Comments to Discussion Paper on Nutrition Claims and Functional Claims
From the Danish Toxicology Centre

The Danish Toxicology Centre welcomes DG SANCO's initiative in requesting comments on a discussion paper prior to proposing legislation.

We have discussed the paper, and in the following we present the results of our discussions. Before each comment we have quoted the paragraph number of the paper that most directly corresponds to our comment.

1. Introduction
Our most general principle for the use of nutritional and functional claims for foods is respect for the consumer, and we feel that this also should be reflected in use of claims within the EU.

We understand that health claims are being dealt with elsewhere, and that they will be the subject of a consultation later. However, in order to differentiate between nutritional claims and **health** claims in the execution of EU food law, it will be a very complex and extensive task for the EU Authority. For instance, upholding Article 2, § 1 (b) of the labeling directive (2000/13/EC) will be almost impossible. Our support for this paragraph is explained below, especially in comment no. 4.

2. §§ 10-11.
We agree that a claim must not confuse or mislead the consumer. Therefore we suggest that a claim should refer to the final use of the food and only include the bio-available substances. We base this on the consideration that the claimed effect of the food products shall be relevant for the consumer's use of the food. For example, if a product after preparation like dilution or heating does not contain the substance in an amount that will differentiate the product from similar ones without the effect, then a nutritional claim would not be appropriate.

3. §7
We want to give our strongest support the viewpoint of the discussion paper's §7. The value of a varied and adequate diet cannot be stressed enough, and we already see tendencies that some aggressive food industries undermine this value with superfluous nutritional claims. We hope the value of a balanced diet will continue to be the bottom line of EU food legislation.

4. §8
As the discussion paper's § 8 puts forth, we find that communication and presentation of claims often are misunderstood by consumers. Therefore, in nutritional claims we suggest prohibition of:

- claims that purposefully cause or exploit fears in the consumer,
- claims that a food is recommended by doctors,
- use of graphics in advertisements and packaging with health workers (doctors, nurses etc.)
- claims that consumption of a certain food can prevent, treat or cure a disease (as already in the labeling directive 2000/13/EC).

These points are all in the Danish Law on Food, Law No. 471 of July 1st, 1998 (§ 20).

5. §9
The problem raised in §9, the overall profile of a food, is difficult to solve. In the following we wish to make a few comments and propose a solution:
A product will always be a part of a more or less complex diet and hence its nutritional value should be defined in this context. Therefore we agree that a single product cannot be classified as "good" or "bad". Another way of classifying food products could be based on the composition of the food, *e.g.*, a recommended daily distribution of energy intake, such as that recommended

by the Danish food authorities (protein: 10-5 %, fat: ≤30 %, carbohydrate: 55-60 %). A classification like this would prevent the use of nutritional claims in the marketing of most snack products, biscuits and the like.

Another way of administering these claims could be based on the purpose of the food, i.e., whether it is a basic component of the diet like bread, milk products and cereals, or just "additional frills." However, this would raise the problem of classifying food; e.g. yogurt is a basic milk product in some countries but in others a much sweeter, dessert-like "frill" product.

6. §46.
It is of the utmost importance that nutritional claims are well documented, especially when used as marketing tools. In principle, the level of documentation prescribed by the Danish Statutory Act on Natural Medicines (Act No. 790 of Sept. 21, 1992) might be applicable to nutritional claims in foods. When bibliographical reference to published literature is used as documentation, it is only allowed with reference to European and North American scientific literature that is general accepted for its quality.

7. §17.
There should be a clear distinction also for the consumer between a physiological claim and a nutritional claim, as the two effects are fundamentally different. The ***nutritional*** composition of the food product should help the consumer maintain an appropriate diet. This is based on knowledge about what the body needs. The ***physiological*** effect of a product is an additional effect over and above what the body needs but still will benefit from.

In addition, as implied in the discussion paper's §17, there are a number of lactic acid bacteria that have well documented positive physiological effects on humans. On this point we wish to present a few aspects of the bacteria that are important for the question of claims.

For a number of strains of these probiotic lactic acid bacteria, the Danish Toxicology Centre has assessed both their safety and their efficacy as medicinal products and as additives for feedingstuffs. As the Commission is aware, these bacteria are winning impasse as part of the routine diet of agricultural animals. We find that it also should be possible to offer humans the possibility of consuming well documented probiotic bacteria as part of our daily maintenance of a healthy microflora. Here we exclude disease prevention or treatment from our considerations, as mentioned above for §8.

For these bacteria in foods, the mere existence of physiological claims requiring EU approval may be a good thing, because the positive effect is strictly strain-dependent (for instance *Lactobacillus acidophilus* strain LA-1) and not just dependent on the bacteria's species (as just *Lactobacillus acidophilus*). By demanding that the food industry document its physiological claim before using it, the EU Authority could monitor use of the claim; undocumented claims would definitely be forbidden.

In addition, the presence of the claim would make it easier for the consumer to know exactly which brand of yogurt or which brand of fruit drink contains the documented strain of bacteria.

8. §§31 - 39
If an EU standard for nutrient claims is to be established, it should be similar to the definitions used by Codex Alimentarius. This would be an advantage both for the customer and for the EU's administration of the standard.