Bureau Nieuwe Voedingsmiddelen
Novel Foods Unit

Fytosterolen (4)

Phytosterols (4)

Tweede beoordeling van de veiligheid voor de consument, volgens de Europese verordening 258/97 betreffende nieuwe voedingsmiddelen en nieuwe voedselingrediënten

Second opinion regarding consumer safety, in accordance with European Regulation 258/97 concerning novel foods and novel food ingredients

aan/to:

de Minister van Volksgezondheid, Welzijn en Sport
the Minister of Health, Welfare and Sport

Nr. 2005-02BNV, Den Haag, 1 juli 2005
No. 2005-02BNV, The Hague, July 1, 2005

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Uw brief

Uw kenmerk
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Onderwerp
Advies Fytosterolen (4)

Mijnheer de minister,

Dit schrijven dient ter beantwoording van uw adviesaanvraag over de veiligheid van nieuwe voedingsmiddelen. Aan de orde is een tweede beoordeling volgens de Europese verordening 258/97, over het gebruik van fytosterolen in sappen en nectars. Het ingrediënt zelf is al eerder toegelaten voor gebruik in een beperkt aantal categorieën voedingsmiddelen. De aanvrager, Coca Cola Services S.A., vraagt nu om een uitbreiding van het productassortiment waaraan fytosterolen mogen worden toegevoegd. Deze aanvraag betreft vruchtensappen, waaronder tomatensappen, en nectars. Nectars zijn vruchtendranken met vastgestelde minimale sapgehaltes. Deze beoordeling is uitgevoerd door het Bureau Nieuwe Voedingsmiddelen van het College ter Beoordeling van Geneesmiddelen. Het bureau heeft hiervoor de Commissie Veiligheid Nieuwe Voedingsmiddelen geraadpleegd, hierna genoemd "de Commissie VNV".

De eerste beoordeling van de aanvraag voor markttoelating is verricht in het Verenigd Koninkrijk door de *Advisory Committee on Novel Foods and Processes* (ACNFP) van de *Food Standards Agency*. De ACNFP concludeert dat het aanvaardbaar is om het productassortiment met toegevoegde fytosterolen uit te breiden, zoals in de aanvraag wordt beschreven. Bij toelating zou echter dezelfde etiketteringsmaatregel moeten worden toegepast die geldt voor andere fytosterolen-bevattende voedingsmiddelen (Europese Verordening 608/2004). De ACNFP beveelt tevens aan dat deze sappen en nectars op de markt gebracht zouden moeten worden in een goed herkenbare verpakking. Gebruik door consumenten buiten de doelgroep zou op deze manier zoveel mogelijk kunnen worden voorkomen. De ACNFP benadrukt de noodzaak om dit te bevestigen door *post launch monitoring*.

De Nederlandse deskundigencommissie plaatst enkele kritische kanttekeningen bij de voorgestelde toelating van dranken op basis van sappen en nectars met toegevoegde fytosterolen. Zij baseert zich op de informatie in het dossier (bijlage A) en op het rapport van de eerste beoordeling door de

ACNFP (bijlage B). Ook heeft zij rekening gehouden met twee rapporten van het Europese Wetenschappelijk Comité voor de Menselijke Voeding over de inneming van fytosterolen en fytostanolen.[1, 2]

Producten met toegevoegde fytosterolen zijn gericht op consumenten die het cholesterolniveau in hun bloed willen verlagen. De aanvrager stelt dat de nieuwe producten een alternatief bieden voor melkproducten met toegevoegde fytosterolen aan gebruikers met een allergie voor melkeiwit of een intolerantie voor lactose. Tevens hebben deze producten een lager vetgehalte dan de meeste toegelaten producten met toegevoegde fytosterolen.

De commissie stemt grotendeels in met het Engelse oordeel dat consumptie van sappen en nectars met toegevoegde fytosterolen veilig is in de hoeveelheden die door de aanvrager worden voorgesteld. Maar in aanvulling op de eerste beoordeling wijst de commissie erop dat onduidelijk is hoeveel verschillende verrijkte dranken de aanvrager op de markt wil brengen.

Het Permanent Comité voor de Voeding en de Diergezondheid van de EU heeft in het verleden het standpunt ingenomen dat toevoeging van fytosterolen alleen moet worden toegestaan in een beperkt aantal categorieën voedingsmiddelen, teneinde overconsumptie te voorkomen.[3] Het uitgangspunt daarbij was dat fytosterolen niet toegevoegd zouden moeten worden aan:

a) voedingsmiddelen die aantrekkelijk zijn voor en geconsumeerd worden door kinderen;
b) dranken, waarvan de consumptie niet gemakkelijk kan worden beheerst door gedefinieerde porties;
c) voedingsmiddelen, rijk aan verzadigde vetten of suikers, waarvan het gebruik ongewenst is voor consumenten die het cholesterolgehalte in het bloed willen verlagen.

Hoewel het niet aan de Commissie VNV is om te besluiten welke producten wel en niet voor verrijking met fytosterolen in aanmerking komen, wijst zij erop dat de consumptie van het soort dranken dat in de aanvraag wordt genoemd moeilijk te beheersen kan zijn. Ook kunnen dit soort producten aantrekkelijk zijn voor consumenten buiten de doelgroep, zoals kinderen. De commissie merkt tevens op dat sommige cholesterol-bewuste consumenten de neiging kunnen hebben om de aanbevolen hoeveelheid fytosterolbevattende producten te overschrijden. De commissie heeft zich al

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[1] Fytostanolen zijn stoffen verwant aan fytosterolen: 'verzadigde fytosterolen' met een vergelijkbare cholesterol-verlagende werking.

[2] General view of the Scientific Committee on Food on the long-term effects of elevated levels of phytosterols from multi dietary sources, with particular attention to the effects on β-carotene (opinion expressed on 26 september 2002). Brussels, Scientific Committee on Food of the EU, 2002; Opinion of the Scientific Committee on Food on a report on Post Launch Monitoring of "yellow fat spreads with added phytosterol-esters" (expressed on 26 september 2002). Brussels, Scientific Committee on Food of the EU, 2002.

[3] SCFCAH section General Food Law: Summary records of 7th meeting, November 10th, 2003. (http://europa.eu.int/comm/food/committees/regulatory/scfcah/general_food/summary07_en.pdf)

herhaaldelijk kritisch opgesteld ten aanzien van voorgestelde verruimingen van het toegestane productassortiment voor fytosterolen en fytostanolen.[4] Sindsdien wordt verplichte etikettering van dit soort producten gedekt door de Europese Verordening 608/2004. Aangezien etikettering een risicomanagement-maatregel is, valt dit echter buiten het mandaat van de Commissie VNV.

De Nederlandse deskundigencommissie wil hier nogmaals het belang benadrukken van aanvullend onderzoek naar de mogelijke langetermijneffecten van blootstelling aan verhoogde niveaus aan fytosterolen (en fytostanolen). Een vergelijkbare conclusie werd ook getrokken door het Europese Wetenschappelijk Comité voor de Menselijke Voeding in 2002.[2] De commissie is niet op de hoogte van initiatieven ten aanzien van studies over chronische blootstelling. Zolang geen overtuigend bewijs beschikbaar is uit dit type onderzoek, blijft de commissie aandringen op risicomanagement maatregelen om inneming van fytosterolen boven het geadviseerde niveau tegen te gaan.

Ik onderschrijf de conclusies en aanbevelingen van de commissie.

Hoogachtend,

A.A.W. Kalis, arts
Directeur Agentschap CBG

[4] Publicaties van de Commissie Veiligheidsbeoordeling van Nieuwe Voedingsmiddelen, Den Haag, Gezondheidsraad (www.gezondheidsraad.nl of www.nieuwevoedingsmiddelen.nl): Fytostanolesters publicatienr. 1999/5VNV, Fytosterolen, publicatienr. 2001/01VNV, Fytosterolen (2) publicatienr. 2001/04VNV, Fytosterolen (3) publicatienr. 2003/01VNV.

Letter to the Dutch Minister of Health, Welfare and Sport

[courtesy translation]

This letter has been prepared in reply to your request for advice regarding the safety of novel foods and food ingredients. The subject in question is a second opinion, in accordance with European Regulation 258/97, concerning the use of phytosterols in juices and nectars. The ingredient itself has previously been authorised for use in a limited range of foods. The applicant, the company Coca-Cola Services S.A., now requests an extension of the range of products which are permitted to contain added phytosterols. This application concerns fruit juices, including tomato juices, and nectars. Nectars are juice drinks with specified minimum juice levels. This assessment has been carried out by the Novel Foods Unit of the Medicines Evaluation Board, that has sought advice from the Committee on the Safety Assessment of Novel Foods ('the Committee').

The initial assessment of the application for market introduction was carried out in the United Kingdom by the Advisory Committee on Novel Foods and Processes (ACNFP) of the Food Standards Agency. The ACNFP concludes that it is acceptable to extend the range of products containing added phytosterols as described in the application dossier. Any approval should, however, be subject to the same labelling measures as other phytosterol-containing foods (European Regulation 608/2004). The ACNFP also recommends that the juice and nectar products should be marketed in a distinctive packaging. In this way, potential consumption by consumers outside the target group should be minimised. The ACNFP stresses the need to confirm this by post launch monitoring.

The Dutch expert Committee makes some critical comments with regard to the proposed authorisation of drinks based on juices and nectars with added phytosterols. It bases its findings on the information contained in the dossier (Annex A) and on the report of the initial assessment by the ACNFP (Annex B). In addition to this, it has also considered two reports by the Scientific Committee on Food reviewing the intake of phytosterols and phytostanols[1,2].

Phytosterol-containing products are aimed at consumers who wish to lower their blood cholesterol level. The applicant states that the new products would provide consumers suffering from milk protein allergy or lactose intolerance with an alternative to dairy

[1] Phytostanols are compounds related to phytosterols: 'saturated phytosterols', having similar cholesterol-lowering effects.

[2] General view of the Scientific Committee on Food on the long-term effects of elevated levels of phytosterols from multi dietary sources, with particular attention to the effects on β-carotene (opinion expressed on 26 september 2002). Brussels, Scientific Committee on Food of the EU, 2002; Opinion of the Scientific Committee on Food on a report on Post Launch Monitoring of "yellow fat spreads with added phytosterol-esters" (expressed on 26 september 2002). Brussels, Scientific Committee on Food of the EU, 2002.

products with added phytosterols. Furthermore, these drinks are low in fat, compared to most approved products with added phytosterols.

The Committee largely agrees with the British assessment that it is safe to consume phytosterol-fortified drinks based on juices and nectars in the amounts proposed by the applicant. However, in addition to the first assessment, the Committee would like to point out that it is unclear how many different fortified drinks the applicant intends to introduce on the market.

The EU Standing Committee on the Food Chain and Animal Health has previously reached agreement that, in order to avoid over-consumption, addition of phytosterols should be allowed only to a limited range of foods.[3] This was based on the opinion that phytosterols should not be added to:

a) "food likely to be attractive and consumed by children;
b) drinks, the consumption of which cannot be easily controlled by way of defined portions;
c) food rich in saturated fats or sugars, which are not appropriate for consumers seeking to reduce their blood cholesterol."

Although it is not its task to decide which products are suitable for fortification with phytosterols, the Dutch expert committee points out that it may be difficult to control consumption of the type of drinks proposed in this application, and that these products may also appeal to individuals outside the target group, for instance children. Furthermore, the Committee notes that some cholesterol-conscious consumers may tend to exceed the recommended amount of phytosterol-fortified products. Repeatedly, the Committee has criticised proposed extension of the product range for phytosterols and phytostanols[4]. Since then, the mandatory labelling of such products is covered by European Regulation 608/2004. However, this is a matter of risk management and therefore beyond the remit of the Committee.

The Dutch expert Committee would like to stress here again the importance of carrying out additional research to evaluate the possible effects of long-term exposure to elevated levels of phytosterols (and phytostanols). This has also been concluded by the European Scientific Committee on Food in 2002.[6] The Committee is not aware of any initiative with respect to chronic studies. In the absence of convincing evidence from this type of research, the Committee continues to stress the importance of risk management measures to prevent intake of phytosterols beyond the advised level.

I endorse the conclusions and recommendations of the Committee.
(signed) A.A.W Kalis, Director MEB Agency

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[3] SCFCAH section General Food Law: Summary records of 7th meeting, November 10th, 2003.

[4] Publications by the Committee on the Safety Assesment of Novel Foods, The Hague, Health Council of the Netherlands (www.healthcouncil.nl or www.novel-foods.nl): Fytostanolesters (in Dutch), publicatienr. 1999/5VNV, Phytosterols, publication no. 2001/01VNV, Phytosterols (2), publication no. 2001/04VNV, Phytosterols (3), publication no. 2003/01VNV.

The Committee / De commissie

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APPLICATION FOR THE APPROVAL OF JUICES AND NECTARS WITH ADDED PHYTOSTEROLS

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27th January 1997 concerning novel foods and novel food ingredients

Application of: Coca-Cola Services s.a.
Dr. Michael Knowles
Chaussée de Mons 1424
1070 Brussels, Belgium

25 October, 2004

APPLICATION FOR THE APPROVAL OF JUICES AND NECTARS WITH ADDED PHYTOSTEROLS

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27th January 1997 concerning novel foods and novel food ingredients

SUMMARY

Coca-Cola Services s.a. (Coca-Cola) seeks European Union (EU) Novel Food approval for juices, including tomato juice, and nectars (juice drinks with specified minimum juice levels) with added tall oil phytosterols. Juices and nectars are typical components of healthy diets and would provide convenient means of consuming additional phytosterols for consumers desiring to do so. Juices and nectars would provide individuals with milk protein allergies or who are lactose intolerant an important alternative to dairy products as a source of phytosterols. They also provide a choice that is lower in fat than other approved foods. The safety of tall oil phytosterols has previously been evaluated and approved by EU authorities. Because of the limited consumption of juices and nectars and established labelling requirements to guide consumer choice the addition of phytosterols to juices and nectars is unlikely to increase individual consumption of phytosterols above the accepted limit of 3 grams per day. Such products will provide a valuable addition to the range of foods available to help those consumers control cholesterol levels through dietary means.

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 nectars[1] 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 (97.5th%tile 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 servings[2] (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 that 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