

Mr Andreas Klepsch
European Commission
By email

12th April 2005

Reference: NFU 539

Initial Opinion: Drinks consisting of fruit juice or nectars with added phytosterols

Dear Mr Klepsch,

On the 23rd October 2004, the UK Competent Authority accepted an application from Coca-cola for approval of drinks containing fruit juices or nectars with added phytosterols as novel foods, in accordance with Article 4 of regulation (EC) 258/97. The Advisory Committee on Novel Foods and Processes (ACNFP) reviewed this application and their opinion is attached. I apologise for the delay in submitting this opinion as the ACNFP's evaluation was extended while we obtained additional information from the applicant.

In view of the ACNFP's opinion, the UK Competent Authority considers that drinks containing fruit juices or nectars with added phytosterols meet the criteria for acceptance of a novel food defined in Article 3(1) of regulation 258/97.

If authorised, all products covered by this opinion must comply with the labelling requirements of (EC) 608/2004. This regulation will ensure that all foods or food ingredients with added plant sterols are labelled consistently and aimed exclusively at consumers who wish to lower their blood cholesterol level.

The labelling also discourages the consumption of plant sterols by pregnant and breast-feeding women, and children under the age of five years, and recommends that plant sterol fortified foods should be consumed as part of a balanced and varied diet

I am copying this letter and the ACNFP's opinion to the applicant.

Yours sincerely,

Dr Chris Jones
For the UK Competent Authority

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

**APPLICATION FOR THE APPROVAL OF DRINKS CONSISTING OF FRUIT
JUICES OR NECTARS WITH ADDED PHYTOSTEROLS**

OPINION

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

OPINION ON AN APPLICATION UNDER THE NOVEL FOODS REGULATION FOR DRINKS CONSISTING OF FRUIT JUICES OR NECTARS WITH ADDED PHYTOSTEROLS

Applicant **Coca Cola Services S.A.**

Responsible Person **Dr Michael Knowles**

EC Classification 2.1

Introduction

1. An application has been submitted by Coca-Cola Services s.a. for the authorisation of fruit juices (including tomato juice) and fruit nectars with added phytosterols as novel foods (NF).
2. This is the first full novel food application made for phytosterol fortified foods since the entry into force of the labelling regulation, (EC) 608/2004. Regulation (EC) 608/2004 sets out measures to reduce the likelihood of the over-consumption of plant sterols. The regulation also requires that at risk groups, who should avoid the consumption of these ingredients be clearly identified by means of clear labelling.
3. This application differs from previous applications for foodstuffs with added phytosterols by virtue of the intended food types. Previous applications have involved foods that contain significant amounts of fat, which facilitates the incorporation of phytosterols. In this case the applicant uses phytosterols in the form of micro-sized particles that can be more readily incorporated into fruit juice and fruit nectars, which are largely fat-free.

I. Specification of the novel food

Information on this aspect is provided on pp 2-4of the application dossier

4. The proposed NF will consist of fruit juices or fruit nectars¹ with added phytosterols at a maximum level of 0.4%. The proposed NF will contain no more than three portions and a 250ml portion of NF will contain up to 1g of phytosterol.
5. There are limits on the designation 'fruit juice' when other ingredients are added. Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and similar products intended for human consumption does not allow products consisting of fruit juice with added phytosterols to be described as a "juice". The general specification for the named fruit will also comply with the recommendation made by the Association of the Industry of Juices and Nectars from Fruit and Vegetables of the EU (AIJN).
6. The phytosterol ingredient is supplied by Cargill Inc, who have recently gained a positive opinion on the equivalence of their ingredient compared with that produced by Pharmaconsult. This opinion, issued in August 2004 by the Finnish Competent Authority (CA), permits the use of Cargill's phytosterol ingredient in a number of specified foodstuffs, namely yellow fat spreads, spicy sauces, milk and fermented milk drinks. The intention to market this ingredient in a range of products (which did not include fruit juice) was notified to the Commission in November 2004.
7. The applicant has provided analytical results to show that the manufacturing method results in a concentration of phytosterols in the final product that consistently meets the specifications.
8. The applicant has also evaluated the stability of the phytosterol ingredient in orange juice using one batch containing 1.12g of total phytosterols. These data showed that the phytosterol content in orange juice is stable and unaffected by the manufacturing process or a 9-week storage period.

Discussion *Members were satisfied with the specification of the novel food.*

II. Effect of the production process applied to the novel food

Information on this aspect is provided on pp 5 – 6 of the application dossier

Production of juices and nectars

9. The juices and nectars (without phytosterols) are currently produced by the applicant in accordance with current EU processing and hygiene legislation and comply with established HACCP procedures. The same processes will apply to products with added phytosterols.

Production of phytosterol ingredient

10. The phytosterol ingredient is derived from tall oil soap, a by-product of wood processing, which is subject to two-stage distillation. The production process has been evaluated by the Finnish CA and they have concluded that the ingredient is

¹ Fruit nectar is a product made by combining fruit juice with water and may have added sugar and/or honey and/or sweeteners. Nectars are not widely available in the UK.

equivalent to existing phytosterol ingredients that have been assessed for safety and authorised under the novel foods regulation (see above).

Production of the NF

11. The applicant will add the phytosterols to concentrated juice or nectar in the form of micro size particles with an average size of 0.01mm, which will be verified by particle size analysis. The mixture will be processed to completely disperse the phytosterols. This mixture will then be blended with water and added vitamins.
12. The final product, or 'juice-based-drink', will be packed in a uniquely shaped container providing 3 servings of 250-330ml. The label will indicate the name of the NF as "orange juice drink with added plant sterols" and the list of ingredients will include "orange juice from concentrate (99.6%); plant sterols (0.4%)".

***Discussion** Members were satisfied with the additional assurance from the applicant that the 'micro-sized' phytosterol particles to be used in the final product are of a size that does not give rise to any safety concerns. Members were also reassured by the applicants' intention to market the product in a uniquely shaped package that would reduce the risk of accidental purchase due to confusion with existing juices and nectars, and consequent consumption of the ingredient by 'at-risk' groups.*

III. History of the source organism

Information on this aspect is provided on p6 of the application dossier

13. The phytosterol ingredient used by the applicant is derived from tall oil obtained from wood of pine trees, as supplied by Cargill Ltd. Following the positive opinion on equivalence obtained from the Finnish Competent Authority this ingredient has been notified as a novel food ingredient and can be sold in a limited range of foods throughout the EU (see above). Similar phytosterols extracted from tall oil have previously been authorised as novel ingredients.

***Discussion** Members had no concerns over the source of the novel ingredient, which had previously been authorised under the novel food regulation.*

IX. Anticipated intake/ extent of use

Information on this aspect is provided on pp 7-14 of the application dossier

14. The mean population consumption of fruit juice and nectars for adults (including consumers and non-consumers) in the UK is 50g/day (97.5thtile 150g/day). Intakes are similar in other EU countries with the exception of Germany, where it is significantly higher (mean of 111g/day; Dossier p11). In the UK consumption levels among actual 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 1.2g/day of phytosterols if these consumers replaced existing juices with the phytosterol-containing product.

15. These products are intended to be consumed only by adult individuals who wish to lower their blood cholesterol level and will be labelled to comply with regulation (EC) 608/2004 which sets a maximum phytosterol intake of 3g/day (Dossier p 8-9). Coca-Cola will recommend consumers to drink the NF with meals as follows:
- (a) 2 servings² (2x 250 ml) per day, morning and evening, if they are using the NF as their sole source of phytosterol or
 - (b) 1 serving (250 ml) per day, if they are already obtaining 1 or 2 servings of phytosterol from other sources.
16. The applicant states that the NF may be more attractive to consumers than yellow fat spreads or dairy products with added phytosterols, especially for consumers who might be lactose-intolerant, and it provides a source of phytosterols that is lower in fat than the existing products (Dossier p 12-13).
17. The applicant is of the view that intake of phytosterols resulting from consumption of the NF, combined with other foods with added phytosterols, will not exceed the recommended limit of 3g/day.
18. As previously noted, the ingredient to be used by the applicant has already been authorised on the basis of an opinion on equivalence, in accordance with articles 3(4) and 5 of the novel foods regulation. If authorised, all products described in the current application will be labelled as required by (EC) 608/2004, including advice on the maximum recommended phytosterol intake and on maintaining adequate carotenoid intake.

Discussion *Members accepted that the measures described by the applicant would help to ensure that regular consumption of this product will be confined to the target group and that consumers will not exceed the levels recommended by the Scientific Committee on Food in 2003, provided that consumers read and respect the labelling advice. Although pricing is ultimately a commercial decision by the manufacturers and retailers, it is expected that the phytosterol-containing products will be significantly more expensive than existing juices and nectars (as is currently the case for spreads and other products with added phytosterols) which would also tend to limit consumption by non-target groups.*

X. Information on Previous Exposure

Information on this aspect is provided on pp 14-15 of the application dossier

19. Yellow fat spreads with added phytostanol esters have been consumed in Finland, since 1996 and in the period 1996-2004, over 50 other products have been placed on the market in the EU. Such products are mainly, but not exclusively, dairy based.
20. Following the submission of applications for approval of foods with added plant sterols under the novel foods regulation, the SCF also produced a report in

² Consuming 250 ml of NF containing 0.4% of added phytosterols is equivalent to consuming 1g of phytosterols.

March 2003 reviewing the intakes of phytosterols and phytostanols and specifying specifies the compositional profile of plant sterol ingredients.

Discussion *Members agreed that the proposed sterol mixture had a profile that is in compliance with that specified by the SCF and there are now a relatively large number of products on the market containing equivalent phytosterol mixtures. The Committee agreed that there is no evidence of any concerns related directly, or indirectly to their consumption provided this does not exceed the levels recommended by the SCF.*

XI. Nutritional Information

Information on this aspect is provided on pp 16-19 of the application dossier

21. The applicant states that the proposed juice drinks and nectars will only contain a small proportion of added phytosterols (up to 0.4%) and the nutritional content of the drink will not differ significantly from conventional juices and nectars. It is also anticipated that consumers could potentially substitute normal juice and nectars with the NF, in which case there should be no impact on overall nutrient intake.
22. The applicant has supplied data to show that consumption of added phytosterols in orange juice decreases total cholesterol by 7.2% and lowers LDL cholesterol by 12.4% when adults drink 240ml of orange juice, containing 1.15g of phytosterols, with their normal meal at breakfast and dinner.
23. Studies relating to the cholesterol lowering efficacy of free, non-esterified phytosterols in low and fat-free foods has been extensively reviewed by Cargill Inc. (Dossier p 18-19). This review concludes that free phytosterols, including fine particle phytosterols are equally effective as phytosterol esters in lowering blood cholesterol. In response to questions from the Committee, the applicant also provided details of additional studies that demonstrate that the size of particles described in the application does not affect the biological properties of the phytosterols.

Discussion *Members agreed that the proposed addition of phytosterols would have no significant impact on the nutritional quality of the fruit juices and nectars, and therefore caused no nutritional concerns. The Committee agreed that the use of fine particle plant sterols is equally effective as free and esterified plant sterols in reducing LDL-cholesterol. Members also noted that it is generally recognised that consumption of plant sterols can interfere with the absorption of fat soluble vitamins and that this applies equally to the phytosterol preparation described in this application for use in juices and nectars. Members noted that it was therefore essential that, as is the case for all existing foods containing added plant sterols, consumption of the NF does not cause consumers to exceed the recommended maximum intake of 3g per day of sterols, and that the NF is not regularly consumed by "at risk" groups such as children and pregnant or lactating women.*

XII. Microbiological Information

Information on this aspect is provided on p 19 of the application dossier

24. The applicant states that micro-organisms or their metabolites are not present in the ingredient or would not be present in the final products following the addition of phytosterol novel ingredient. This is supported by the information produced by Cargill in their substantial equivalence dossier.
25. The applicant has stated that the production of juices and nectars with added phytosterols is adequately controlled throughout in order to ensure its microbiological safety.

Discussion *Members agreed that the addition of the phytosterol mixture would not increase the risk of microbial contamination.*

XIII Toxicological Aspects

Information on this aspect is provided on pp 20-21 of the application dossier

26. The safety of plant sterols in foods has been reviewed by the SCF between April 2000 and April 2003. The applicant is of the view that the proposed addition to fruit juices and nectars does not give rise to any additional concerns.

Discussion *Members agreed that the safety of plant sterols has previously been demonstrated and that the ingredient that the applicant intends to use has been shown to be equivalent to phytosterol mixtures whose safety has previously been assessed in accordance with regulation (EC) 258/97.*

Overall discussion

27. The applicant has provided a reasoned argument as to why the consumption of the novel foods will not increase the risk of over-consumption of phytosterols amongst the target population. The applicant has also indicated that they intend to market the products in distinctive packaging to minimise the risk of at-risk groups accidentally consuming the products in place of similar, non-fortified drinks.
28. This application does not address the toxicology, microbial safety and allergenicity issues related to phytosterols in detail because the ingredient they intend to use has previously been authorised under regulation (EC) 258/97. This assessment is not altered by the fact that the phytosterol ingredient is to be added to juices and nectars in a microparticulate form.
29. The products described in this application will comply with EU labelling requirements, including regulation (EC) 608/2004 (phytosterol labelling) and Directive 2001/112/EC (fruit juices and similar products). Compliance will ensure that consumers are informed of the nature of the product, which will be clearly

marked to show that it contains phytosterols and is not suitable for consumption by "at-risk" groups. The labelling will also indicate that the products should be consumed as part of a healthy diet and that individuals should not consume more than the recommended daily amounts.

30. Members noted the applicant's intention to market juices and nectars as alternative sources of phytosterols for consumers who do not wish regularly to consume existing products such as spreads and dairy-based products. However, the Committee considered that, compared with the existing products, there may be an increased risk of consumption of phytosterol-containing fruit juices by non-target groups who do not need to reduce their cholesterol level but may nevertheless be attracted to this product. In this regard the Committee considered that the applicant's intention to market the product in a distinctive packaging would reduce the possibility of confusion between products with and without added phytosterols. The Committee repeated its earlier advice that the overall intake of phytosterols should be monitored to confirm whether consumption is largely limited to the target group and that consumers do not regularly exceed the recommended maximum intake of 3g per day.

Conclusion

The Advisory Committee on Novel Foods and Processes is satisfied by the evidence provided by Coca-Cola Services SA that Drinks consisting of Fruit Juices and Nectars with added Phytosterols are acceptable, subject to the applicant's adherence to the proposed specification and the production parameters described above. The Committee notes that these products will need to comply with the same labelling rules as other phytosterol-containing foods and recommends that the juice and nectar products should be marketed in a distinctive packaging that reduces the possibility of confusion with conventional juices and nectars. To minimise potential consumption by children, the products should not be marketed in single serving packs.

12th April 2005