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Nutrition Claims and Functional Claims

Discussion Paper by Directorate General Health and Consumer Protection (SANCO D4)

Comments

1. General Comments

BLL in the name of all its members welcomes the Commissions` initiative to deal with **nutrition and functional claims**. All these – in the broadest sense health-related claims – are the **focus of interest of food industry and consumers alike**. For the latter a healthy and balanced diet is increasingly the “Leitmotiv” of their selection of foods.

There is a need for **harmonisation** with regard to nutrition and functional claims because of substantial differences in the member states with regard to interpretation of community law in this area and divergent national legislation. This is the case for nutrition claims and functional claims alike and leads to substantial barriers to inter-community trade and competition.

However, we regret that the **discussion paper is limited with regard to functional claims** and does not cover all functional claims. **Health claims**, especially “**enhanced function claims**” and “**reduction of disease-risk claims**” are not covered and are to be subject of a separate consultation at a later stage.

This approach to functional claims is in our view not adequate with regard to the special interests of the food industry and consumers alike with regard to health claims. In addition, we are convinced that separating functional claims into health claims and other functional claims will prove impossible and unsuccessful. With the Commission we are of the opinion that consumers will normally hardly differentiate between different health related functional claims, that may, in addition, be “overlapping”. The **main concern for consumers** is that **claims are true, scientifically substantiated** and formulated in a way, that is **generally understood**. Attempts to differentiate between the different health claims with the aim of it establishing different legal frameworks is not regarded as helpful.

We therefore call for the Commission to establish a **legal framework for all functional claims including health claims**. In our view that should be done by a revision of Article 2 of Directive 2000/13/EC (Labelling Directive) to the end that functional claims including health claims do not fall under the prohibition of claims that attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties.

Harmonisation with regard to nutrition claims would ideally be dealt with in the framework of the necessary **revision of the Directive on Nutrition Claims**. The **German Regulation on Nutrition labelling** in its § 6 contains provisions on reduced contents of sodium, carbohydrates etc. that should serve as a basis for discussions.

2. Detailed Comments

INTRODUCTION

Consumers' interest with regard to a healthy and balanced diet and the inter-relationship between nutrition and health can only be satisfied adequately, if according information is provided via general and public education and via food labels and advertising for foodstuffs alike. Product-specific and product-related nutritional information is the only way to approach consumers directly and provide information for their daily choice in food. As a **marketing tool** it is therefore a **legitimate interest of the food industry** and serves the common aim of better consumer information (3).

There is a **need for harmonisation** although Article 2 of the Labelling Directive sets the general principles and criteria for all claims. However, because of its general scope and wording member states have "used" the room for manoeuvre and developed substantial differences in interpretation and application of the law. With regard to **nutrition claims** there is a need for harmonisation, because the directive on nutrition labelling until now only sets criteria for the admissibility and scope of nutrition claims, does not cover specific claims as for example comparative nutrition claims. With regard to **functional claims** there is a need for harmonisation not least because of the establishment of Codes of Practice in the different member states that have not served to enhance uniform and common understanding (4 and 5).

GENERAL CONSIDERATIONS

We support the Commission's general consideration with regard to principle criteria for claims. They can all be developed from the general principles in **Article 2 of the Labelling Directive** that basically already establishes that all claims must be **true, scientifically substantiated and formulated in a way that will not mislead consumers**. There is therefore no need to establish new or additional provisions to that end (6. – 11.).

We also agree that there are **no “good” or “bad” foods “per se”**, but only a more or less balanced diet. We therefore advocate that **all nutrition and functional claims be admissible for all foodstuffs**. Products with high fat content such as margarine are part of a balanced diet. Information on a reduced fat content can be a valuable information (**9. and 41.**).

NUTRITION CLAIMS

The definition of the Directive on Nutrition Labelling should serve as a basis for discussion. We agree with the commission that claims should be possible with regard to other than the “classical” nutrients (**17.**).

We support the Commission’s intention to take the **Codex Guidelines** on nutrition claims as a **starting point for discussions (18.)** There is however need for changes in detail. The Codex Guidelines on saturated or poly-unsaturated fatty acids are not acceptable, because they would stand in the way of valuable consumer information with regard to many foodstuffs that would not match the criteria.

In addition we would like to point at **Regulation 2991/94/EC** that contains additional definitions “light” etc with regard to fat spreads, that the Codex establishes a value of **0,5g per 100g/ml** for the term **sugar-free** and to the general consideration that product specific provisions take precedence (**18. and attachment**).

With regard to all the other points raised with regard to nutrition claims we would like to point again to the principles of Article 2 of the Labelling Directive that will answer most of the questions. That is especially true for all claims relating to cholesterol. In our view, a general prohibition of **cholesterol-related claims** is – especially with regard to the controversies in the scientific debate – not justified, however, operators have to ensure that the messages are correctly understood (**24. and 25.**).

CRITERIA FOR MAKING NUTRITION CLAIMS

We support the Commission in their view that nutrition claims should be **admissible for all foodstuffs** and not only for a special category of foodstuffs as functional food (**27.**).

With regard to all the different claims mentioned in the Discussion Paper we refer again to the general principle of Article 2 of the Labelling Directive and on the basic principle that all true and scientifically substantiated claims should be admissible. In addition:

- Claims as **“without added”** or **“no added”** or **“low”** should also be admissible with regard to foods that are in principle “without added” or “no added” or “low”. However, operators will have to ensure that consumers are properly informed and not misled by such claims (**27., 29., 30.**);

The necessity to provide **15%** of the Recommended Daily Allowances (**RDA**) whenever claims on vitamins and minerals are made, does not properly reflect the diversity of foodstuffs and needs therefore **revision** with regard to those foodstuffs that, as for example beverages, may have difficulties in fulfilling this criterion.

- With regard to “**increased**” or “**reduced**” nutrition claims, we support the Codex approach of **25%** minimum difference. However, the Commission needs to take care of that approach being **consistent in all relevant pieces of legislation** (e.g. in the Directive on Sweeteners) (**33.**).

FUNCTIONAL CLAIMS

The Codex definition of “Nutrient Function Claims” is seen as favourable, because it covers a wider spectrum of claims. We do however call on the Commission to take into account all the additional definitions – also with regard to Health Claims – in the different member states, in the Council of Europe, within FUFOSSE and for example in the United States and Canada (**30. – 39.**).

CRITERIA FOR THE USE OF FUNCTIONAL CLAIMS

With regard to criteria for functional claims we would, firstly, like to refer once again to our general remarks, especially with regard to the necessity of covering the whole spectrum of health related and functional claims.

Again, we would also with regard to functional claims like to reiterate the general principle that all true and scientifically substantiated claims should be admissible. We are aware of the special need to communicate functional claims in such a way they would not mislead consumers but are a proper response to the interest in the inter-relationship between nutrition and health (**40. – 47.**).

In the interest of legal certainty all functional claims need to be exempted from the prohibition in Article 2, 1 lit. b) of the Labelling Directive, that would then expressly state that they do not fall under the prohibition of claims that attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties. The clarification that they are not preventive claims is of utmost importance. For the details we refer to our Position Paper on Health Claims (attached).

We would like to add the following: We are not advocating that Article 2, 1 lit b Labelling Directive should be changed with the aim of making claims on prevention, treatment or curing of diseases admissible. However, there is clarification needed that functional claims including health claims do not fall under that prohibition because they are not claiming properties of prevention, treatment or curing.

We agree with the central role and importance the Commission attributes to adequate scientific substantiation and effective control of functional claims. However, the discussion paper names but only very general criteria of adequate scientific substantiation. In addition, those mentioned seem to be stemming from different sources that were however all dealing with health claims. Furthermore, the systems of control mentioned are also only few of those available and to be discussed. (47. – 50.).

We will therefore comment only very generally and to the end that the **principle of proportionality** is applicable with regard to scientific substantiation and control and measures and requirements set in so far. Well known and generally expected scientific knowledge will not need to be substantiated again and would certainly not justify a system general prohibition that could only be overcome by a pre-market approval. Accordingly, new information based on recent research would need more extensive scientific substantiation and control. The duty of the operators to prepare a complete scientific dossier that is readily available and could thus serve as a basis for effective control is a model we could envisage as sufficient and effective (“**dossier-solution**” according to the Directive on cosmetics).

We would finally like to remind the Commission of the enormous work that has been done with regard to functional claims and especially Health Claims in the different member states, the Council of Europe, FUFOSSE and in other countries like the USA and Canada. All these experiences and results should not be neglected, the general principles are certainly valid for all kinds of functional claims.

3. Summary

- Functional claims need to be regulated conclusively and comprehensively; that presupposes that Health Claims are covered.
- Functional claims and nutritional claims need to be discussed and regulated separately; the approach of a joint discussion is felt to be not helpful, if not counter-productive.
- Functional claims and nutritional claims need to be generally admissible for all foodstuffs; a separate category of functional foods is disapproved.
- Requirements for scientific substantiation and control need to be proportionate; a system of general pre-market approval is not.