

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

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, phytosterols and argan oil 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 January – July 2005, the Commission received a total of sixteen notifications from companies for the marketing of 2 noni juice, 13 phytosterol ingredients and 1 oil derived from *Arginia spinosa* that are considered to meet the criteria set out above:

	Date of notification	Product / notifier	Opinion prepared by	Notes
A	28 January 2005	Noni juice/ Resort Health Products	France	Opinion attached (Confidential)
B	14 December 2004 (wrongly addressed received 2 May 2005)	Noni juice/ Trisana GmbH	Germany	Opinion attached (Confidential)
C	20 April 2005	Plant sterols and plant sterol esters for the addition to yellow fat spreads (excluding cooking and frying fats and spreads based on butter or other animal fat), salad dressings including mayonnaise and milk type products as specified by Commission Decision 2004/333/EC, spicy sauces as specified by Commission Decision 2004/334/EC and milk based fruit drinks as specified by Commission Decision 2004/336/EC/ Cognis	Finland	Opinion attached (Confidential)
D	22 April 2005	yellow fat spreads, salad dressings, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added phytosterols/ phytosterols (Redurol™)/Forbes Medi-Tech	Finland	Opinion attached (Confidential) Member states have not yet been notified – Dated 6 June, to be posted MS shortly
E	22 April 2005	yellow fat spreads, salad dressings,	Finland	Opinion attached

		milk type products, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added phytosterols/phytostanols (Phyto-S-Sterols™)/Forbes Medi-Tech		(Confidential)
F	22 April 2005	Yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added plant sterol esters/ Forbes Medi-Tech	Finland	Member states have not yet been notified – Dated 6 June, to be posted MS shortly
G	10 May 2005	Yoghurt type products with added phytosterols/phytostanols (Reducol™)/ Juustoportti Oy	Finland	Technical notification
H	11 May 2005	Milk type and yoghurt type products with added phytosterols/ ELSA Estavayer	Directly to Commission	Technical notification
I	27 May 2005	Yoghurt type products and other dairy products with added phytosterols/Novandie	Directly to Commission	Technical notification
J	30 May 2005	Foods with added phytosterols: Yellow fat spreads excluding cooking or frying fats and spreads based on butter or other animal fat/ Mifa AG	Directly to Commission	Technical notification
K	17 June 2005	Milk based beverages with added phytosterols/Pingo Doce	Directly to Commission	Technical notification
L	27 June 2005	Milk beverages with added phytosterols/Robert Wiseman & Sons Ltd.	Directly to Commission	Technical notification
M	5 July 2005	Yellow fat spreads with added phytosterols/phytostanols/Kerry Foods	Ireland	Opinion attached (Confidential)
N	5 July 2005	Salad dressings and mayonnaise with added phytosterols/ Hommann Feinkost GmbH	Finland	Opinion attached (Confidential)
O	13 July 2005	Yellow fat spreads with added phytosterols/Fayrefield Foods	Directly to the Commission	Technical notification
P	23 May 2005 + 5 July 2005	Oil from <i>Argania spinosa</i> from unroasted almonds/Princess de Mogdor	France	Opinion attached (Confidential)

3. Seven of these (G, H, I, J, K, L and O) 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. 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 - Resort Health Products

4. The applicant notified the Commission on 15 January 2005 of its intention to market Hawaiian noni juice in accordance with Article 5 of Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion

from the French Competent Authority (CA) that this product is substantially equivalent to that marketed by Morinda Inc (now called Tahitian Noni Inc), which was authorised as a novel food ingredient in June 2003; a copy of the opinion is attached at Annex 1 (confidential).

5. **Composition:** The applicant intends to market Hawaiian noni juice of which the juice of *Morinda Citrifolia* L is the only ingredient.
6. **Production process:** Noni fruit from Hawaii is harvested and partially peeled. The French CA has confirmed that the noni juice does not undergo fermentation however the applicant has stated that the noni fruit is allowed to mature for 1-2 days in order to obtain a soft consistency before it is pressed and filtered. Two filtering stages are used to allow the skins and seeds to be removed before the juice is pasteurised and bottled.
7. **Microbiological information:** The applicant has demonstrated that anthraquinones (lucidin and rubiadin) are at a concentration of less than 10/kg. The French CA are of the opinion that the applicant has demonstrated that the product is microbiologically safe.
8. **Conclusion:** The French CA is of the opinion that Hawaiian noni juice to be marketed by Resort Health Products Ltd. is substantially equivalent to the product already on the market. The French CA has also highlighted that the applicant company is planning to produce offering other powders, lotions and infusions which will be derived from noni juice but these have not been assessed or approved in accordance with Regulation (EC) 258/97. No detailed information was provided in the opinion on the nutritional value, metabolism or intended use on this noni juice product..

(B) Noni juice - Trisana GmbH

9. The applicant notified the Commission on 2 May 2005 of its intention to market "Naturally noni" in accordance with Article 5 of Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the German Competent Authority (CA) that this product is substantially equivalent to that marketed by Morinda Inc (now called Tahitian Noni Inc), which was authorised as a novel food in June 2003; a copy of the opinion is attached at Annex 2 (confidential).
10. **Composition:** The applicant intends to market "Naturally noni", noni juice consisting of 87% *Morinda citrifolia* juice and pear, grape and blueberry juice made from concentrates. The German CA is satisfied that the compositional analysis provided by the applicant demonstrates that "Naturally noni" is equivalent to Morinda's Tahitian noni.
11. **Metabolism:** The applicant did not provide any data with regards to the metabolism of noni juice however, the German CA is of the opinion that based on its composition "Naturally noni" would not be physiologically different to the approved product.

12. **Intended use:** The SCF opinion of 4 December 2002 refers to a daily intake of 30 ml for noni juice containing 89% noni juice and 11% fruit juice concentrate. The applicant has indicated that this is also the recommended daily intake for their noni juice.
13. **Production process:** The noni fruit is harvested from Tahiti, Hawaii, Vanuatu and Somoa. The noni fruit is then chopped, pressed by hand to ensure that any undesirable parts are removed, coarse filtered and heated. The noni juice concentrate is filtered before it is transported in bottles where it is then mixed with other fruit juices, pasteurised and bottled.
14. **Level of undesirable substance:** The applicant has HACCP quality assurance system and GMP requirements are in place throughout their production process. The German CA is satisfied that the measures in place are in accordance with Commission Directives 89/109/EC and 2002/72/EC.
15. **Conclusion:** The German CA is of the opinion that “Naturally noni” to be produced by Trisana GmbH is substantially equivalent to the approved product already on the market. The German CA has also highlighted the need for the applicant to comply with Article 2 of Commission Decision 2003/426/EC¹ with regards to labelling.

(C) Plant sterols and plant sterol esters for the addition to yellow fat spreads (excluding cooking and frying fats and spreads based on butter or other animal fat), salad dressings, milk type products, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added plant sterol esters - Cognis

16. The applicant notified the Commission on 20 April 2005 of its intention to market yellow fat spreads (excluding cooking and frying fats and spreads based on butter or other animal fat), salad dressings including mayonnaise and milk type products. 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 3 (confidential).
17. The applicant intends to market their phytosterols and phytosterol esters as an ingredient in all foodstuffs authorised in Commission Decisions 2004/333/EC², 2004/334/EC³ and 2004/336/EC⁵.
18. Members will wish to note that the applicant company has already received an opinion on substantial equivalence for their phytosterol esters from the ACNFP in May 2004. The Finnish CA has highlighted that the phytosterol ester are essentially the same as that which was looked at by the ACNFP.
19. **Conclusion:** The Finnish CA is of the opinion that the plant sterol esters are substantially equivalent to the plant sterol esters authorised under Commission Decision 2004. The Finnish CA has noted that the applicant

is already aware of the labelling requirements for plant sterols set out under Regulation (EC) 608/2004⁸ and has drawn the applicants attention to the conditions set out in Commission Decision 2004/333/EC-2004/336/EC²⁻⁴ which should be respected.

(D) Yellow fat spreads, salad dressings, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added phytosterols/ phytostanols (Reducol™) - Forbes Medi-Tech

20. The applicant notified the Commission on 22 April 2005 of its intention to market yellow fat spreads, salad dressings, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added phytosterols/ phytostanols (Reducol™) in accordance with Article 5 of Novel Foods 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 4 (Confidential).

21. The plant sterol ingredient consists of free plant sterols and stanols, which have been obtained from tall oil, and is in fact the same ingredient which was previously assessed and subsequently authorised by Commission Decision 2004/845/EC⁶. The applicant intends to extend the existing use of this ingredient by marketing it as an ingredient for use in all the other foodstuffs authorised in Commission Decision 2000/500/EC⁷ and 2004/333/EC-2004/336/EC²⁻⁵.

22. **Conclusion:** The Finnish CA is satisfied that the Forbes plant sterol/stanols are substantially equivalent to the products already on the market (Commission Decision 2000/500/EC¹ and 2004/333/EC-2004/336/EC²⁻⁵). The Finnish CA has noted that the applicant is already aware of the labelling requirements set out under EC Regulation 608/2004⁸ but has drawn the applicant's attention to the conditions set out in Commission Decision 2000/500/EC¹ and 2004/333/EC-2004/336/EC²⁻⁵, which should be respected.

(E) Yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added phytosterols/phytostanols (Phyto-S-Sterols™) - Forbes Medi-Tech

23. The applicant notified the Commission on 22 April 2005 of its intention to market yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added phytosterols/phytostanols (Phyto-S-Sterols™) in accordance with Article 5 of Novel Foods 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 (confidential).

24. **Composition:** The plant sterol ingredients consist of free plant sterols and stanols, which have been isolated from tall oil. The applicant has indicated that the ingredient, production process and source of sterols are the same as their ingredient Reducol™. However, the manufacturing process differs slightly but results in a final product whose composition is line with Commission Decisions 2004/333/EC-2004/336/EC²⁻⁵. The company supplied data on five batches of their ingredient, which has satisfied the Finnish CA that there plant sterol ingredient is acceptable for food use.
25. The applicant intends to market their plant sterol ingredients as an ingredient in all foodstuffs authorised in Commission Decision 2004/333/EC-2004/336/EC²⁻⁵. The Finnish CA has noted that the amounts of plant sterols to be added to the list of foodstuffs are in accordance with the conditions laid out in these Commission Decisions and that the applicant has confirmed that the products will be labelled according to Regulation (EC) 608/2004⁸.
26. **Level of undesirables:** The Finnish CA is satisfied that the applicant has demonstrated the microbiological safety of their plant sterol ingredient.
27. **Conclusion:** The Finnish CA is therefore, of the view that Forbes Medi-Tech's Phyto-S-Sterols™ ingredient is substantially equivalent to the products already on the market and authorised under Commission Decisions 2004/333/EC-2004/336/EC²⁻⁵.

(F) Yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks with added plant sterol esters - Forbes Medi-Tech

28. The applicant notified the Commission on 22 April 2005 of its intention to market yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added plant sterol esters in accordance with Article 5 of Novel Foods 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 6 (confidential).
29. **Intended use:** The applicant intends to market their plant sterol esters as an ingredient in all foodstuffs authorised in Commission, Decisions 2000/500/EC⁷ and 2004/333/EC-2004/336/EC²⁻⁵.
30. **Production process:** The plant sterol ingredient is obtained from tall oil, and is produced in two stages. Firstly a two-step distillation process is used to extract sterols from tall oil. This process been evaluated by the Finnish CA and is mentioned above in section E. However, the plant

sterols are then esterified with a food grade fatty acid which is produced by Cognis and which was considered by the ACNFP in May 2004.

31. **Composition:** The applicant has analysed four batches of their ingredient. These have been shown to have the same sterol composition as Phyto-S-Sterols™. The Finnish CA is therefore satisfied that the sterol composition meets the criteria set out in the Commission Decisions 2004/333/EC-2004/336/EC²⁻⁵.
32. **Conclusion:** The Finnish CA is satisfied that these sterol esters can be considered to be substantially equivalent to the products already on the market (Commission Decision 2000/500/EC¹ and 2004/333/EC-2004/336/EC²⁻⁵). The Finnish CA has noted that the applicant is already aware of the labelling requirements set out under Regulation (EC) 608/2004 but has drawn the applicant's attention to the conditions set out in Commission Decisions 2000/500/EC⁷ and 2004/333/EC-2004/336/EC²⁻⁵ which should be respected.

(M) Yellow fat spreads with added phytosterols/phytosterols – Kerry Foods

33. The applicant notified the Commission on 5 July 2005 of its intention to market yellow fat spreads with added phytosterols/phytosterols. The notification was supported by an opinion on substantial equivalence from the Irish Competent Authority (CA). A copy of the Irish opinion is attached in Annex 7 (confidential).
34. The applicant's yellow fat spreads with added phytosterols/phytosterols was compared with the yellow fat spreads, which were authorised by the Commission Decisions 2004/333/EC², 2004/334/EC³ and 2004/336/EC⁵. Yellow fat spreads are defined by Council Regulation (EC) 2991/94 and exclude cooking and frying fats and spreads based on butter or other animal fats.
35. The Irish CA was satisfied that, based on the information provided by the applicant, the yellow fat spreads with added phytosterols/phytosterols are substantially equivalent to the products already on the market. However, the Irish CA requested that the applicant provide examples of certificates of analysis for aflatoxins. The applicant has provided this additional information, which has satisfied the Irish CA.
36. The Irish CA also drew the applicant's attention to the labelling requirements set out under Commission Regulation (EC) 608/2004⁸.

(N) Salad dressings and mayonnaise with added phytosterols - Hommann Feinkost GmbH

37. The applicant notified the Commission on 5 July 2005 of its intention to market salad dressings and mayonnaise with added

phytosterols/phytostanols. 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 (confidential).

38. **Product specification:** The applicant intends to market their plant sterol/stanol ingredient in salad dressings and mayonnaise, which have previously been authorised by Commission Decision 2004/333/EC². The Finnish CA has stated that the plant sterol ingredient to be included in these products is Diminicol[®] produced by Teriaka Ltd., which was authorised by Commission Decision 2004/336/EC⁵ to be added in dairy products.
39. **Composition:** The company provided the Finnish CA with data and certificates of analysis showing the plant sterol ingredients profile and purity which corresponds to the specification of phytosterols/phytostanols in Commission Decision 2004/333/EC² and 2004/336/EC⁵.
40. **Conclusion:** The Finnish CA was satisfied that the applicant's salad dressings and mayonnaise with added Diminicol[®] were substantially equivalent to the approved products already on the market corresponding to Commission Decisions 2004/333/EC² and 2004/336/EC⁵. The Finnish CA has noted that the applicant is already aware of the labelling requirements set out under EC Regulation 608/2004⁸.

(P) Oil from unroasted argan nuts (“almonds”) (*Argania spinosa*) - Princess de Mogdor

41. The applicant notified the Commission on 23 May 2005 and 5 July 2005 of its intention to market argan oil from roasted and unroasted argan nuts (“almonds”) in accordance with Article 5 of Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion on substantial equivalence from the French Competent Authority (CA). A copy of the French opinion is attached in Annex 9 (confidential).
42. The French CA issued an opinion in May 2002 on the equivalence of Argan (*Argania spinosa* L) oil which concluded that the oil from roasted argan nut is substantially equivalent to vegetable oils (such as peanut oil and sesame oil) which are already on the market. The French CA's original opinion is also attached in annex 9 for information.
43. **Conclusion:** The French CA was satisfied that the information provided by the applicant demonstrates that their Argan oil from unroasted argan nuts is the same as the argan oil previously evaluated. The French CA drew attention to the provisions of the regulations on edible oils and fats which should be respected.
44. The French CA has stated that regular checks should be carried out on the applicant's oil for levels of contaminants such as pesticides, mycotoxins and hydrocyanic acid. A similar condition was applied to the earlier product obtained from roasted argan nuts.

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 Resort Health products. **(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 Trisana GmbH. **(Confidential)**
- Annex 3:** Opinion on the substantial equivalence of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added plant sterol esters to be placed on the market by Cognis. **(Confidential)**
- Annex 4:** Opinion on the substantial equivalence of yellow fat spreads, salad dressings, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added phytosterols/ phytostanols (Reducol™) to be placed on the market by Forbes Medi tech. **(Confidential)**
- Annex 5:** Opinion on the substantial equivalence of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added phytosterols/phytostanols (Phyto-S-Sterols™) to be placed on the market by Forbes Medi Tech. **(Confidential)**
- Annex 6:** Opinion on the substantial equivalence of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces, milk based fruit drinks) with added plant sterol esters to be placed on the market by Forbes Medi Tech. **(Confidential)**
- Annex 7:** Opinion on the substantial equivalence of Yellow fat spreads with added phytosterols/phytostanols to be placed on the market by Kerry Foods. **(Confidential)**
- Annex 8:** Opinion on the substantial equivalence of Salad dressings and mayonnaise with added phytosterols to be placed on the market by Hommann Feinkost GmbH. **(Confidential)**
- Annex 9 :** Opinion on the substantial equivalence of Oil from *Argania spinosa* from roasted and unroasted almonds to be placed on the market by Princess de Mogdor. **(Confidential)**

References:

1. Commission Decision 2003/426/EC of 5 June 2003 authorising the placing on the market of "noni juice" (juice of the fruit of *Morinda citrifolia* L.) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. *Official Journal L 144* , 12/06/2003 P. 0012 - 0012
2. 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.

3. 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.
4. 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
5. 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.
6. Commission Decision 2004/845/EC of 12 November 2004 authorising the placing on the market of milk based beverages 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 L366 11.12.2004
7. Commission Decision 2000/500/EC of 24 July 2000 authorising the placing on the market of yellow fat spreads with added phytosterol esters
8. Commission Regulation (EC) 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterols esters, phytostanols and/or phytostanols esters of the European Parliament and of the Council. OJ L97/44 1.4.2004.