

## ERNA RESPONSE TO THE EUROPEAN COMMISSION DISCUSSION PAPER ON NUTRITION AND FUNCTIONAL CLAIMS

The European Responsible Nutrition Alliance (ERNA), an alliance of food supplement manufacturers and suppliers, welcomes the European Commission's initiative in the harmonisation of nutrition and function claims. In response to the points raised in the Discussion Paper (SANCO/1341/2001), we would like to make the following comments:

### 1. NUTRITION CLAIMS

**(para 17)** As the Commission correctly recognises, there are a number of substances, such as antioxidants, that do not have a nutritional effect, but rather have a physiological effect. However, where this is the case, such effects should fall within the category of functional claims rather than nutrition claims. The definition of nutrition claims therefore does not need to be changed on this account.

**(para 22)** The word diet may be useful to the consumer and should be allowed if it is qualified e.g. "as part of a low fat diet".

**(para 31)** With regard to specific requirements for nutrient content claims we consider that such claims may be used for nutrients with established RDI as follows: "high", "rich in" or "good source" provided the product contains 20% or more of the RDI for that nutrient (on the basis of a reasonable daily consumption); "contains" and "provides" provided the product contains 10-19% of the RDI for that nutrient.

In the case of a substance where there is no established RDI, a claim that does not imply that there is a lot of that nutrient e.g. '4 grams of omega-3 fatty acids' may be allowed.

### 2. FUNCTIONAL CLAIMS

**(para 38)** We believe that the Codex Alimentarius definition of a "nutrient functional claim" forms a good basis for the definition of a functional claim, but that this definition needs to be amended to take into account substances other than nutrients. For example:

"A functional claim is a claim that describes the physiological role of the nutrient or other substance in growth, development and normal functions of the body"

### 3. APPLICATION OF NUTRITION AND FUNCTIONAL CLAIMS (para 27)

ERNA believes that general rules should be developed that will cover all food products, and that the creation of a new category of 'functional food' is neither practically nor legally feasible.

### 4. A SYSTEM FOR FUNCTIONAL CLAIMS (Para 48 and 49)

ERNA believes that the strength of any functional claim relating to diet-health relationships should depend entirely upon the level of supportive evidence available. However, it foresees that universal pre-marketing approval for all claims would lead to considerable duplication of work and, as a result, lead to unnecessary costs and delays.

For practical reasons, ERNA envisages the establishment of two types of claims:

**A. Generic claims:** Where there is wide scientific consensus on the existence of a health/diet relationship, generic claims should be established. This type of claim has been successfully developed in, for example, the US and Sweden. These can be used for any product for which there is sufficient support of that claim.

**B. Product-specific claims:** when companies wish to make claims other than these generic claims, product-specific claims should be made. Product-specific claims would require the provision of specific evidence of the claimed effect as in accordance with guidelines for scientific substantiation of health claims.

Companies wishing to make specific product claims should be subject to an approval procedure, provided that this scientific evaluation is:

- made by those experts best equipped to assess the evidence available
- subject to established objective criteria
- sufficiently transparent to provide reasoning for the decisions made
- sufficiently rapid and confidential to ensure that the competitive advantages relating to investment in specific research are not lost.

Any other product looking to make a similar claim would be expected to

submit an equivalent level of evidence. The option of allowing a company exclusive use of a product-specific claim over a given period should also be considered.

Ideally, the European Commission may wish to regulate such a system making use of internal resources and expertise, for example under the remit of a newly formed European Food Safety Authority. However, other comparable approval systems in the EU e.g. novel foods procedure are widely perceived not to be working efficiently and ERNA questions whether a new body such as the EFSA should or can manage this burden. In this respect, there is great concern about the potential damage of approval procedures to the competitiveness of European industry.

We would ask the Commission to consider the establishment of a co-regulatory system at EU-level with the involvement, for example, of industry and consumer bodies. In this respect, the Commission may wish to take note of existing co-regulatory systems that have been established nationally, such as the UK Joint Health Claims Initiative.

## **5. HEALTH & DISEASE RISK-REDUCTION CLAIMS**

ERNA believes that the issue of 'health' and 'disease risk-reduction claims' is inextricably linked to the discussion on nutrition and function claims. While 'disease risk-reduction claims' may require greater scientific substantiation, ERNA cannot agree with the European Commission that they are inherently more complex than nutrition and functional claims. They could be dealt with under the same co-regulatory procedure as described above.

By refusing to even discuss the issue of health claims, the European Commission appears unusually out of touch with other national and international fora and in the long term may run the risk of protracting the problem of trade barriers that arise due to health claims. ERNA strongly recommends that the Commission broadens the scope of its claims initiative to take into consideration disease risk-reduction claims.