

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**PHYTOSTEROLS FROM PRIMA PHARM****Issue**

The company Prima Pharm intends to market a phytosterol preparation for use as an ingredient in various food categories. The Committee is asked to consider whether this ingredient can be regarded as substantially equivalent to phytosterols currently marketed by Teriaka.

Background

1. Under Article 3(4) of the Novel Foods Regulation (EC) 258/97, the company Prima Pharm is requesting an opinion from the UK Competent Authority (CA) on the equivalence of their phytosterols (for use in yellow fat spreads, milk based fruit drinks, yoghurt type products, cheese type products, soya drinks, milk and fermented milk type products), with phytosterols sold by Teriaka for use in the same range of products.
2. Teriaka initially gained authorisation for use of its phytosterols in: yellow fat spreads, milk based fruit drinks, yoghurt type products and cheese type products (Annex 1). Two subsequent authorisations, based on opinions on substantial equivalence from the Novel Food Board of Finland in July and October 2004, extended the range of Teriaka products to include milk type and fermented milk products and soya drinks. Prima Pharm's application dossier is attached as Annex 2.
3. Regulation (EC) 258/97 makes provision for novel foods or ingredients that are substantially equivalent to an existing product to be placed on the market once the applicant has informed the European Commission. In all cases to date involving new phytosterol ingredients, the Commission has required that the applicant first obtain an opinion on equivalence from a member state. Prima Pharm is requesting such an opinion from the UK CA.
4. According to article 3(4) of (EC) 258/97, the notification procedure applies to "foods or food ingredients ... which on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies ... are substantially equivalent to existing foods or food ingredients as regards their:
 - Composition,
 - Nutritional Value,
 - Metabolism
 - Intended use and
 - Level of undesirable substances contained therein."

5. Prima Pharm obtain their phytosterols from a company called les Derives Resiniques et Terpeniques (DRT). It should be noted that data on DRT's tall oil phytosterols were included in Teriaka's original novel food application, along with data from another supplier of phytosterols derived from vegetable oils (ADM). However, DRT phytosterols have not been used by Teriaka since gaining approval. DRT's phytosterols have therefore been through the approval process but have not actually been placed on the market. Because each novel food authorisation is addressed exclusively to the applicant, the authorisation granted to Teriaka does not permit DRT or other companies to market the same ingredient.

Evaluation

(A) Composition Annex 2 p 5-7

6. The Prima Pharm phytosterol mix is extracted from tall oil pitch from *Pinus maritima* (synonym *Pinus Pinester*). The production process is described in Appendix 2 of the dossier (Annex 2) and involves extraction, crystallisation and drying. The process is one that is commonly used to purify phytosterols and corresponds to the process described in the Teriaka application, according to the SCF opinion¹. The specification of the product described in the current application is within that specified in the Teriaka authorisation (Commission Decision 2004/336/CE).

(B) Nutritional Value and Metabolism Annex 2 p 9-14

7. There is no information to suggest that the nutritional value or metabolism of Prima Pharm phytosterols will be any different to those used by Teriaka. The anticipated intake of these phytosterols is not likely to be increased as the ingredient is to be used in the same range of products already approved.

(C) Intended Use Annex 2 p 14

8. The applicant intends the ingredient to be used in yellow fat spreads, milk based fruit drinks, yoghurt type products, cheese type products, milk type products, soya drinks, and fermented milk products. These products are the same as existing products on the market containing Teriaka phytosterols.

(D) Level of undesirable Substances Annex 2 p15-18

9. Limited information on undesirable substances was given in Teriaka's original application. However, Prima Pharm have provided data on the levels of a number of classes of potential contaminants including: dioxins (PCDD's and PCDF's, Appendix 5), polycyclic hydrocarbons (Appendix 6) herbicides and pesticides (Appendix 7) and heavy metals (Appendix 8). The applicant claims that all contaminants measured are within acceptable levels in compliance with EU regulations.

(E) Other Relevant Data

10. **Labelling:** Annex 2 p17 The applicant states that the labelling of the products containing the phytosterols will be in accordance with Commission Regulation (EC) 608/2004 concerning the labelling of food with added phytosterols.

¹ SCF (2003) Opinion of the Scientific Committee on Food on applications for approval of a variety of plant sterol enriched foods.

11. **Toxicology:** ^{Annex 2, Appendix 10} The applicant has given a brief overview of relevant publications looking at the long-term safety of phytosterols and has also included some studies carried out with DRT's phytosterols. These studies address acute toxicity (Appendix 10, p80-91), skin irritation (App 10, p92-97) and skin sensitisation (App 10, p98-110). No adverse results were reported in any of these studies.
12. Members should be aware that they have previously reviewed these data as part of the Teriaka application (ACNFP 52/2). The applicant has submitted these supplementary data in order to comply with the ACNFP guidelines for submission of a request for substantial equivalence.

Committee Action Required

13. The Committee is asked if it has any objections or comments regarding this application or whether it is content to agree that substantial equivalence has been established between phytosterols supplied by Prima Pharm and the phytosterols marketed by Teriaka, in accordance with Article 3(4) of regulation 258/97.
14. If not, the Committee is asked what additional information the applicant should supply in order to demonstrate equivalence.

**Secretariat
September 2005**

Annexes attached:

Annex 1 – Commission Decision 2004/336/EC.

Annex 2 – Prima Pharm's dossier requesting the UK CA's opinion regarding the substantial equivalence of Prima Pharm's phytosterol product with Teriaka's.

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Commission Decision 2004/336/EC authorising the placing on the market of yellow fat spreads, milk based fruit drinks, yoghurt type products and cheese type products with added phytosterols/phytosterols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council.

This document is available on the European Commission website at:

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

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Prima Pharm's dossier requesting the UK CA's opinion regarding the substantial equivalence of Prima Pharm's phytosterol product with Teriaka's.

This document has been published on the Food Standards Agency website at:

<http://www.food.gov.uk/science/ouradvisors/novelfood/assess/>

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