EHPM RESPONSE TO THE DISCUSSION PAPER ON NUTRITION AND FUNCTIONAL CLAIMS

The European Federation of Health Product Manufacturers (EHPM) welcomes the publication by the European Commission of a Discussion paper on claims. The issue of claims has been the topic of much discussion within the industry throughout the 90's and it is opportune that this discussion should now take place in a broader context. The EHPM would, however, like to register its disappointment that the discussion paper is limited to nutrition and functional claims. Although these claims are probably the easiest on which to reach agreement on a pan-EU basis, this should not preclude discussion on other types of claim, including health claims.

SPECIFIC COMMENTS

Definitions

As the Discussion Paper correctly recognises, there are a number of substances included in foods which have a physiological effect rather than a nutritional effect. The EHPM considers that claims relating to these effects should fall within the category of functional claims rather than nutrition claims.

In addition, discussion on the definition of food supplements has been part of the process of the adoption of the Food Supplements Directive. As a result the European Commission, the European Parliament and a majority of Member States have recognised the need to include in that definition acknowledgement that food supplements can be foodstuffs that are concentrated sources of nutrients, and also other substances, such as antioxidants or fibres*, with a nutritional or physiological function.*

EHPM therefore proposes the following definitions for nutrition and functional claims for foods:

- **Nutrition claims**:
  - describe the level of a nutrient contained in a food.
  - compare the nutrient levels and/or energy value of two or more foods.

- **Functional claims**:
  - as defined in the Codex Alimentarius proposal with the addition of specific wording to ensure that ingredients such as fibre, antioxidants, lactic bacteria ingredients, etc., which have a physiological rather than a nutritional effect, are covered:

    'A functional claim is a claim that describes the physiological role of the nutrient <u>or other substances</u> in growth, development and normal functions of the body.'

CRITERIA FOR THE EVALUATION/AUTHORISATION OF NUTRITION AND FUNCTIONAL CLAIMS

Nutrition Claims: Council Directive 90/496/EEC on nutrition labelling gives a definition of a nutrition claim. EHPM supports this definition as a basis for nutrition content and nutrition content comparative claims. Given that the information transmitted in a nutrition claim is factual, EHPM

considers that the basic criteria for a system for the approval/authorisation of such claims should be that information is presented in a clear, factual and unambiguous manner so as to maximise the consumer's understanding of the information given.

Functional Claims: EHPM considers that all functional claims must be based on supportive evidence that prove the diet-health relationship and that the weight of evidence should depend on whether the claim in question is a nutrient function claim or an enhanced function claim.

Nutrient Function claims: are well established, well accepted claims supported by bibliographic evidence of the physiological role of the nutrient in growth, development and normal functioning of the body.

Enhanced Function Claims: are claims which set out the specific beneficial effects of the consumption of foodstuffs or other substances with a nutritional or physiological function and provide information on their positive contribution to health/ health- related conditions/ the improvement of a function/ modifying or preserving health. In all cases such claims must be relevant to improvement of a state of well-being.

The EHPM considers that two separate procedures would be appropriate for the evaluation/authorisation of nutrient function and enhanced function claims:

Nutrient Function Claims:
EHPM does not consider that a pre-marketing approval for this type of well-established 'generic' claim is required and would lead to unnecessary and excessive costs and delays. Instead EHPM proposes the creation of a 'Positive List' of generic claims where supporting evidence must be held by the manufacturer, but prior approval is not required. Similar systems already exist in Sweden and are under development in the UK.

Enhanced Function Claims:
EHPM considers that pre-marketing approval should be required for this type of non-generic claim which is linked to a specific product. This approval should be provided by a national or an international independent organisation. The EHPM believes that this authority should work in the form of a co-regulatory system, by which the industry regulates itself based on an agreement with authorities.

The weight of evidence to be provided should depend on the type of claim and should include bibliographic material as published in generally accepted standards, text books, monographs, etc. For some claims further evidence may be required which may be obtained from various forms of experimental study.

EHPM considers that part of the role of the assessment body will be to determine the evidence required for enhanced function claims which are specific, not generic. Essential elements of the actual assessment procedure for products seeking pre-market approval for enhanced function claims are:

- established and objective criteria to be used throughout the assessment process
- assessments to be carried out by acknowledged experts in food, nutrition and supplementation
- the approval procedure to be transparent

- the approval process to carried out within an agreed time-scale

- confidentiality of information to be maintained throughout so as to avoid conflict of interests between different companies

GENERAL COMMENTS

EHPM's primary concern is that the Discussion Paper does not address health claims, including risk reduction claims. As a Discussion Paper as opposed to a formal proposal for legislation, an ideal opportunity for wide-ranging debate on this difficult but central issue has been missed. The European Commission should note that health claims are already regulated in some Member States, while in others they are not – but products making health claims are present on these markets. This situation creates both trade barriers within the internal market in the EU and confusion for consumers, thereby making harmonisation necessary.

The EHPM believes that health/risk reduction claims should be included in the debate and considers that the following principles should form the basis for discussion on a procedure to allow their use:

- Health/risk reduction claims may only be made for products that are safe and are regulated by food law.

- Health/risk reduction claims should not encourage the consumer to take any action which could be detrimental to their health.

- The company that places the product on the market is responsible for justifying the claim.

- The health/risk reduction claim must be accurate, not misleading, and be backed by appropriate scientific evidence.

- When presenting a health/risk reduction claim for a specific product, the additional factors that should be considered by the user for its effective use should also be communicated (eg. the role of this product in the diet).

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