparency. This means that opinions provided regarding food or nutrition must be independent, and to be accessible to the public. The Directorate-General for Consumer Policy and Consumer Health Protection has to act on the opinions delivered by the

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\(^{30}\) These three instruments are written based on legal note: Consumer health and food safety ([www.eu.int/scadplus/leg/en/lvb/132013.htm](http://www.eu.int/scadplus/leg/en/lvb/132013.htm)), or it will be stated otherwise.


\(^{32}\) OJ L31, 1.2.2002

\(^{33}\) Ibid.
scientific committees. Later these opinions are forward to the Directories that are responsible of drafting the legislative texts.

**Control and inspection** consists of introduction of risk assessment procedures, monitoring the entire food production chain, and auditing the national monitoring systems. This task is mainly done by the Food and Veterinary Office. However, the Commission stresses the need to ensure that rules relating to the internal market are implemented correctly and in good time.\(^{34}\) The Community’s role is to check that the requisite controls are being performed in an equivalent and effective manner throughout the internal market.

Directive 89/397/EEC gives provisions on the official control of foodstuffs.\(^{35}\) The competent authorities control foodstuffs, food additives, vitamins and minerals, and other nutrients used in the food products throughout the Community.

### 2.2.2. Food Safety Legislation

There are several regulations and directives on food safety in the EU. However, two directives are of key interest to food manufacturers, since they list the authorised food additives (e.g. sweeteners, colours, and others), the foods in which these additives may be used and maximum use levels. These two Directives are presented bellow:

- Directive 93/43/EEC on the hygiene of foodstuffs,\(^{36}\) known as the General Food Hygiene Directive;

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\(^{34}\) The EU web-site, *Green Paper: The general principles of food law in the EU* ([www.eu.int/scadplus/leg/en/lvb/121220.htm](http://www.eu.int/scadplus/leg/en/lvb/121220.htm))

\(^{35}\) OJ L186, 30.6.1989

\(^{36}\) OJ L175, 19.7.1993

\(^{37}\) OJ L40, 11.2.1989
The General Food Hygiene Directive (93/43/EEC)

The Directive lays down general rules on hygiene and procedures. It covers the preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of foodstuffs to be carried out in a hygienic way (Article 3). This Directive controls most retailers, caterers, the production and supply of all foods that are not of animal origin. Article 3(2) deals with risk management and Article 3(3) requires food business to meet the specific hygiene rules, which are laid down in the Annex to this Directive.

Article 5 allows the industry to issue the guides of good hygiene practice. If a national competent authority believes that such a guide meets the requirements of Article 3, it must forward to the European Commission. The European Commission will make it available to the other member states.

Article 7 allows member states to introduce national hygiene legislation that exceeds the requirements in the Directive provided they do not restrict or hinder intra-community trade in relevant food.


Directive 89/107/EEC contains general safety and authorizing measures concerning food additives. The definition of “food additives” is the following:

“any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods”.

Substances used as nutrients (e.g. vitamins and minerals) in foodstuffs are not regarded as additives. Annex I to this Directive contains a list of additive categories. Annex II sets out general criteria concerning technological need for, safety and use of food additives. Additives may only be used for certain purposes including improvement of keeping quality and stability of food and to aid in the
manufacture, processing and treatment of food.\textsuperscript{38} The approval for food additives must specify the foodstuffs, to which additives may be added and the conditions of their use, be limited to the lowest level of use needed to achieve the intended effect and take account of any acceptable daily intake.\textsuperscript{39} Intake of additives by special groups of consumers must also be considered.\textsuperscript{40}

This Directive makes provision concerning detailed lists of authorized food additives, conditions and limitations of their use. There is a specific requirement that provisions affecting public health are referred to the Food Scientific Committee. Articles 7 and 8 of this Directive give provisions on requirements for the labelling of additives.

The Directive also prescribes some general requirements for the food use of flavourings. More specific requirements are covered by Directive 88/388/EEC on flavourings used in foodstuffs.\textsuperscript{41} Food additives such as sweeteners and colours fall under specific Directive, i.e. Directive 94/35/EC\textsuperscript{42} and Directive 94/36/EC\textsuperscript{43}, respectively. The list of permitted sweeteners and the list of authorised colours are provided in the Annexes to these Directives.

Other additives than sweeteners and colours, are covered by Directive 95/2/EC\textsuperscript{44}. These additives are antioxidants and preservatives, and others, also additives used in food for infants and young children. They are very strictly controlled.

To conclude: with regards to food safety issues there have to be considered (1) Regulation 178/2002 laying down the general principles and requirement of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as well as (2) Directive 93/43/EEC on general food hygiene, and (3) Directive 89/107/EEC on safety requirements regarding food additives.

\textsuperscript{39} Ibid.
\textsuperscript{40} Ibid.
\textsuperscript{41} OJ L184, 15/07/1988, p. 61-66
\textsuperscript{42} OJ L237, 10/09/1994, p. 3-12
\textsuperscript{43} OJ L237, 10/09/1994, p. 13-29
\textsuperscript{44} OJ L61, 18/03/1995, p. 1-40
2.3. Food Labelling

Another issue that EU nutrition policy covers is nutrition and foodstuff labelling. It aims at improving consumer’s choice through the label on food. Because the buying behaviour is mostly determined by package and label on the product, the authorities have to make sure that a claim stated on the product is true, correct, understandable, and not misleading. This is a challenge for marketers and food operators – how to communicate health benefits to the consumers in understandable, acceptable, and legal way. In this respect the EU food labelling legislation plays an essential role.

There are mainly three Directives, which govern labelling issues – Council Directive 90/496/EEC on nutrition labelling,\(^{45}\) Directive 2000/13/EC of the European Parliament and of the Council relating to the labelling, presentation and advertising of foodstuffs,\(^{46}\) and Directive 2002/46/EC relating to food supplements.\(^{47}\) Since food manufactures have to comply with Labelling Directives – what requirements food or food supplement must meet before placing it on the market; thus, these Directives are essential and their detailed presentation is given bellow.

2.3.1. Foodstuff Labelling

Directive 2000/13/EC concerns the labelling of foodstuffs to be delivered as such to the ultimate consumer; it gives provisions on generally food additives that are used in the manufacture of food products. It applies also to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers.

The key principles of Directive 2000/13/EC are:\(^{48}\)

- To contribute to the smooth functioning of the internal market by removing impediments to few circulation of products and equal conditions of competition;
- To inform and protect the consumer;
- To prohibit the use of information that might mislead the purchaser.

\(^{45}\) OJ L276, 6/10/1990, p. 40
\(^{46}\) OJ L109, 6.5.2000, p. 29
\(^{47}\) OJ L183, 12.7.2002, p. 51
\(^{48}\) Goodburn, K. (2001), *EU Food Law*, Woodhead Publishing Limited, p. 120
The labelling, presentation and advertising of foodstuffs must not mislead the consumer, and should not attribute to foodstuff properties for the prevention, treatment or cure of a human illness. All foodstuffs must carry labelling that contains certain minimum information. Any additional information is subject to the principle that it should not mislead the consumer. Article 3 gives labelling requirements for foodstuff:

(a) The name of the food;
(b) The list of ingredients;
(c) The net quantity;
(d) Minimum durability;
(e) Any special storage conditions or conditions of use;
(f) The name and address of the manufacture or of a seller;
(g) Instructions for use when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions;
(h) Alcoholic strength by volume for beverages containing more than 1.2% by volume.

The name of the food
The name in the member state where the food is produced is given equal status to the name of that food in the member state where it is marketed. It should enable consumers to know the true nature of the food. The name cannot be the brand or fancy name nor the trade mark used on the label. If the food has been treated or its physical condition has been changed (e.g. dried, concentrated or frozen) this must be indicated in the food name, if omission of such information would confuse the consumer.

The list of ingredients
The list of ingredients must show all ingredients in descending order of weight (greatest first), and quantity or categories of ingredients expressed as a percentage. However, ingredients need not be listed in the case of fresh fruit and vegetables, water, cheese, butter, milk, and products comprising a single ingredient. Directive defines “ingredient” as any substance that is used in the manufacture or preparation of the food and is still present in the finished product. It includes additives; however, if an additive does not perform a significant technological function in the final product, it need not be identified in the ingredients list. A compound ingredient may be included in the list under its own name and in terms of its overall weight, provided that its name is immediately followed by a
list of its own ingredients, unless it constitutes less than 25% of the product. The 25% rule exemption does not apply to those additives in a compound ingredient which serve a technological function in the final food, which must all be listed. Categories of ingredients are listed in Annex I and Annex II to this Directive (2000/13/EC).

**Net quantity**
In the case of pre-packaged foodstuffs, net quantity should appear on the food label. The net quantity must be expressed in units of volume (for liquids) or mass (for other products), unless EU or national provisions lay down that some other type of quantity is required. More detailed requirements on net quantity are laid down in Council Directives 75/106/EEC relating to the making-up by volume of pre-packaged liquids, and 76/211/EEC relating to the making-up by weight or by volume of pre-packaged products.

**Minimum durability**
Directive defines date of minimum durability as the date until which the foodstuff retains its specific properties when properly stored. It should be indicated “best before”. If foodstuffs are highly perishable, should be stated “use by” date. The durability date is not required for fruit and vegetables, soft drinks and juices, beverages containing 10% or more by volume of alcohol, salt and sugar, bakers’ wares, and chewing gums.

**Other requirements**
Directive gives provisions on any special storage conditions or conditions of use. On food label should appear the name and address of the manufacture or of a seller as well as instructions for use when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions. The minimum mandatory information on labels should be in a language easily understood by the consumer.

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50 Ibid.
Every Member State may use safeguard measures, meaning that the marketing of foodstuffs can only be prohibited if it can be justified, under Article 30 of the EC Treaty, on the grounds such as the protection of public health, or the protection of industrial or commercial property.

The Directive prevents member states from imposing other mandatory information unless this has been authorised at EU level.

2.3.2. Nutrition Labelling

Nutrition information helps consumers to make an informed choice about the products presented to them. Particularly if diet and health are important to the consumers; nutrition information may be a deciding factor between purchasing the product and leaving it on the shelf. Directive 90/496/EEC gives provisions on nutrition labelling of foodstuffs. The standardised format of nutrition labelling within the Community makes easier for consumers to compare one product with another. The principles underlying EU legislation on nutrition labelling are consumer information and education, and the removal of technical barriers to trade.⁵³

The main objective of Directive 90/496/EEC is to lay down rules on nutrition labelling in order to ensure free movement of foods in the EU while guaranteeing consumer protection. Its legal basis is Article 95 of the EC Treaty, providing an internal market measure and avoiding technical barrier to trade. The key principle is to assist the consumer in choosing foods appropriate to a healthy diet. The rules are applicable to all foods and drinks for the ultimate consumer and for mass caterers (e.g. restaurants, hospitals, canteens, etc.). However, this Directive is not applicable to waters intended for human consumption, as well as to diet food supplements. Article 1 defines “nutrition claim” as any representation and any advertising which states or implies that a food has particular nutrition properties. “Nutrients” are proteins, fat, dietary fibre, vitamins and minerals, and other nutrients listed in the Annex to this Directive.

Nutrition labelling is not compulsory unless a nutrition claim or health claim appears on labelling, presentation or advertising of a product. The Directive prohibits any nutrition claims that do not relate to energy. The information on the label shall contain either Group 1, which states the energy value (in kJ), and the amount of protein, carbohydrate and fat (in grams); or Group 2, which states

the energy value (in kJ), and the amount of protein, carbohydrate, sugar, fat, saturated fatty acids, dietary fibre and sodium (in grams), and be given in tabular form with numbers aligned. Which group to use, it depends on nutrition claim made on food. For example, if a claim is made that a product is “low in fat”, Group 1 information must be given. If a claim “saturated fat” is made on the product, Group 2 information must be provided. However, if a claim is made that green vegetables are low in fat, it is not necessary to include the nutrition information.

The energy value and amount of nutrients on the label shall be given in figures. The information shall be expressed per 100g or per 100ml per package and may be expressed also per serving or per portion of the product. Information on vitamins and minerals must be expressed not only per 100mg/ml but also as a percentage of the recommended daily allowance (RDA). Table 1 presents vitamins and minerals, and their recommended daily allowance.

Table 1:  
*Vitamins and minerals, and their recommended daily allowance*

<table>
<thead>
<tr>
<th>Vitamins and minerals</th>
<th>RDA</th>
<th>Vitamins and minerals</th>
<th>RDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>800 µg</td>
<td>Folacin</td>
<td>200 µg</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>5 µg</td>
<td>Biotin</td>
<td>0.15 mg</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>10 mg</td>
<td>Pantothenic acid</td>
<td>6 mg</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>60 mg</td>
<td>Calcium</td>
<td>800 mg</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>2 mg</td>
<td>Phosphorus</td>
<td>800 mg</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>1 µg</td>
<td>Iron</td>
<td>14 mg</td>
</tr>
<tr>
<td>Thiamin</td>
<td>1.4 mg</td>
<td>Magnesium</td>
<td>300 mg</td>
</tr>
<tr>
<td>Riboflavin</td>
<td>1.6 mg</td>
<td>Zinc</td>
<td>15 mg</td>
</tr>
<tr>
<td>Niacin</td>
<td>18 mg</td>
<td>Iodine</td>
<td>150 µg</td>
</tr>
</tbody>
</table>


All nutrition information should be presented on the label in a clearly visible place and in language easily understood by the consumer. If there is not enough space on the product, the nutrition information should be given in the leaflets. Member States shall not introduce more detailed nutrition labelling specification than those contained in this Directive.
2.3.3. Food Supplements Labelling

Directive 2002/46/EC lays down specific rules for food supplements such as vitamins and minerals. Preamble of this Directive states that only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be presented in food supplements although this doesn’t mean that their presence therein is necessary.\textsuperscript{54} Annexes I and II to this Directive establish a list of vitamins and minerals, and their substances, respectively, which may be used in the manufacture of food supplements.

This Directive shall not apply to medical products. Article 2 of the Directive gives definitions on “food supplements” and “nutrients” as the following:

(a) “Food supplements” means foodstuffs the purpose of which is to supplement the normal diet and which concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form such as capsules, pastilles, tablets, pills and other similar forms (…)

(b) “Nutrients” means the substances such as vitamins and minerals.

Excessive intake of vitamins and minerals may result in adverse effects; therefore it is necessary to set up the maximum safe level. Article 5 provides that maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacture shall be set, taking the following into account:

- Upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account the varying degrees of sensitivity of different consumer groups;
- Intake of vitamins and minerals from other dietary sources.

On the nutrition labels should appear (Article 6):

(a) The name “food supplement”;

(b) The name of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances;

(c) The portion of the product recommended daily dose;

(d) A statement that food supplements should not be used as a substitute for a varied diet;

\textsuperscript{54} OJ L183, 12.7.2002
A statement that the products should be stored out of the reach of young children;
Nutrition label must not attribute to food supplements the property of preventing, treating or curing a human disease.

2.4. Conclusion on EU Nutrition Policy
In this chapter the main issues concerning EU Nutrition policy has been presented. These are food safety, and nutrition and foodstuff labelling. The main Directives with regards to food safety and labelling were reviewed. Figure 2 shows the relationship of food safety instruments and their responsible bodies.

Figure 2: Food safety instruments and their responsible bodies
3. Markets for Functional Food

The previous chapter has introduced to the concepts of functional food, nutrition and health claims; and it has addressed the main issues – food safety and food labelling. However, having functional food on the market is worth nothing if there is no demand for it. The proceeding chapter will look at three largest markets for such food – Japan, the US, and the EU. Japan is the first country, which has found the relationship between food and human health. The US has issued legislation on functional food. It is interesting to have a closer look at their experiences. The US and Japan markets are described based on Euromonitor survey.

In the EU, the main focus will be placed on Danish functional food market. It will be done with the help of research papers and articles.

3.1. Japan

Japan was the first country to permit health claims for foods with added functional ingredients, and it is the largest market in the world for functional foods, with sales of US$11.7 billion in 2003 and still it is expected to grow. This is because that Japan has well-established regulatory system, government supports research of functional food development, and Japanese market is more diverse and innovative compare to other countries. In Japan consumers are more open to experimentation. Japan has a fast ageing population, with 25% of the population expected to be above the age of 65 by 2010. This offers strong potential to the development of functional foods aimed at this age group, since most illnesses increases with age.

Diversity is a notable feature of the market. Important product categories include probiotic dairy products and functional drinks. Many products are focused on cholesterol reduction while dietary fibre, oligosaccharides, calcium and the fatty acids are also common ingredients across a range of products.

Japan benefits from the permitting of health claims on some approved functional foods through the FOSHU system. The FOSHU system is unique because it focuses on health claims for specific

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55 Japan market for functional food is described based on Euromonitor survey, or it will be stated otherwise.
56 FOSHU stands for Foods for Specified Health Use. FOSHU is a group of food for which health claims were legalized.
products. Approved products are permitted to make health claims on product labels. Previously a complex and time-consuming procedure, revisions in 1997 have made the licensing system much more simple – individual ingredients are licensed, rather than individual products. Now almost half of all functional food products in the market bear the FOSHU symbol. In order for a product to be approved as FOSHU, companies need to go an application process that takes about one year to complete. Applications are submitted to local district authorities and the Ministry of Health and Welfare. Together with the applications, the applicant company has to include scientific documentations showing the nutritional basis for a health claim, the basis for the recommended dose of the functional ingredient, information demonstrating the safety of the ingredient, information on physical and chemical characteristics, and relevant test methods. The labels of FOSHU products must include the approved health claim, recommended daily intake of the food, nutrition information, and guidance on healthy eating, a warning against excessive intake, and any other special precautions relating to intake, preparation and storage. Companies can market functional food without obtaining FOSHU approval as long as they refrain from making claims that the product can reduce the risk of a disease or health related condition. For example, the claim “health supporting drink” doesn’t need FOSHU approval.

Japanese market also benefits from a positive consumer attitude towards functional foods, and from a widespread understanding of the health issues facing consumers due to government health campaigns. A lack of cynicism towards novelty foods has also allowed the market to develop, as consumers are interested in experimenting with new product types.

Functional foods offer Japanese manufacturers a rare opportunity to bolster margins, as consumers are generally willing to pay higher prices for these products. Therefore a large number of Japanese food manufacturers have diversified into this area.

The main markets for functional food are beverages and dairy products, mainly due to increased sales of functional sports drinks. These are particularly popular during the hot and humid summer season. Growth was largely driven by the launch of amino acid drinks such as Kirin’s Amino Supli, which promised not only hydration but also cosmetic benefits such as better skin and healthy eyes.

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Dairy products accounted for 29% of total value sales in 2003. Bakery products and snacks was the smallest sector in 2003, accounting for only 17% of total value sales.

Figure 3 depicts the market share distribution for functional food concerning three main food sectors – beverages, bakery products, snacks and dairy products.

Figure 3: *The market share for functional food in Japan, 2003*

![Figure 3: The market share for functional food in Japan, 2003](image)

Source: Euromonitor

3.2. **The US**

The US was the first country to enact a law allowing health claims for nutrients naturally contained in conventional foods; also it is the only country to allow health claims for dietary supplements. The US is the second largest market in the world for functional foods, with sales of over US$10.5 billion in 2003. This is mostly due to massive sales of functional beverages, with sports drinks and fortified juices. Functional foods account for around 3% of total food sales in the US, and is expected to double within 2003-2008 period. There are mainly the beverages sector, and bakery products and snacks that have the high market share for functional food, accounted for 84.4%, and 13% of value sales in 2003, respectively. The beverages industry is relatively mature and well established compared to the other sectors. The success of bakery products and snacks was achieved by changes in lifestyles rather than by active marketing. In the US the dairy products is small sector, which accounted for 2.5% of total value sales in 2003.

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59 The US market for functional food is described based on Euromonitor survey, or it will be stated otherwise.
Graphical presentation of the market share for functional food in the US is shown in Figure 4.

Figure 4: *The market share for functional food in the US, 2003*

Source: Euromonitor
Note: Numbers are rounded

A lot of American consumers believe that functional food is good for human health and well-being. Functional food is accepted not only by young consumers who are willing to try a new product but also by elderly. They feel a real need to build up their diet. However, it is worth noticing that taste is a very important criterion when selecting functional foods. This is a challenge for producers and researchers to find a way to add ingredients that should not distort the taste of a whole product. Perception of tasting differently may face a challenge in gaining consumer's acceptance. Health benefits alone are not enough, as consumers are not willing to sacrifice flavour for function.

American experience about functional food implies that there has been developed information transference channel, which allows consumers to get information about a new product and its benefits. In this respect, the media plays an essential role linking between food and diet, which makes the average consumer to be highly knowledgeable about health issues such as reducing cholesterol, etc. Trust in functional food was gained through improved packaging and labelling requirements. The Food and Drug Administration (FDA) allows claims for some ingredients to be made on packaging and in advertising, which has played a significant role in securing acceptance. Moreover, the US Government supports functional ingredients development.
3.3. The EU

The EU is the third largest market for functional food. Euromonitor survey shows that the functional food market in the EU is on the growth phase – between 1998 and 2003 growth rate was 60%, and between 2003 and 2008 is expected to grow by 40%. Consumers are buying most familiar functional foods such as beverages added with vitamins and vitamins enriched dairy products.

In the EU, the largest market for functional food is beverages. This is because consumers are less sceptical with regard to functional drinks – young consumers who purchase energy drinks are less concerned about health effect of this product. Dairy products market seems to promise a good market potential in the future since its market is predicted to grow by 6%. Bakery and snacks is expected to show slower growth than dairy products. This market includes medicated confectionery and functional chewing gum.

Among all EU member states, functional food markets vary significantly. The UK represented the largest market for functional food in the EU in 2003, with sales of $ 2625 million. German consumers are concerned about health and wellbeing; the market is expected to grow by 45% over the 2003-2008 period. In France, sales increase due to health awareness, communication of health benefits and innovation. However, it still remains a small market. Denmark, as it will be shown bellow, is the most restrictive country among all EU member states concerning functional food.

From the reviewed literature it can be concluded that it will take some time and effort in order to change Danish consumers’ attitude and buying behaviour for functional food. The reasons are the following:

(1) The majority of Danish consumers are conservative – they are not willing to try a new product. The research by Greens Analyseinstitut showed that 77% of Danish consumers are against of

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60 Euromonitor
61 Ibid.
62 Ibid.
63 Ibid.
64 Ibid.
65 Ibid.
66 Ibid.
enriched product, whereas only 21% would accept such foods. Joachim Scholderer, the professor at MAPP center, stated that for consumers it is the most important that food they buy taste good; they are not concerned about eating a healthy food. Charlotte Jacobsen, the researcher at MAFF, added that not only taste but also smell of food products are the main criteria, which influence consumers’ buying decision for food. That buying intention for functional food is mainly determined by convenience and taste, was also founded by Bech-Laesen, T., et al. in their study.

(2) The Danish consumers don’t trust and don’t believe that a product enriched with vitamins may help to feel healthy. Instead they are more willing to buy dietary supplements such as vitamins whenever they need them. Every second of the Danish adults (54%) takes vitamins.

Every third of Danish consumer is not interested in healthy food. According to BEUC survey, one third (33%) of Danish consumers don’t trust claims. The reason of not trusting the claim is that they cannot judge if the claim is true, or that they believe the claim could be misleading. This could be explained by the lack of information. Furthermore, Bech-Larsen, T., et al. found in their study that the more elaborated the claim, the more it affects consumers buying intention.

(3) People in Denmark consume a lot of milk and milk products. When a consumer drinks milk and takes food supplements enriched with calcium, which leads to the excess of calcium, this is not good for ones health. It is not healthy to intake the excess of any kind of vitamins or minerals. For example, risk of having breath cancer may increase for those people who have too much intake of vitamin C. Another example, fish oil Omega-3 capsules are good for brains and nerves; it reduces

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67 Axholm, A., Større åbenhed over for berigede fødevarer, Børsen, 13 September, 2004
68 Knudsen, J.W., Paradoksernes paradis, Børsen, 2 May, 2005
69 The news on Danish TV, DR1 Magazine Penge, 09 03 2006
71 Axholm, A., Større åbenhed over for berigede fødevarer, Børsen, 13 September, 2004
72 Bull, E., Hver tredje ligeglad med sund mad, Børsen, 9 August, 2004
73 BEUC, the European Consumers’ Organization: Report on European Consumers’ Perception of Foodstuffs Labelling, 31 August, 2005 (www.euractiv.com)
74 Ibid.
76 Note: during the last five years consumption for milk and milk products is decreasing due to obesity and overweight problem in Denmark (Source: Danish news on TV).
77 Iversen, C., Vitaminer i mad på dagsordenen i EU, Børsen, 8 Marts, 2004
risk to have cardiovascular disease. However, too much intake of Omega-3 may lead to health problems.

(4) The rules concerning functional food in Denmark are very strict, which makes more difficult for producers and food operators to comply with. It is interesting to note, that dietary supplements such as fish oil Omega-3 capsules are prohibited to produce in Denmark, whereas they are allowed to import from other countries and sell them on the Danish market. Furthermore, the consumers prefer Danish product to imported product. The main reason is that they are more confident about safety requirements if food is produced in Denmark than it is imported from other countries.

The development and acceptance of functional food, and the authorization procedure takes a lot of time; the costs of introducing such food are high, also strict Danish legislation regarding technical requirements hinders the imports of functional food on the Danish market.

(5) Danish consumers may perceive functional food being similar to genetically modified food (GMF or known as GMO – Genetically Modified Organism); and if consumers are against to GMF, they will also be against to functional food. Thus, enriched food will not be accepted by the consumers.

(6) However, concerning consumers’ perception of foodstuffs labelling, the survey showed that 86% of Danish respondents are interested in nutrition. According to BEUC survey, the most common sources of nutritional information are food labels, television, newspapers, magazines, and friends, whereas the Internet, doctors, and consumer advice services are the least popular. Although interested in nutrition, respondents didn’t read the nutritional information. Information such as price, best before, and brand name were the most read in the shop. Portion size and fat quantity

\[\text{Chapter 6 in this paper explores the advantages and disadvantages of Omega-3 PUFAs.} \]

\[\text{Knudsen, J.W., Nyt æg afvist af myndighederne, Børsen, 22 September, 2003} \]

\[\text{The news on Danish TV, DR1 Magazine Penge, 09 03 2006} \]

\[\text{Ibid.} \]

\[\text{Redder, H., Berigede fødevarer kommer til Danmark, Børsen, 28 September, 2001, and Redder, H., EU lægger pres på Danmark, Børsen, 7 April, 2003} \]

\[\text{This point (6) “Consumers’ perception of foodstuffs labelling” is presented based on BEUC survey, Report on European Consumers’ Perception of Foodstuffs Labelling, 31 August, 2005 (www.euractiv.com). Appendix 2 to this report presents the main findings of BEUC survey. Note: BEUC survey is described by using secondary/published data. There is no information whether the results are valid or significant. The aim to use BEUC survey was to show the Danish consumers interest and their attitude with regards to functional food.} \]
were read by over 50% participants. Information on sodium / salt and additives was not read by many interviewees. 60% of interviewees found the list of ingredients difficult to understand.

Two-thirds of respondents would like to see the presentation of nutritional table improved, with increased letter size and improved clarity; to use more commonly used terms. They would like to see on the front of pack whether fat, sugar, or salt levels are high, medium or low. The interviewees wanted to see nutritional information on the label such as fat, sugar, vitamins, cholesterol, minerals, energy value, protein, fibre, sodium/salt, saturated- and unsaturated fatty acids. 59% of respondents declared that nutritional claims (e.g. low in fat or sugar, high in vitamins or minerals, etc.) often caught their attention, and they read them. Over half of interviewees agreed that a claim would lead them to buy a product.

BEUC argues that consumers are not well informed about nutrition. Additionally, older people have more difficulties finding nutritional information on the label; they are less interested in nutrition compared to the other age groups. Women look more frequently than men at the list of nutrition information. Women are more familiar and can better comprehend with the labels on food products; also they go shopping more frequently than men. Bech-Larsen, T., et al. found in their study that women in general have a larger knowledge of the effect of enrichments than the men.

To conclude: despite these problems mentioned above, Denmark is a good market for functional food, since obesity is a big problem in Denmark and it is still predicted to increase. Therefore people become more interested in healthy lifestyle.

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84 Note: this figure (and also the following figures if it is not stated otherwise) includes all respondents in Germany, Denmark, Spain, Hungary, and Poland.

3.4. Conclusion on Markets for Functional Food

The US and Japanese markets for functional food are on the mature stage on their life cycle whereas European market is only on its growing stage. It implies that there are a lot of potentials and new opportunities for producers and marketers to introduce this product to the European citizens.

Table 2 summarizes the key success factors (or failures) in Japan, the US and the EU concerning functional food industry. Since the EU consists of 25 different countries with different consumer demands for functional food, the attention was paid to Denmark.
Table 2: The key success factors or failures – comparison between Japan, the US, and the EU (Denmark) concerning functional food

<table>
<thead>
<tr>
<th>Item</th>
<th>Country</th>
<th>Japan</th>
<th>The US</th>
<th>The EU - Denmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers’ attitude</td>
<td>Open to diversification and novelty; increasing demand for such food since the population is aging.</td>
<td>Consumers believe that functional food is good for health.</td>
<td>Conservative consumers, not ready for changes.</td>
<td></td>
</tr>
<tr>
<td>Products’ attributes</td>
<td>Promoted not only products’ health benefits, but also taste, convenience and price.</td>
<td>Taste is important; improved packaging and labelling requirements.</td>
<td>Convenient, flavour, affordable price, packaging.</td>
<td></td>
</tr>
<tr>
<td>Distribution channels</td>
<td>Functional food is positioned as mass product and it is sold through distribution channel like supermarkets.</td>
<td>Mainstream product, sold through various distribution channels, particularly supermarkets.</td>
<td>Supermarkets</td>
<td></td>
</tr>
<tr>
<td>Government’s role</td>
<td>Established government health campaigns, which leads to gain a positive consumer attitude towards functional foods, and to understand the health issues facing consumers. The government supports the research of functional ingredients.</td>
<td>Supports functional ingredients development; is in favour to promote health benefits of food products.</td>
<td>Reluctant to issue regulations that allow for manufactures to produce foods enriched with vitamins, since Danish consumers consume a lot of food supplements like vitamins; excess of vitamins may harm human health.</td>
<td></td>
</tr>
<tr>
<td>Legal system</td>
<td>FOSHU system, i.e. licensing of individual ingredients. Legal system is more flexible.</td>
<td>FDA allowance of claims on packaging and advertising. Legal system is more flexible. In the legislation are no restricted claims.</td>
<td>Legal system is strict; the approval process of claims is complex and lengthy.</td>
<td></td>
</tr>
<tr>
<td>Media</td>
<td>Media plays an essential role in reporting on their miraculous effect on health.</td>
<td>Developed information channel that gives consumers an opportunity to know about a new product and its benefits.</td>
<td>No particular attention to media.</td>
<td></td>
</tr>
</tbody>
</table>
4. EU Legislation on Nutrition and Health Claims

The previous chapters have presented the main markets for functional foods and what should be considered when a food product is about to be introduced on the market, i.e. safety and labelling requirements. The proceeding chapter will look closer at the legislation regarding nutrition and health claims at the EU level and at the Danish national level.

In the EU, foods are regulated by Regulation 178/2002 laying down the general principles and requirements of food law and laying down procedures in matters of food safety; Directive 2000/13/EC – on the labelling, presentation and advertising of foods; Directive 90/496/EEC – on nutrition labelling on foodstuffs. At international level Codex Alimentarius has adopted General Guidelines on Claims and Guidelines for the Use of Nutrition Claims. At national level there are national codes regarding food safety, good marketing practices, and health claims substantiation. For example, in Denmark foods are regulated by Lov om Fødevarer and the Marketing Practices Act. In the UK – British code provides the rules on authorization procedure, and others.

However, there is no legislation in the EU, which regulates nutrition and health claims. Claims for specific biological functions of nutrients such as “calcium aids in the development of strong bones and teeth”, “vitamin B6 is important for the maintenance of a healthy nervous system”, and claims relate to the amount of nutrients components in a food such as “low energy” or “sugar free” are regarded as nutrition claims and are permitted under food law.86 Since consumers are becoming more aware of what they eat and the link between diet and health, the market for healthy food and food supplements began to increase. Claims on the foods have become an important marketing tool. Promoting public health and assuring fair trade competition as well as avoiding misleading and incorrect claims paved the way for a legislation, which would regulate nutrition and health claims. Thus, in 2003 the European Commission has made a proposal for a Regulation on Nutrition and Health Claims made on Food.

This chapter aims at introducing to proposed Regulation, showing pros and cons of the implementation of this Regulation, as well as making a comparison between the EU proposal and the US Scheme on Nutrition and Health Claims – what the EU can learn from the US experience.

86 Goodburn, K. (2001), EU Food law, Woodhead publishing limited
Six EU member states, i.e. Belgium, the Netherlands, France, Sweden, Spain and the UK, have made a significant progress towards developing guidelines on health claims. However, there is very little information published on the Danish legislation with regards to claims. Later this chapter will try to address the main issues with regards to nutrition and health claims in the Danish legislation, i.e. \textit{Lov om Fødevarer} (Food Law) and Marketing Practices Act.

4.1. \textbf{Background}

Until 1999 functional food in the EU was regulated by EU Food Law. Nutrition and health claims in each Member State were subject to \textit{Codex Alimentarium} rules. The Commission has made a big step forward by making a proposal on nutrition and health claims, which aims at:\textsuperscript{87}

- achieving a high level of consumer protection by providing further voluntary information, beyond the mandatory information foreseen by EU legislation;
- improving the free movement of goods within the internal market;
- increasing legal security for economic operators;
- ensuring fair competition in the area of foods;
- promoting and protecting innovation in the area of foods.

A starting point in adopting any provision in the EU legislation is Article 14 of the EC Treaty, which sets up the objective of the EU; that is to secure well-functioning internal market. Because the EU consists of 25 different countries, their national legislations may vary across the Community. Proposed Regulation is based on Article 95 of the EC Treaty, which describes the provision harmonizing the internal market. In other words, Article 95 of the EC Treaty allows the Community to take measures to bring about the well-functioning of the internal market.

The proposal for a regulation on nutrition and health claims was foreseen in the White Paper on Food Safety in 1999. On 17\textsuperscript{th} of July, 2003, the EU Commission has submitted this proposal to the European Parliament and the Council. The European Economic and Social Committee gave its opinion on 26\textsuperscript{th} of February, 2004. The opinion of the European Parliament, first reading, was given on 26\textsuperscript{th} of May, 2005. Adoption of the common position was 8\textsuperscript{th} of December, 2005. The proposal was submitted to the European Parliament and the Council for the second reading. 16\textsuperscript{th} of May,

2006, the European Parliament welcomed the Commission’s proposal. The final Regulation is expected to be completed and approved by the Commission by summer, 2006.

Figure 5 shows time span of the implementation of the proposed Regulation.

**Figure 5:** *Time span of the implementation of the proposed Regulation*

<table>
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<tbody>
<tr>
<td>White Paper on Food Safety</td>
<td>Commission Proposal submitted to EP and Council</td>
<td>Opinion given by Social Committee</td>
<td>First reading, opinion given by EP; adoption of the common position</td>
<td>Second reading – EP and Council</td>
<td>The final Regulation expected to be approved by Commission</td>
</tr>
</tbody>
</table>

### 4.2. Overview of the Proposal for a Regulation on Nutrition and Health Claims made on Food

**Objective and scope**

The objective of the proposed Regulation is to harmonise Community rules to facilitate free circulation of such products and to ensure high level of consumer protection. The proposal only relates to the addition of vitamins and minerals, and other nutrients to food. Only certain vitamins and minerals would be permitted in food products.

Article 1 defines the scope of the Regulation indicating that this Regulation is intended to harmonize the provisions laid down by law in the Member States in order to ensure the effective functioning of the internal market and providing a high level of consumer protection; and it shall apply to nutrition and health claims in the labelling and advertising of foods.

**Definitions**

The basic definitions such as “claim”, “nutrient”, “nutrition claim”, “health claims”, “reduction of disease risk claim” are presented in Article 2. *Nutrition claim* refer to what is or is not contained in the product. However, some nutrition claims can be misleading even being true. For example, the

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claim “90% fat free” may be correct but it may mislead consumers since it implies that this product has a low fat content while in fact 10% fat represents reasonably high fat content. *Health claims* refer to what a food or food component does to the consumer. It is prohibited to make any claims that are misleading to consumers. The Commission makes a list of such well established claims that are permitted. The distinction between established claims and novel claims is that for the later type, scientific evaluation and pre-marketing approval is required. Only claims that can be substantiated and are evaluated by the European Food Safety Authority are permitted on the EU level.89

*Criteria for nutrition and health claims*

Article 3 says that the use of nutrition and health claims shall not (a) be misleading; (b) doubtful about the safety and/or the nutritional adequacy of other food; (c) state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general; (d) refer to changes in bodily functions in improper terms either textually or through symbolic representations. This may lead to confusing and misleading a consumer.

*Nutrient profile*

Article 4 gives a definition on nutrient profile. In food should be presented such nutrients as fat, sugar, and salt. Chapter 2 above has described that foods containing too much fat, sugar, or salt are not allowed to bear health claims. The nutrient profiles shall be based on scientific knowledge about diet, and nutrition, and their relationship to health. Not long time ago, there was on-going debate whether Article 4 is necessary to include in the final Regulation. European Parliament proposed to delete this Article arguing that the compulsory labelling of nutrient profiles could discriminate against individual products, which would be classified as “good” or “bad”.90 MEPs believe it is not so much the composition of the product that matters as the use made of it and above all the balance of a person’s diet.91

However, Markos Kyprianou, the Commissioner for Health and Consumer Protection, said that he would not accept the deletion of Article 4, which he considered as the cornerstone of the whole

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89 Commission press release: *Commission proposal on nutrition and health claims to better inform consumers and harmonize the market*, 16/07/2003 (IP/03/1022)
80 Bortone, A.F., *Food labelling that tells the truth*, 25 May, 2005 (www.europarl.eu.int)
81 Ibid.
Furthermore, Satu Hassi, the member of European Parliament with regards to human health and nutrition, said: “I support the ‘nutrition profile’ proposal by the Commission, where the basic idea is that you must not market anything with a health claim if the product is in some other way harmful for health”.  

**Conditions for nutrition and health claims**

Article 5 describes the use of nutrition and health claims, which can be permitted if some conditions are fulfilled:

(a) It has been shown to have a beneficial nutritional or physiological effect based on scientific evidence;

(b) The substance for which the claim is made is contained in a significant quantity\(^94\) or in a quantity that will produce the nutritional or physiological effect;

(c) The substance for which the claim is made is in a form that is available to be used by the body.

The use of nutrition and health claims shall only be permitted if the average consumer understands the beneficial effect as expressed in the claim. According to Article 2, “Average consumer” means the consumer who is reasonably well informed and reasonably observant and circumspect.

Nutrition information shall be provided in accordance with Directive 90/496/EEC,\(^95\) if a nutrition or health claim is made.

Article 6 of the proposed Regulation states that nutrition and health claim shall be based on scientific evidence. Justification of the use of a nutrition or health claim is necessary if a food business operator is making such claim.

**Specific conditions for nutrition claims**

Article 8 states that nutrition claims shall only be permitted if they are in conformity with this Regulation and comply with the conditions set out in the Annex.\(^96\)

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\(^{93}\) Personal interview with Satu Hassi, the member of European Parliament, by e-mail

\(^{94}\) “Significant quantity” is defined in Appendix 1 to this paper.

\(^{95}\) See sub-chapter 2.3.2.

\(^{96}\) Nutrition claims and conditions applying to them are shown in Appendix 3 to this paper.
Comparative claims

Article 9 allows making a nutrition claim which compares the quantity of a nutrient and/or the energy value of a food with foods of the same category. However, it should only be made if the foods being compared are easily identified by the average consumer or clearly indicated. The comparison shall relate to the same quantity of food.

Permitted health claims

Article 10 shows conditions of permitted health claims. Health claims are permitted if the following information is included on the label:

(a) a statement indicating the importance of a balanced diet and a healthy lifestyle;
(b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
(c) a statement addressed to persons who should avoid using the food;
(d) a warning not to exceed quantities of the product that may represent a risk to health.

Restricted or implied health claims

Article 11 describes restricted health claims:

(a) claims, which make reference, non-specific benefits of the nutrient or food for overall good health, well-being;
(b) claims, which make reference to psychological and behavioural functions;
(c) claims, which make reference to slimming or weight control;
(d) claims, which make reference to the advice of doctors or other health professionals, or suggest that health control be affected by not consuming the food.

Likely as Article 4, Article 11 is also under loop, which is being highly discussed in the EU Institutions. The European Parliament proposed to have more relaxed rules, meaning that claims about weight and about the advice of health professionals should be allowed if they are scientifically substantiated and authorized by the competent authority. But the European Parliament would ban claims targeted directly at children.\(^\text{97}\) Thus, Article 11 could be deleted or modified in the final text of the Regulation. Since obesity is a very big problem in the EU, particularly among

children, provision on claims on food addressed to children would prevent young consumers from misleading and incomplete information.

Reduction of disease risk claims
For reduction of disease risk claims the label shall bear a statement indicating that diseases have multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect. Also such kind of claims should be authorized (Article 13).

Authorization
Health claims are permitted if they are authorized. Articles 14 to 16 describe the authorization procedure.

The European Parliament wants to see more relaxed rules on authorization procedure; it would prefer to change “authorization” to “notification” procedure. However, the Commission doesn’t agree with this proposal. It argues that strict authorization procedure is necessary in order to protect consumers’ health, to avoid unsubstantiated claims, and to ensure fair trade within the Community.  

Thus, Article 14 to 16 will appear in the final text of the Regulation as they are.

Final provisions – Community Register and monitoring
The final chapter of this Regulation presents general provisions, including community register, data protection, notification procedure, safeguard measures, etc. The Commission shall establish a Community Register of nutrition and health claims made on food (the Register), which the main function is to register the authorized health claims, the nutrition claims and the conditions applying to them, as well as rejected health claims. The Register shall be made available to the public (Article 18 (3)).

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In summary, manufacturers and food operators making nutrition and health claims shall fulfil the requirements in conformity with this Regulation. Any information about foods or its components and their nutritional value used in labelling and advertising, which is not clear, inaccurate, not meaningful, and cannot be substantiated should not be permitted. This refers to general claims (e.g. “preserves youth”), claims that refer to psychological and behavioural functions (e.g. “improves your memory”, “reduces stress”), or slimming claims (e.g. “reduces your calories intake”). All these claims don’t inform consumers properly, they are meaningless and not verifiable. Consumers should see such claims that explain the specific health benefits of a food or food component. However, these claims could be allowed if they are scientifically substantiated.

Every Member State should implement the Regulation on nutrition and health claims made on foods in its national law. However, there can be some advantages and disadvantages of the implementation of this Regulation. The following sub-chapter will show pros and cons of this matter.

4.3. Pros and Cons of the Implementation of Proposed Regulation

Advantages:
Firstly, the main advantage of the Regulation is harmonization, meaning that it gives an opportunity for manufactures to label product and make nutrition and health claims according to applied common rules and requirements throughout the Community, which leads to the free movement of goods within the internal market. It also ensures fair competition in food industry.

Secondly, it contributes to a high level of protection of human health and promotes the protection of consumer interest. It is expected that claims made on food to be more understandable and will avoid misleading the consumers. Clear and understandable claims will lead consumers to make better choices towards healthier dietary patterns. Even those consumers who are conservative and used to buy the same product, clear label and showed nutrition and health claims on foods may change consumers attitude and they may consider of buying that product because they don’t need to spend a lot of time for understanding that claim. Consumers are more likely to trust the claim made on food if it is approved by the competent authority.

99 Commission press release: Commission proposal on nutrition and health claims to better inform consumers and harmonize the market, 16/07/2003 (IP/03/1022)
Thirdly, it ensures that foods bearing nutrition and health claims are labelled and advertised in a truthful and meaningful manner. It protects from unauthorized claims. Because according to proposed Regulation, foods that bear unauthorized health claims will be banned.

Fourthly, through nutrition and health claims made on food, consumers are informed about that food special features and benefits for human health. In this respect, labelling of such food or the use of claims can act as a marketing tool. Appropriate labelling can point consumers to make informed and meaningful choices.

Fifthly, the implementation of the Regulation would encourage consumers to choose healthy diet, meaning that people will stay healthier and longer on job market, which, in turn, for the national Governments it will lead to reduced expenses spent on social-health system. Thus, the Government wouldn’t need to spend a lot of money on hospitalization in order to cure and treat sick people; instead it may support innovation and development for functional food.

Disadvantages:
The disadvantage of this Regulation is that implementing it into the national law is costly and time consuming procedure, meaning that Government would spend a lot of money and time until it would get benefits from satisfied consumers and foreign investors. It would take long time to agree with consumers’ lobby groups and law-makers on the common issues. Thus, the problems could be the lack of knowledge regarding legal issues, stakeholders, and lack of time.

Secondly, even after the Regulation implementation into national law, there can be some discrepancies and flexibility, meaning that national Government is free to adapt provisions that protect its citizens. That is to protect human health, and to ensure food safety. This can be understood in terms of trade barriers, because importers, willing to sell products in another Member State, have to make sure that these products are complied with the legislation of an importing country.\textsuperscript{100}

Thirdly, implementation of the Regulation may bring the problem how to do it in the right way, and how to present claims that consumers are able to understand them. Therefore the Government may

\textsuperscript{100} Refer to \textit{Cassis de Dijon} case: C-120/78 (1979) ECR 649
make information campaign and market research regarding communication on health benefits and consumers understanding of food labels.

Fourthly, the last but not least disadvantage may be thinking of overlapping of the legal sources regarding misleading advertising. The main objective of the Regulation on nutrition and health claims is to inform consumers and to avoid misleading and vague claims. Since there is legislation on misleading advertising, for example, The Marketing Practices Act or Unfair Commercial Practices Directive (Directive 2005/29/EC), the question is whether the proposed Regulation is necessary. However, the objective of legislation on misleading advertising is to take action against advertising deemed misleading, whereas the proposed Regulation prevents misleading labelling and advertising concerning nutrition and health claims made on foods before it is used and approved.

4.4. The Comparison between the EU Proposed Regulation and the US Scheme on Nutrition and Health Claims

The Commission has stated that its proposal for the EU Regulation on nutrition and health claims is similar to the existing system in the US. However, there are some discrepancies concerning the US and the EU legislation on nutrition and health claims. The biggest difference is that the US legal system is more flexible, whereas in the EU is stricter.

In the US, the food must comply with a minimum “good” nutrient content requirement in order to bear a health claim. “Good” nutrients are: Vitamins A and C, iron, calcium, protein, and fibre.101 Health claims cannot be made for those products where certain nutrients like fat, saturated fat, cholesterol, and sodium are exceeded. However, both the minimum “good” nutrient content requirement and the “bad” nutrient or “disqualifying” criteria are evaluated on a case-by-case basis. It has to be considered whether there is a sound scientific support for a health claim. In other words, the US system permits assessment of individual products and claims and do not adapt prohibition on whole categories of food.102 These individual assessments ensure claims are meaningful and

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Note: One or more of “good” nutrient must be present at least 10% of the Recommended Daily Intake (TDI) or Recommended Daily Value (RDV).
102 American Chamber of Commerce to the European Union, Position Paper on the Proposal for an EU Regulation on Nutrition and Health Claims made on food, December 2003
understandable to the consumer. This differs from Article 11 of the EU proposed Regulation, which sets out a number of claims that would be prohibited.

Under the US system, claims known as “structure/function” claims (i.e. claims that describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, “calcium builds strong bones”) are not regulated as health claims. However, under the EU proposal such kind of claims is regulated as health claims, and it requires pre-market approval. Nutrition claims under the EU proposal include claims about “other substances” as well as claims about nutrients and calories. “Other substances” are not covered in the US system.

Under the EU proposal, the level of substantiation required to gain pre-market approval would be that of generally accepted scientific data. Under the US system, it provides for three different levels of scientific substantiation: significant scientific agreement, which is required for unqualified claim. For example: “Diets low in sodium may reduce the risk of high blood pressure”, “A diet low in fat may reduce the risk of some cancers”. Authoritative statement, a health claim which is made based on an authoritative statement from a scientific body of the US Government. For example: “Diets rich in whole grain goods and other plant foods and low in fat and cholesterol, may help to reduce the risk of heart disease and certain cancers”. The list of qualified health claims has been created by FDA for claims that do not have significant scientific agreement.

The US system, unlike the EU proposal, permits claims which compare a new version of product with a previous version. This provides an incentive to manufacturers to improve their product.

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104 See the proposed EU regulation on nutrition and health claims. “Other substances” are defined as substances other than nutrients that have a nutritional or physiological effect.
106 Ibid.
Note: all unqualified health claims must meet the Significant Scientific Agreement standard as provided for by Congress in 1990, web-site: http://www.cfsan.fda.gov/~dms/ssaguide.html. The recent court decisions resulting qualified health claims focused on a manufacturer's right to make statements about diet/disease relationships when the science supporting the claim did not meet the Significant Scientific Agreement standard, provided that the claim about the relationship was stated or "qualified" in such a way as to not mislead consumers.
In both regulatory systems – the US and the EU – drugs, as products “intended for use in the diagnosis, cure, mitigation treatment or prevention of disease in man or other animals” consider being as drug claims and not permitted in food labelling. Under the Nutrition Labelling and Education Act (1990), foods with approved health claims are not considered drugs due to the labelling of a health claim, which must mention a disease or health-related condition. These claims should be approved by FDA. The same condition is set up in the EU Proposal – European Food Safety Authority is responsible for review and approval of health claims.

Regarding food additives, manufactures must obtain pre-market approval under the Federal Food, Drug and Cosmetic Act (FDCA), or demonstrate that such ingredients are Generally Recognized as Safe (GRAS). In 1994 Congress enacted the Dietary Supplement Health and Education Act (DSHEA), which prevents dietary supplements from being subject to the approval requirements applied to food additives. In other words, there is no need to approve dietary supplements. Because of this reason manufacturers try to market a functional food as a dietary supplement rather than as a conventional food with added ingredients, which have to be approved by FDA. The FDA has its authority to remove an unsafe product from the market. If the FDA charged that the ingredient of the product is unsafe under the food provisions of the FDCA, a manufacturer has the burden of prove that that ingredient is exempt from such requirements.

In the US, the label of a dietary supplement or food product may contain one of three types of claims: a health claim, nutrient content claim, or structure/function claim. Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition. Nutrient content claims describe the relative amount of a nutrient or dietary substance in a product. A structure/function claim is a statement describing how a product may affect the organs or systems of the body and it can not mention any specific disease. As it was stated above health claims need FDA approval. Structure/function claims do not require FDA approval but the manufacturer must submit a notification to FDA no later than

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110 GRAS must be based on experts’ deductions, and accepted scientific procedure. The food additives such as pesticides, pesticide residues, and colour additives will not be considered as GRAS. FDA has published a list of sanctioned substance, 21 C.F.R. Part 81.
111 The Dietary Supplement Health and Education Act (DSHEA) of 1994: www.fda.gov/opacom/laws/dshea.html
112 The US Food, Drug, and Cosmetic Act (FDCA)
113 For more information regarding nutrition and health claims in the US refer to Appendix 4 to this paper.
30 days after marketing the food product that includes the text of the structure/function claim. Also on the product labels containing such claims must appear: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease".

To conclude: the description above shows that the EU Proposal and the US Regulatory Scheme have more differences than similarities. The EU has taken a more restrictive approach, whereas the US Regulatory Scheme is more flexible. The EU Proposal includes prohibited health claims, authorization procedures, nutrition profiles and other provisions. However, in both regulatory systems, the main principle is the same – to inform consumers about health benefits, to give truthful and not misleading information on food labels in order to enable them to make informed choices.

**Can the US Scheme work out in the EU?**

The immediate answer is that the US regulatory scheme cannot work in the EU, because of the following problems:

The first problem is that the EU consists of 25 member states, which differ in their culture, consumer demand and attitude regarding functional food, the requirements of national authorities, etc. Therefore it would make more difficult, if at all, to agree on common solution concerning nutrition and health claims made on food.

The second problem occurs regarding free trade within the Community. Each member state has to implement the EU legislation in its national law, in order to protect its consumers’ health and to promote healthy product. The exporters and importers have to comply with that country’s, where products are going to, national regulation. The European Court of Justice has developed few cases where product marketed as a food additive in the Member State of origin but treated as a medical product in the Member State of import. Therefore harmonization is necessary. The proposal for regulation on nutrition and health claims made on food will give for traders, manufactures and marketers an opportunity to deal with functional foods that bear health claims. Assume there is a

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116 Joined cases C-211/03, C-299/03 and C-316/03 to C-318/03
flexible legal environment in the EU (like in the US). It will be difficult to control and assess products that carry health claims among all member states within the Community.

*What can the EU learn from the US experience?*

The national governments of member states should pay more attention on information channel (e.g. media, advertisements, etc.), that provide correct information to consumers, as well as support research and development regarding functional food; to encourage manufactures to produce enriched foods. The EU could also learn through examples. Table 4 in Appendix 4 to this paper presents three examples showing the relationship between nutrition and health benefits. These examples are provided by the US Code of Federal Regulations, and subtracted from the Petitions for Health Claims. Thus, the EU could consider including some examples as well as establishing approved health claims list in the EU legislation on nutrition and health claims.

The following Table 3 summarizes the similarities and differences of the US System and the EU Proposal.

<table>
<thead>
<tr>
<th>Similarities and Differences: the US System and the EU Proposal</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>EU Proposal</th>
<th>US Regulatory Scheme</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-market approval required</strong></td>
<td>It would be required for all health claims unless the claim is listed on the list of well-recognized claims.</td>
</tr>
<tr>
<td><strong>Level of substantiation required</strong></td>
<td>Generally accepted scientific data.</td>
</tr>
<tr>
<td><strong>Regulation of structure/function claims</strong></td>
<td>It would be regulated as health claims; also, some would be regulated as “reduction of disease risk claims”. Pre-market approval required.</td>
</tr>
<tr>
<td><strong>Label statements</strong></td>
<td>In the labelling should appear statement indicating</td>
</tr>
</tbody>
</table>
importance of a balanced diet and a healthy lifestyle, quantity of the food and pattern of consumption required to obtain the claimed beneficial effect, statement addressed to persons who should avoid using the food, and warning not to exceed quantities of the product that may represent a risk to health.

<table>
<thead>
<tr>
<th>Prohibited claims</th>
<th>Article 11 of the EU Proposal describes prohibited claims.</th>
<th>No such claims under the US Regulatory Scheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive list of generic claims</td>
<td>Proposal establishes a positive list of generic nutrition claims. It would disallow “%fat free” claims.</td>
<td>US also has generic list of claims. However, it would allow “%fat free” claims if the claim meets the criteria for low fat.</td>
</tr>
<tr>
<td>Comparative claims</td>
<td>EU proposal requires that food for which the claim is made be compared to a range of foods in the same category that are not eligible to bear the claim. It disallows claims compared between old and new products in the same brand.</td>
<td>US allow comparative claims – comparing new product with old product; products do not have to be compared with a range of other foods in the same category.</td>
</tr>
<tr>
<td>Serving size</td>
<td>Claims under EU proposal based on 100 g.</td>
<td>Claims in US are made based on reference amount customarily consumed.</td>
</tr>
<tr>
<td>Establishment of nutrient profile</td>
<td>EU proposal calls for the establishment of criteria for when claims can and cannot be made. The EU system would not allow for these criteria to be waived on a case-by-case basis.</td>
<td>No such prohibition in the US. Foods must comply with minimum “good” nutrient content requirements, and disqualifying levels for fat, saturated fat, cholesterol, and sodium. It has to be waived by FDA as part of approval for individual claims.</td>
</tr>
</tbody>
</table>

Source: Adapted from American Chamber of Commerce to the European Union, *Position Paper on the Proposal for an EU Regulation on Nutrition and Health Claims made on food*, December 2003
4.5. Denmark: Consumer Policy and National Legislation on Nutrition and Health Claims

Previous chapters above looked closer at the Consumer policy at the EU level, and the EU legislation with regards to claims, food safety, and labelling. Even the objective of Consumer policy is the same in all EU member states – consumers’ protection, and public health promotion – the instruments used for achieving this objective may differ within the Community.

The proceeding sub-chapter will look at the public health issues at the Danish national level. The aim of this chapter is three folds: 1) to present the Danish consumer organizations and their role in consumer policy, 2) to describe Danish national legislation concerning consumers’ issues such as food safety, labelling, nutrition and health claims; and 3) to show authorization procedure if a company wants to market fortified food in Denmark.

4.5.1. Danish Consumer Policy and Consumer Organizations

The main objectives of Danish consumer policy are the following:

- Consumer protection – legal rights against unfair practices, food and product safety;
- Providing accurate information to allow consumers to make informed and free choices;
- Providing a complaints system in order for consumers to obtain remedies;
- Promoting cooperation between consumer and business operator to solve problems without the need for legislation.

There are few consumer organizations in Denmark, which play an important role in order to protect consumers’ interests: Danish Consumer Agency, Consumer Ombudsman, The Danish Consumer Council, Consumer Information Centre, and Danish Veterinary and Food Administration operating under Ministry of Family and Consumer Affairs, and others.117

**Danish Consumer Agency** is responsible for ensuring safe products on the market; it is appointed as a general product safety authority. It administers the Price Marketing and Display Act and the Product Safety Act. The Agency acts as secretariat of the Consumer Complaints Board and the

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117 For more information on the National Consumer Agency, the Consumer Ombudsman, Consumer Complaints Board refer to [www.fs.dk](http://www.fs.dk); the Danish Consumer Council: [http://www.fbr.dk](http://www.fbr.dk); Danish Veterinary and Food Administration: [http://www.uk.foedevarestyrelsen.dk/Forside.htm](http://www.uk.foedevarestyrelsen.dk/Forside.htm)
Consumer Ombudsman. The Agency operates directly under the Product Safety Act and enforces regulations covering many of the products not already under the control of a particular department.

*The Consumer Ombudsman* makes sure that business activities are conducted in accordance with good market practices. He lays down guidelines for good practices as set out in the general clause of the Marketing Practices Act.

*The Danish Consumer Council* is a lobby group, which represents the interests of consumers, and which has a strong influence in Parliament; it is closely integrated into the legislative process. The Consumer Council is involved in a wide range of consumer issues: food quality, environmental protection, health services, and others.

*Danish Consumer Information Centre* is responsible for testing goods and products in their laboratories, and providing information to consumers through various sources. It provides information to consumers in different ways: on the internet, via telephone hotline, consumer magazines, and others. The Consumer Information Centre’s laboratory delivers the results based on laboratory investigations in the areas of household equipment, food, textiles, hygiene, as well as other subjects concerning nutrition, safety, consumer rights, etc.

*Veterinary and Food Administration’s* main purpose is to ensure the safety and high quality of food, to advice on healthy eating habits and to protect the consumers against misleading marketing of food. It sets the national limit to the content of chemicals such as pesticide, dioxin and others. It also sets the standards for labelling and description of contents. Veterinary and Food Administration gives guidance on nutrition. It controls restaurants, shops and food manufactures whether they are complying with the food legislation. The results are presented publicly.

Table 4 summarizes consumers’ organizations and their responsibility areas with regards to safety, labelling, and claims.
Table 4: *Main Consumers’ Organizations, their responsibility areas, and legal instruments*

<table>
<thead>
<tr>
<th>Consumers’ organization</th>
<th>Responsibility</th>
<th>Legal instrument / Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danish Consumer Agency</td>
<td>Product safety</td>
<td>Product Safety Act</td>
</tr>
<tr>
<td>The Consumer Ombudsman</td>
<td>Laying down guidelines on good market practices: makes sure that claims made on food are not misleading, accurate, and truthful.</td>
<td>The Marketing Practices Act</td>
</tr>
<tr>
<td>The Danish Consumer Council</td>
<td>Lobbying and decision making in the interest of consumers such as food quality and others.</td>
<td>Information campaign</td>
</tr>
<tr>
<td>Danish Consumer Information Centre</td>
<td>Providing information to consumers.</td>
<td>Telephone hotline, its homepage, ethical database, consumer magazines</td>
</tr>
<tr>
<td>Veterinary and Food Administration</td>
<td>Food safety, food quality control, guidance on nutrition, ensuring not misleading marketing of food.</td>
<td>Food legislation</td>
</tr>
</tbody>
</table>

4.5.2. Danish National Legislation

In Denmark, there are mainly two legislations that regulate food products, and claims made on them. These are Danish Food Law (*Lov om Fødevarer* or *Fødevarelov*), and the Marketing Practices Act.

**Danish Food Law (*Lov om Fødevarer*):**¹¹⁸

The Danish Food Law, likely as the EU Food Legislation, aims at ensuring a high level of protection of human health. It establishes the rights of consumers to safe food and to accurate information.

The purpose of the Danish Food Law (*the Law*) is to protect consumers from misleading advertisement, and to ensure that food product sold to consumers is of a high quality (section 1, §1). *The Law* sets up general rules on food safety, food comparison, marketing, labelling and advertising, rules on foodstuffs substances, authorities and food control, nutrition and others.

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¹¹⁸ This section is written based on *Lov om Fødevarer*, 1st of July 1998, nr. 471: [www.a-consult.dk/bek/bk98471.htm](http://www.a-consult.dk/bek/bk98471.htm), or it will be stated otherwise.
The Ministry of Food, Agriculture and Fisheries (the Ministry) is responsible for making sure that a food product meets high quality and hygiene standards and it doesn’t harm consumers’ health. According to Section 2, §12, The Ministry can set the rules for allowing such ingredients or additives to be added in food as well as technology used in manufacture process. Food additives and substances can be added in food if they are authorised and approved by the Ministry. According to section 3, §15, additives and substances have to be approved before that food appears on the market. If these additives were not pre-approved, the Ministry may prohibit such enriched food to be placed on the market. The Ministry establishes a positive list of approved food additives – what, how, and how much the foods may contain of these additives.

Section 4 describes the rules on marketing the food product. The main message is that claim has to be clear, correct, and not misleading. If a food carries health claim, that this food has a health effect, or if this food is for people with special needs, it has to be stated clearly that the food is for special need. The Ministry issues the rules on product information – how to use that product, and for which customer segment, as well as in which language the information should be given, and to warn the consumer if the product has its adverse effect. Section 4, §20, gives provisions on forbidden marketing. It is not allowed to advertise that enriched food can treat or cure disease, or the food is advised by the doctor, nor to show health-persons’ picture on the advertisement.\footnote{Koktvedgaard, M. (2005), \textit{Lærebog i konkurrenceret}, 6th edition, p. 254, and \textit{Lov om Fødevarer}, section 4, §20, 1st of July 1998.}

The Danish Food Law also covers food supplements. However, as it was described in Chapter 2 above, food supplements are very close related to medical products; it is not easy to find a boarding line. For example, a fish oil Omega-3 capsule can be both a food supplement and natural medicine.\footnote{Kræftens Bekæmpelse (cancer.dk): \textit{Naturlægemidler og kosttilskud – hvad er forskellen} (http://www.cancer.dk/alt+om+kraeft/behandling/alternativ+behandling/foer+dau+gaar+i+gang/naturlaegemidler+og+kosttilskud.asp)} In this case the firm itself can decide whether the product can be sold as food supplement or as a natural medicine.\footnote{Ibid.} The problem is that if Omega-3 capsule is considered to be a natural medicine, then it will be regulated by Medical Act instead of Food Law. Omega-3 capsule is a dietary supplement, if it doesn’t have a curing effect; it can be consumed in small quantities, and it could be taken by all group of population.\footnote{Ibid.}
The Marketing Practices Act:123

The Marketing Practices Act (the Act) is general framework legislation regulating market practices by private companies; it deals with advertising and selling requirements of the products. The Act aims to regulate competition and protect consumers. It contains a number of special bans, such as a ban on quantitative restrictions, trading samples, etc. The main principle of the Act is lined out in section 1: “The Act applies to private business activity and comparable public activity. Actions that conflict with good marketing practice must not be undertaken as part of such activity.” In other words, enterprises may not carry out activities contradicting fair marketing practice. Now the problem is to find out what fair marketing practice is about. The Act gives the answer. It is not allowed to:

- use false, misleading information on Your product;
- give wrongful information about Your competitors;
- use guarantee as a purpose for selling Your product;
- use other enterprises slogans and logo in order to market Your product;
- use gifts as a marketing tool to sell Your product;
- be persistent or cause inconvenience to the customers.

All companies, when selling a product or making an offer, have to give proper, clear, and understandable information concerning the product, relating to service available, maintenance, etc. Also the Act lays down the provisions allowing for Consumer Ombudsman to issue the guidelines ensuring that business activity complies with the good marketing practices. If he observes that there has been an infringement of this Act, Consumer Ombudsman may impose penalties.

Shortly, the Danish Food legislation aims to protect consumers from misleading advertising and unfair marketing practices, as well as to ensure fair competition. Danish Food Law gives provisions on general requirements for food safety, food control, misleading advertising, and others. The Marketing Practices Act sets up the rules on good marketing practises.

4.5.3. Authorization Procedure – Marketing Fortified Food in Denmark

The foods fortified with vitamins, minerals or other nutrients have to be marketed in Denmark subject to pre-approval procedure. A company, which wants to market its fortified food product, should send an application of enriched substances in foodstuffs to the Danish Veterinary and Food Administration (DVFA) for approval. The product must not be placed on the markets until 6 months is over from the date of application; that is after such product has been approved by DVFA. Together with the application, the company should include information on the added nutrients – the amount added to each product, and information on the energy contained in the product should be expressed as parts per 100 ml / 100 g of the product.

Later all documents are forward to the Danish Institute for Food and Veterinary Research (DIFVR), which assess the risk carried out on a case-by-case basis, and decides whether the addition of substances to food can be approved. DIFVR has to make sure that the fortified food is safe that such food could be consumed by any population group. It has to consider the upper tolerable level for each nutrient, which was carried out by competent scientific bodies, as well as the available data from the national dietary surveys.

The fortified food will not be approved if one of the population groups risk may exceed the upper tolerable level. In this case the product cannot be placed on the market. Figure 6 summarizes authorization procedure of fortified food in Denmark.

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124 Danish Veterinary and Food Administration: http://www.uk.foedevarestyrelsen.dk/Food+Safety/Fortified_food/forside.htm
If a company wants to sell its fortified food not only in Denmark but also in another EU country, and that food is marketed with a health claim, the health claim should be substantiated by the European Food Safety Authority.

4.6. Conclusion on EU Legislation on Nutrition and Health Claims

In this chapter the legislation on nutrition and health claims has been presented on both the EU level and Danish national level. On the EU level, the main focus was placed on Commission’s proposal for a Regulation on nutrition and health claims made on food. Pros and cons of the implementation of this Regulation were described. Also proposed Regulation was compared to the US Regulatory Scheme. The objective of this comparison was to show similarities and differences of two countries legislations, and what the EU could learn from the US experience.

On the Danish national level, two main legislations concerning food safety, claims, advertisement and good marketing practices were described. These are Danish Food Law and the Marketing Practices Act.
5. Functional Food Examples

So far, the theory on legal matters regarding functional food, nutrition and health claims have been described. It was shown the necessity for improving human health and the demand for functional food on both European and Danish national markets. However, many manufacturers and food operators failed to comply with the legal requirements for functional food to be accepted on the market. In the proceeding chapter classical examples of Benecol, Kellogg and Novartis’s Aviva will be presented with the help of internet sources as well as legal sources. The reason to show these cases is to see what the manufactures did wrong; and what should be considered in order to avoid such mistakes.

5.1. Benecol

Benecol margarine was started in Finland in 1989. It was quickly introduced and sold on the European as well as American markets: the US, the UK, Germany, Italy, Spain, Portugal, Austria and others. Benecol had websites promoting the range of products available. For example, in the UK the website proclaims: “Benecol: experts in reducing cholesterol”.\textsuperscript{125} In the eyes of consumers, Benecol was positioned as a product, which had a medical focus. It was a problem because only people who know they have high cholesterol are likely to purchase this product.\textsuperscript{126} Thus, Benecol failed in defining its target market: its target market was consumers with high cholesterol. In the US, its website said that consumers can “start to see results in as little as two weeks”.\textsuperscript{127} However, consumers have not seen results fast enough. Benecol lost consumers’ acceptance and trust. Also, Benecol failed to be accepted by the consumers because its price was too high and the health benefits not clear to justify this.\textsuperscript{128} Furthermore, packaging is also important in order to communicate product’s value to the buyer. But the package of Benecol margarine is not particularly eye-catching.

Benecol case was ruled out in the US. The FDA required that the manufacture should submit a petition for his margarine product “Benecol” for FDA pre-market approval. The manufacturer claimed that Benecol is a dietary supplement based on its “plant stanol ester” ingredient, and it

\begin{flushleft}
\textsuperscript{125} Euromonitor  \\
\textsuperscript{126} Ibid.  \\
\textsuperscript{127} Ibid.  \\
\textsuperscript{128} Ibid.  
\end{flushleft}
doesn’t need approval. But the FDA rejected this argument saying that dietary supplement “means a product that is not represented for use as a conventional food…”\textsuperscript{129} The FDA stated that margarine looks and tastes like regular margarine and is sold in the supermarkets next to the butter, meaning that Benecol is a conventional food and therefore it cannot be marketed as a food supplement.\textsuperscript{130}

FDA regulations provide that a substance that is the subject of a health claim must “contribute taste, aroma, or nutritive value, or any other technical effect to the food”.\textsuperscript{131} Thus, Benecol had to be pre-approved.

Shortly, looking from marketing perspective, Benecol’s sales decreased because the target market was restricted to cure rather than prevent disease, high premium price was unjustifiable and was not acceptable to the consumers, lack of product claim information in order to catch consumers’ attention and to increase sales. Looking from legal perspective, the manufacture failed to submit a petition for this product. The manufacture lacked the understanding what dietary supplement is about.

5.2. Kellogg\textsuperscript{132}

The Danish Veterinary and Food Administration has rejected an application from Nordic Kellogg's A/S to market twelve new breakfast products and six bars enriched with various vitamins and minerals. The application has been rejected because the company wishes to add iron, calcium, vitamin B\textsubscript{6} and folic acid in amounts that are too high. It bases its decision on a scientific risk assessment produced by the Danish Institute for Food and Veterinary Research (DFVF).

The Danish maximum levels are based on the “Upper Safe Limits” for the intake of vitamins and minerals determined by the European Commission's Scientific Committee on Food. If the maximum levels are exceeded, the total intake from enriched food, non-enriched food and dietary supplements can reach a level that exceeds the upper safe limits, and may consequently represent a potential health risk. The DFVF based its calculations on large-scale surveys of the diet of Danes and their intake of dietary supplements.

\textsuperscript{130} \textit{Euromonitor}
\textsuperscript{131} Code of Federal Regulation, Title 21 Volume 21 \{21 C.F.R. §101.14(b)(3)(i)\}
\textsuperscript{132} Kellogg case was found on the website of the Ministry of Family and Consumer Affairs, Danish Veterinary and Food Administration: \url{http://www.uk.foedevarestyrelsen.dk/Nutrition/New_ruling_enriched_food/forside.htm}
These surveys showed that around half of the adult population and 70% of children in the ages 4-10 years regularly consumed dietary supplements – typically a multivitamin mineral tablet.\textsuperscript{133}

Kellogg’s A/S has applied for permission to enrich the relevant products with other nutrients which would not comprise any health risk, and these have been approved by the Danish Veterinary and Food Administration. The Danish Veterinary and Food Administration emphasises that the breakfast products already on the market in Denmark do not have a nutrient content that represents a health risk.

Shortly, Kellogg’s A/S failed to introduce its products enriched with various vitamins and minerals on the Danish market, because the amount of substances (vitamins and minerals) that the company wished to add in the products was too high. Furthermore, the Danish consumer demand was overestimated.

5.3. \textbf{Novartis’s Aviva}\textsuperscript{134}

Novartis is a pharmaceutical company, which produces genetically modified seeds, as well as medical products, launched the range of products \textit{Aviva} in November 1999 in the UK. Novartis claimed that the \textit{Aviva} functional foods offered health benefits to consumers including benefits for bones, heart and digestion.

Products in the range included drinks such as a hot chocolate and juice, biscuits and cereal bars. Its products were sold through supermarkets as well as health food shops in the UK, and through drugstores and chemists in Switzerland. The failure of \textit{Aviva} was a wrong positioning strategy of this product. It was positioned as a medical product, and consumer demand was overestimated. Also, too high price of \textit{Aviva} was not accepted by the consumers. It didn’t taste good, and its benefits were not sufficiently clearly communicated.\textsuperscript{135} It was thought that good and well-known brand’s image of pharmaceutical company Novartis may help to boost up sales of a new product like \textit{Aviva}. However, it proved to be disadvantage of launching a food product. Novartis focused only on health benefits, forgetting that for consumers taste and convenience are the most important

\textsuperscript{133} In Chapter 3 above has also been presented and given other examples concerning Danish consumers’ eating habits, their attitude regarding enriched food and dietary supplements.


\textsuperscript{135} Euromonitor
food attributes. Thus, *Aviva* didn’t catch the consumers’ attention and high price was not justifiable. Furthermore, *Aviva* had very narrow focus – addressed specific medical problems.

Marcus Williams, Genetically Modified Food – UK and World News (gmfoodnews.com) stated, that "*Novartis made several mistakes in launching the Aviva range, at a time when the public is especially conscious of the ingredients used in food. Several Aviva products contained soya, which consumers are avoiding because of the GM connection, and Aspartame, the artificial sweetener, which has according to the US Food and Drugs Administration (FDA) 92 possible side effects, including death. Furthermore, the ingredients were not comprehensively labelled, so that the consumer could not tell if the vegetable oil and vegetable fat being used were from a GM suspect source.*"\(^{136}\)

Shortly, *Aviva* food products were not sufficiently labelled. These products contained too much sweeteners; therefore it could not bear a health claim. The company had a wrong positioning strategy – *Aviva* was positioned as a medical product.

### 5.4. Conclusion on Functional Food Examples

The cases of Benecol, Kellogg, and Novartis’s Aviva give the following implications:

- It is not enough to have a good brand image; it doesn’t mean that if a company is successful in one production line like pharmaceuticals, it could be also successful in lunching a new product line like enriched food (*Novartis’s Aviva*).
- It should not be forgotten that the primary function of functional food is a satisfied consumer; that is to provide consumers with foods’ attributes like taste, convenience, etc. Consumers are not willing to sacrifice taste and convenience for health benefits (*Novartis’s Aviva*).
- Nutrition and health claims have to be stated in a clear and understandable language. Unclear and confused health claims are hard to comprehend and to be accepted by consumers.

• Price has to be justified, i.e. consumers are not willing to pay a price for a food product, which health benefit is doubtful, or the benefit is not seen fast enough (Benecol, Novartis’s Aviva).

• Ingredients of the food have to be stated clearly. For example, a food contains too much sugar (Novartis’s Aviva), or vitamins and minerals reach the maximum limit of product’s content (Kellogg). These products cannot bring health benefits to consumers; therefore food labels cannot bear health claims.

• It is important to make good positioning / marketing strategy as well as to choose the right distribution channel. Also it is important to define target market well – consumer segment has to be targeted with conscious. Furthermore, packaging should catch buyers’ attention (Benecol, Novartis’s Aviva).

6. The Case of Fish Oil Omega-3 PUFAs and Foods Enriched with them

The proceeding chapter will try to combine all issues and theories presented so far in the paper into the practical case. Claims made on six different categories of food enriched with fish oil Omega-3 will be evaluated. These foods are tuna salad, minced fish meat, bacon liver paste, whole grain bread, yoghurt, and muesli bar.

The main source of Omega-3 is fatty fish. However, there are other sources of Omega-3 fatty acids. Figure 7 bellow shows different categories of fats. This chapter is limited to presenting Omega-3 fatty acids; other categories of fats are out of the scope of the report.
6.1. Benefits of Omega-3 PUFAs

Dieticians and medical professionals suggest that people should eat more fish, because fish is low in fat, high in protein and an excellent source of Omega-3 PUFAs. Essential fatty acids are special fats that the body needs as much as it needs vitamins. There are many scientific studies that show the benefits of fish oil. According to most studies, fish oil appears to help prevent death caused by heart disease. For example, studies of Envit (or so-called Eskimo) people found that their diets contain a lot of fat from fish and they seldom suffer heart attacks. This is probably because of Omega-3 PUFAs that contain fish.

Other examples could be like Asthma - children who eat fish may be less likely to develop asthma. Brain and eyes - fish rich in Omega-3 fatty acids can contribute to the health of brain.

Source: The CLL Topics, the website www.clltopics.org is an information forum that covers a range of topics of interest. The article by Venkat, Ch., Omega-3 Fatty Acids, January 2005 (http://www.clltopics.org/Phyto/Omega3.htm)

137 Aurora Health Care, Health information: Fish oil (www.aurorahealthcare.org)
138 Bull, E., Fiskeolie hjælper mod hjertesygdom, Børsen, 20 September, 2004
139 Ibid.
140 These examples are found at www.aurorahealthcare.org
tissue and the retina. **Cancer** - the Omega-3 fatty acids in fish may reduce the risk of many types of cancers by 30% to 50%, especially of the oral cavity, colon, breast, ovary and prostate. **Cardiovascular disease** - eating fish every week reduces the risk of heart disease and stroke by reducing blood clots and inflammation, improving blood vessel elasticity, lowering blood pressure, lowering blood fats and boosting 'good' cholesterol. **Dementia** - elderly people who eat fish or seafood at least once a week may have a lower risk of developing dementia, including Alzheimer's disease. **Depression** - people who regularly eat fish have a lower incidence of depression (depression is linked to low levels of Omega-3 fatty acids in the brain). **Diabetes** - fish may help people with diabetes manage their blood sugar levels.

However, all of these benefits listed above may be achieved if people eat balanced diet. If the diet unbalanced and they eat too much fat, and not live active life, even eating Omega-3 enriched foods will not bring a positive effect on human health. It is worth noticing, that fish oil is not a medicine which may cure diseases but it may reduce the probability and risk of getting a disease. One should know that high intakes of Omega-3 fatty acids may bring serious health problems; it could cause excessive bleeding in some people. American Heart Association recommends that people should eat a variety of fish at least twice a week. People taking more than 3g/day of Omega-3 fatty acids from supplements should do so only under a physician’s care. The best source of Omega-3 fatty acids is fatty fish. Fatty fish like mackerel, lake trout, herring, sardines, albacore tuna and salmon are high in two kinds of Omega-3 fatty acids: eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

Other sources of Omega-3 fatty acids are soybeans, canola, walnut and flaxseed. These contain alpha-linolenic acid (LNA), which can become Omega-3 fatty acid in the body. However, there is only limited information and studies done to show a cause-and-effect relationship between LNA and heart disease.

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141 Note: Here “medicine” is meant as medical device, which may treat, or cure any disease. One of the criteria for functional foods and/or food supplements is that food product should not treat or cure any human disease. However, food supplements enriched with fish oil Omega-3 can also be understood as natural medicine (for more information see Chapter 4.5.2 above).


It is worth noticing that consumers should not take for grand that Omega-3 fatty acid may reduce the risk of any disease listed above. For example, researchers led by Catherine MacLean, MD, PhD of RAND Health in Santa Monica, California, have found that there is insufficient evidence that Omega-3 PUFAs may decrease the risk of cancer. They scrutinized 38 studies published between 1966 and October 2005 that investigated the purported link between Omega-3 PUFAs and different types of cancer and met certain criteria.\(^{146}\)

Three studies showed decreased risk of breast cancer with Omega-3 PUFAs consumption, one for colorectal cancer, one for lung cancer and one for prostate cancer.\(^{147}\) Only one study looked at Omega-3 PUFAs consumption and skin cancer, and this found that there was an increased risk.\(^{148}\) In other words, increased consumption of Omega-3 may lead to increase the risk of getting skin cancer.

Josephine Querido, science information officer at Cancer Research UK, said: "The jury is still out as to whether eating more omega-3 fatty acids will reduce your risk of developing cancer, and the evidence from this study is largely inconclusive. But, previous studies have suggested that diets high in fish oils can reduce the risk of bowel cancer. The best way to reduce your risk of many cancers remains to eat a healthy, balanced diet, with plenty of fruit and vegetables".\(^{149}\)

To conclude: Omega-3 PUFAs may bring positive effect on human health if people eat a healthy and balanced diet with fruits and vegetables. It is better to eat fatty fish twice per week. However, for those people who don’t like raw fish, Omega-3 enriched foods or food supplements such as Omega-3 capsules could be a solution. However, too much intake of Omega-3 may lead to health problem. Fish oil Omega-3 is necessary in order to keep healthy heart and for development of brain.


\(^{147}\) Ibid.

\(^{148}\) Ibid.

\(^{149}\) Ibid.
6.2. Legal Evaluation of Claims made on Foods Enriched with Fish Oil Omega-3 PUFAs

This sub-chapter guides through legal evaluation of claims made on different categories of food enriched with fish oil Omega-3: tuna salad, minced fish meat, bacon liver paste, whole grain bread, yoghurt drink, and muesli bar. Food products address two consumer segments – elderly people, and young consumers. Claims proposals for each food category were developed by a group of Master students, Peter and Brain. Food products and proposed claims made on them are presented in Table 5 below.\(^{150}\)

Table 5: *Food products and proposed claims made on them*

<table>
<thead>
<tr>
<th>Nr.</th>
<th>Name of food product</th>
<th>Proposed claims made on food</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Tuna salad with fish oil</td>
<td>“The new tuna salad with fish oil from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis tuna salad with fish oil in all cases is a good nutrition and it helps with good life”.</td>
</tr>
<tr>
<td>2.</td>
<td>Minced fish meat with fish oil</td>
<td>“The new minced fish meat with fish oil from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis minced fish meat with fish oil in all cases is a good nutrition and it helps with good life”.</td>
</tr>
<tr>
<td>3.</td>
<td>Bacon liver paste with Omega-3</td>
<td>“The new bacon liver paste with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis bacon liver paste with Omega-3 in all cases is a good nutrition and it helps with good life”.</td>
</tr>
<tr>
<td>4.</td>
<td>Whole grain bread with Omega-3</td>
<td>“The new whole grain bread with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis whole grain bread with Omega-3 in all cases is a good nutrition and it helps with good life”.</td>
</tr>
<tr>
<td>5.</td>
<td>Yoghurt drink with Omega-3</td>
<td>“The new yoghurt drink with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. A high content of Omega-3 DHA fatty acids has a big influence on the brain”.</td>
</tr>
<tr>
<td>6.</td>
<td>Muesli bar with Omega-3</td>
<td>“The new muesli bar with Omega-3 from Vitalis contains the essential fatty acids EPA and DHA, which are necessary nutrients needed for the body. A high content of Omega-3 DHA fatty acids has a big influence on the brain”.</td>
</tr>
</tbody>
</table>

Note: Proposed claims are the same for two consumers segments.

\(^{150}\) Original claims’ examples (in Danish) can be found in the Appendix 5 to this paper. Note: Claims are translated from the Danish. Therefore there can be some deviations in translation. Legal evaluation is given based on English version
Health claims for each category of functional food will be evaluated based on model depicted in Figure 8.

Figure 8: *The model of legal evaluation of claim examples*

![Diagram of model of legal evaluation of claim examples](image)

Source: Own model, which was developed based on theory presented in this paper.

Note: *All food products are qualified as foods (concerning Article 2 of Regulation 178/2002). Therefore the detailed explanation regarding this matter will not be included in the following discussion.*
**Tuna salad with fish oil**

The claim for tuna salad states that the product contains the right fatty acids, which are essential nutrients needed for the body, therefore this is a nutrition claim:

“The new tuna salad with fish oil from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis tuna salad with fish oil in all cases is a good nutrition and it helps with good life”.

Whether a claim could be made for a food, it is important to find out the composition of the product or so-called nutritional profile. If tuna salad exceeds the maximum limit of protein, carbohydrate, sugar, fat, saturated fatty acids, dietary fibre and/or sodium then claim should be made with conscious. In other words, foods with high content of more than one of the elements – fat, sugar or salt – will be banned for carrying a nutritional claim. For example, if tuna salad is high in both fat and salt the nutrition claim as outlined above cannot be used.

However, a nutrition claim will still be permitted, if only one nutrient such as salt, sugar or fat exceeds the maximum limit. The nutrient exceeded has to be stated clearly on the food labelling that the food product contains too much of this nutrient in question. Unfortunately, nutritional profile cannot be seen on the package of tuna salad (refer to advertising presented in Appendix 5), therefore it is difficult to assess whether this food product is qualified to bear the nutrition claim.

The manufactures should consider not only nutritional profile, but also whether the consumer segment understands the claim. “The right fatty acids”, “in all cases”, and “good life” are not stated clearly. Thus, making this kind of claim on tuna salad, some improvements are needed.

**Minced fish meat with fish oil**

For this kind of food product the comments are the same as for tuna salad with fish oil described above. In addition, a sign of “2 gange om ugen” on the package of minced fish meat may mislead the consumers: to eat minced fish meat twice per week?! In fact, the sign “2 gange om ugen” promotes to eat fatty fish twice per week. Therefore this sign could be eliminated or more information could be provided in the leaflets.

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**Bacon liver paste with Omega-3**

The claim is a nutrition claim, because it shows the composition of this food product: it contains the right fatty acids, which are essential nutrients needed for the body:

_“The new bacon liver paste with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis bacon liver paste with Omega-3 in all cases is a good nutrition and it helps with good life”._

In order for bacon liver paste to bear such claim, it has to fulfil certain criteria: (1) nutritional profile, whether salt and fat, particularly saturated fat, do not exceed the maximum limit. Directive 90/496/EEC on nutrition labelling for foodstuff, which was presented in Chapter 2.3.2, gives provisions on declared nutrients and on calculation of energy value. (2) The claim has to be correct, understandable, and not misleading; whether the consumers are enable to comprehend the information and to understand its significance in the context of the daily diet. Particularly “the right fatty acids”, “in all cases”, and “good life” need more attention and explanation.

Thus, this claim could appear on bacon liver paste, if some improvements are considered.

**Whole grain bread with Omega-3**

_“The new whole grain bread with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis whole grain bread with Omega-3 in all cases is a good nutrition and it helps with good life”._

The comments for whole grain bread with Omega-3 are the same as for tuna salad and for bacon liver paste described above. Furthermore, this kind of food product is qualified to bear the claim, if “whole grain food” contains 51% or more whole grain ingredient. Also, fat and salt should not exceed the upper limit. Since the nutrition information cannot be seen on this food product, it is difficult to say whether whole grain bread with Omega-3 is qualified to bear the nutrition claim.

In addition, health claim could also be a possible solution to promote grain bread with Omega-3.
Yoghurt drink with Omega-3

“The new yoghurt drink with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. A high content of Omega-3 DHA fatty acids has a big influence on the brain”.

This is a health claim because it describes the effect of nutrients on human health – “A high content of Omega-3 DHA fatty acids has a big influence on the brain”. Comments concerning nutritional profile are the same as for foods described above. However, the most attention should be paid whether sugar amount doesn’t exceed the maximum limit. If it does, nutrition claim could be made instead. Furthermore, in order for food product to claim “a high content of Omega-3 fatty acids”, the food must contain more than 30% of the Recommended Nutritional Intake (2 g/day) per 100g or 100 ml or 100 kcal.\(^{152}\)

In addition, statement such as “a high content” is not clear. Too much of Omega-3 intake is not good for human health (refer to Chapter 6.1 concerning Omega-3 advantages and disadvantages). Also elderly consumers may find “DHA fatty acids” difficult to comprehend.

Thus, making this kind of claim on yoghurt drink with Omega-3, some improvements and more considerations are necessary.

Muesli bar with Omega-3

“The new muesli bar with Omega-3 from Vitalis contains the essential fatty acids EPA and DHA, which are necessary nutrients needed for the body. A high content of Omega-3 DHA fatty acids has a big influence on the brain”.

Since the claim describes what food or food components do – “Omega-3 fatty acids has a big influence on the brain” – this is a health claim. Comments with regards to nutritional profile are the same as for food products described above. In addition, muesli bar contains chocolate (refer to advertising presented in Appendix 5), therefore health claim has to be done with conscious. Chapter

\(^{152}\) EFSA: “Opinion of the scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to nutrition claims concerning Omega-3 fatty acids (…)” (www.efsa.eu.int/science/nda_opinions/catindex_en.html)
7.3 below describes foods for which health claim will be restricted. For example, health claim cannot be made for a chocolate bar.

As it was stated above for yoghurt drink, muesli bar claiming “a high content of Omega-3 fatty acids” must contain more than 30% of the Recommended Nutritional Intake (2 g/day) per 100g or 100 ml or 100 kcal.\textsuperscript{153}

So, in order for muesli bar to bear health claim, there have to be considered whether “8 nutrients” (i.e. protein, carbohydrate, sugar, fat, saturated fatty acids, dietary fibre, and sodium) do not exceed the maximum limit. Particularly, the most attention should be paid for sugar. The solution could be (1) to improve the content of muesli bar. For example, instead of chocolate, the food may contain grains. Then a health claim could be made. (2) Otherwise, if one of the nutrients exceeds its maximum amount level, then a nutrition claim could be made. In this case, muesli bar should bear a statement, that it contains too much sugar.

Manufactures should also consider the consumer segments, particularly elderly people. The claim stated on the muesli bar may not be easily readable, because of the size of muesli bar. Therefore the claim for this kind of food product could be simplified and more information could be provided in the leaflets.

Thus, muesli bar with Omega-3 is not likely to bear the health claim, or it has to be considered such issues as nutrition profile, clarification of the claim, and letter size.

\textbf{6.3. Conclusion on the Case of Fish Oil Omega-3 PUFAs and Food Enriched with them}

This chapter has described and evaluated six categories of foods enriched with Omega-3 PUFAs based on legal framework presented in this paper. The nutrition claim: "The new (X food) with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis (X food) with Omega-3 in all cases is a good nutrition and it helps with good life" could be made for tuna salad, minced fish meat, bacon liver paste, and whole grain bread,\textsuperscript{153}

\textsuperscript{153} EFSA: “Opinion of the scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to nutrition claims concerning Omega-3 fatty acids (…)” (www.efsa.eu.int/science/nda_opinions/catindex_en.html)
if (1) more than one declared nutrients do not exceed the maximum amount level, and (2) underlined statements are explained. In addition, it could be possible for whole grain bread to bear a health claim.

The health claim: “The new (X food) with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. A high content of Omega-3 DHA fatty acids has a big influence on the brain” could be made for yoghurt drink, if (1) declared nutrients do not exceed the maximum limit (particularly, the amount of sugar), and (2) underlined statements are explained. Muesli bar is not likely to bear health claim, because it contains chocolate. Appendix 5 to this paper summarizes all claims and gives comments.

7. Discussions

This chapter describes the main issues concerning functional food, nutrition and health claims made on food. It shows the necessity of the introduction of functional food on the Danish market, the barriers and how to avoid them; as well as the foods for which health claims will be restricted. It tries to draw the line between substantiated health claim, partially substantiated health claims and un-permitted health claims.

7.1. Why it is necessary to have Functional Food on the Danish Market

In Scandinavia, about 65% of consumers consume some type of Omega-3 fatty acid, compared to about 3% in North America. The fact that consumers in Scandinavia consume a lot of Omega-3 could be seen from two perspectives: on the one hand, consumers are aware of fish oil and its benefits to health, therefore introducing a new food product enriched with fish oil it could be accepted more easily by the consumers. However, on the other hand, consumers may not be willing to try a new product, for example, bread enriched with fish oil Omega-3 because they may perceive the bread as smelly fishy; and they are not willing to sacrifice taste for health benefits. Therefore they prefer to take food supplements such as fish oil Omega-3 capsules.

154 Schutt, E., A true oil: Omega 3’s gaining ground as ingredient with many potential benefits and indications (journal on-line “Nutraceuticals World”: http://www.nutraceuticalsworld.com/jan022.htm)
The discussion about adding Omega-3 PUFAs to food products usually revolves around one main issue: taste. About Danish consumers’ demand regarding enriched food products were already described in Chapter 3.3. It has to be much done in order to change consumers’ perception and attitude regarding functional food.

It is necessary that fish oil enriched foods to be introduced on the Danish market, because of social-, economical-, and psychological issues. Danish consumers are very busy people that they don’t have time to prepare food at home. Therefore they are used to eat fast food, which is unhealthy and leads to overweight problem. In their free time many Danish people, particularly young generation, sit at the computers for many hours. All in all, it brings overweight and obesity problem, which leads not only to health problem (i.e. increase the risk of heart attack, getting diabetes, etc.) but also to social-psychological problem like discrimination and difficulty for overweight people to integrate in the society – they may feel desperate and lonely. Looking from economical perspective, Danish government’s expenses will increase because of hospitalization and medical treatment; overweight people have a high risk to become sick. Thus, all of these problems call for healthy lifestyle and balanced diet. Therefore people can intake Omega-3 fatty acid needed for their health. If they don’t eat / don’t like raw fish, they may eat fish oil enriched food product.

However, there can be some obstacles in order to introduce fish oil enriched food on the Danish market. The following sub-chapter will look closer at this matter.

### 7.2. The Main Barriers of Introducing Fish Oil Omega-3 PUFAs Enriched Food on the Danish Market

Manufactures and food operators producing functional foods or food supplements may face with many problems. These problems could be summarized as the following:

- **Technical challenges**: how to incorporate functional ingredients without compromising taste. Particularly, incorporating Omega-3 fatty acids into foodstuff may destroy food’s taste. Functional food manufactures have also to pay attention in correlation of nutrients and products’ characteristics; some nutrients may not be compatible with some base product. Manufactures have also to consider shelf life of products and nutrients. Some nutrients may not survive in a product with respect to heating, humidity, etc.
• **Cultural differences**: consumers’ demand may differ in each Member State. It is necessary to well-define Danish consumers attitude and buying behaviour for functional food;

• **Legal requirements**: national legislation is different in each country. For example, in Italy and France health claims are prohibited. And some functional ingredients may be allowed in one country, whereas the same ingredients may be prohibited. Functional food in Denmark is very strictly regulated. It is important for producers and food operators to know the national law.

There are two approaches, which manufacturers may consider:

1. Fortification to foods, which are already on the market – just adding ingredients to existing foodstuffs.

2. Developing and introducing new food line – fortified food.

Concerning these two approaches, the legislation may differ. It would make easier for regulators and manufacturers to comprehend with the rules, if the first approach is taken. For example, regarding the first approach, there should be taken into account these issues:

• Technical issues: correlation between nutrients and existed food – shelf life, chemical reaction, and oxidation, etc.; what are the technical barriers that it should not destroy taste of enriched food.

• Legal issues: what nutrients to allow to incorporate in the food, how much, and for which type of food, etc.

• Marketing issues: how to communicate health benefits to the consumer, which price to set up, which distribution channel to use, etc.

Regarding the second approach, it would make more difficult for law makers and producers, because of these issues:

• What type of product to launch? Has a manufacture all possible recourses (investment, capital, know-how, etc.) for launching fortified food? For example, even having all needed resources, fortified baby-food will still be very hard to introduce on the market, because this kind of food is very strict regulated in the EU. The authorization procedure of this food may take a lot of time or even enriched baby-food will never appear on the market. Therefore the manufactures have to know the legal framework prior they take actions.
Novartis’s Aviva case (Chapter 5.3) showed that having a good brand image it is not enough to introduce a new product line, because it may lead to wrong perception. Novartis is known as pharmaceutical company, and its new product line – fortified food – was not accepted by consumers since they couldn’t perceive any additional value to their health.

In order to avoid barriers, manufacturers have to be familiar with all issues – marketing and law; and the best way to do it is to have experts in each field: to develop network and to collaborate closely with stakeholders – Danish Consumers Organization and Research Centres, for example.

To conclude: there are many problems, which arise with introducing a new food product enriched with fish oil – which food and how to supplement it with Omega-3 PUFAs. That is to consider food’s base, shelf life, storage conditions (e.g. temperature, humidity, etc.) (technical barriers), and how to market, label, and make health claims for such food (legal barriers).

7.3. For which Foods the Use of Health Claims will be Restricted

Foods which contain too much salt, sugar, and fat

However, not for all kinds of foods health claims can be made. It is obvious that eating too much sweet, fatty or salty food cannot bring positive effect on human health. Therefore foods, which contain a lot of sugar, fat, and salt, cannot bear health claims. Appendix 3 to this paper shows the maximum and minimum level of nutrients in order to make claims.

Satu Hasi, the member of European Parliament with regards to human health and nutrition says, that it is prohibited to market anything with a health claim if the product is in some other way harmful for health. Later she gave an example, which is relevant for her country – Finland: A yogurt, which contains bacteria that are beneficial for your health. But if there is a lot of sugar in the yogurt, as there are in almost all sweetened varieties, it is not healthy. In a normal Finnish sweetened yogurt there is 8 Finnish sugar pieces per 2 dl can. Thus, it is prohibited to make a health claim for this kind of yoghurt.

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155 Personal interview with Satu Hassi, the member of the European Parliament, by e-mail
156 Ibid.
So, even if yoghurt enriched with Omega-3 PUFAs, it cannot claim that consuming this product would decrease the risk of cancer. One of the solutions to this problem could be to improve content of yogurt; that is to use only minimum level of sugar. Another solution could be to make a nutrition claim instead of health claim. Yoghurt could bear a nutrition claim, stating that this yoghurt is high in Omega-3, and evidence showed that daily intake of Omega-3 PUFAs is good for reducing the risk of various disease.

The Danish social-democrat Torben Lund, a speaker-man at the European Parliament with regards to enriched foods, says that unhealthy food cannot be made healthy. For example, an orange cannot be substituted by vitamins-slicks, or a glass of milk cannot be substituted by calcium enriched chocolate.157 Dorthe Pedersen, FI consultant, said that the Danish authorities are not interested to make unhealthy product to be healthy by enriching them with the vitamins or minerals.158

So, health claim cannot be made on the chocolate even if it is enriched with vitamins. For foods which contain saturated fat, health claims should be prohibited.

**Foods for infants and young children**

Foods for infants and young children (until 12 years of age) are likely not to bear health claims, because they need balanced diet, and enriched foods may destroy their daily intake. As it was shown in the previous chapters, too much intake of vitamins or other substances is harmful for human health. The baby food area is specifically regulated by EU legislation: Directive 2003/13/EC on processed cereal-based foods and baby foods for infants and young children,159 Directive 2003/14/EC on infant formulae and follow-on formulae,160 and others.

Directive 2003/13/EC prohibits the sale of processed cereal-based foods and baby foods if those foods contain pesticide residues above certain levels. Specific maximum residue levels of pesticides in processed cereal-based food and baby foods are set up in Annex I to this Directive.

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157 Iversen, C., *Vitaminer i mad på dagsordenen i EU*, Borsen, 8 Marts, 2004
159 OJ L41, 14.2.2003, p. 33
160 OJ L41, 14.2.2003, p. 37
Directive 2003/14/EC prohibits the use of pesticide residues in infant food, if they are above maximum residue level, which is provided in Annex II to this Directive.

*Beverages which contain more than 1.2% by volume of alcohol*

For beverages which contain more than 1.2% by volume of alcohol health claim cannot be made, because it may bring social and health problem. It is worth noticing that a reduction in alcohol or energy content will be allowed.

*Fruit and vegetable*

For fruit and vegetables health claims should be made with care, because they may contain too much sugar. However, it was argued that also for fruit and vegetables health claims could be allowed. This is more obvious in Australia. Food Standards Australia New Zealand (FSANZ) said it is not true that certain fruits would be excluded from health claims because they contained too much naturally occurring sugar.\(^{161}\) Health claims will be prohibited if foods contain more than 16g total sugars, 4g saturated fat or 325 mg salt.\(^{162}\) The sugar limit would not apply for generic health claims on fruit, such as “oranges are a good source of vitamin C”.\(^{163}\)

The proposed Regulation on nutrition and health claims made on food provides that a claim, which states that food is a natural source of vitamins and/or minerals may only be made where the food product contains at least 15% of the recommended daily allowance specified in the Annex to Council Directive 90/496/EEC per 100g or 100ml.\(^{164}\)

Another problem with regards to claims making on fruits and vegetables is that claims such as “fruit is healthy” is allowed if the nutritional and/or health benefits are explained in order to show the benefits of this type of food product.\(^{165}\)

Furthermore, the Danish social-democrat Torben Lund, the speaker-man at the European Parliament with regards to enriched foods, says, that vitamins and minerals cannot be added to fresh products

\(^{161}\) News on-lines about nutrition: *Fruit will be allowed health claims*, 31 January, 2006 (http://www.nutraingredients.com/news/ng.asp?id=65498-fsanz-health-claims-fruit)

\(^{162}\) Ibid.

\(^{163}\) Ibid.

\(^{164}\) COM(2003) 424 final

\(^{165}\) News on-lines about nutrition: *Fruit will be allowed health claims*, 31 January, 2006 (http://www.nutraingredients.com/news/ng.asp?id=65498-fsanz-health-claims-fruit)
such as vegetables, fruits, fish and meat, because too much intake of vitamins has an adverse effect.\textsuperscript{166}

To conclude: health claims will be restricted for those foods, which contain too much salt, sugar, and fat. For example, the use of health claims will be restricted for cakes, candies, sodavand. Yoghurt falls in a gray area, meaning that it can bear health claim if yoghurt doesn’t exceed the maximum level of sugar content. However, if it does – the yogurt may bear a nutrition claim.


Scientific substantiation is necessary in order to increase consumer’s confidence and to assure fair competition. However, not for all types of claims substantiation could be made. The purpose of this sub-chapter is to draw the line between substantiated-, partially substantiated-, and un-permitted health claims, as well as to show what criteria should be considered for scientific substantiation of health claims.

Substantiated health claims

In the EU all health claims have to be scientifically substantiated. For example, “Whole grain may keep your heart healthy”, or “Fruit and vegetables consumption may help to reduce the risk of cancer”. Example of acceptable health claim with regards to Omega-3 fatty acids is:

“\textit{Omega-3 fatty acids have a positive effect on blood lipid and can therefore help protect against cardiovascular disease. Fish product X is rich in Omega-3 fatty acids}”.

The health claims have to be substantiated based on generally accepted scientific data, and the companies must justify their use on the products concerned.

There are mainly two types of claims that are debated in the EU, namely behavioural health claims and general well-being claims, which were prohibited under Article 11 of the proposed Regulation. It was argued that there are many factors, other than dietary ones, that can influence psychological and behavioural functions.\textsuperscript{167} These factors are exercise, smoking, pollution, infection and sun

\textsuperscript{166} Iversen, C., \textit{Vitaminer i mad på dagsordenen i EU}, Børsen, 8 Marts, 2004
\textsuperscript{167} Why EU Law Says Food Can’t Effect Your Mind (www.patrickholford.com/content.asp?id_Content=1081)
exposure, etc. Claim which states that this food may help to support well-being could be preferred for consumers who have mental problem; they may choose this product rather for antidepressants.168 Recalling Chapter 2.1 above, health claims should be made for food products but not for medicines. Health claims should not bear words such as “curing”, “treating”, or “preventing” any human disease. So, behavioural and well-being claims will be allowed if they are authorized by a competent authority. Furthermore, the Commission stated that all health claims, which were prohibited under the Article 11 of the proposed Regulation, are now allowed, if scientifically substantiated.169 The main disadvantage of authorization process is that it may take some time for health claims to be approved, or it may never be authorized. Therefore it is important to know what documents are necessary for good scientific substantiation, and what criteria health claims should meet.

Good scientific substantiation of the claim requires that scientific evidence is of good quality and it is either expressed or implied that the science should sustain peer-review.170 A manufacturer or food operator who makes health claim has to submit necessary documentations, showing the relationship between food or food component and health benefits, to competent authority (e.g. in the US health claims are approved by FDA, in the EU – by EFSA). The rules and requirements of this procedure are set up in the EU legislation, guidelines and codes. For example, in the UK, the British code of practice details the type of data that should be presented for substantiation. There are few requirements concerning substantiation of health claims:

- The evidence must be based on relevant data from human. It is not enough to make experiments with animals;
- To demonstrate that the food, when consumed in reasonable quantities, can achieve or contribute to the claimed beneficial effect;
- To demonstrate that the effectiveness of substances incorporated into the food is not reduced.

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168 *Why EU Law Says Food Can’t Effect Your Mind* ([www.patrickholford.com/content.asp?id_Content=1081](http://www.patrickholford.com/content.asp?id_Content=1081))

169 COM/2006/0002 final - COD 2003/0165

International Life Science Institute (ILSI) draws up the following criteria for the scientific substantiation of health claims on foods and food components:  

- Comply with existing legislation;
- Scientifically substantiated totality of evidence;
- Specify who may benefit from effect;
- Claims primarily based on human intervention studies;
- Markers to be used if the enhanced function or disease risk cannot be measured directly;
- Markers should be validated;
- Markers should be changed in a biologically relevant way and be statistically significant for the target group.

In order for health claims to be authorized, foods bearing such claims must meet specific nutritional profiles provided in the Annex to proposed Regulation on nutrition and health claims made on food.  

To conclude: substantiated health claims are those claims, which are made for food products that meet specific nutritional profiles, wording of the claims are understandable, not misleading and meaningful to the consumers, and there is shown a beneficial effect.

There are few criteria that must be met in order to substantiate a health claim. These are the following:

- It is able to demonstrate that the food or its components will contribute to a significant positive health benefit when consumed by the target group;
- The effect must be achieved by the consumption of a reasonable amount of food;
- The claimed effect must be maintained over a reasonable period of time;
- It should be provided the scientific data needed to support a claim. The conclusion should be based on human studies and not just on animal or biochemical studies.

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172 See Appendix 3 to this paper
**Partially substantiated health claims**

Partially substantiated health claims are not easily understood. Usually a health claim is either permitted, which is scientifically substantiated, or prohibited, which is not substantiated. However, some health claims may fall in a “grey area”. In other words, claims may contain only a partial truth regarding the health effects on food products. These claims are “purifies your organism” or “helps your body resist stress”, for example. These claims are general, and cannot be verified. They have to be used with conscious, since they may mislead consumers.

In a “grey area” may fall also fish oil Omega-3 claims. For example, fish oil Omega-3 capsules can be seen as food supplement and/or natural medicine. Manufactures and food operators have to decide themselves how to market and sell this product, because food product and medicine are regulated by different legislations.\(^{173}\)

Another problem with regards to substantiation of health claims is that laboratorial trials may be out-dated. Thus, claims may be supported by incomplete scientific evidence. It is necessary to present up-to-date information in order to keep consumers informed on recent development within the food industry, and that consumers could make informative choice when buying food product.

To conclude: a health claim has to be precise, and based on recent scientific evidence.

**Un-permitted health claims**

Un-permitted or unsubstantiated health claims are claims, which are not approved by the EFSA. These claims are deceptive and misleading; they involve “miracle cures”, for example, for cancer, arthritis, heart disease, liver disease, and other conditions. Products cannot carry health claims if they contain excessive levels of fat, sugar, salt, or cholesterol, or contain no nutritive value at all. A food label cannot claim to cure, mitigate, treat or prevent disease, since these claims are so-called medical claims. For example, “drinking milk prevents osteoporosis” would be unacceptable use of a drug claim for a food product.\(^{174}\)

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\(^{173}\) See Chapter 4.5.2  
Un-permitted health claim could be illustrated by an example of Noni juice given by Deborah Condon (irishhealth.com). Noni juice, which is made from the exotic fruit *Morinda citrofolia*, claimed to provide health benefits to the consumers like “relieving diabetes and fibromyalgia”. The Food Safety Authority of Ireland (FSAI) said that there is no scientific evidence available to justify claims that the juice provides special health benefits beyond those of other fruit juices. Furthermore, FSAI stated that consumers may be misled by these scientifically unsubstantiated health claims. They may choose to forgo conventional medical treatment in favour of Noni juice. Thus, health claim cannot be permitted if it may mislead the consumer. Functional food (in this case Noni juice) cannot substitute the medical devices needed for treatment.

FSAI added that while the sale of Noni juice in the EU is legal, medical claims about the product are illegal. Any product that carries medical claims requires pre-market approval as a medicine and they are approved by the Irish Medicines Board.

To conclude: any information about foods and their nutritional value used in labelling, marketing and advertising, which is not clear, not accurate and not meaningful, and cannot be substantiated, will not be permitted.

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176 Ibid.
177 Ibid.
8. Conclusions and Recommendations

Nowadays consumers are becoming more aware of what they eat, and the relationship between food and health effect. This is because of increase in elderly, obesity problem; consumers become more educated, are more open to innovation and new technology, have higher income and are concerned of reducing the risk of disease and to maintain in good health. Therefore it calls for the necessity of improving human health through healthy life and eating habits. Functional food could be a solution to improve people health. However, it brings some problems for food manufacturers and law makers – how to produce and market enriched food, and also how to communicate the health benefits to the consumers in understandable, informative and trustful way.

Therefore the paper has touched the main issues regarding enriched food looking from two perspectives – marketing and law. These issues such as food safety, labelling requirements, nutritional profile and others, which are necessary to consider when making nutrition or health claims on foods, were described in the paper. The main focus was placed on legal framework – regulations and directives – regarding functional food, nutrition, and food supplement. Since there is no legislation on nutrition and health claims, the European Commission has made a proposal for a Regulation on Nutrition and Health Claims made on Food. The paper has presented the proposed Regulation, and showed the likely outcome of the implementation of such proposal in the EU.

The most debated articles of the proposed Regulation were articles 4 and 11. Reviewed legal literature and interviewed law makers at the EU Institutions led to the conclusion that articles 4 “Nutrient profile” will be kept; article 11 “Restricted or implied claims”, if not deleted, it could be changed stating that even restricted health claims, which are in this article, could be allowed if they are scientifically substantiated. Because proposed Regulation doesn’t have provision on marketing food directed at children, this could be included in article 11 “Restricted claims”, or it could be provided in a separate article. Since obesity is a very big problem in the EU, particularly among children, provision on health claims on food addressed to children, would prevent young consumers from misleading and incomplete information.

The report has also looked at the biggest markets for functional food, namely, the US and Japan. Since the US was the first country, which has invoked legislation regulating functional food, more
attention was paid to presenting the US legislation on nutrition and health claims – what the EU may learn from the US experience. The EU is third biggest market for functional food. However, the main focus was placed on the Danish national market for this kind of food. Reviewed literature led to the conclusion that there has to be more done in order for Danish consumers to accept enriched foods.

Based on theory – legal framework – the paper has evaluated health claims examples made on six different categories of food enriched with fish oil Omega-3: tuna salad, minced fish meat, bacon liver paste, whole grain bread, yoghurt drink and muesli bar. The claim examples were developed by Master students – Peter and Brain.

The nutrition claim: "The new (X food) with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis (X food) with Omega-3 in all cases is a good nutrition and it helps with good life" can be made for tuna salad, minced fish meat, bacon liver paste, and whole grain bread, if some improvements are considered.

The health claim: “The new (X food) with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. A high content of Omega-3 DHA fatty acids has a big influence on the brain” can be made for yoghurt drink. However, the claim has to be improved. Since muesli bar contains chocolate, it is not likely to bear a health claim. The report has also shown other foods, which cannot be qualified for bearing health claims.

Regular consumption of fish can help to improve human health; it can reduce the risk of various diseases. Since not everybody can eat raw fish and in turn to have essential fatty acids – Omega-3 PUFAs – fish oil Omega-3 enriched food could be a solution. However, introducing Omega-3 PUFAs enriched food law makers and food operators would face with many problems – technical barriers (e.g. shelf life, storage conditions, temperature, humidity, etc.) as well as legal problems (how to market, label and make claims on foods). These problems were discussed in the paper.

There are few recommendations that food manufactures and law makers should consider when making functional food, nutrition and health claims:
To present claims made on food products in a proper way, meaning that claims are understood by an average consumer and that claims provide true and correct information. If the claim is too long and not easily readable, more information could be provided on the leaflets or brochures attached to the food in question.

To improve information channels – media and advertising. However, because of the lack of information consumers are more likely to choose such product which is known and has already been consumed.

To gain consumers’ awareness and trust, nutrition or health claim should be approved by a competent authority. The sign of such authorization could be shown on the front package of the product.

Consumers should know adverse effect of functional food; it has to be clearly stated on the label.

The most important for consumers is food attributes like taste, smell and convenience. The functional foods could be added with additional flavour. For example, yoghurt enriched with Omega-3 may contain strawberries flavour, and this could be stated on the front package of this food product.

The package of enriched food product should catch attention of the consumers. The price should be affordable and justifiable.

In addition to outlined recommendations above, there are few more considerations for food manufactures and law makers / national governments, respectively, are the following:

**Recommendations for food manufacture:**

- To make market research – is there a consumer demand for such functional food in question;
- To define target groups for functional food, and to develop a good positioning strategy;
- To evaluate its own capabilities – is there any resource (know-how, financial and technological capabilities, legal issues, etc.);
- To promote enriched products through advertising on spot, e.g. in the supermarkets, at schools, etc.;
- To improve labels on food product by increasing letter size, and using more understandable labels. For example, instead of sodium could be stated salt;
• Manufacturers and food operators when making nutrition or health claim have to consider whether the food product is qualified to bear the claim in question, and whether the claim meets certain criteria. In other words, it has to be considered nutritional profile, substances used in the food product, etc.

**Recommendations for law makers / national government:**

• To modify article 11 “Restricted or implied health claims” of the proposed Regulation, stating that health claims provided in this article could be allowed if they are scientifically substantiated. However, marketing food directed at children should be banned. Other articles could be kept in the final text of the Regulation as they are in the proposal;

• To develop information channels (e.g. media, advertising, educational programs, Internet web-site, etc) promoting public health, dietary products and nutrition, and eating habits. Educational program with regards to healthy life and eating habits could be presented in the schools. Young consumers should know the consequences of settle life and fast food and how to avoid obesity and other health problems;

• To establish a list of approved health claims. Examples of the relationship between nutrition and health effect could be included.
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45. The European Commission: Communication from the Commission on the Precautionary principle (www.eu.int/scadplus/leg/en/lvb/132042.htm)

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49. The European Food Information Council: Backgrounder on Food Safety (www.eufic.org)

50. The European Food Information Council: Backgrounder on Functional Foods (www.eufic.org)


52. The National Consumer Agency, the Consumer Ombudsman, and Consumer Complaints Board: www.fs.dk

53. The Danish Consumer Council: http://www.fbr.dk

54. The Danish Veterinary and Food Administration: http://www.uk.foedevarestyrelsen.dk/Forside.htm, http://www.uk.foedevarestyrelsen.dk/Food+Safety/Fortified_food/forside.htm

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57. Why EU Law Says Food Can’t Effect Your Mind (www.patrickholford.com/content.asp?id_Content=1081)
Legal sources:


62. Commission’s *White Paper on Food Safety*


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87. Joined cases C-211/03, C-299/03 and C-316/03 to C-318/03

88. Dietary Supplement Health and Education Act (DSHEA) of 1994:  
   http://www.fda.gov/opacom/laws/dshea.html

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## Appendix 1: Main Concepts used in this Paper

<table>
<thead>
<tr>
<th>Item</th>
<th>Definition</th>
<th>Source</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food</td>
<td>Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by human.</td>
<td>Article 2 of Regulation 178/2002 (OJ L 31, 01/02/2002)</td>
<td>Margarine, milk, fish, yoghurt, etc.</td>
</tr>
<tr>
<td>Functional food</td>
<td>Food, which is consumed as part of the normal diet and that contain components, which provide health benefit beyond basic nutrition.</td>
<td>IFIC, 2004, and The European Food Information Council: <em>Backgrounder on Functional Foods</em></td>
<td>Omega-3 enriched bread, yoghurt fortified with calcium, etc.</td>
</tr>
<tr>
<td>Food supplement</td>
<td>Foodstuff, which supplements the normal diet and which contains of sources of nutrients or other substances with a nutritional or physiological effect.</td>
<td>Article 2 of Directive 2002/46/EC (OJ L 183, 12.7.2002)</td>
<td>Fish oil Omega-3 capsules, Magnus B6, etc.</td>
</tr>
<tr>
<td>Food additives</td>
<td>Any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food (…). It is used for a technological purpose in the manufacture, processing, preparation, packaging, transport or storage of such food results (…) becoming directly or indirectly a component of such food.</td>
<td>Article 1 of Directive 89/107/EEC (OJ L 40, 11.2.1989)</td>
<td>Colour, preservative, antioxidant, etc.</td>
</tr>
<tr>
<td>Nutrients</td>
<td>Any substance that can be metabolized by an organism to give energy and build tissue.</td>
<td>Dictionary on-line: <a href="http://www.wordreferenc.com/">http://www.wordreferenc.com</a></td>
<td>Protein, fat, vitamins and minerals, etc.</td>
</tr>
<tr>
<td>Nutrition claim</td>
<td>Any representation and any advertising which states or implies that a food has particular nutrition properties; what is or is not contained in the product.</td>
<td>Article 1 of Directive 90/496/EEC (OJ L 276, 6.10.1990)</td>
<td>“Low fat”, “sugar free”, “rich in vitamin C”, etc.</td>
</tr>
<tr>
<td>Health claim</td>
<td>Any representation and any advertising which states, suggests, or implies a relationship between a foodstuff (or one of its components) and health.</td>
<td>David Byrne, <em>Health, Nutrition and Labelling</em>, SPEECH/03/89, Brussels, 19 Feb. 2003</td>
<td>“Whole grain may keep your heart healthy”, “Calcium may reduce the risk of osteoporosis”.</td>
</tr>
<tr>
<td>Medical product</td>
<td>Any substance presented for treating or preventing disease in human being or animals.</td>
<td>Article 1 of Directive 65/65/EEC (OJ L 22, 9.2.1965)</td>
<td>Pills, tablets, etc.</td>
</tr>
<tr>
<td>Significant quantity</td>
<td>The product should contain at least 15% of the recommended daily intake per 100g or 100 ml of the product.</td>
<td>Directive 90/496/EEC (OJ L276, 6.10.1990)</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 2: BEUC Survey on Consumer Understanding of Labelling and Nutritional Claims

Figure 1: Percentage of Interviewees wanting Nutritional Information on the Label in each Country


Figure 2: Do You trust Nutritional Claims?

Figure 3: Would the Claim "Rich in Calcium" lead You to buy the Product?


Figure 4: What is the Main Your Source of Information about Nutrition?

## Appendix 3: Nutrition Claims and Conditions applying to them

### Table 1: Compulsory Nutrients – Energy, Fat, Saturated Fat, Sugar, and Sodium/Salt

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Free</th>
<th>Low</th>
<th>Reduced / Less</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy</td>
<td>A claim may only be made where the product contains less than 4 kcal (17 kJ) / 100ml.</td>
<td>A claim may only be made where the product contains less than 40 kcal (170 kJ) / 100g and less than 20 kcal (80 kJ) / 100ml.</td>
<td>A claim may only be made where the energy value is reduced by at least 30%.</td>
</tr>
<tr>
<td>Fat</td>
<td>A claim may only be made where the product contains no more than 0.5g of fat per 100g or 100ml. Claims “X% fat-free” shall be prohibited.</td>
<td>A claim may only be made where the product contains no more than 3g of fat per 100g or 1.5g of fat per 100ml.</td>
<td>(Not given)</td>
</tr>
<tr>
<td>Saturated fat</td>
<td>A claim may only be made where the product contains no more than 0.1g of saturated fat per 100g or 100ml.</td>
<td>A claim may only be made where the product contains no more than 1.5g of saturates per 100g for solids or 0.75g of saturates per 100ml for liquids and in either case saturated fat must not provide more than 10% of energy.</td>
<td>(Not given)</td>
</tr>
<tr>
<td>Sugar</td>
<td>A claim may only be made where the product contains no more than 0.5g of sugars per 100g or 100ml.</td>
<td>A claim may only be made where the product contains no more than 5g of sugars per 100g or 100ml.</td>
<td>(Not given)</td>
</tr>
<tr>
<td>Sodium / Salt</td>
<td>A claim may only be made where the product contains no more than 0.005 of sodium / salt per 100g.</td>
<td>A claim may only be made where the product contains no more than 0.12g of sodium / salt per 100g or per 100ml.</td>
<td>A claim that a food is very low in sodium, may only be made where the product contains no more than 0.04g of sodium / salt per 100g or per 100ml.</td>
</tr>
</tbody>
</table>

### Table 2: Voluntary Nutrients – Fibre, Protein, and Vitamins / Minerals

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Source of nutrient</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibre</td>
<td>A claim that a food is a source of fibre may only be made where the product contains at least 3g of fibre per 100g or at least 1.5g of fibre per 100 kcal.</td>
<td>A claim that a food is high in fibre may only be made where the product contains at least 6g of fibre per 100g or at least 3g of fibre per 100 kcal.</td>
</tr>
<tr>
<td>Protein</td>
<td>A claim that a food is a source of protein may only be made where at least 12% of the energy value of the food is provided by protein.</td>
<td>A claim that a food is high in protein may only be made where at least 20% of the energy value of the food is provided by protein.</td>
</tr>
<tr>
<td>Vitamins / Minerals</td>
<td>A claim that a food is a natural source of vitamins and/or minerals may only be made where the product contains at least 15% of the recommended daily allowance (RDA)* per 100g or 100ml.</td>
<td>A claim that a food is high in vitamins and/or minerals may only be made where the product contains at least 30% of RDA per 100g or 100ml.</td>
</tr>
</tbody>
</table>


Note: *RDA specified in the Annex of Council Directive 90/496/EEC.*
Table 1: Definitions of Nutrient Content Claims

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Free</th>
<th>Low</th>
<th>Reduced/Less</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calories</td>
<td>Less than 5 cal per reference amount and per labelled serving.</td>
<td>40 cal or less per reference amount (and per 50 g if reference amount is small). Meals and main dishes: 120 cal or less per 100 g</td>
<td>At least 25% fewer calories per reference amount than an appropriate reference food. Reference food may not be &quot;Low Calorie&quot; Uses term &quot;Fewer&quot; rather than &quot;Less&quot;.</td>
<td>&quot;Light&quot; or &quot;Lite&quot;: if 50% or more of the calories are from fat, fat must be reduced by at least 50% per reference amount. If less than 50% of calories are from fat, fat must be reduced at least 50% or calories reduced at least 1/3 per reference amount. For dietary supplements: Calorie claims can only be made when the reference product is greater than 40 calories per serving.</td>
</tr>
<tr>
<td>Total Fat</td>
<td>Less than 0.5 g per reference amount and per labelled serving.</td>
<td>3 g or less per reference amount. Meals and main dishes: 3 g or less per 100 g and not more than 30% of calories from fat</td>
<td>At least 25% less fat per reference amount than an appropriate reference food Reference food may not be &quot;Low Fat&quot;.</td>
<td>&quot;__% Fat Free&quot;: OK if meets the requirements for &quot;Low Fat&quot; 100% Fat Free: food must be &quot;Fat Free&quot; For dietary supplements: calorie claims cannot be made for products that are 40 calories or less per serving</td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>Less than 0.5 g saturated fat and less than 0.5 g trans fatty acids per reference amount and per labelled serving.</td>
<td>1 g or less per reference amount and 15% or less of calories from saturated fat. Meals and main dishes: 1 g or less per 100 g and less than 10% of calories from saturated fat.</td>
<td>At least 25% less saturated fat per reference amount than an appropriate reference food. Reference food may not be &quot;Low Saturated Fat&quot;.</td>
<td>Next to all saturated fat claims, must declare the amount of cholesterol if 2 mg or more per reference amount; and the amount of total fat if more than 3 g per reference amount. For dietary supplements: saturated fat claims cannot be made for products that are 40 calories or less per serving</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Less than 2 mg per reference amount and per labelled serving.</td>
<td>20 mg or less per reference amount.</td>
<td>At least 25% less cholesterol per reference amount than an appropriate reference food Reference food may not be &quot;Low Cholesterol&quot;</td>
<td>Cholesterol claims only allowed when food contains 2 g or less saturated fat per reference amount; or for meals and main dish products – per labelled serving size for &quot;Free&quot; claims or per 100 g for &quot;Low&quot; and &quot;Reduced/Less&quot; claims.</td>
</tr>
<tr>
<td>Food Group</td>
<td>Requirement</td>
<td>Example</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
<td>---------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>Sodium</td>
<td>Must declare the amount of total fat next to cholesterol claim when fat exceeds 13 g per reference amount and labelled serving (or per 50 g of food if reference amount is small). For dietary supplements: cholesterol claims cannot be made for products that are 40 calories or less per serving.</td>
<td>Less than 5 mg per reference amount and per labelled serving. 140 mg or less per reference amount. Meals and main dishes: 140 mg or less per 100 g at least 25% less sodium per reference amount than an appropriate reference food. Reference food may not be &quot;Low Sodium&quot;</td>
<td>&quot;Light&quot; (for sodium reduced products): if food is &quot;Low Calorie&quot; and &quot;Low Fat&quot; and sodium is reduced by at least 50%. &quot;Very Low Sodium&quot;: 35 mg or less per reference amount. For meals and main dishes: 35 mg or less per 100 g &quot;Salt Free&quot; must meet criterion for &quot;Sodium Free&quot;. &quot;No Salt Added&quot; and &quot;Unsalted&quot; must conditions of use and must declare &quot;This is Not A Sodium Free Food&quot; on information panel if food is not &quot;Sodium Free&quot;. &quot;Lightly Salted&quot;: 50% less sodium than normally added to reference food and if not &quot;Low Sodium&quot;, so labelled on information panel.</td>
<td></td>
</tr>
<tr>
<td>Sugars</td>
<td>&quot;Sugar Free&quot;: Less than 0.5 g sugars per reference amount and per labelled serving. Not Defined. No basis for recommended intake</td>
<td>At least 25% less sugars per reference amount than an appropriate reference food. May not use this claim on dietary supplements of vitamins and minerals</td>
<td>&quot;No Added Sugars&quot; and &quot;Without Added Sugars&quot; are allowed if no sugar or sugar containing ingredient is added during processing. The terms &quot;Unsweetened&quot; and &quot;No Added Sweeteners&quot; remain as factual statements. Claims about reducing dental caries are implied health claims. Does not include sugar alcohols.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Approved claims</th>
<th>Food requirements</th>
<th>Claim requirements</th>
<th>Model claims, statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium and Osteoporosis - 21 CFR 101.72</td>
<td>- High in calcium,</td>
<td>Indicates disease depends on many factors by listing risk factors or the disease: Gender – Female. Race – Caucasian and Asian. Age – Growing older.</td>
<td>Regular exercise and a healthy diet with enough calcium helps teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.</td>
</tr>
<tr>
<td></td>
<td>- Assimilable (Bioavailable),</td>
<td>Primary target population: Females, Caucasian and Asian races, and teens and young adults in their bone-forming years. Additional factors necessary to reduce risk: Eating healthful meals, regular exercise. Mechanism relating calcium to osteoporosis: Optimizes peak bone mass. Foods or supplements containing more than 400 mg calcium must state that total intakes of greater than 2,000 mg calcium provide no added benefit to bone health.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Supplements must disintegrate and dissolve, and - Phosphorus content cannot exceed calcium content</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium and Hypertension - 21 CFR 101.74</td>
<td>- Low sodium</td>
<td>Required terms: - &quot;Sodium&quot;, &quot;High blood pressure&quot; Includes physician statement (Individuals with high blood pressure should consult their physicians) if claim defines high or normal blood pressure.</td>
<td>Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.</td>
</tr>
<tr>
<td>Dietary Fat and Cancer - 21 CFR 101.73</td>
<td>- Low fat (Fish &amp; game meats: &quot;Extra lean&quot;)</td>
<td>Required terms: - &quot;Total fat&quot; or &quot;Fat&quot; - &quot;Some types of cancers&quot; or &quot;Some cancers&quot; Does not specify types of fats or fatty acids that may be related to risk of cancer.</td>
<td>Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.</td>
</tr>
<tr>
<td>Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease - 21 CFR 101.75</td>
<td>- Low saturated fat, - Low cholesterol, and - Low fat (Fish &amp; game meats: &quot;Extra lean&quot;)</td>
<td>Required terms: - &quot;Saturated fat and cholesterol&quot;, - &quot;Coronary heart disease&quot; or &quot;Heart disease&quot; Includes physician statement (individuals with elevated blood total – or LDL – cholesterol should consult their physicians) if claim defines high or normal blood total – and LDL – cholesterol.</td>
<td>While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.</td>
</tr>
<tr>
<td>Fiber-</td>
<td>- A grain product, fruit,</td>
<td>Required terms:</td>
<td>Low fat diets rich in fiber-</td>
</tr>
<tr>
<td>Containing Grain Products, Fruits, and Vegetables and Cancer - 21 CFR 101.76</td>
<td>or vegetable that contains dietary fiber; - Low fat, and - Good source of dietary fiber (without fortification)</td>
<td>&quot;Fiber&quot;, &quot;Dietary fiber&quot;, or &quot;Total dietary fiber&quot; - &quot;Some types of cancer&quot; or &quot;Some cancers&quot; Does not specify types of dietary fiber that may be related to risk of cancer.</td>
<td>containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble Fiber, and Risk of Coronary Heart Disease - 21 CFR 101.77</td>
<td>- A fruit, vegetable, or grain product that contains fiber; - Low saturated fat, - Low cholesterol, - Low fat, - At least 0.6 grams of soluble fiber per RA (without fortification), and, - Soluble fiber content provided on label</td>
<td>Required terms: - &quot;Fiber&quot;, &quot;Dietary fiber&quot;, &quot;Some types of dietary fiber&quot;, &quot;Some dietary fibers&quot;, or &quot;Some fibers&quot; - &quot;Saturated fat&quot; and &quot;Cholesterol&quot; - &quot;Heart disease&quot; or &quot;Coronary heart disease&quot; Includes physician statement (&quot;Individuals with elevated blood total – or LDL – cholesterol should consult their physicians&quot;) if claim defines high or normal blood total - and LDL – cholesterol.</td>
<td>Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.</td>
</tr>
<tr>
<td>Fruits and Vegetables and Cancer - 21 CFR 101.78</td>
<td>- A fruit or vegetable, - Low fat, and - Good source (without fortification) of at least one of the following: Vitamin A, Vitamin C, or Dietary fiber</td>
<td>Required terms: - &quot;Fiber&quot;, &quot;Dietary fiber&quot;, or &quot;Total dietary fiber&quot;; - &quot;Total fat&quot; or &quot;Fat&quot;, - &quot;Some types of cancer&quot; or &quot;Some cancers&quot; Characterizes fruits and vegetables as &quot;Foods that are low in fat and may contain Vitamin A, Vitamin C, and dietary fiber.&quot; Characterizes specific food as a &quot;Good source&quot; of one or more of the following: Dietary fiber, Vitamin A, or Vitamin C. Does not specify types of fats or fatty acids or types of dietary fiber that may be related to risk of cancer.</td>
<td>Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, Vitamin A, or Vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamin A and C, and it is a good source of dietary fiber.</td>
</tr>
<tr>
<td>Folate and Neural Tube Defects - 21 CFR 101.79</td>
<td>&quot;Good source&quot; of folate (at least 40 mcg folate per serving) - Dietary supplements, or foods in conventional food form that are naturally good sources of folate (i.e., only non-fortified food in conventional food form)</td>
<td>Required terms: - Terms that specify the relationship (e.g., women who are capable of becoming pregnant and who consume adequate amounts of folate) &quot;Folate&quot;, &quot;folic acid&quot;, &quot;folacin&quot;,&quot;folate a B vitamin&quot;, &quot;folic acid, a B vitamin,&quot; &quot;folacin, a B vitamin,&quot; &quot;neural tube defects&quot;, &quot;birth defects, spinal bifida, or Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect.</td>
<td>Does not specify types of fats or fatty acids or types of dietary fiber that may be related to risk of cancer.</td>
</tr>
</tbody>
</table>
- The claim shall not be made on products that contain more than 100% of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D

- anencephaly”, "birth defects of the brain or spinal cord -- anencephaly or spinal bifida”, "spinal bifida or anencephaly, birth defects of the brain or spinal cord". Must also include information on the multifactorial nature of neural tube defects, and the safe upper limit of daily intake.

### Dietary Sugar Alcohol and Dental Caries - 21 CFR 101.80

- **Sugar free**
- The sugar alcohol must be xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, or a combination.

**Required terms:**
- "does not promote," "may reduce the risk of," "useful [or is useful] in not promoting" or "expressly [or is expressly] for not promoting" dental caries;
- "sugar alcohol" or "sugar alcohols" or the name or names of the sugar alcohols, e.g., sorbitol;
- "dental caries" or "tooth decay." Includes statement that frequent between meal consumption of foods high in sugars and starches can promote tooth decay.

*Packages with less than 15 square inches of surface area available for labeling may use a shortened claim.*

#### Full claim:
Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay.

#### Shortened claim (on small packages only):
Does not promote tooth decay.

### Soy Protein and Risk of Coronary Heart Disease - 21 CFR 101.82

- At least 6.25 g soy protein per RA
- Low saturated fat,
- Low cholesterol, and
- Low fat (except that foods made from whole soybeans that contain no fat in addition to that inherent in the whole soybean are exempt from the "low fat" requirement).

**Required terms:**
- "Heart disease" or "coronary heart disease"
- "Soy protein"
- "Saturated fat" and "cholesterol"

Claim specifies daily dietary intake levels of soy protein associated with reduced risk. Claim specifies amount of soy protein in a serving of food.

(1) 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies __ grams of soy protein.

(2) Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides __ grams of soy protein.

### Plant Sterol/stanol esters and Risk of Coronary Heart Disease - 21 CFR 101.83

- At least 0.65 g plant sterol esters per RA of spreads and salad dressings, or
- At least 1.7 g plant sterol esters per RA of spreads, salad dressings, snack bars,

**Required terms:**
- "May" or "might" reduce the risk of CHD
- "Heart disease" or "coronary heart disease"
- "Plant sterol esters" or "plant sterol esters" ; except "vegetable oil" may replace the term "plant"

(1) Foods containing at least 0.65 gram per serving of vegetable oil sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 grams, as part of a diet low in saturated fat and
and dietary supplements.
- Low saturated fat,
- Low cholesterol, and
- Spreads and salad dressings that exceed 13 g fat per 50 g must bear the statement "see nutrition information for fat content"
Salad dressings are exempted from the minimum 10% DV nutrient requirement (see General Criteria below – Table 3)

<table>
<thead>
<tr>
<th>if vegetable oil is the sole source of the sterol/stanol ester</th>
<th>Claim specifies plant sterol/stanol esters are part of a diet low in saturated fat and cholesterol. Claim does not attribute any degree of CHD risk reduction. Claim specifies the daily dietary intake of plant sterol or stanol esters necessary to reduce CHD risk, and the amount provided per serving. Claim specifies that plant sterol or stanol esters should be consumed with two different meals each a day.</th>
<th>cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies __ grams of vegetable oil sterol esters. (2) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 grams of plant stanol esters in two meals may reduce the risk of heart disease. A serving of [name of food] supplies __ grams of plant stanol esters.</th>
</tr>
</thead>
</table>

Table 3: General Criteria All Claims Must Meet

- All information in one place without intervening material (Reference statement permitted).
- Only information on the value that intake or reduced intake, as part of a total dietary pattern, may have on a disease or health-related condition.
- Enables public to understand information provided and significance of information in the context of a total daily diet.
- Complete, truthful, and not misleading.
- Food Contains, without fortification, 10% or more of the Daily Value for one of six nutrients (dietary supplements excepted):

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Daily Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>500 IU</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>6 mg</td>
</tr>
<tr>
<td>Iron</td>
<td>1.8 mg</td>
</tr>
<tr>
<td>Calcium</td>
<td>100 mg</td>
</tr>
<tr>
<td>Protein</td>
<td>5 g</td>
</tr>
<tr>
<td>Fiber</td>
<td>2.5 g</td>
</tr>
</tbody>
</table>

- Not represented for infants or toddlers less than 2 years of age.
- Uses "may" or "might" to express relationship between substance and disease.
- Does not quantify any degree of risk reduction.
- Indicates disease depends on many factors.
- Food contains less than the specified levels of four disqualifying nutrients:

<table>
<thead>
<tr>
<th>Disqualifying nutrients</th>
<th>Foods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat</td>
<td>13 g</td>
</tr>
<tr>
<td>Saturated</td>
<td>4 g</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>60 mg</td>
</tr>
<tr>
<td>Sodium</td>
<td>480 mg</td>
</tr>
</tbody>
</table>


Note: Abbreviations: RA = reference amount, IU = International Units
<table>
<thead>
<tr>
<th>Food</th>
<th>Food additives</th>
<th>Dietary supplements</th>
<th>Medical foods</th>
<th>Foods for special dietary use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foods are presumed to be safe unless the FDA determines that a particular food is injurious to health.</td>
<td>Presumption is that food additives are unsafe until proven otherwise. Any ingredients used in a multi-ingredient food product must be pre-approved by the agency unless the ingredient is exempt. Ingredients would be exempt if they are: (a) Generally Recognized as Safe (GRAS) (as demonstrated by scientific evidence or long-time use in food); or (b) the subject of a prior sanction (an informal approval by FDA issued prior to the enactment of the 1958 Food Additives Amendment).</td>
<td>Presumption is that dietary supplements are safe until proven otherwise. Dietary supplements containing ingredients not in use prior to Oct. 15, 1994 may be marketed 75 days after the manufacturer provides notice and substantiation that the ingredient can “reasonably be expected to be safe.” FDA approval and thorough scientific testing are not required. Notification and substantiation are not required for ingredients that were in use before Oct. 15, 1994. Such products can be banned by FDA only upon a showing of “significant or unreasonable risk.” It is very difficult for FDA to remove a dietary supplement from the market.</td>
<td>Ingredients are subject to food additive provisions. There is no additional regulatory framework that: creates specific quality assurance requirements; ensures that the foods are safe under their conditions of intended use; or ensures that they provide nutrients that they claim to provide within safe ranges or ensures that benefits claimed are supported by adequate scientific evidence.</td>
<td>Ingredients are subject to food additive requirements. There is no additional regulatory framework to ensure that foods are safe for their intended use.</td>
</tr>
</tbody>
</table>

Table 5: FDA Regulation of Health Claims Based upon Regulatory Category

<table>
<thead>
<tr>
<th>Food</th>
<th>Dietary supplements</th>
<th>Medical foods</th>
<th>Foods for special dietary use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory Conditions</strong></td>
<td><strong>Regulatory Conditions</strong></td>
<td><strong>Regulatory Conditions</strong></td>
<td><strong>Regulatory Conditions</strong></td>
</tr>
<tr>
<td>Permitted if: 1) the claim has been approved by specific FDA regulation; or 2) the claim is based on an “authoritative statement” of an agency other than FDA with scientific expertise and the FDA does not object to the claim within a 120-day notification period. To be eligible for a health claim, substance must contribute taste, aroma, nutritive value, or other technical effects. Nutritive value refers to value in sustaining human existence.</td>
<td>Same requirements as for food.</td>
<td>May be made without pre-market approval.</td>
<td>Generally, subject to the same requirements as food.</td>
</tr>
<tr>
<td><strong>Key Problems:</strong></td>
<td><strong>Key Problems:</strong></td>
<td><strong>Key Problems:</strong></td>
<td><strong>Key Problems:</strong></td>
</tr>
<tr>
<td>Length of approval process encourages manufacturers to seek alternate means of marketing the product, such as making structure/function claims or promoting the product as a medical food.</td>
<td>Same as foods.</td>
<td>Manufacturers are marketing products directly to consumers with serious health conditions that should be closely monitored by a physician.</td>
<td>FDA disfavors approving new regulations for this category.</td>
</tr>
</tbody>
</table>

Source: Centre for Science in the Public Interest (CSPI), *Functional Foods: Public Health Boom or 21st Century Quackery?* (http://www.cspinet.org/reports/functional_foods/)
<table>
<thead>
<tr>
<th>Food</th>
<th>Dietary supplements</th>
<th>Medical foods</th>
<th>Foods for special dietary use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Requirements</strong></td>
<td><strong>Requirements</strong></td>
<td><strong>Requirements</strong></td>
<td><strong>Requirements</strong></td>
</tr>
<tr>
<td>No specific requirements beyond statutory mandate that claim should not be false or misleading and should not claim to cure, mitigate, or treat a disease. The substance that is the subject of the claim must contribute to the taste, aroma, or nutritive value or have a technical effect on the food. Nutritive value refers to value in sustaining human existence. Examples include: promoting growth, replacing loss of essential nutrients, or providing energy.</td>
<td>All requirements applicable to food apply, with the exception of the nutritive-value requirement. Claims do not need to relate to the nutritive value of the component that is the basis for the claim. In addition: Manufacturer must notify FDA that claim is being made within 30 days after marketing begins. Products making claim must bear the following statement: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”</td>
<td>No restrictions on claims other than prohibitions on false or misleading labels or labelling.</td>
<td>Generally treated the same as food.</td>
</tr>
<tr>
<td><strong>Key Problems:</strong></td>
<td><strong>Key Problems:</strong></td>
<td><strong>Key Problems:</strong></td>
<td><strong>Key Problems:</strong></td>
</tr>
<tr>
<td>Claims misleadingly imply disease prevention and treatment. Consumers may not distinguish scientifically valid FDA-approved health claims from structure/function claims based on evidence that has not been reviewed by the FDA.</td>
<td>Same problems as food, but adverse impacts may be greater for consumers who rely on supplements to treat serious health conditions.</td>
<td>FDA does not require pre-market approval of claims and does not limit the use of this category to bona fide medical products used under the supervision of a physician.</td>
<td>Same problems as conventional foods.</td>
</tr>
</tbody>
</table>

Table 7: Three Examples Regarding Relationship between Nutrition and Health Benefits provided by the US Code of Federal Regulations (CFR) based on Petitions for Health Claims

1. Relationship between calcium and osteoporosis:

Calcium intake contributes to low peak bone mass and has been identified as one of many risk factors in the development of osteoporosis. Peak bone mass is the total quantity of bone present at maturity, and experts believe that it has the greatest bearing on whether a person will be at risk of developing osteoporosis and related bone fractures later in life. An adequate intake of calcium is thought to exert a positive effect during adolescence and early adulthood in optimizing the amount of bone. However, the upper limit of peak bone mass is genetically determined. The mechanism through which an adequate calcium intake and optimal peak bone mass reduce the risk of osteoporosis is thought to be as follows. All persons lose bone with age. The rate of bone loss after skeletal maturity also influences the amount of bone present at old age and can influence an individual's risk of developing osteoporosis. Maintenance of an adequate intake of calcium later in life is thought to be important in reducing the rate of bone loss particularly in the elderly.

Calcium intake is not the only recognized risk factor in the development of osteoporosis. Other factors including a person's sex, race, hormonal status, family history, body stature, level of exercise, general diet, and specific life style choices such as smoking and excess alcohol consumption affect the risk of osteoporosis. Maintenance of an adequate intake of calcium throughout life is particularly important for a subpopulation of individuals at greatest risk of developing osteoporosis and for whom adequate dietary calcium intake may have the most important beneficial effects on bone health.

Regular exercise and a healthy diet with enough calcium help everybody maintain good bone health and may reduce their high risk of osteoporosis later in life. Adequate calcium intake is important, but daily intakes above about 2,000 mg are not likely to provide any additional benefit.

A health claim associating calcium with a reduced risk of osteoporosis may be made on the label or labelling of a food provided that:

- The claim makes clear that adequate calcium intake throughout life is not the only recognized risk factor in this bone disease by listing specific factors, including sex, race, and age that place persons at risk of developing osteoporosis and stating that an adequate level of exercise and a healthful diet are also needed;
- The claim does not state or imply that the risk of osteoporosis is equally applicable to the general United States population. The claim shall identify the populations at particular risk for the development of osteoporosis. These populations include white (or the term “Caucasian”) women and Asian women in their bone forming years approximately 11 to 35 years of age or the phrase “during teen or early adult years” may be used. The claim may also identify menopausal or the term “middle-aged” women, persons with a family history of the disease, and elderly (or “older”) men and women as being at risk;
- The claim states that adequate calcium intake throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and
early adulthood. The phrase “build and maintain good bone health” may be used to convey the concept of optimizing peak bone mass. When reference is made to persons with a family history of the disease, menopausal women, and elderly men and women, the claim may also state that adequate calcium intake is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss;

- The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate calcium intake throughout life;
- The claim states that a total dietary intake greater than 200% of the recommended daily intake (2,000 milligrams (mg) of calcium) has no further known benefit to bone health. This requirement does not apply to foods that contain less than 40% of the recommended daily intake of 1,000 mg of calcium per day.

Health claims examples could be used in food labelling to describe the relationship between calcium and osteoporosis:

(a) “Regular exercise and a healthy diet with enough calcium helps teen and young adult maintain good bone health and may reduce their high risk of osteoporosis later in life”.
(b) “Adequate calcium intake is important, but daily intakes above about 2,000 mg are not likely to provide any additional benefit.

2. Relationship between sodium and hypertension (high blood pressure):

Hypertension, or high blood pressure, generally means a systolic blood pressure of greater than 140 millimetres of mercury (mm Hg) or a diastolic blood pressure of greater than 90 mm Hg. Normal blood pressure is a systolic blood pressure below 140 mm Hg and diastolic blood pressure below 90 mm Hg.

High blood pressure is a public health concern primarily because it is a major risk factor for mortality from coronary heart disease and stroke. Individuals with high blood pressure are at greatest risk, and individuals with moderately high, high normal, and normal blood pressure are at steadily decreasing risk. The scientific evidence indicates that reducing sodium intake lowers blood pressure and associated risks in many but not all hypertensive individuals. The populations at greatest risk for high blood pressure, and those most likely to benefit from sodium reduction, include those with family histories of high blood pressure, the elderly, males because they develop hypertension earlier in life than females, and black males and females. Sodium intake, alcohol consumption, and obesity are identified risk factors for high blood pressure.

Sodium intakes exceed recommended levels in almost every group in the United States. One of the major public health recommendations relative to high blood pressure is to decrease consumption of salt. On a population-wide basis, reducing the average sodium intake would have a small but significant effect on reducing the average blood pressure, and, consequently, reducing mortality from coronary heart disease and stroke.

Sodium is an essential nutrient, and experts have recommended a safe minimum level of 500 milligrams (mg) sodium per day and an upper level of 2,400 mg sodium per day.

A health claim associating diets low in sodium with reduced risk of high blood pressure may be made on the label or labelling of a food provided that:
The claim states that diets low in sodium “may” or “might” reduce the risk of high blood pressure;

- In specifying the disease, the claim uses the term “high blood pressure”; in specifying the nutrient, the claim uses the term “sodium”;
- The claim does not attribute any degree of reduction in risk of high blood pressure to diets low in sodium;
- The claim indicates that development of high blood pressure depends on many factors.

The food shall meet all of the nutrient content requirements for a “low sodium” food. In specifying the nutrient, the claim may include the term “salt” in addition to the term “sodium”. The claim may state that individuals with high blood pressure should consult their physicians for medical advice and treatment.

Health claims examples could be used in food labelling to describe the relationship between sodium and high blood pressure:

- “Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors”.
- “Development of hypertension or high blood pressure depends on many factors. [This product] can be part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure”.

3. Relationship between dietary saturated fat and cholesterol and risk of coronary heart disease:

Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total- and low density lipoprotein (LDL)-cholesterol levels are major risk factors in the development of coronary heart disease.

High coronary heart disease rates occur among people with high blood cholesterol levels of 240 milligrams/decaliter (mg/dL) (6.21 millimoles per liter (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Dietary lipids (fats) include fatty acids and cholesterol. Total fat, commonly referred to as fat, is composed of unsaturated fats, and saturated fat. Recommended daily cholesterol intakes are 300 mg or less per day.

The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease.

Coronary heart disease is a major public health concern in the United States, primarily because it accounts for more deaths than any other disease or group of diseases. There is a continuum of mortality risk from coronary heart disease that increases with increasing levels of blood LDL-cholesterol. Individuals with high blood LDL-cholesterol are at greatest risk. The scientific evidence indicates that reducing saturated fat and cholesterol intakes lowers blood LDL-cholesterol and risk of heart disease in most individuals. There is also evidence that reducing saturated fat and cholesterol intakes in persons with blood cholesterol levels in the normal range also reduces risk of heart disease. Other risk factors for coronary heart disease include a family history of heart disease,
high blood pressure, diabetes, cigarette smoking, obesity (body weight 30% greater than ideal body weight), and lack of regular physical exercise.

A health claim associating diets low in saturated fat and cholesterol with reduced risk of coronary heart disease may be made on the label or labelling of a food provided that:

- The claim states that diets low in saturated fat and cholesterol “may” or “might” reduce the risk of heart disease;
- In specifying the disease, the claim uses the terms “heart disease” or “coronary heart disease”; in specifying the nutrient, the claim uses the terms “saturated fat” and “cholesterol” and lists both;
- The claim does not attribute any degree of risk reduction for coronary heart disease to diets low in dietary saturated fat and cholesterol;
- The claim states that coronary heart disease risk depends on many factors.

The food shall meet all of the nutrient content requirements for a “low saturated fat”, “low cholesterol”, and “low fat” food. The claim may identify one or more of the following risk factors in addition to saturated fat and cholesterol about which there is general scientific agreement that they are major risk factors for this disease: A family history of coronary heart disease, elevated blood total and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity. In specifying the nutrients, the claim may include the term “total fat” in addition to the terms “saturated fat” and “cholesterol”. The claim may state that individuals with elevated blood total- or LDL-cholesterol should consult their physicians for medical advice and treatment.

Health claims examples to be used in food labelling to describe the relationship between dietary saturated fat and cholesterol and risk of heart disease:

(a) “While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease”.

(b) “Development of heart disease depends upon many factors, but its risk may be reduced by diets low in saturated fat and cholesterol and healthy lifestyles”.

(c) “Development of heart disease depends upon many factors, including a family history of the disease, high blood LDL-cholesterol, diabetes, high blood pressure, being overweight, cigarette smoking, lack of exercise, and the type of dietary pattern. A healthful diet low in saturated fat, total fat, and cholesterol, as part of a healthy lifestyle, may lower blood cholesterol levels and may reduce the risk of heart disease”.


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Note: *6 different categories of food products: 1 – Tuna salad with fish oil; 2 – Minced fish meat with fish oil; 3 – Bacon liver paste with Omega-3; 4 – Whole grain bread with Omega-3; 5 – Drink-yoghurt with Omega-3; and 6 – Muesli bar with Omega-3.

**Consumer segments: A – Elderly people, and B – Young people.

<table>
<thead>
<tr>
<th>Food product*</th>
<th>Consumer segment*</th>
<th>Proposed claim</th>
<th>Legal basis for claim</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>A</td>
<td>“The new tuna salad with fish oil from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis tuna salad with fish oil in all cases is a good nutrition and it helps with good life.”</td>
<td>Directive 90/496/EEC, COM (2003) 424 final</td>
<td>1) “The right fatty acids” is not clear. Would it be better to say “good fats”? 2) “In all cases” better to eliminate. 3) “It helps with good life” change to “which helps to improve ones health in daily life”. 4) To consider 8 nutrients content.</td>
</tr>
<tr>
<td>1.</td>
<td>B</td>
<td>“”</td>
<td>“”</td>
<td>“”</td>
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<tr>
<td>2.</td>
<td>A</td>
<td>“The new minced fish meat with fish oil from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis minced fish meat with fish oil in all cases is a good nutrition and it helps with good life”.</td>
<td>Directive 90/496/EEC, COM (2003) 424 final</td>
<td>1) Comments are the same as for 1 (A). 2) Sign “2 gange om ugen” is not clear – to eat minced fish meat twice per week?! In which quantity, etc. More information could be provided in the leaflets.</td>
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<td>2.</td>
<td>B</td>
<td>“”</td>
<td>“”</td>
<td>“”</td>
</tr>
<tr>
<td>3.</td>
<td>A</td>
<td>“The new bacon liver paste with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis bacon liver paste with Omega-3 in all cases is a good nutrition and it helps with good life”.</td>
<td>Directive 90/496/EEC, COM (2003) 424 final</td>
<td>Comments are the same as for 1 (A).</td>
</tr>
<tr>
<td>3.</td>
<td>B</td>
<td>“”</td>
<td>“”</td>
<td>“”</td>
</tr>
<tr>
<td>4.</td>
<td>A</td>
<td>“The new whole grain bread with Omega-3 from Vitalis contains the right fatty acids, which are essential nutrients needed for the body. Therefore Vitalis whole grain bread with Omega-3 in all cases is a good nutrition</td>
<td>Directive 90/496/EEC, COM (2003) 424 final</td>
<td>1) Other comments are the same as for 1 (A). 2) The claim given is a nutrition claim. Health claim could be a possible solution. 3) To consider “whole grain bread” – whether the food contains more than 51% of grains.</td>
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and it helps with good life”.

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<td>4.</td>
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<td>“”</td>
<td>“”</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>1) “The right fatty acids” is not clear. Would it be better to say “good fats”?</td>
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<td></td>
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<td></td>
<td>2) “A high content” may mislead the consumers. Too much of Omega-3 intake is not good for human health. Also, to consider whether claim “high in Omega-3 fatty acids” is qualified (30% of the Recommended Nutritional Intake – 2 g/day).</td>
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<td>3) Elderly consumer segment might have difficulty to understand “DHA fatty acids”.</td>
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<td>4) To consider 8 nutrients content. Health claim for yoghurt cannot be made if the amount of sugar exceeds the maximum limit.</td>
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<td>5.</td>
<td>B</td>
<td>“”</td>
<td>“”</td>
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<td></td>
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<td></td>
<td>1) This is a health claim; however, this food product contains chocolate, which makes the claim more difficult. To consider 8 nutrients content; and if they exceed the maximum limit, health claim cannot be made. Would it not be better to produce muesli bar with corn or simply with nuts instead of chocolate?</td>
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<td></td>
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<td></td>
<td>2) Not all people from this segment may understand EPA and DHA. It could be simply stated “good fats” or it could be explained in the leaflets / brochures.</td>
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<td></td>
<td></td>
<td></td>
<td>3) Muesli bar is a small item, meaning that the claim will be stated in small letters. It will make for elderly consumers difficult to read. Or the claim could be simplified.</td>
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<td>Comments are the same as for 5 (A) and 6 (A).</td>
</tr>
</tbody>
</table>

NB: Claims are translated from the Danish. Therefore there can be some deviations. Remarks and comments are given based on English version.
Tuna salad with fish oil for elderly consumer segment:
Tuna salad with fish oil for young consumer segment:
Minced fish meat with fish oil for elderly consumer segment:
Minced fish meat with fish oil for young consumer segment:
Bacon liver paste with Omega-3 for elderly consumer segment:
Bacon liver paste with Omega-3 for young consumer segment:
Whole grain bread with Omega-3 for elderly consumer segment:
Whole grain bread with Omega-3 for young consumer segment:

Viljen til Sejr
Overskud til at klare stressede situationer

Ny Grov kerne rugbrød med Omega-3

Den nye Grov kerne rugbrød fra Vitalis med Omega-3 indeholder de rigtige fedtsyrer, som er nødvendige næringsstoffer for kroppen.

Vitalis Grov kerne rugbrød med Omega-3 er derfor på alle måder god ernæring og hjælper med til et godt liv.
Yoghurt drink with Omega-3 for elderly consumer segment:
Yoghurt drink with Omega-3 for young consumer segment:
Muesli bar with Omega-3 for elderly consumer segment:

Bevar Vitalitet
Så du også kan lege senere i livet

Ny Müslibar med Omega-3
Den nye Müslibar fra Vitalis med Omega-3 indeholder de essentielle fedt syrer EPA og DHA, som er nødvendige næringsstoffer for kroppen. Et højt indhold af Omega-3 DHA fedtsyrer har stor betydning for hjernen.

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Muesli bar with Omega-3 for young consumer segment: