European Heart Network Response to Discussion Paper on Nutrition Claims and Functional Claims (SANCO/1341/2001)

Introduction

The European Heart Network (EHN) welcomes this discussion paper as a first step in developing a proposal for legislation covering nutrition claims and some health claims. In this response we first make some general comments, then some comments on: a) definitions for claims; b) defining conditions under which claims may be made and c) types of evaluation and authorisation system for claims. Our comments are based on our recently published position paper on nutrition and health claims (attached).

General comments

As outlined in our joint letter (with the Confederation of the food and drink industries in the EU - CIAA) of 10 July 2001 our main criticism of the discussion paper is that it does not cover all types of health claim and in particular disease risk reduction claims. EHN notes that health claims and in particular disease risk reduction claims will be the subject of a separate consultation, but EHN considers functional claims to be a type of health claim and strongly suggests that any measure covering functional claims should also cover all other types of health claim including disease risk reduction claims.

EHN believes that consumers do not see a great distinction between different types of health claim (including functional claims e.g. 'helps lower cholesterol' and disease risk reduction claims such as 'helps lower risk of heart disease' and claims which might be described as intermediate between functional and disease risk reduction claims such as 'helps maintain a healthy heart') and therefore considers that functional claims and all other health claims should be regulated in the same way.

Definitions of claims

EHN strongly agrees that 'for reasons of clarity of the rules' it will be necessary to provide clear definitions of types of claim in any future Community legal measure or measures (*paragraph 15* of the discussion paper). EHN is reasonably content with the definitions of the term 'claim' and of some types of claim outlined in *paragraphs 12-39* of the discussion paper, but prefers the following definitions:

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').

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 (<u>in and of itself</u>) 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, formerly Article 2 of the 1979 Food Labelling Directive.

EHN considers that definitions for types of claim should ideally be based on research into consumer perceptions so that claims which consumers perceive as equivalent are then controlled in a similar manner. EHN acknowledges the lack of such research.

In line with our view that any future measure covering functional claims should also cover other types of health claim then such a measure would need to have a definition of a health claim. This definition should enable a distinction to be made between health claims and medicinal claims

To that end, EHN also considers that there needs to be a more precise definition of a medicinal claim than contained within Article 2.1(b) of the Food Labelling Directive in order to clarify its scope for application. In EHN's experience some interpret this definition to include disease risk reduction claims and even claims such as 'helps maintain a healthy heart' and others do not, leading to great inconsistency in the use of such claims.

Defining conditions under which claims may be made

Permissible claims

EHN recommends that nutrition and health claims (including functional claims) should only be made 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.

Therefore EHN considers that certain health and nutrition claims should not be allowed. Claims relating to dietary cholesterol are possibly a case in point *(paragraphs 24 and 25* of the discussion paper). EHN agrees that dietary cholesterol intake is not one of the major factors in coronary heart disease; therefore, it could be argued that claims for dietary cholesterol are not particularly relevant to public health. Claims in relation to dietary cholesterol may be confusing because consumers are likely to confuse dietary cholesterol with blood cholesterol and may therefore believe that foods which claim to be low in/free from dietary cholesterol etc. are better for their heart than is warranted.[1]

Criteria for claims

EHN has outlined some general criteria for making claims in its position paper. The discussion paper poses numerous questions in relation to specific criteria for making nutrition and functional claims. Here we only comment on three aspects of those specific criteria.

1. EHN does consider that health and nutrition claims should only be allowed when the overall profile of the product is nutritionally acceptable (*paragraph 9* of the discussion

[1] However, if a foodstuff high in dietary cholesterol and low in saturated fats, like eggs, achieved a substantial reduction in dietary cholesterol one could imagine allowing a claim on reduced dietary cholesterol if added to this claim was the information that: to lower blood cholesterol it is not enough to lower intake of dietary cholesterol but also to reduce the intake of saturated fat coming from other foods.

paper). EHN acknowledges that defining what is 'nutritionally acceptable' is difficult and might be controversial but considers that it is possible. It should be possible, for example, to specify that 'low fat' claims should be made for products which have a minimum salt content. What is precisely meant by minimum would need to be determined but could for example be either 'low salt' as defined by Codex or reduced salt (whichever is most practical).

2. EHN recommends that the EU criteria for nutrition claims should be based on the Codex Alimentarius Guidelines on Nutrition Claims but one of the Codex criteria for making comparative nutrition claims, which the discussion paper fails to mention, is that when making a comparative nutrition claim the food should be based on a difference in nutrient content of at least 25% and that there should be a minimum absolute difference in the nutrient content. EHN suggests that this additional criterion for making comparative nutrition claim should be incorporated into any EU criteria for nutrition claims (*paragraphs 32-36* of the discussion paper).

3. EHN agrees (*paragraph 26* of the discussion paper) that the terms sodium and salt are virtually interchangeable (certainly in consumer perceptions) and that the conditions warranting the claims for sodium should also be those for claims about salt content.

Types of evaluation and authorisation system for claims.

EHN acknowledges that many of the general principles for making nutrition and health claims are similar. As noted above for example, EHN considers that both nutrition and health claims should only be made 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. EHN considers, however, that there needs to be a directive covering nutrition claims and a separate directive covering health claims (including functional claims). This is because EHN considers that a directive on nutrition claims should be relatively simple to draw up compared with a directive on health claims.

It should be possible for a directive on nutrition claims to include a list of nutrients for which a nutrition claim can be made. The Codex Guidelines on the Use of Nutrition Claims (CAC/GL 23-1997) suggests that 'Nutrition claims should be consistent with national nutrition policy and support that policy. Only nutrition claims that support national nutrition policy should be allowed' The list of nutrients for which nutrition claims can be made could be the list of nutrients that appear in generally agreed population dietary guidelines (e.g. those of the Eurodiet Project). It should also be possible to specify the precise conditions under which a nutrition claim can be made.

EHN considers however that, in the case of health claims, it would not be possible for the directive to specify a list of health claims which could be made. EHN therefore

considers that the directive should only set out the general conditions under which a health claim should be made.

EHN considers that a body will need to be set up to authorise the use of, and specify conditions for use of, particular health claims (including functional claims). Such bodies have been found to be necessary in countries seeking to introduce statutory controls on health claims (such as the US, Australia, Canada, etc.) and in Member States of the EU who have developed voluntary systems (the UK, Sweden, the Netherlands, etc.)

One of the most important tasks of such a body will be to consider whether the totality of the scientific evidence supports the use of particular health claims. EHN considers that, in order to ensure consistency in the use of health claims throughout Europe, such a body should be a European-level body (*paragraph 48* of the discussion document). The body should also set particular conditions (with regard to both labelling and composition) for particular health claims. EHN considers that the body should be within the new European Food Authority.

EHN considers that this body should examine whether the scientific evidence supports the use of a particular health claims prior to the use of the health claim (i.e. pre-marketing approval or at least pre-marketing advice). EHN does consider that, because many health claims relate to the same nutrient/food component-health relationship, it would be possible and indeed desirable for the body to compile a list of permissible nutrient/food component–health relationships for which a health claim might be made and the conditions under which a claim can be made (*paragraph 48* of the discussion document). EHN does not consider that this list should necessarily specify the precise wording for all permissible claims.

EHN recommends that the process by which particular health claims are approved should be based on the systems for regulating health claims that are being developed for Australia and Canada. The main feature of these systems is that they ensure a transparent, consistent, rigorous and systematic process for the scientific substantiation of claims. EHN notes that considerable resources need to be devoted to the scientific substantiation of health claims if it is to be done consistently and rigorously but considers the EU should have a similar high-quality systems to those of Australia and Canada.