

# Nutrition and Health Claims: a European Heart Network Position Paper April 2001

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# **Summary**

'Nutrition' claims are messages on food packaging or advertising that draw attention to the nutritional composition of products. 'Health' claims are messages that draw attention to their possible health benefits. Many consumers look at food labels when they buy food, and research shows that nutrition and health claims are potentially a useful and easily understandable part of food labels. The food industry increasingly wants to use claims of this sort. There is a growing market for so-called 'functional

foods', that is, foods with added ingredients which may give them particular health benefits, and food producers want to explain these benefits on labels and in advertisements.

There are sound health reasons for permitting valid claims that reflect public health needs. For example, it is estimated that up to a third of premature deaths from cardiovascular diseases (CVD) in the European Union (EU) stem from unhealthy diets. However, at present there is an ambiguous and fragmented legal framework both in the EU and in the Member States. The danger is that, because of competitive pressures in the food industry, more and more claims will be used which are not scientifically valid or which focus on minority or trivial health issues. If this happens, consumers will become increasingly cynical, and an opportunity to use claims for the benefit of health, consumers, and industry will have been lost. In this paper, the European Heart Network (EHN) suggests a legal framework which would work in the interests of all concerned, although it believes that the paramount principle in EU policy on 'nutrition' and 'health' claims should be the protection and promotion of public health. The European Heart Network's recommendations are summarised below:

### **Types of claims permitted:**

- Food producers should be allowed to make nutrition claims and certain health claims, namely nutrient function claims and disease risk reduction claims. They should be prohibited from making a claim that a food can treat, cure or prevent a disease (a medicinal claim).
- Article 2.1(b) of the Food Labelling Directive (prohibiting the use of medicinal claims) should be amended to clarify its scope for application, including specifying a more precise definition of a prohibited medicinal claim.
- There should be a Directive or Directives governing the use of nutrition and health claims.

### Criteria for claims:

Nutrition and health claims should be allowed only if they are scientifically valid, are
relevant to public health, are worded in such a way as to ensure that they are not
confusing to the public, and apply to foods that also meet safety and other criteria such
as labelling and compositional standards.

### a. Nutrition claims

- An EU Directive on nutrition claims should be based on the Codex Alimentarius Guidelines on Nutrition Claims. In particular the Directive should incorporate the Codex Guidelines' general principles for making nutrition claims.
- The Directive should contain criteria for making relative/comparative nutrition claims (e.g. 'lower fat', 'higher in vitamins') that reflect those in the Codex Guidelines.
- The Directive should contain a table of compositional criteria for absolute nutrition claims (e.g. 'low fat', 'high in vitamins'), all of which are related to population dietary goals.

# b. Health claims

- An EU Directive on health claims should be based on the systems for regulating health claims that are being developed for Australia and Canada.
- The Directive should ensure a transparent, consistent and systematic approach to the scientific substantiation of claims.
- The Directive should ensure a systematic, transparent and consistent approach to ensuring that health claims are relevant to public health.
- The Directive should specify clear qualifying and disqualifying conditions, including compositional criteria. The compositional criteria should reflect those in the relevant nutrition claims Directive.

# 1.0 Introduction

'Nutrition' claims are messages on food packaging or advertising that draw attention to the nutritional composition of products. 'Health' claims are messages that draw attention to their possible health benefits. Health and nutrition claims can be confusing and even misleading, but they have the potential to work for the benefit of consumers and the food industry, whilst contributing to addressing the major problem of premature death and suffering from cardiovascular disease (CVD) and other dietrelated diseases in the people of the European Union (EU). In this paper, the European Heart Network (EHN) suggests a way forward to construct a legal framework that would work in the interests of all concerned.

# 1.1 The health perspective

Cardiovascular disease is the main cause of death in the EU, killing over 1.5 million people each year. There is a wealth of established evidence on the relationship between diet and CVD. It is estimated that up to a third of premature deaths from CVD in the EU stem from unhealthy diets, which means that at least 60,000 deaths a year amongst people under the age of 65 could be avoided if diets were improved.

Numerous expert committees have reviewed the association between diet and CVD and have published dietary goals and guidelines to reduce the risk of CVD. The EHN has published its own dietary goals and guidelines, based on those of its member organisations and the latest scientific consensus. The Eurodiet Project funded by the European Commission (EC), in which EHN was closely involved, has recently agreed a set of population dietary goals for the EU that are currently under consideration by the EC. In

In order to move towards dietary goals of this type, and reduce the incidence of CVD and the number of deaths, coordinated public health strategies are needed at both Member State and EU level. To be effective these strategies will have many components, consisting among other things of clear, useful and accurate information on food labelling, including 'nutrition' and 'health' claims.

### 1.2 The consumer perspective

A pan-European survey of consumer attitudes toward food and health showed that food labelling provided the fourth most important source of information on healthy eating. It was used by an average of over a fifth of people, but with higher levels amongst younger people. It was used least frequently as a source of healthy eating information in Greece (9%), and most frequently in Sweden (35%). However, the proportion of people looking at food labels in order to decide what to buy, rather than just as a source of healthy eating information, has consistently been shown in surveys to be higher than this, with more than half of those buying looking at the label first. A Canadian study indicated that male students who do not look at labels before buying do not do so because they are sceptical about the truthfulness of the information on the label. In fact, repeated research shows that consumers have a great deal of difficulty in interpreting the numerical information given on the 'nutrition panel' on

foods. They see nutrition and health claims as a quick and easy way of determining how healthy a food product is, although a large proportion of them still express cynicism about the validity of health claims. It seems that this distrust applies particularly to long and complex claims. Short, one-phrase claims are more understandable, and more likely to influence purchasing decisions. In summary, claims have the potential to be more useful to consumers than other types of information found on the label, as long as they are easy to understand and scientifically trustworthy.

# 1.3 The industry perspective

There is growing consumer awareness of the link between diet and health. Industry has responded to this growing awareness by modifying existing products, for example by reducing the fat in milk or increasing the fibre in breakfast cereals, but also increasingly by producing functional foods, foods with added ingredients which may give them particular health benefits. The new spreads with added phytosterols or phytostannols, compounds that are believed to help reduce blood cholesterol levels, are examples of functional foods.

As reported in the previous section, many consumers look at food labels for nutrition and health information and manufacturers have responded to this demand for information with nutrition and health claims. Use of claims by one manufacturer increases the competitive pressure on other manufacturers, and this escalation has resulted in a pronounced increase in the use of claims on food packaging and in food advertising, raising increasing concern amongst enforcement agencies and health organisations about the validity of some of the claims.

In the absence of a legal framework, the food industry has developed voluntary controls. For example, some retailers have developed their own 'healthy eating' ranges of food, where products have to meet certain compositional criteria to be admitted to the scheme. The Confederation of the Food and Drink Industries of the EU has developed a Code of Practice on the use of health claims. However, the difficulty with a voluntary system is that if one or more manufacturers break it, the competitive pressures on other manufacturers to do the same can become intense.

# 1.4 Definitions of different types of claim

The following definitions are used in this paper.

Claims are any message, or representation, whatever the method or form of transmission, including brand names, that states, suggests or implies that a food has particular characteristics, properties or effects linked to its nature, composition, nutritional value, method of production, processing or any other quality (Draft EC Directive on Claims, 1994, Article 1).

**Nutrition claim** means any message that states, suggests or implies that a foodstuff has particular nutritional properties due to its energy value and/or to its nutrient content (e.g. 'low fat', 'lower fat').

**Health claim** means any message that states, suggests or implies a relationship between a foodstuff or food component and health.

Health claims can be further subdivided into nutrient function claims and disease risk reduction claims:

a) **Nutrient function claim** means any message that states, suggests or implies the physiological role of a nutrient in normal bodily functions (e.g. 'folic acid contributes to the normal growth of the foetus').

Some authorities (including the Codex Alimentarius Commission) consider that nutrient function claims can be subdivided further and that a sub-category of **enhanced function claim** can be distinguished from other nutrient function claims. This type of claim states, suggests or implies that the effect on function is beyond the normal physiological effect (e.g. 'calcium improves bone density').

b) **Disease risk reduction claim** means any message that states, suggests or implies a relationship between the reduced or increased consumption of a nutrient and the risk of a disease (e.g. 'folic acid reduces the risk of spina bifida', 'eating fruit and vegetables reduces the risk of heart disease').

**Medicinal claim** means any message that states, suggests or implies that a food has the property of treating, preventing or curing human disease (e.g. 'this food prevents cancer'). This type of claim is prohibited under Article 2.1(b) of the EU's general Food Labelling Directive, 'iii formerly Article 2 of the 1979 Food Labelling Directive ix

Because the differences between these types of claims are quite small, particular claims may be difficult to classify. Moreover, it is not all certain that consumers see clear distinctions between types of claims. For example, does a red heart-shaped logo on a packet of high fibre breakfast cereal imply that the fibre helps reduce blood cholesterol levels, thereby helping maintain a healthy heart (a nutrient function claim), that consuming the cereal would help reduce the risk of heart disease (a disease risk reduction claim), or that consuming the cereal would, in and of itself, prevent heart disease (a medicinal claim)? There needs to be more research to explore how consumers understand claims.

# 1.5 The European Heart Network's views on 'nutrition' and 'health' claims

In 1998 the EHN developed and published<sup>i</sup> policy proposals to address the issue of the fragmented and inconsistent approach to the use of 'nutrition' and 'health' claims in the EU. The main points were that:

- the Commission should draw up a Directive or Directives covering the use of health and nutrition claims'
- and that the Directive or Directives should:
  - 'incorporate the general principles for making nutrition and health claims as agreed by the Codex Alimentarius' and

- 'ensure that there are detailed and specific rules for making nutrition and health claims, along the lines of the US Nutrition Labelling and Education Act.'

However, since then the European Commission has published its White Paper on Food Safety, which proposes various new measures that are relevant to nutrition and health claims<sup>xiv</sup> The present document sets out EHN's current policy on the regulation of health and nutrition claims in the light of this and other recent developments, which are described more fully in Section 2.0.

# 2.0 Existing and proposed rules on 'nutrition' and 'health' claims

Under current EU legislation there are only a few rules governing the use of 'nutrition' and 'health' claims. The two main pieces of legislation are the general Food Labelling Directive<sup>x</sup> and the 1990 Nutrition Labelling Directive. Article 2.1(b) of the general Food Labelling Directive prohibits the use of a claim that states that a food prevents, treats or cures a human disease, or that refers to such a property. The 1990 Nutrition Labelling Directive defines a nutrition claim as 'any representation or any advertising message which states, suggests or implies that a food has particular nutritional properties due to the energy or nutrients it contains, or does not contain.' This Directive also specifies that when a nutrition claim is made, nutrition labelling is compulsory.

Under EU legislation there is no legal definition of a health claim or of the possible categories of health claims. Article 2.1(b) of the general Food Labelling Directive is the most important piece of legislation affecting the use of health claims, but it has been interpreted very differently in different Member States. In some Member States it is taken to be a prohibition on all health claims including nutrient function claims (as defined in Section 1.4). In other Member States the article is not regarded as a prohibition on all health claims. For example, a claim that 'this food can help lower cholesterol' would not be allowed in some Member States because the enforcement authorities consider that the claim implies that the food could help prevent coronary heart disease. In other Member States it would be allowed because enforcement authorities do not think it implies that the food could help prevent this disease.

Therefore, most interested parties, including food manufacturers, consumers and health organisations, consider that the present legal framework governing both 'nutrition' and 'health' claims is inadequate.

Since the early 1980s the European Commission has been considering the possibility of a Directive or Directives on 'nutrition' and/or 'health' claims on food packaging and in advertising. Some of the drafts of these directives, had they been implemented, would have provided a detailed framework of rules for health and nutrition claims.

Meanwhile, some EU Member States have drawn up their own laws, although it is not clear whether they should have done so, given that legislation on claims is supposed to be harmonised at European level. In other Member States voluntary Codes of Practice have drawn up by governments or by the food industry. In one notable case,

the Joint Health Claims Initiative in the UK, a code of practice governing the use of health claims was drawn up by a tripartite alliance of the food industry, consumers and enforcement authorities.

In the absence of any significant EU-wide legal framework for health and nutrition claims, the only EU-wide guidelines are those mentioned previously which were produced by the Confederation of the Food and Drink Industries of the European Union. Vii

The diverse rules and voluntary codes of practice on 'nutrition' and 'health' claims currently operating in Europe were reviewed in a recent report commissioned by the European Commission. xii

Meanwhile the Codex Alimentarius Commission, formed in 1961 to develop internationally acceptable standards for food, has progressively become more influential. In 1994 the Final Act of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) was signed, establishing the Agreements on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) and on Technical Barriers to Trade (TBT Agreement). The SPS and TBT agreements make specific reference to Codex standards and thus, for the first time, Codex standards could be invoked during disagreements under the GATT.

During the 1990s the Codex drew up and agreed guidelines on nutrition claims, xiii and in 2000 it issued a consultation on draft guidelines for their use. The same document included a consultation on draft recommendations for health claims. These guidelines and recommendations reflect much of the current thinking about the appropriate use and regulation of claims from both Europe and elsewhere. They are likely to be influential, and could provide the basis for the development an EU framework.

In its White Paper on Food Safety, the European Commission recognised the importance of some form of control of 'nutrition' and 'health' claims, and undertook to consider a) whether specific provisions should be introduced into EU law to govern 'functional' claims and nutrition claims; b) the need to bring the Nutrition Labelling Directive into line with consumer needs and expectations; and c) amending the Misleading Advertising Directive to ensure that advertising and labelling provisions in respect of claims provide a coherent legislative framework. \*\*Proposals that address all of these are scheduled for adoption by the Commission during 2000-2001.

### 3.0 Recommendations

### 3.1 What types of claims should be permitted?

There is currently a debate in European food-policy-making circles about what types of 'nutrition' and 'health' claims should be allowed, and under what circumstances.

All agree that food producers should be allowed to make '**nutrition**' claims. Most agree that some types of health claims should also be allowed. Nearly all agree that

'medicinal' claims, claims that a food can treat, cure or prevent a disease, should be prohibited.

Some argue that Article 2.1(b) of the general Food Labelling Directive, which prohibits the use of medicinal claims, needs to be revised to allow manufacturers to make 'nutrient function' claims and 'disease risk reduction' claims. Most agree that this article should be amended to clarify its scope because it is currently interpreted differently in different Member States.

EHN has considered consumer, industry, and health views carefully and makes the following recommendations:

- EHN recommends that food producers should be allowed to make certain nutrition claims and health claims, namely nutrient function claims and disease risk reduction claims. They should be prohibited from making a claim that a food can treat, cure or prevent a disease (a medicinal claim).
- EHN recommends that Article 2.1(b) of the Food Labelling Directive should be amended to clarify its scope. An example of revised wording might be that labelling and advertising must not 'attribute to any foodstuff the property of treating, curing or completely preventing a human disease'.
- EHN continues to recommend that there should be a Directive or Directives governing the use of 'nutrition' and all types of 'health' claims.

### 3.2 Criteria for making 'nutrition' and 'health' claims

Opinions differ on the precise nature of the qualifying criteria for 'nutrition' and 'health' claims. In general, consumer and health bodies favour tougher restrictions than the food industry. EHN believes that the paramount principle in EU policy on health and nutrition claims should be the protection and promotion of public health. All agree that claims should be scientifically valid, i.e. nutrition claims should be accurate in that the food should contain the amount of nutrient claimed and health claims should reflect the scientific evidence relevant to the claim. It is, however, possible for a claim to be technically truthful but still misleading or confusing for consumers. So most agree that there should be rules governing the wording of claims, and indeed other ways of making claims such as the use of pictures, diagrams, etc., as well as their technical validity. Similarly, most agree that food, bearing claims, should meet safety and other criteria such as labelling and compositional standards.

• EHN recommends that nutrition and health claims should be allowed only if they are scientifically valid, are relevant to public health, are worded in such a way as to ensure that they are not confusing to the public, and apply to foods that meet safety and other criteria such as labelling and compositional standards.

As stated previously, the Codex guidelines on 'nutrition' claims and draft guidelines on 'health' claims could provide a starting point for developing EU rules.

### a) Nutrition claims

EHN is not entirely satisfied by the Codex approach to criteria for nutrition claims<sup>xv</sup>, but given that there has been extensive discussion at an international level for many years in order to draw up the Codex guidelines, and that there is now broad international agreement about the regulatory approach to the criteria, then EHN considers that the Codex guidelines could provide the basis for EU rules on nutrition claims.

An example of a useful approach taken by Codex is that it specifies that comparative claims (e.g. 'lower fat', 'higher in vitamins') should be based on a difference in nutrient content of at least 25%, (except for micronutrients, where a 10% difference would be acceptable), and that there should be a minimum absolute difference in the nutrient content.

Therefore, with the Codex Guidelines as a reference:

• EHN recommends that an EU directive on nutrition claims should be based on the Codex Alimentarius Guidelines on Nutrition Claims. In particular the Directive should incorporate the Codex Guidelines' general principles for making nutrition claims.

### In addition:

• EHN recommends that the Directive should contain criteria for making relative/comparative nutrition claims (e.g. 'lower fat', 'higher in vitamins') which reflect those in the Codex guidelines.

However, the Codex criteria for making absolute nutrition claims such as e.g. 'low fat', 'high in vitamins' bear no relationship to current population nutritional goals as recommended by the World Health Organisation, the Eurodiet Project, and many Member States, and EHN believes that these criteria should be revised before being incorporated into EU Directives.

For example, the Codex qualifying criteria for a low fat claim is 3g of fat per 100g of food. The Eurodiet report and other international expert reports recommend a population goal of less than 30% of energy from fat. The two numbers bear no apparent relationship to one another. On the other hand, one of the Codex qualifying criteria for a low saturated fat claim is that less than 10% of the energy content of the food should be from saturated fat. This does bear some relation to generally agreed population dietary goals. For example the Eurodiet report recommends a population goal of less than 10% of energy from saturated fat. EHN considers that logical and consistent methods should be developed in order to ensure that nutrition claims, and the criteria for their use, help towards the attainment of population dietary goals.

This could be done either by using modelling techniques (e.g. based on the total number of people consuming a product, the proportion likely to consume a low/high nutrient alternative, and the compositional difference between the standard and modified product necessary to make a significant contribution to achieving dietary goals) or by using multiples or fractions of the goals.

• EHN recommends that a Directive on nutrition claims should contain a table of criteria for absolute nutrition claims (e.g. 'low fat', 'high in vitamins') which are related to population dietary goals.

# b) Health Claims

The 1990 US Nutrition Labelling and Education Act is still a useful model for regulating health claims. However, recent developments in the regulation of health claims, notably in Canada<sup>xvi</sup> and Australia<sup>xvii</sup> but also in Sweden, the UK and the Netherlands, together with experience of the implementation of the US Nutrition Labelling and Education Action, suggest that other models might be more appropriate for the EU.

In Canada and Australia, for example, more rigorous rules for the scientific substantiation of health claims are being developed than under the US system. The Canadian system distinguishes between generic and product-specific health claims, as does the UK system; this offers more flexibility to accommodate consumer, health and commercial interests.

### EHN recommends:

- An EU Directive on health claims should be based on the systems for regulating health claims that are being developed for Australia and Canada.
- The Directive should ensure a transparent, consistent, rigorous and systematic approach to the scientific substantiation of claims.

The more recent international reports on health claims have emphasised the importance of assessing the relevance of health claims to public health, as well as ensuring that they are scientifically valid. There is more and more information available, including EU-funded studies, on the health and economic impact of different diseases and the relative importance of dietary and nutritional factors in causing these diseases. This information could be used as the basis of a systematic approach to ensuring that health claims promote public health.

### EHN recommends:

• The Directive on health claims should ensure a systematic, transparent and consistent approach to ensuring that health claims are relevant to public health.

Finally, both the Codex Guidelines and the international reports listed above recognise the importance of having clear qualifying and disqualifying conditions, including compositional criteria.

### EHN recommends:

• The Directive should specify clear qualifying and disqualifying conditions, including compositional criteria. The compositional criteria should reflect those in the relevant nutrition claims Directive (as advocated by EHN).

### Note:

This paper has been sent out for consultation among all the members of the European Heart Network (EHN). It has been modified according to comments received and is considered to reflect the view of the entire EHN membership. Some members have more detailed positions and readers of this paper are invited to contact their national EHN member(s).

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<sup>&</sup>lt;sup>i</sup> European Heart Network (1998) Food, Nutrition and Cardiovascular Disease Prevention in the European Union. EHN: Brussels.

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<sup>&</sup>lt;sup>v</sup> Consumers' Association (1995) Food Labelling Survey. CA: London.

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viii European Commission (2000) Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. Official Journal L 109 pp 29-42.

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<sup>&</sup>lt;sup>x</sup> European Commission (2000) Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. *Official Journal* L 109 pp 29-42. xi European Commission (1990) Council Directive No 90/496/EEC of 24 September 1990 on nutrition

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