

Association européenne pour le droit de l'alimentation European Food Law Association

EFLA comments on the consultation paper on nutritional and functional claims, prepared by DG SANCO (SANCO/1341/2001)

EFLA welcomes the SANCO discussion paper as a first initiative by the European Commission to address the 'Health' Claims issue and is happy to see a project for harmonising some practices which are already in operation within the member States. EFLA is also happy with the perspective of a facilitation in trade which can be expected for a number of products within the EU, in a way which is in line with Codex and which, therefore, will also facilitate international trade.

However, EFLA regrets that the discussion is, at this stage, limited to nutrition and functional claims, without addressing 'Health' claims in general. There is a risk that addressing this complex issue only partially, might lead to an incomplete and inconsistent framework, the maintenance of current diverging national approaches leading to trade barriers and the creation of legal uncertainty as to which claims would be covered.

EFLA recognises that for reasons of clarity the use of uniform terminology is required. The definitions laid down by Codex Alimentarius¹ could provide a good starting point. Vague concepts such as 'significant source', 'recommended', ... should be appropriately defined when included in legislation. EFLA would however be reluctant to have definitions of the different types of claims in normative legislation, as a basis for differentiation between procedures, level of substantiation, etc since such definitions overlap and are bound to lead to grey zones of legal uncertainty.

The definition of "nutrition claim" in Council Directive 90/496/EEC was adopted for the purpose of nutrition labelling and primarily focuses on nutrition properties due to the calorific value of a product. The European Commission acknowledges that nutrition claims concern not only proteins, carbohydrates, fat, components of macronutrients, vitamins and minerals but an increasing number of other substances, such as fibre, antioxidants or lactic bacteria. EFLA believes that a sufficiently broad definition should be adopted. EFLA therefore suggests the definition for "nutrition claim" as set out in the Codex Alimentarius Guidelines (CAC/GL 23/1997) as a starting point for further discussions.

The term "functional claim" in the context of the discussion paper could be misleading as it does not cover claims relating to functional foods but deals with so-called "nutrient function claims" as defined CAC/GL 23/1997 and in the draft Codex Guidelines for Nutrition and Health Claims (ALINORM 01/22 Appendix VIII). EFLA therefore suggests replacing the term "functional claims" with "nutrient function claims".

Establishing a coherent framework would certainly require adaptation of the labelling directive, the nutritional labelling directive, the misleading advertising directive and would also necessitate congruence between the general food law regulation, currently under development and the medicinal product directive, currently under revision.

¹ The general guidelines on claims (CAL/GL 1-1979 /Rev. I- 1991) and the proposed draft guidelines for use of health and nutrition claims, still under discussion (Alinorm 01/22).

Furthermore, EFLA suggest that, in the legislative process, account be taken of forms of co-regulation at EU level, such as existing codes of practice, in order to facilitate enforcement and effectively use resources in other fields of consumer protection. In the same time, a particular attention should be given to clarity as to the applicable rules and to legal certainty.

In order to be effective, EFLA calls for a clear, simple, coherent, transparent, predictable, and easily enforceable framework, based on the following principles:

- EFLA would underline the importance of not creating artificial boundaries, since borderlines give rise to grey areas and thereby legal uncertainty. This in turn means that there should be:
 - No creation of a new category of ‘functional foods’.
 - No discrimination of foods: Possibility for all foods to carry claims.
 - No discrimination between nutrients and substances with a physiologic function.
 - No discrimination of claims: All types of claims form a continuum.
- EFLA would underline the necessity of objective and clear principles for regulating Nutrition and Nutrient Function Claims, therefore:
 - The burden of proof should lie with the industrial operator.
 - The substantiation should be based on generally accepted scientific principles. The Council of Europe guidelines should be taken into account. The appropriateness of the scientific substantiation should be judged upon on a case by case basis.
 - Communication should be in line with the scientific substantiation.
- EFLA would insist on procedures that are proportional to the intended goal, enforceable, allow the necessary flexibility, both in time and in resources, to safeguard competitiveness, while providing a maximum level of consumer protection:
 - EFLA does not favour the establishment of lists restricted to permitted or forbidden claims, which entail long and burdensome procedures, which will not cover the various ways of communication, and will lift the burden of proof from the manufacturer.
 - EFLA questions the need and appropriateness of installing pre-marketing approval. A notification procedure for food labels to the competent authorities of Member States or the "dossier solution" of the cosmetics directive should be sufficient to facilitate monitoring procedures. Food operators having the intention to use ‘Health’ claims should anyway be obliged to have a complete documentation at hand to be presented to the food controlling agencies when requested.

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