

**Hälsopåståenden i märkning och
marknadsföring av livsmedel
Livsmedelsbranschens regler
(egenåtgärdsprogram)**

**Health Claims in the Labelling and Marketing
of Food Products
The Food Industry's Rules
(Self-Regulating Programme)**

19 August 2002

**Yttrande beträffande granskning av vetenskaplig dokumentation bakom
produktspecifikt hälsopåstående**

Produkt

Primaliv yoghurt med müsli, portionsförpackning med 200 g yoghurt och 26.5 g müsli

Tillverkare/Marknadsförare

Skånemejerier ek. för., Malmö

Sammanfattning

Produktens dokumentation har granskats enligt livsmedelsbranschens regler. De studier på människa som bifogas ansökan om granskning stödjer att produkten reducerar/utjämnar nivån av blodglukos (blodsocker) efter måltid. Produkten skall överensstämja med den som använts i studie 2, innehållande 4 g beta-glukan. Processtekniken skall vara densamma som i den testade produkten.

**Statement concerning evaluation of the scientific documentation behind a product
specific health claim**

Product

Primaliv yoghurt (200g) with müsli (26.5g)

Producer/Applying company

Skånemejerier ek för, SE-205 03 Malmö

Experts appointed by the Research Committee of SNF Swedish Nutrition Foundation

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Background

There is today an increasing frequency of obesity and diabetes all over the world. There is an urgent need to try to delay or reverse this development with preventive measures including dietary changes and increased physical activity in the population. Dietary guidelines in the Western world include recommendations about not only a reduced fat intake but also an increased amount of carbohydrate-rich foods, especially those which give a low and extended blood glucose (and insulin) response after a meal – e.g. foods with a low glycaemic index (GI). There is epidemiological evidence for the beneficial effect of foods with low GI. There has – so far – been a lack of palatable low-GI breakfast products. Most breakfast müsli are rather high-GI-products putting a burden on those with fasting blood glucose above the normal average level.

The present application concerns a product consisting of a low-fat yoghurt and müsli enriched in beta-glucans from oats (for nutrient composition see table 1). The suggested claim is that the product "balances the blood sugar level after a meal". Consumption of one cup of yoghurt containing 4 g beta glucans is regarded sufficient to achieve this physiological response. The primary target group for this product is health-conscious consumers aged 35-65 years. Secondary target group is patients with type 1 or type 2 diabetes.

It is well documented that certain soluble, gel-forming types of dietary fibre in foods is one factor that can lower the GI. The properties of the fibre, such as viscosity, are important in this respect, and can be altered by processing.

The product

The application concerns a product consisting of 200 g flavoured or "natural" yoghurt with 26.5 g müsli based on oat bran enriched in beta-glucans. The müsli is packed separately in the lid of the container and intended to be mixed into the yoghurt just before consumption. The product has a low fat content (0.5%) and is a good source of several nutrients and dietary fibre.

Scientific documentation

Three human studies are included in the file. The effect on blood glucose and insulin response has been studied up to two hours after testmeals. The intended portion size of the product and a control yoghurt without müsli, respectively, have been included and the amount of digestible carbohydrates in both the test meal and the control meal was adjusted to 50 g with white bread. This is a commonly used standard in determinations of GI, and may in practice also be consumed together with yoghurt products as an alternative to breakfast cereals.

Two of the studies (appendix 2 and 4) include the specific product mentioned in the application, while one study (appendix 3) has used a product where both processing and recipe differed from that used in the other studies. Thus, the results from this study are not directly relevant for the application. Of the other two studies (appendix 2 - 4g beta glucans

and appendix 4 - 3g beta-glucans) only the study including 4g beta glucans showed a statistically significant reduction of blood glucose and insulin after the meal.

The studies raise some methodological questions:

- 1) Which is the most relevant control for comparison with the product– another yoghurt, white bread, or another youghurt and white bread corresponding to the müsli component of the product. There is as yet no international standards or consensus in this respect. The design of the studies can be considered adequate for their purpose.
- 2) The number of test subjects differ in the three studies and it is unclear why this is so. International standards are underway but not yet in place. The number of participants should ideally be based on a calculation of power to detect a significant, physiologically relevant difference between the test meal and the control meal. Although it is concluded that the effect demonstrated in study 2 (4g beta glucans) is physiologically important (especially for individuals with glucose intolerance) this statement is not supported by proper references, and is another issue on which international consensus should be developed.

With the design used as described above, there was a substantial difference in the content of white bread between the test meal and the control situation in study 2 (10.6g) and study 4 (4.8g). There is a possibility that the different effects in study 2 (significant reductions of glucose and insulin) and study 4 (no significant effect) could be partly explained by different proportions of carbohydrates from white bread and müsli, although it is most likely that the effects are mediated by the beta-glucans.

Do the studies support the suggested claims?

Only one study actually shows a statistically significant effect (study 2 – 4g). There is a similar, non-significant trend in study 4 (3g). Study 3 (5g) shows a significant effect albeit with a müsli preparation made with different methodology and recipe. Thus, there is no real demonstration of a dose response effect.

If the application had concerned an unknown food/ingredient without earlier documentation these studies would clearly not have been sufficient. With regard to the effects of beta-glucans from oats there is, however, a substantial literature supporting that the effect of the müsli in study 2 is real and mediated by beta-glucans. Furthermore, the other two studies do to some extent support this conclusion (effect also in study 3 but different product, trend but not significant in study 4).

Conclusions and recommendations

It is concluded that the human studies submitted with the application would support a product-specific health claim concerning effects on blood glucose levels.

A prerequisite is that the marketed product is the same as that investigated in study 2, containing 4 g beta-glucan. The processing technique applied should be identical and checked regarding depolymerisation of the beta-glucan, since viscosity seems to be a key determinant for the blood glucose lowering effect.

The wording of the claim should be discussed. "Balances" is a very unspecific claim just indicating that changes – small or large – in opposite directions are of a similar magnitude. "Reduces" or "smoothens out" glucose levels after the meal might be more correct.

It is not justified to make health claims specifically for subjects with diabetes until more studies have been performed in subjects with diabetes, although products with low glycemic index may be useful in the treatment of this disease.

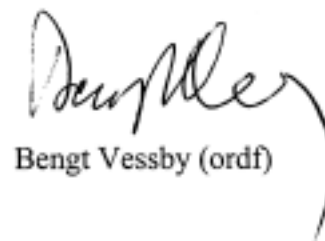
Malmö/Aarhus/Uppsala augusti 2002



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