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Directorate General Health and Consumer Protection
(SANCO D4)
European Commission

Dear Sirs

Discussion Paper on Nutrition Claims and Functional Claims

Thank you for providing us with the opportunity to comment on the above.

It is vitally important to ensure that any claims made on products are communicated in a manner that is both understood and meaningful to consumers. Claims that are not understood are indeed useless and potentially misleading. Consumer perception of images, logos and product endorsement should also be considered, as there is also the potential for these to mislead. Typically many restaurants will use a small heart or apple symbol to denote 'healthier options' on menus, without having any sound nutritional criteria for substantiating such a claim.

The need for the overall nutritional profile of products to be taken into consideration could be overly restrictive in some instances; particularly where the food is intended to be consumed with other food items as part of a meal. Also defining a suitable nutritional profile would indeed be difficult, unless the product(s) were specifically targeted at sub groups in the population. Discarding the idea of classifying specific products or product groups as 'good' or 'bad' should be encouraged and emphasis given to how and where a particular product could make a positive contribution to the overall balance of the diet.

MLC considers that some aspects of bioavailability and nutrient shelf life will be difficult to legislate on. A number of factors can influence bioavailability including consumption with other foods containing enhancers and inhibitors to absorption, and individual nutritional status. Similarly, nutrients degrade at different rates and under different storage conditions.

The format of claims should be clear and take account of how the product will be consumed. Obviously this should be in line with instructions and take account of the addition of any other recommended ingredient or cooking methods, such as frying which will influence the nutrient profile of the product as consumed. A nutritional claim based on a product as sold, when instructions clearly require the product to be deep fried, is misleading.

Definitions of the different types of claims

The Codex definition of claims is sufficiently broad to encompass both nutritional and functional food claims. It also has the potential for encompassing claims for the presence of for example phytochemicals, but it is unclear whether these would be considered to be a nutritional claim in future. In light of this the definition of “nutritional claim” by the Council Directive 90/496/EEC needs to be updated and extended to include claims for such substances which have a physiological effect rather than directly nutritional effect. Alternatively, such substances need to be covered by an agreed definition for functional foods, as presently alternative definitions exist.

Existing definitions on functional foods:

- IFIC defines functional foods as ‘*food that provide health benefit beyond their basic nutrition*’.
- ILSI defines functional foods as ‘*foods that by virtue of physiologically active food components provide benefits beyond basic nutrition*’.

The criteria for making Nutrition claims

Some confusion exists with regards to claims and the conditions for making these claims. As a result there is the potential for being misleading. Ideally, Member States need to rationalise the conditions for applying claims and adopt similar thresholds.

- In some cases substantially different conditions are set for **weight and volume**. This is potentially misleading as in most cases the volume equivalent would be essentially identical to the weight and therefore similar thresholds should apply.
- **Energy free** and **without energy** should mean exactly that and although the threshold is set at only 4kcal/100ml it is still potentially misleading. In the case of **fat-free** and **without fat** the threshold of 0.15g/100g or 100ml is so low that it can be considered insignificant.
- The **low fat** figure of 3g/100g is exceptionally low, and makes it difficult to apply to a number of nutritionally improved products with less than 10% total fat content. Such nutritionally modified products have an important part to play as part of a healthy balanced diet and need to be recognised as such.
- It is recognised that sodium is meaningful scientifically and that it can be present in foods in other formats such as monosodium glutamate, but attempts to address consumer confusion about sodium are needed. Perhaps claims on **sodium** should be progressively supported by claims on added **salt**, as consumers more readily understand this.
- The Codex conditions for claims on **sources of protein** is potentially confusing which in turn makes the conditions for applying **high protein/rich in protein/excellent source of protein** also cumbersome. The 12g figure (preferably) or the 12% of energy figure, (20% in the case of high protein) used in some Member States would be simpler to apply.
- The alternative ways of applying a **source of fibre** claim i.e. as at least 3g/100g or 1.5g/kcal is potentially misleading. It is appreciated why the later is related to energy value but this could be a difficult concept for the consumer to grasp. This also applies to

claims of **high fibre**. The thresholds of 3g/100g(source of fibre) and 6g/100g(high fibre) would seem more straightforward.

- Codex conditions for claims on source of **vitamins and /or minerals** is confusing for the consumer, but it is appreciated that as specific vitamins and minerals are required in very different quantities the threshold criteria needs to be sufficiently flexible to account for this.
- The use of reference to **RNV and/or RDA** needs to be continually supported by a consumer education programme to ensure that these terms are fully understood and appropriately applied.

Wording of nutritional and functional claims

Specifications relating to the wording of claims would be helpful to rationalise terminology and further reduce potential consumer confusion. The use of the term '**light**' and '**lite**' should be prohibited, as they are commonly open to misinterpretation. Similarly, the term '**diet**' used in the absence of a qualifying statement such as 'as part of a low energy diet' could be misinterpreted.

X% fat free claims are misleading and should be prohibited. These should be replaced with claims that are in line with the low/reduced fat criteria.

Claims on **vitamins and minerals** need to be reviewed in light of a revision of the RDAs. Greater consideration needs to be given to the scope of population groups encompassed by the RDAs. It is noted that many foods that are generally considered as good dietary sources of some micronutrients for specific sub groups currently do not qualify for a claim.

Comparative claims must be clearly expressed and related to a specific reference product. However, this becomes more difficult when applied to composite recipe type products that have been nutritionally modified from a traditional recipe. In the case of meat this comparison may need to be made on a historical basis given the progressive changes in recipes and production methods.

The 25% minimum difference set by Codex for the terms '**increased**' and '**reduced**' seems realistic for energy content and for macronutrients. However, it would be unrealistic, and in some instances dangerous to apply this threshold to micronutrients. Setting the threshold at 33% or 50% for reduced fat claims is unrealistic

The proposed controls on claims relating to **cholesterol** require to be seriously reviewed as the potential for the consumer to be misled about products which will assist in reducing elevated blood cholesterol is significant. Consumer education about which factors can influence blood LDL and HDL cholesterol levels is essential if the target of reducing the numbers suffering from CHD by 200,000 is to be achieved by 2010. Accurate and meaningful nutritional labelling has a major part to play in supporting this national target.

Evidence indicates that consumers are confused about the difference between **salt and sodium**. If claims were expressed in terms of **salt** content this would help reduce confusion and misinterpretation. The use of **low sodium** and **very low sodium** should rightly be reserved for foods intended for particular nutritional use, as there is likely to be a need for dietetic intervention and individually tailored guidance given to consumers requiring to use them for health reasons.

Functional claims should not encourage over-consumption of a given food product but can only relate to the product as sold. However, they should be underpinned by the same principles of promoting a varied and balanced diet and advocate that there are no inherently good or bad foods.

The degree of elimination of particular allergens must be controlled and expressed in a manner that the consumer can interpret and make an informed decision about prior to consuming. This would be particularly important in the case of nuts and nut extracts.

Application of rules on claims

The rules on claims should apply to foods making those claims and not to all foods (i.e. those not making claims). Thus nutritional claims' control should apply to all foods making a nutritional claim, and functional foods claims' should be reserved for foods which meet a defined criteria making them eligible to make such a claim. Similarly, foods that do not conform to defined claims criteria would be ineligible to make the relevant claim.

The use of a claim should be underpinned by a ruling that requires the application of a method of validating the chemical identity and quantity of the nutrient for which a claim is made. Depending on the type of claim it needs to be clarified whether standard nutritional analysis is sufficient, or more accurate chemical analysis is required. In the former it has to be recognised that there will be margins of error even if conducted by a suitably qualified person using appropriate reference data.

Level of scientific substantiation

It is vital that all functional food claims are based on scientific evidence and that it is kept under regular review. How it could be prohibitive to enforce clinical trials as the gold standard similar to that required for drugs. With regards to who should carry out this, there needs to be procedures that will enable international (EC) acceptance of scientific evidence through the Scientific Committee structure. A voluntary **pre-market approval** system might assist with this, but the burden would be disproportionate were it to be made compulsory. However, suppliers should maintain dossiers of supporting evidence, which can be made available to enforcement officials on request.

We would appreciate being kept informed of any further developments in this area.

Yours faithfully

Martin Grantley-Smith
Head of Government Relations