Statement of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to a novel food application on fruit juices and nectars with added phytosterols (Request Nº EFSA-Q-2006-057)

(expressed on 15 February 2007 at its 15th plenary meeting corresponding to item 7.1 of the agenda)

BACKGROUND

In October 2004, Coca-Cola Services S.A. (Belgium) submitted an application under Article 4 of the Novel Foods Regulation (EC) Nº 258/97 to the UK Competent Authority for approval of placing on the market juices, including tomato juice, and nectars with added phytosterols.

In the “General view of the Scientific Committee on Food (SCF) 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” it was expressed that it was prudent to avoid plant sterol intakes exceeding a range of 1-3 g/day (SCF, 2002a). 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.

In subsequent opinions concerning foods with added phytosterols, the SCF and the European Food Safety Authority (EFSA) came to the conclusion that the addition of phytosterols was safe, provided that management measures were undertaken to avoid excessive intake of phytosterols.

For these reasons, the Commission Regulation (EC) Nº 608/2004 concerning the labelling of foods and food ingredients with added phytosterols and Commission Decisions on authorizing 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) also accepted that phytosterols should not be added to a wide range of foods. So far, the addition of phytosterols has been authorized for 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) certain rye breads.
On 12 April 2005, the UK Competent Authority forwarded its initial assessment report of the product concerned (i.e. fruit juices and nectars with added phytosterols) to the European Commission. In the report the UK Advisory Committee on Novel Foods and Processes (ACNFP) concluded that juices or nectars with added phytosterols may be regarded as safe as other food products with added phytosterols.

Following notification of the UK 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. There were also concerns over the expansion of phytosterols enrichment to the category of fruit juices and nectars with the theoretical risk of over-consumption by non-target groups, specifically for children.

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) Nº 178/2002, the European Commission requests the EFSA to issue an opinion on an application by Coca-Cola concerning drinks consisting of fruit juices or nectars with added phytosterols.

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 “fruit juices” and “fruit nectars” may lead to an intake of phytosterols exceeding 3 g of added phytosterols per day.

**COMMENTS**

The recommended daily intake proposed by the applicant would be as follows: a) two servings (2 x 250 mL) each containing 1 g phytosterols per day, morning and evening, for consumers using the NF as their sole source of additional phytosterols or b) one serving (250 mL) per day, if they are obtaining 1 or 2 g phytosterols from other sources. The applicant provided the information that the mean population consumption of fruit juice and nectars for adults (including consumers and non-consumers) in the UK is 50 g/day (97.5th percentile 150 g/day). It is pointed out that intakes are similar in other EU countries with the exception of Germany, where it is significantly higher (mean of 111 g/day). In the UK consumption levels among consumers of fruit juice are 100 g/day (mean) and 300 g/day (97.5th percentile), which would be equivalent to an intake of 0.4 and 1.2 g/day of phytosterols if these consumers replaced existing juices with the phytosterols-containing product.

The Panel also considered and took note of published data available on the purchasing behaviour of consumers of yellow fat spreads containing phytosterols that suggested the product reached the intended target group and that negligible amounts were consumed by children (Lea and Hepburn, 2006; SCF, 2002b; Simojoki et al., 2005).

However quantitative data for the intake of added phytosterols from a range of food products were not available.

CONCLUSION

In accordance with the previous Opinions of the SCF and the Panel (SCF, 2002a, 2003a, 2003b and 2003c; NDA, 2003 and 2006), the Panel concludes that fruit juices or nectars 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.

In line with its previous statement (NDA, 2006), the Panel has no basis to conclude whether the addition of phytosterols to the proposed “fruit juices” and “fruit nectars” will lead to an intake of phytosterols exceeding 3 g per day, as there are no quantitative data available at present.

Introducing fruit juice and nectar with added phytosterols would mean adding a new range of products to the market. In this context, the Panel reiterates its previous recommendation and those of the SCF that appropriate risk management measures should be applied to minimize 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 for the approval of juices and nectars with added phytosterols, submitted by Coca-Cola Services S.A. (Belgium) to the European Commission, dated 25 October 2004.

REFERENCES


SCF (Scientific Committee on Food) (2002a). General view of the Scientific Committee on Food on the long-term effect of the intake of elevated levels of phytosterols from multiple


PANEL MEMBERS


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