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FOOD STANDARDS AGENCY

Dr Kjell Sjöberg
Triple Crown AB
Björnnäsvägen 27
113 47 Stockholm
Sweden

27 July 2004 Reference: NFU 504

Dear Dr Sjöberg,

OPINION ON THE SUBSTANTIAL EQUIVALENCE OF A FREE PHYTOSTEROL INGREDIENT

The Advisory Committee on Novel Foods and Processes (ACNFP) has now completed your request for an opinion on the substantial equivalence of your free phytosterol ingredient with the existing phytosterol esters ingredient.

I am pleased to inform you that, in view of the positive opinion given by the ACNFP, the Food Standards Agency, UK Competent Authority for all novel food issues, is content that your free phytosterol ingredient meets the criteria for equivalence, as defined in Article 3(4) of regulation (EC) 258/97.

This opinion is issued on the basis that your free phytosterol ingredient is to be used in milk type products and yoghurt type products in accordance with the conditions specified in Commission Decision 2004/335/EC.

We also advise that you inform all customers that food products containing plant sterols should be labelled in accordance with Regulation (EC) 608/2004.

Please note that, in accordance with Article 5 of (EC) 258/97, you should notify the European Commission when you intend to market your free phytosterol ingredients when they are first marketed. You should send this to Mr Andreas Klepsch at the following address:

European Commission
DG SANCO
Rue de la Loi 200
B-1049
Brussels
Belgium

If you have any other queries, please do not hesitate to contact my colleague, Dr Chris Jones (Tel: 00 44 (0) 207 276 8572) or myself.

Yours sincerely,

Annie-Laure Robin
Novel Foods Division

Enc.: ACNFP opinion

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON SUBSTANTIAL EQUIVALENCE OF FREE PHYTOSTEROLS CONSIDERED UNDER ARTICLE 5 OF THE NOVEL FOODS REGULATION

Applicant **Triple Crown AB**
Björnnäsvägen 27
113 47 Stockholm
Sweden

Responsible Person **Dr Kjell Sjöberg**

Introduction

1. A request was submitted by Triple Crown to the UK Competent Authority for an opinion on the equivalence of their free phytosterols compared with the existing phytosterol esters used by Unilever and authorised by Commission Decision 2004/335/EC[1]. Triple Crown has sought authorisation for their free phytosterols to be used as an ingredient in milk-type products and yoghurt-type products. The application from Triple Crown indicates that they have the same supplier of phytosterols (Cognis) as Unilever, who use the phytosterols in their esterified form.
2. According to Article 3(4) of (EC) 258/97, the notification procedure applies to "foods or food ingredients… which on the basis of scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies… are substantially equivalent to existing foods or food ingredients as regards their:
   - Composition
   - Nutritional value
   - Metabolism
   - Intended use
   - Level of undesirable substances contained therein".

[1] Commission Decision 2004/335/EC of 31 March 2004 authorising the placing on the market of milk type products and yoghurt type products with added phytosterol esters …

Composition

3. The applicant is claiming equivalence to the specification for phytosterols set out in Annex 2 of Commission Decision 2004/335/EC. Although the phytosterols currently added to defined products are esterified to increase their solubility, the applicant intends to use their phytosterols in their free form. The applicant has highlighted that phytosterols are both ingested and excreted by humans in their free forms, whether they are ingested as free phytosterols or as phytosterol esters.
4. The ingredient is isolated from the same vegetable oils (mainly soy oil) used to produce the existing phytosterol ester ingredient. The applicant has provided data on the specification of its ingredient.
5. The production process of the phytosterol ingredient involves using an emulsifier (E471) and casein as a stabilising agent. Food producers using the ingredient will apply control systems to monitor it in their regular production. In addition, the quality and safety of the final dairy product will be controlled by using an appropriate HACCP system.

Discussion: *The Committee noted that the data provided on the phytosterols content of Triple Crown's ingredient complied with the specification of phytosterols in Commission Decision 2004/335/EC. However, the applicant's documentation specifies a maximum level of 6% for the presence of brassicasterol and other sterols/stanols. Products containing these components within the range of 3-6% would exceed the limits recommended by the Scientific Committee on Food*[2] *and specified in Decision 2004/335/EC. The applicant should therefore ensure that its product complies with the EC specification on phytosterols and ensure that levels of brassicasterol and other sterols/stanols are both below 3%.*

Nutritional value and metabolism

6. The consumption of Triple Crown's free phytosterols in yoghurt has been shown to lower the level of low-density lipoprotein (LDL) cholesterol in humans by about 12% when consumed at a dose of 1.8g/day over a period of two weeks. This effect is similar to the effect reported for the existing phytosterol esters and, therefore, the absence of esterification on Triple Crown's phytosterol ingredient does not affect their activity on blood cholesterol levels.

Discussion: *The Committee acknowledged that the cholesterol-lowering effects demonstrated for Triple Crown's phytosterols, which are of a similar dimension in the older, mildly hypercholesterolemic subjects as in the younger, normocholesterolemic, are not specific to Triple Crown's phytosterol ingredient. Similar effects have been reported for other preparations of phytosterols and phytosterol esters*[2]*.*

[2] Scientific Committee on Food, SCF/CS/NF/DOS/20 ADD 1 Final, 3 October 2002, General view of the Scientific Committee on Food on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on beta-carotene (expressed on 26 September 2002)

Intended use

7. The applicant intends their free phytosterols to be used in skimmed milk, semi-skimmed milk and low fat yoghurt with added fruits and sugar, as a cholesterol-lowering food ingredient. These products are similar to existing products with added phytosterol esters. The recommended daily intake of the ingredient in these products will be about 1.8 g/day, which is comparable with the phytosterol intake associated with the existing products and is in line with the conditions specified in Commission Decision 2004/335/EC. The applicant is also planning to manufacture a product that will give 1.5 - 2 g of phytosterols in a single portion. All these products will be labelled in accordance with the requirements set in Commission Regulation (EC) No. 608/2004[3] and the applicant provided specimens of the wording that would be used on food labels.

Discussion: *The Committee was content that Triple Crown intends to market their phytosterols mixture in yoghurt- and milk- type products only. The Committee wishes to highlight that this opinion does not extend to other food products, such as chocolate, dough/bread, jelly and mashed potatoes, that are mentioned in their European patent EP1009385. The Committee noted some inaccuracies in the proposed labelling of Triple Crown's products and highlighted the need for the applicant to adhere to the requirements described in (EC) 608/2004. The Committee acknowledged that this regulation prevents overconsumption of phytosterols.*

Levels of undesirable substances

8. No undesirable substances have been identified in the free phytosterols produced by the applicant.

Discussion: *The Committee was satisfied with the microbiological data provided on the casein and the emulsifier E471. Microbiological data were not provided on the final phytosterol mixture, but the Committee was content that appropriate HACCP systems and the proposed quality control measures were sufficient to avoid any bacterial contamination arising from Triple Crown's compound ingredient.*

Additional information

9. A comparison of the phytosterols produced by the applicant and the existing ingredient was made to highlight their similarities in activity, phytosterol profile, intended use, level of intake, labelling, processing and control systems.

Discussion: *The Committee did not comment on this additional information provided by Triple Crown.*

[3] Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters

Conclusion

10. The Committee is content that Triple Crown's approach to demonstrate the equivalence of their free phytosterols, to be used in yoghurt- and milk- type products, with the existing phytosterol esters is consistent with the criteria set in Article 3(4) of the Novel Foods Regulation (EC) 258/97.

11. Therefore, the free phytosterols produced by Triple Crown can be considered substantially equivalent to the existing phytosterol esters and used in the same products as those described in Commission Directive 2004/335/EC.

12. Triple Crown should ensure that the labelling of products containing their phytosterols must comply with Commission Regulation 608/2004 concerning the labelling of foods with added phytosterols, and more specifically to Article 2 of this regulation.

27 July 2004