

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

PLANT STEROL ENRICHED RICE DRINK

Issue

The Committee is asked to consider an initial opinion from the Finnish Competent Authority on an application for authorisation of a plant sterol enriched rice drink as a novel food, under the Novel Foods Regulation (EC) No. 258/97.

The Committee is asked whether it agrees with this initial opinion and whether they have any further comments to make on the application. The Committee's advice will form the basis for the UK's formal response to the European Commission.

Introduction

1. On 1 February 2005, the European Commission forwarded the Finnish Competent Authority (CA)'s initial opinion on an application made under Article 4(1) of Regulation (EC) No 258/97 from the Finnish company Teriaka Ltd. Under the time scales set out in the regulation, the UK and other Member States have until 2 April 2005 to provide comments or objections to the initial opinion.
2. The Finnish CA has sought advice from the Finnish Novel Foods Board and has issued a positive opinion for the marketing of this novel food in the EU.
3. A translation of the Finnish Initial Assessment Report and the full dossier from the applicant are respectively attached as Annexes **A** and **B**. Annex B includes 6 appendices.

Background

4. In November 2001 the Committee considered the Finnish CA's opinion on an earlier application from Teriaka, which covered the addition of plant sterols to a range of foods (yellow fat spreads, milk-based fruit drinks, yoghurt type products and cheese type products). A copy of the UK CA's comments on this opinion can be found in Annex D. At that time the Committee comments related to the toxicology and allergenicity of the plant sterol ingredient. The UK comments were addressed by the Scientific Committee on Food in its opinions of March and September 2003. Teriaka's application was accepted in June 2004 under Commission Decision 2004/336/EC.
5. Teriaka has subsequently extended the range of its products to milk and soy-based drinks (authorised in July 2004) and fermented milk type products (authorised in October 2004). These extensions were granted under the notification procedure, claiming equivalence to products already on the market from other manufacturers. Details of these notifications have been provided in paper ACNFP/68/7 (detailed in paragraphs 7-8 and annex 4) and ACNFP70/09 (detailed in paragraphs 41-45 and annex 5).

6. Teriaka now proposes that phytosterols should be added to rice drinks as a mixture with vegetable oils and water, which they market under the registered trade name Diminicol®. The sterols are obtained from vegetable oil or from tall oil and their safety has already been evaluated in previous novel food applications. In March 2003 the Scientific Committee on Food (SCF) published its opinion on a variety of application of plant sterol enriched foods¹ which included Teriaka's application. The oil component is edible vegetable oil, which may be from various sources, depending on the application. In the case of the rice drinks, the applicant proposes to use sunflower oil.
7. Members will recall that over the last four years they have considered a number of applications for foods fortified with phytosterols. In the course of these considerations, Members have expressed concern that the increasing number of phytosterol fortified products may lead to over-consumption of the ingredient and effect vitamin status. Members also raised concerns that some products would be attractive to children. Other Member States raised similar concerns and, following an assessment of the risk of high level consumption by the Scientific Committee on Food; the need for a risk management strategy was highlighted. Given that products with added phytosterols have a history of consumption prior to May 1997 and are therefore outside the scope of the novel foods regulation, effective risk management could not be achieved by limiting the number and scope of novel food authorisations. As a result, the labelling regulation (EC) 608/2004 was adopted in early 2004 that applies to all foods with added plant sterols or stanols. This regulation lays down measures to prevent over consumption and requires that at risk groups be clearly identified on packaging.
8. In accordance with the Novel Foods Regulation (EC) 258/97, Teriaka's plant sterol enriched rice drink has been classified as a complex novel food from non-GM sources source (class 2.1). Teriaka prepared its application pursuant to Commission Recommendation 97/618/EC, which schemes are as follows:

I	Specification of the NF	X
II	Effect of the production process applied to the NF	X
III	History of the organism used as the source of the NF	X
IV	Effect of the genetic modification on the properties of the host organism	-
V	Genetic stability of the GMO	-
VI	Specificity of expression of novel genetic material	-
VII	Transfer of genetic material from GM microorganisms	-

VIII	Ability to survive in and colonise the human gut	-
IX	Anticipated intake/extent of use of the NF	X
X	Information from previous human exposure to the NF or its source	X
XI	Nutritional information on the NF	X
XII	Microbiological information on the NF	X
XIII	Toxicological information on the NF	X

I Specification of the Novel Food (NF)

Annex B p. 7-10, Appendices 1,3 and 4

9. The NF is a mixture of water, rice base, Teriaka's plant sterol ingredient (0.25%), emulsifier E471², salt and stabiliser E407³. (Members should note that the

¹ SCF/CS/NF/DOS/15 ADD 2 Final: http://europa.eu.int/comm/food/fs/sc/scf/out174_en.pdf

² Mono- and di-glycerides of fatty acids

³ Carrageenan

Finnish CA wrongly implies in paragraph 17 of its opinion that the emulsifier and the stabiliser are components of the Diminicol® ingredient.) It is envisaged that a 200ml portion of this rice drink will contain 0.5g of plant sterols. The applicant states that the NF, minus its plant sterol content, is identical to rice drinks currently sold on the EU market (see Annex B, appendix 4).

10. In its opinion, the Finnish CA is satisfied that the plant sterol ingredient to be used in the NF is the same as that considered by the Finnish Novel Food Board in 2001. The Finnish CA states that certificates of quality and purity including analyses of the residues have been accepted by the Finnish Board, as part of the assessment of Teriaka's original application. The Finnish CA therefore concludes that the plant sterol ingredient may be regarded as safe for use in a rice drink.
11. The Finnish CA also points out that Teriaka will adjust the amount of plant sterols added in rice drinks according to their package size, so the plant sterol level do not exceed 3g per container. Finally, as Teriaka Ltd will not be the producer of the final rice drink and will only supply the plant sterol ingredient to rice drink manufacturers, the Finnish CA accepted that the composition of the NF may slightly vary depending on the producer's practice.

II Effect of the production process applied to the NF

Annex B p.11-13, Appendices 3 & 5

12. The production of the plant sterol ingredient is identical to what has previously been described in Teriaka's application in 2001. Water, sunflower oil and plant sterols are mixed into a homogenous mixture.
13. The applicant has provided a flow chart of the NF production on page 13 of Annex B and has stated that the production, minus the addition of plant sterols, is identical to the production of rice drinks currently sold on the EU market. Rice is grounded, hydrolysed; filtered and heated up to 70°C before emulsifiers, stabilisers and the plant sterol ingredient are added. The amount and quality of added plant sterols is controlled. This ingredient replaces fat and water found in traditional rice drinks. The product is then aseptically processed and packaged.
14. The same HACCP schemes as these used in conventional rice drink production are in place to control the safety and quality of the NF along with an in-house checking programme, where the amount of plant sterols is checked and constantly analysed. This programme has been approved by Finnish local authorities (see appendix 5 of Annex B).
15. In their initial opinion, the Finnish CA concludes that the processes used for the production of the Teriaka's plant sterol ingredient and the NF are acceptable. It also accepts that the plant sterol ingredient would remain chemically and microbiologically stable in cool storage conditions.

III History of the organism used as the source of the NF

Annex B p.16

16. The Finnish CA has confirmed that the NF consists of ingredients that are already on the market, including Teriaka's plant sterol ingredient. It has also noted that rice itself and rice drinks (without added plant sterols) are available in all Member States

IX Anticipated intake and extent of use of the NF

Annex B p.14-15

17. The applicant recommends an intake of three daily portions (200ml), each containing 0.5g of plant sterols, which would provide a total daily intake of 1.5g of phytosterols. The applicant envisages that the NF will provide an alternative to soya milk or milk based drinks that are marketed with added plant sterol, and considers that the NF marketing will therefore not contribute to an increase of the current EU plant sterol consumption. Soya drink and rice drinks can both replace cow's milk based drinks in the diet of people with lactose intolerance or cow's milk allergy and in the diet of vegetarians or vegans.
18. Data on user groups and consumption of rice drinks within the EU have not been presented and, as a result, the Finnish CA has been unable to calculate the anticipated intake for the NF. However, consumption data on 'other milk products' in 19-64 years old adults from the British National Diet & Nutritional Survey have been taken into consideration. Based on these data, anticipated plant sterol intake from consuming the NF would be 0.28-0.34g per day. The applicant has highlighted that the actual consumption for rice drinks would be much lower because these figures include other similar products such as soya milk.
19. The Finnish CA agrees with the applicant that the intake of the fortified rice drinks is not expected to increase the total consumption of plant sterols. The product will only offer an alternative source of plant sterols for consumers who cannot use plant sterol enriched-milk or soy milk based drinks and wish to lower their blood cholesterol level. Moreover, rice drink is not widely consumed in the EU which reduces the possibility of unintended exposure to plant sterols via the NF. Finally, The Finnish CA highlights that, as required by regulation (EC) 608/2004, the NF will not be recommended to pregnant or breast-feeding woman and to young children. It indicated that this was an important point because this product may be attractive to children allergic to milk or soy products.

X Information from previous human exposure to the NF or its source

Annex B p.16-17, table 4

20. The Finnish CA has considered this in conjunction with item III (see paragraph 18 above).

XI Nutritional information on the Novel Food

Annex B p. 18 - 19, p.9-10 (tables 2 and 3)

21. The applicant anticipates that cholesterol conscious consumers could potentially replace traditional rice drinks with the NF and is of the view that the presence of the phytosterol ingredient would not affect the nutritional content of the drinks (see tables 2 and 3 in Appendix B, pages 9-10). Rice drinks are regarded as an alternative protein source for consumers who are allergic to milk and other dairy protein sources.
22. Studies relating to the effects of the plant sterol ingredient have already been discussed in relation to Teriaka's application in 2001. During this time, the main cholesterol-lowering function of their plant sterol ingredient along with the nutritional implications and anticipated effects were considered to be the same as with other plant sterol enriched products.

23. Consumption of the NF, as with any other source of phytosterols, could contribute to reduced blood levels of fat-soluble vitamins and their precursors. The Finnish CA notes that the NF would be subject to the labelling rules in regulation (EC) 608/2004, which requires products to carry a statement about the consumption of fruits and vegetables. Additionally, products would be labelled as unsuitable for young children and pregnant or lactating women, the population groups most at risk from low levels of fat-soluble vitamins (see Annex A, paragraph 35).

XII Microbiological Information

Annex B p.20, Appendix 3

24. The applicant states that the microbiological safety of the NF is ensured through an HACCP scheme and in-house checking programmes (see paragraph 15).
25. In addition to the information previously supplied in 2001 the applicant has provided a study report on the microbiological stability of Teriaka's plant sterol ingredient in cool storage (appendix 3 of annex B). This study is not specifically discussed in the initial opinion and demonstrates that the microbiological composition of the plant sterol ingredient is stable throughout 12-months storage.
26. The Finnish CA was satisfied that sufficient information has been provided to demonstrate the NF microbiological safety. The production process corresponds with traditional processes and the sources of the raw material do not give any reason to expect problems with the microbiological safety of the final product.

XIII Toxicological information

Annex B p.21-22

27. The toxicological safety of plant sterol enriched foods has been extensively reviewed between 2000 and 2003 by the SCF. The toxicological assessment of the Diminicol® plant sterols was also previously carried out by the Finnish CA in Teriaka's original application (2001) which was later approved.
28. The applicant has considered the possible allergenicity of rice protein and has stated that rice allergenicity is little compared with soya and recent studies on rice hydrolysate formula in children allergic to cows milk found soya to be an alternative source of protein.
29. The Finnish CA was satisfied that the applicant has shown that the NF and its plant sterols are safe for human consumption. It adds that data on the toxicological and allergenic properties of the plant sterols did raise any concerns. Finally, the Finnish CA accepts that rice drink in itself will not be harmful for human health and that allergy to rice proteins is not common.

Labelling information

Annex B p.10, Appendix 2

30. The NF will be intended for those people who wish to lower their blood cholesterol level and will be labelled in accordance with Regulation (EC) 608/2004 to prevent over consumption and requires to identify risk groups be clearly on the packaging. The applicant is fully aware of this regulation and has confirmed that their products will be labelled as required by (EC) 608/2004, including advice on the maximum recommended plant sterol intake and on carotenoid level.

Committee Action Sought

31. The Committee is asked whether it agrees with the initial opinion from the Finnish CA that rice drinks with added phytosterols should be granted authorisation as a novel food and whether it wishes to make any additional comments on the application.

Secretariat
March 2005

Annexes attached

Annex A: A translation of the Finnish Competent Authority's Initial Assessment Report on the application made by Teriaka Ltd to place on the market a plant sterol enriched rice drink. **CONFIDENTIAL**

Annex B: Application dossier to place a plant sterol enriched rice drink on the novel food market (including annexes as listed). **CONFIDENTIAL**

- **Appendix 1:** *Specification of Diminicolâ,*
- **Appendix 2:** *Draft for package label of Diminicolâ rice drink,*
- **Appendix 3:** *Study report – chemical and microbiological stability, study of Diminicolâ ingredients, produced with vegetable oil derived plant sterols, in coll storage conditions,*
- **Appendix 4:** *Specification of rice drink,*
- **Appendix 5:** *Approval by local authorities of the in-house checking program of Teriaka (in Swedish) and*
- **Appendix 6:** *Summary by the applicant for further circulation the Members States of European Union*

Annex C: 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.

Annex D: Letter to the European Commission on the UK's comments on the Finnish opinion on the application to place plant sterol enriched fat ingredient Diminicol® on the novel food market.

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

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.

This document has been published on the European Union website at:

http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_105/l_10520040414en00490051.pdf

**Secretariat
March 2005**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Letter to the European Commission on the UK's comments on the Finnish opinion on the application to place plant sterol enriched fat ingredient Diminicol® on the novel food market.

**Secretariat
March 2005**

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DG-Sanco
Rue de la Loi 200
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Brussels
Belgium

10 December 2001

Reference: NFU 360

Initial opinion from the Finnish CA on the application to place the Plant sterol enriched fat ingredient Diminicol[®] on the novel food market.

Dear Mr Klepsch

The UK Competent Authority (UK CA) sought comments from the Advisory Committee on Novel Foods and Processes (ACNFP) on the initial opinion from Finland under the 60-day rule of the Novel Food Regulation (EC) 258/97. Several concerns were raised as listed below:

1. The product is microcrystalline plant sterols / stanols, and not sterol / stanol esters. Consequently this material cannot be assumed to be substantially equivalent to plant sterol /stanol esters which have already been subject to toxicological testing.
2. Concerns were raised as to the allergenic potential of the Diminicol products due to one of the sources of the phytosterols being peanuts. The company should confirm that the processing of the vegetable oil derived plant sterols (phytosterols) removes all traces of protein, and thereby ensuring that any possible allergenicity of the source materials is removed.

3. The suggested labelling of the products containing the Diminicol ingredients was not satisfactory. The labelling should state clearly and specifically that these products are not nutritionally appropriate for pregnant or lactating mothers and young children.
4. Some of the plant sterol enriched products (yoghurts and fruit milk drinks) were perceived to be potentially desirable to children, and there was concern that even if they were marketed at premium price with an indication of the target population (middle aged people), there may still be consumption by children.
5. Data should be provided on the possibility of effects on the absorption (not blood level) of fat-soluble vitamins and carotenoids over the longer term. Similar concerns have been raised previously with other phytosterol/ester products. In addition effects on carotenoids such as lutein may have implications for deteriorating vision in the elderly.
6. In view of the number of applications for foodstuffs containing phytosterols and their esters being considered under (EC) 258/97, concerns have already been raised by the UK Competent Authority concerning the potential for the cumulative consumption of plant sterols from a range of different products. In view of this, there was concern that with the addition of a number of products containing plant sterols onto the market the potential for over consumption of plant sterols would be increased further.

The UK Competent Authority broadly agreed with the initial opinion of the Finnish Competent Authority and therefore does not support the marketing of these products until the concerns listed above have been addressed, and therefore formally objects to this application.

Yours sincerely

Sue Hattersley
Novel Foods Division