

**Statement of the Scientific Panel on
Dietetic Products, Nutrition and Allergies on a request from the
Commission related to a novel food application on
rice drinks with added phytosterols**

(Request N° EFSA-Q-2005-242)

(expressed on 15 February 2006 at its 13th plenary meeting
corresponding to item 8.1 of the agenda)

BACKGROUND

On 12 November 2004, Teriaka Ltd., Helsinki (Finland) submitted an application under Article 4 of the Novel Foods Regulation (EC) N° 258/97 to the Finnish authorities for approval of placing on the market a rice drink containing the plant sterol ingredient Diminicol.

The phytosterol ingredient Diminicol was authorised for use in foods, namely in yellow fat spreads, milk-based fruit drinks, yoghurt-type products and cheese-type products by Commission Decision 2004/336/EC. The applicant has extended the range of food categories through the notification procedure under the Novel Foods Regulation to milk, fermented milk and soya drinks.

In the “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 β -carotene” (SCF, 2002), it was expressed that it was prudent to avoid plant sterol intakes exceeding a range of 1-3 g/day; and since a number of foods appeared to be potential candidates for enrichment with plant sterols, additional management measures might be needed to avoid excessive intakes. For these reasons, the Commission Regulation (EC) N° 608/2004 concerning the labelling of foods and food ingredients with added phytosterols and Commission Decisions on authorising the placing on the market of products with phytosterols established (among other things) that foods with added phytosterols should be presented in such a way that they could easily be divided into portions containing a maximum of 1 g (in case of 3 portions/day) or 3 g (in case of 1 portion/day) of added phytosterols. A container of beverages should not contain more than 3 g of phytosterols.

The Commission and Members States (MS) agreed that phytosterols should be added to a limited range of foods. So far, it has been authorised for phytosterols to be added to foods falling into one of the following four groups: a) yellow fat spreads, excluding cooking and frying fats and spreads based on butter or other animal fat; b) milk-type products; c) spicy sauces and salad dressings; and d) rye breads.

On 12 January 2005, the Finnish authorities forwarded their initial assessment report of the product concerned (i.e. rice drinks with added phytosterols) to the European Commission. The initial assessment was carried out by the Novel Food Board (NFB, Finland), which had reached the conclusion that this product may be regarded as safe as other food products with

added phytosterols and that it is comparable to soya drinks with added phytosterols that have already been authorised for marketing.

Following notification of the initial assessment report, MS presented their comments/objections, and it emerged that views differed on this issue. Several MS opposed the placing on the market of the product. In particular, there were concerns that this additional source of phytosterols may lead to their over-consumption, i.e. more than 3 g/day of additional phytosterols.

In view of the divergent opinions of the MS and the Community interest in this matter, the European Commission has decided to seek the opinion of the EFSA.

TERMS OF REFERENCE

In accordance with Article 29 (1) (a) of Regulation (EC) N° 178/2002, the European Commission requests the EFSA to issue an opinion on rice drinks with added phytosterols, and in particular, EFSA is asked to consider whether, in the light of the existing availability of a range of foods with added phytosterols, the addition of phytosterols to the proposed “rice drinks” would increase concerns with respect to “over-consumption” (more than 3 g of additional phytosterols per day).

COMMENTS

The recommended daily intake proposed by the applicant would be three 200 mL portions of the rice drink, each portion containing 0.5 g of phytosterols, amounting to a daily intake of 1.5 g of phytosterols.

No data on the consumption of rice drinks in the EU was presented in the application.

In the responses (dated 20 June 2005) to the comments/objections raised by Member States, the applicant emphasized that Diminicol[®] rice drink is intended to be an alternative to plant sterol enriched cow’s milk (later milk) or milk based products or “soy milk”.

The Diminicol phytosterol ingredient concerned is the same ingredient that was assessed by the SCF in 2003 (SCF, 2003a). In the “General View” and subsequent Opinions (SCF, 2002, 2003a, 2003b and 2003c; NDA, 2003), the SCF and the Panel came to the conclusion that the addition of phytosterols to foods was safe, provided that the enriched food products are not consumed in amounts resulting in total phytosterol intakes exceeding 3 g/day. In addition, since a number of foods appeared to be candidates to be enriched with phytosterols, it was recommended to consider additional management measures to avoid excessive intakes (i.e. more than 3 g of additional phytosterols per day).

CONCLUSION

In accordance with the previous Opinions of the SCF and the Panel, the Panel concludes that rice drinks with added phytosterols can be accepted provided that food products with added

phytosterols are not consumed in amounts resulting in total phytosterol intakes exceeding 3 g/day.

The Panel has no reason to believe that the introduction of rice drinks with added phytosterols will increase concerns with respect to over-consumption of phytosterols. However, quantitative data to substantiate this view is not available at present. Therefore, the Panel reiterates its previous recommendation and those of the SCF that appropriate risk management measures should be applied to minimise the likelihood of a daily intake exceeding 3 g of phytosterols/phytostanols, in particular from the cumulative intakes of different types of products.

The Panel considers that quantitative intake data of phytosterols added to foods in the EU are needed for an adequate assessment and conclusion with respect to risk of over-consumption.

DOCUMENTATION PROVIDED TO EFSA

Application dossier to place plant sterol enriched Diminicol[®] rice drink on the novel food market submitted by Teriaka Ltd to the European Commission, dated 27 September 2004.

REFERENCES

NDA (Scientific Panel on Dietetic Products, Nutrition and Allergies) (2003). Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to a novel food application from Forbes Medi-Tech for approval of plant sterol-containing milk-based beverages. The EFSA Journal 15, 1-12. http://www.efsa.eu.int/science/nda/nda_opinions/216_en.html

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