PHYTOSTEROL-ESTERS:

USE IN A RANGE OF FOOD PRODUCTS

SUMMARY

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Date : July 2002
Document reference: D02-027

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1. ADMINISTRATIVE DATA

Applicant:	Unilever Plc Unilever House Blackfriars London EC4P 4BQ
Manufacturer:	Unilever Bestfoods UK Limited Brooke House Manor Royal Crawley RH10 2RQ
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2. APPLICATION

This application seeks approval for the use of phytosterol-esters to be included as a cholesterol-lowering ingredient in ‘milk’ and ‘yoghurt’ type products. This is in addition to the approved use in Yellow Fat Spreads.

The ‘milk’ type products would include skimmed, semi-skimmed and vegetable oil based milk variants. The ‘yoghurt’ type products would include a range of natural and fruit flavoured yoghurts. It is understood that, under EU milk legislation (EC Directive 95/2) and the varying national legislation across member states covering yoghurt, the addition of phytosterol-esters, and other ingredients required to stabilise the products, will prevent the use of the term ‘milk’ and ‘yoghurt’, to describe these Novel Foods.

Phytosterol-esters are considered to be the Novel Food Ingredient and the ‘milk’ and ‘yoghurt’ type products with added phytosterols-esters the Novel Foods.

3. IDENTIFICATION OF ESSENTIAL INFORMATION REQUIREMENTS

The structured scheme (Table II, Part I under EC Regulation No. 258/97) has been followed to determine which of schemes I-XIII are essential to provide data permitting a safety and nutritional evaluation of the Novel Food Ingredient.

With phytosterol-esters falling into Class 1.1 the following information should be provided:

I. Specification of the Novel Food
II. Effect of the production process applied to the Novel Food
III. History of the organism used as the source of the Novel Food
IX. Anticipated intake/extent of use of the Novel Food
X. Information from previous human exposure to the Novel Food or its source
XI. Nutritional information on the Novel Food
XII. Microbiological information on the Novel Food
XIII. Toxicological information on the Novel Food

This information is provided in document D02-018 ‘Phytosterol-esters: use in a range of food products’. Where appropriate, reference has been made in D02-018 to Unilever’s previous application for the use of phytosterol-esters in Yellow Fat Spreads which was approved under Regulation (EC) No 258/97 in European Commission Decision 2000/500/EC of 24 July 2000.

4. SUMMARY

Under Regulation (EC) No 258/97 on Novel Foods and Food Ingredients, Unilever received approval for the use of phytosterol-esters as a novel food ingredient in Yellow Fat Spreads in European Commission Decision 2000/500/EC of 24 July 2000 (EC, 2000). Under Article 3 of this decision, Unilever was required to establish a surveillance programme to accompany the marketing of the product. The results of this surveillance programme, referred to as Post Launch Monitoring, showed that intakes of the spread were lower than that assumed in the Novel Foods submission with no evidence of adverse health effects.

This indicates that there is an opportunity to offer consumers alternative or additional healthy foods to deliver optimal cholesterol-lowering benefits without increasing the intake of phytosterols above the level already approved. This application seeks approval for the use of phytosterol-esters to be included as a cholesterol-lowering ingredient in 'milk' and 'yoghurt' type products. This is in addition to the approved use in Yellow Fat Spreads.

The phytosterol-esters to be used in the 'milk' and 'yoghurt' type products are identical to those currently used in Yellow Fat Spreads. The 'milk' and 'yoghurt' type products containing phytosterol-esters have been tested for their microbiological and chemical stability over time, including the impact of pasteurisation, and these have been found to be similar to standard products.

The phytosterol-esters will be added to the product such that a 250ml serving of the 'milk' type product will provide 1g of free phytosterols. The 'yoghurt' type product will be produced in individual serving pots with phytosterol-esters added such that each individual pot provides 1g free phytosterols. The recommended intake will be 2-3g free phytosterols/day.

The cholesterol-lowering effect of phytosterol-esters has been demonstrated in various food types including 'milk' and 'yoghurt' type products. The effect is comparable to that seen with Yellow Fat Spreads.

The range of products will be labelled with clear instructions on how to eat an appropriate amount of the spreads, 'milk' or 'yoghurt' type products to obtain an average of 2-3g of free phytosterols per day to optimise cholesterol-lowering benefits. Consumers will also be informed that consuming higher amounts will not provide any significant additional cholesterol-lowering benefit. Labelling will continue to include the information from the original approval indicating target consumers, lack of suitability for children, pregnant and lactating women and advice to those receiving cholesterol-lowering medication. This will be adapted, if necessary, in line with the Scientific Committee on Foods current deliberations on multiple intakes of phytosterol products.

If consumers use the product as recommended on the labelling then it is anticipated that the intake will be 2-3g of free phytosterols per day. This level of intake does not exceed that originally expected from the use of Yellow Fat Spreads containing 8% phytosterol-esters approved by the EC.

There is no evidence to suggest that consumers will not follow the labelling advice regarding recommended intakes, particularly as this states that there is no additional cholesterol-lowering benefit from eating more than the recommended 2-3g free phytosterols/day. However, should consumers not follow the labelling advice then the potential daily intake of phytosterols has been modelled based on the consumption patterns of unfortified products. This has been done using both intake data from dietary surveys and consumer purchase data. This shows that even if consumers do replace all spread, 'milk' and 'yoghurt' type product intake with phytosterol-ester products the potential daily intake of phytosterol-esters is still within the range of intakes considered in the original risk assessment and does not raise any toxicological concerns.

However, it is highly unlikely that consumers will replace all intakes of spread, 'milk' and 'yoghurt' type products by the equivalent phytosterol-ester products in this way. Post Launch Monitoring data and studies of consumer purchase data of phytostanol-ester products in Finland and the UK indicates that intakes of cholesterol-lowering foods are lower than those of the unfortified counterparts. This is confirmed by UK consumer purchase data that indicates that consumers who buy phytosterol/stanol-ester products also buy unfortified products.

In conclusion, this application demonstrates that extension of the range of phytosterol-ester products available in the EU to include 'milk' and 'yoghurt' type products in addition to Yellow Fat Spreads will not lead to over-consumption of phytosterols resulting in adverse public health effects.