

## ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

## NONI JUICE AND PHYTOSTEROLS: NOTIFICATIONS UNDER ARTICLE 5 OF THE NOVEL FOODS REGULATION (EC) 258/97

**Issue**

This paper provides members with information on a series of notifications that have been recently received by the European Commission for noni juice and phytosterols to be marketed in the EU.

**Background**

1. The Novel Foods Regulation (EC) 258/97 includes a provision for applicant companies to submit a notification to the European Commission for a novel food or food ingredient that is "substantially equivalent" to a product that is already on the market. According to Article 3(4) of the regulation, this simplified procedure applies to "foods or food ingredients substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein"
2. During August-December 2004, the Commission distributed a total of nine notifications from companies for the marketing of noni juice and phytosterol ingredients that are considered to meet the criteria set out above:

	<b>Date of notification</b>	<b>Product / notifier</b>	<b>Opinion prepared by</b>	<b>Notes</b>
<b>A</b>	16 August 2004	"SomaNoni"/TICO CATALANA S.A.	Spanish	Opinion attached (Annex 1)
<b>B</b>	13 October 2004	Noni juice/COSMOS-AN Europe	Netherlands	Opinion attached (Annex 2)
<b>C</b>	14 October 2004	Noni juice/ Noni Hawaii BV	Netherlands	Opinion attached (Annex 3)
<b>D</b>	2 November 2004	Noni Juice/ Nature's products	UK	Technical notification
<b>E</b>	30 August 2004	Yellow fat spreads / Dairygold	Ireland	Opinion attached (Annex 4)
<b>F</b>	5 October 2004	Milk and yoghurt type products / Lactogal	Directly to the Commission	Technical notification
<b>G</b>	6 October 2004	Fermented milk products/ Teriaka	Finland	Opinion attached (Annex 5)
<b>H</b>	24 October 2004	Yellow fat spreads, salad dressings, mayonnaise, spicy sauces, milk type drinks with fruit and/or cereals, milk-based fruit drinks and fermented milk type products /Cargill	Finland	Opinion attached (Annex 6)
<b>I</b>	23 November 2004	Fermented milk type products / Danone	Finland	Technical notification

3. Three of these (D, F and I) are technical notifications where the “novel” product is accepted on the basis that the applicant company intends to market *exactly* the same product that has already received authorisation under the novel food regulation. These are included in the table for information for information. The remaining notifications are discussed below. As these raise no new issues compared with previous novel food applications reviewed by the Committee, they are presented for information.

#### **(A) Noni juice - TICO CATALANA S.A**

4. The applicant notified the Commission on 16 August 2004 of its intention to market “SomaNoni” in accordance with Article 5 of Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the Spanish Competent Authority that this product is substantially equivalent to that, marketed by Morinda Inc, which authorised as a novel food in June 2003; a copy of the opinion is attached at Annex 1.
5. **Product specification:** The applicant intends to market “SomaNoni” a noni juice consisting of 92% of *Morinda citrifolia* and 8% pure honey. “SomaNoni” is registered with the Coast Rica Ministry of Health under the number 2101-A-51836.
6. **Product process:** The applicant has demonstrated that the fruit used to produce “SomaNoni” is the same as the approved product and that the manufacturing process used by the applicant is similar to the process used in the production of other fruit juices and nectars. The commercial product “SomaNoni” is made by mixing the juice and honey and then pasteurising the mixture to 80°C.
7. **Microbiological information:** The applicant provided documentation to show that their noni juice will be microbiologically monitored according to the British Pharmacopoeia and United States Pharmacopoeia.
8. The Spanish CA have drawn attention to the fact that the applicant must ensure that all the compounds present in their product should be within the limits laid down in the corresponding legislation.
9. **Nutritional Aspect:** The Spanish CA are aware that equivalence cannot be established as it contains 8% absolute honey, and the composition of honey has not been given. The applicant however, provided details regarding the nutritional characteristics of “SomaNoni”, this showed that the compositional data did not differ significantly from the approved product. The Spanish CA also note that the juice is comparable with other fruit juices.

10. **Anticipated intake:** The SCF's opinion of 4 December 2002 refers to a daily intake of 30ml for noni juice, containing 89% noni juice and 11% fruit juice concentrates. The applicant has indicated that the daily intake of "SomaNoni" will also correspond with the SCF opinion.
11. **Product labelling:** The product labels will include the daily intake recommendation, of 33ml/day taken half an hour before eating. However, the Spanish CA have stated that if the applicant wishes to use the words food supplement on the label, a notification would have to be made in accordance with Directive 2002/46/EC.
12. **Toxicological test:** The Spanish CA is of the view that the safety of "SomaNoni" can be supported by the toxicological information in the SCF opinion (SCF/CS/NF/DOS/18 Add 2 FINAL).
13. **Conclusion:** The Spanish CA is of the opinion that "SomaNoni" to be marketed by Tico is substantially equivalent to the product already on the market.

**(B) - Noni juice/COSMOS-AN Europe**

14. The applicant notified the Commission on 13 October 2004 of its intention to market "Tahiti Trader Noni Saft" in accordance with Article 5 of Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the Netherlands Competent Authority that this product is substantially equivalent to that, marketed by Morinda Inc, which authorised as a novel food in June 2003, a copy of the opinion is attached in Annex 2.
15. **Identity of the source:** The applicant has stated that the noni fruit is grown in French Polynesia from the species *Morinda citrifolia* L which is the same area as the noni harvested by Morinda Inc. The Netherlands CA were satisfied that the information provided by the applicant demonstrates that the fruit used in its product is from the *Morinda citrifolia* L.
16. **Product specification:** "Tahiti Trader Noni Saft" is a pasteurised fruit drink which contains 89% noni juice and the remainder is a mixture of blueberries, grapes, pears and raspberries. The applicant has provided details on the pure, unfermented noni juice ingredient.
17. **Product process:** The noni fruits are harvested by the Siaoisi noni company of San Diego. The ripen fruits are selected and shipped in cold storage containers to Flavor specialities Inc. Noni extract is produced by placing the fruit in a percolator. The extract is then filtered and pasteurised. This noni juice puree is then cooled in liquid containers and transported to Triple H Food Company where it is mixed with other fruit juices and pasteurised again. The end product is bottled and sold to Tahiti Trader Company. The sole distributor of "Tahiti Trader Noni Saft" is the applicant company, Cosmos-An Europe.
18. The Netherlands CA are aware that noni extract does not involve the use of a concentrated intermediate product, which differs from the manufacture

of Morinda Inc's product. However they are of the opinion that this difference is not relevant to the assessment as it does not lead to any compositional difference.

19. The applicant has HACCP quality assurance system and GMP throughout the processing process and the Netherlands CA are satisfied that the applicant has a controlled production process which limits possible microbiological contamination risk.
20. **Level of undesirable substances:** The applicant originally tested four different batches of the final product for a range of undesirables and heavy metals, none of these were detected.
21. The Netherlands CA were aware that the noni tree might contain compounds with carcinogenic properties such as anthraquinones and were unsure how the applicant company would ensure that these compounds were in the final product. Whilst the applicant assured the CA that no twigs, leaves or bark present in the final product the Netherlands requested further analyses. The applicant then provided analyses, which demonstrated that no anthraquinones were detected.
22. The Netherlands CA considered that they were unable to conclude that the absence of lucidin and rubiadin had been demonstrated. However they considered it unlikely that fruit juice drinks based on noni juice contain any lucidin or rubiadin and emphasised that there is a need for the competent authorities in the EU to reach an agreement concerning detection limits.
23. **Anticipated intake:** The SCF's opinion of 4 December 2002 refers to a daily intake of 30ml for noni juice, containing 89% noni juice and 11% fruit juice concentrates. The applicant has indicated that the daily intake of "Tahiti Trader Noni Saft" will also correspond with the SCF opinion.
24. **Nutritional value and metabolism:** The Netherlands CA have concluded that the applicant has adequately demonstrated that the nutritional value and metabolism of "Tahiti Trader Noni Saft" is not fundamentally different from the approved product.
25. **Conclusion:** The Netherlands CA is of the opinion that "Tahiti Trader Noni Saft" to be marketed by Cosmos-AN Europe is substantially equivalent to the product already on the market.

### **(C) Noni Juice – Noni Hawaii BV**

26. The applicant notified the Commission on 14 October 2004 of its intention to market Noni Hawaii juice in accordance with Article 5 of Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the Netherlands Competent Authority, a copy of the opinion is attached in Annex 3.
27. **Identity of source:** The applicant has stated that the trees from which the noni fruit is harvested belong to *Morinda citrifolia* L, the same plant species

as the noni juice produced by Morinda. The applicant provided an expert opinion from the University of Hawaii to support this. The Netherlands CA were satisfied that the source of noni fruit is the same as the approved product.

28. **Product specification:** The noni juice produced by the applicant is pure and unfermented noni juice.
29. **Production:** Noni Hawaii BV consists of a Dutch company, which is based, in Groningen and the Hawaiian company Herbal Blessings.
30. Noni fruit is harvested and pressed to produce a juice, which has been separated from the pulp and seeds, by Hawaiian Herbal blessings. The juice is then pasteurised and shipped in refrigerated liquid containers to a company in the Netherlands where it is pasteurised again before bottling.
31. The production of Noni Hawaii noni juice does not involve a concentrated intermediate product like Morinda's product, however, the Netherlands CA are of the opinion that the difference in preparation is not relevant as it does not lead to any changes in composition of the final product.
32. The applicant has provided a certificate from the company's HACCP quality system. However, the Netherlands CA were aware that no information had been provided about good agriculture or good manufacturing practises and has assumed that hygiene regulations are observed throughout the process to ensure that the product is free from contamination. The quality assurance procedures involve and involve testing of various characteristics in samples from each batch of noni. The Netherlands CA have concluded that the production of noni by Noni Hawaii BV meet the general food safety requirements.
33. **Level of undesirable substances:** The applicant has tested a range of Noni Hawaii noni juice for undesirables. No pesticides were used in the cultivation of the fruit and none were found in the analyses of the final product. Also analyses of six batches showed no contamination of heavy metals. The Netherlands CA were satisfied with this information.
34. As part of the production process the applicant has stated that the twigs, leaves and bark are manually removed from the harvested fruit which should remove the possibility of contamination from anthraquinones. The Netherlands accepted that this would help but was of the view that there was a lack of adequate data to demonstrate the absence of undesirable substances such as anthraquinones, (such as lucidin and rubiadin). The Netherlands CA were therefore unable to conclude the absence of lucidin and rubiadin but considered that it is unlikely that Noni Hawaii noni juice contains any lucidin and rubiadin.
35. **Intended use:** The SCF's opinion of 4 December 2002 refers to a daily intake of 30ml for noni juice, containing 89% noni juice and 11% fruit juice concentrates. The applicant has indicated that the daily intake of Noni Hawaii juice will also correspond with the SCF opinion.

36. **Nutritional value and metabolism:** The Netherlands CA are of the opinion that the nutritional value and metabolism of Noni Hawaii noni juice will not differ from the approved product by Morinda. This opinion is based on the previous information supplied by the applicant
37. **Conclusion:** The Netherland CA have concluded that Noni Hawaii noni juice is substantially equivalent to the approved product already on the market.

#### **(E) Yellow fat spreads with added phytosterols/phytostanols – Dairygold**

38. The company notified the Commission on 5 October 2004 of its intention to market yellow fats spreads with added phytosterols/phytostanols in accordance with article 5 of the Novel Food Regulation (EC) 258/97. The notification was supported by an opinion on substantial equivalence from the Irish Competent Authority (CA). A copy of the Irish CA is attached at Annex 5.
39. The applicant's yellow fat spread with added phytosterol/phytostanols was compared with that produced by Archers Daniel's Midland (ADM) and authorised under Commission Decision 2004/333/EC<sup>1</sup>. The definition for yellow fat spreads is defined by Council Regulation (EC) 2991/94 and exclude cooking and frying fats and spreads based on butter or other animal fats.
40. The Irish CA were satisfied that, based on the information provided by the applicant company, the yellow fat spreads with added phytosterols/phytostanols are substantially equivalent to the approved product by ADM. The Irish CA drew attention to the labelling requirements set out under Commission Regulation (EC) 608/2004.

#### **(G) Fermented milk type products – Teriaka**

41. The Company notified the Commission on 6 October 2004 of its intention to market fermented milk type products with added phytosterols/phytostanols (Diminciol®) in accordance with article 5 of the Novel Food Regulation (EC) 258/97. The notification was supported by an opinion on substantial equivalence from the Finnish Competent Authority (CA). A copy of the Finnish opinion is attached in Annex 5.
42. The applicant company has previously received approval under Commission Decision 2004/336/EC<sup>2</sup>, this however was for a limited range of products. The Finnish CA have stated that the plant sterol ingredient Diminicol® is the same ingredient as that which was previously assessed and approved to be marketed under Commission Decision 2004/336/EC<sup>2</sup>.
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The Company previously notified the Commission on 13 July 2004 of its intention to market milk type products and soya drinks with added phytosterols/phytosterols (Diminicol®).

43. The Company provided the Finnish CA with certificate of analyses showing the plant sterol profile of the Diminicol® ingredient. The Diminicol® milk drink is described as a semi-skimmed or skimmed milk type drink, where the milk has been partially or fully replaced by vegetable fat.
44. Overall the Finnish Competent Authority was of the opinion that the fermented milk products with added Diminicol® ingredient are substantially equivalent to the approved plant sterol products already on the market and corresponds with Commission Decision 2004/333/EC – 2004/336/EC<sup>1-4</sup>.
45. The Plant sterol ingredient will be added in single portions so that the total daily intake of sterols will not exceed 3g. The Finnish Ca drew attention to the labelling requirements set out Commission Regulation (EC) 608/2004 concerning phytosterol-labelling regulation.

**(H) Yellow fat spreads, salad dressings, mayonnaise, spicy sauces, milk type drinks with fruit and/or cereals, milk-based fruit drinks and fermented milk type products – Cargill**

46. The Company notified the Commission on 24 October 2004 of its intention to market yellow fat spreads, salad dressings, mayonnaise, spicy sauces, milk type drinks with fruit and/or cereals, milk-based fruit drinks and fermented milk type products with added phytosterols/phytosterols in accordance with article 5 of the Novel Food Regulation (EC) 258/97. The notification was supported by an opinion on substantial equivalence from the Finnish Competent Authority (CA). A copy of the Finnish opinion is attached in Annex 8. The Committee has previously been informed of this opinion in relation to a new application for the use of phytosterols in fruit juices and nectars (ACNFP 69/X and ACNFP/70/3).
47. **Composition:** The applicants phytosterol/phytosterol ingredient was compared in particular with the plant sterol ingredient which was produced by Pharmaconsult Oy Ltd. (formerly Multibene) and authorised under Commission Decision 2004/334/EC.
48. The source of the phytosterol/phytosterol ingredient produced by Cargill is tall oil, which is refined, and the final product is in crystalline form. The Finnish CA was of the opinion that Cargill's phytosterol/phytosterol ingredient is substantially equivalent to the approved plant sterol products already on the market and corresponds with Commission Decision 2004/334/EC.
49. **Level of undesirable substances:** The applicant provided certificates of analyses, which showed the plant sterol ingredient to be pure and free from detectable levels of heavy metals and pesticides.

50. **Anticipated intake:** The applicant intends to use their plant sterol ingredient in the following products:

- Yellow fat spreads, excluding cooking or frying fats and spreads based on butter or other animal fat
- Salad dressings, mayonnaise and spicy sauces (single portions)
- Milk-type drinks, milk-type drinks with fruit and/or cereals, milk-based fruit drinks, fermented milk type products, soy drinks
- Cheese type products

51. The plant sterol ingredient will be added to single portions packages so that the total daily intake of sterols will not exceed 3g. The Finnish CA drew attention to the labelling requirements set out Commission Regulation (EC) 608/2004 concerning the labelling of foods with added phytosterols.

52. Overall the Finnish Competent Authority was of the opinion that the yellow fat spreads, salad dressings, mayonnaise, spicy sauces, milk type drinks with fruit and/or cereals, milk-based fruit drinks and fermented milk type products with added phytosterols/phytostanols are substantially equivalent to the approved plant sterol products already on the market.

**Secretariat  
January 2005**

**References:**

1. Commission Decision 2004/333/EC of 31 March 2004 authorising the placing on the market of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L105 14.04.2004.
2. 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 as novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L105 14.04.2004
3. Commission Decision 2004/336/EC of 31 March 2004 authorising the placing on the market of yellow fat spreads, milk based fruit drinks, yoghurt type products and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L105 14.04.2004.
4. Commission Decision 2004/334/EC: of 31 March 2004 authorising the placing on the market of yellow fat spreads, milk type products, yoghurt type products, and spicy sauces with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L105 14.04.2004.

## **Annexes attached**

**Annex 1:** Opinion on the substantial equivalence of Noni juice (juice of the fruits of *Morinda citrifolia*) to be placed on the market by Tico Catalana S.A. **(CONFIDENTIAL)**

**Annex 2:** Opinion on the substantial equivalence of Noni juice (juice of the fruits of *Morinda citrifolia*) to be placed on the market by Cosmos-AN Europe. **(CONFIDENTIAL)**

**Annex 3:** Opinion on the substantial equivalence of Noni juice (juice of the fruits of *Morinda citrifolia*) to be placed on the market by Noni Hawaii BV. **(CONFIDENTIAL)**

**Annex 4:** Opinion on the substantial equivalence of yellow fats spreads with added phytosterols/phytostanols to be placed in the market by Dairygold. **(CONFIDENTIAL)**

**Annex 5:** Opinion on the equivalence of fermented milk products with added phytosterols/phytostanols (Diminicol®) to be placed on the market by Teriaka Ltd. **(CONFIDENTIAL)**

**Annex 6:** Opinion on the equivalence of yellow fat spreads, salad dressings, mayonnaise and spicy sauces, milk-type drinks, milk-type drinks with fruit and/or cereals, milk based fruit drinks, fermented milk type products and cheese type products with added phytosterols / phytostanols to be placed on the market by Cargill. **(CONFIDENTIAL)**