

## ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

## PHYTOSTEROLS FROM NATURIS

## ISSUE

Naturis has responded to the questions raised by the Committee in April 2008. Members are asked to consider this information and further information provided by the Secretariat on existing phytosterol products, and to decide whether this provides sufficient information for the Committee to conclude that substantial equivalence has been established for this product, and whether it is content with the proposed draft opinion.

**Background**

1. At the November 2007 meeting, the Committee considered an application from Naturis for an opinion on equivalence of their phytosterol ingredient with phytosterols marketed by ADM. Naturis is intending to use their phytosterol ingredient in the same food categories specified in ADM's authorisation, namely: yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products.
2. At the January 2008 meeting the Committee considered the applicant's response to its request for further information regarding production process used by the US manufacturer of the phytosterol and information on the composition of the remaining 5% of the phytosterol ingredient. Members were broadly content with the information provided but requested further information from the applicant on the composition of the remaining 5% of the ingredient. At the April meeting Members remained concerned at the absence of data to support the applicant's statement on the identity of the minor components and again requested for this information to be provided.
3. The applicant has provided a GC trace for Members consideration (**Annex A**)
4. The Secretariat has also provided extra information on the composition of existing phytosterol products that have been authorised under the novel foods regulation attached as **Annex B**. The Secretariat notes that the minor components of existing products, other than phytosterols and phytostanols, have not apparently been identified and quantified. The equivalence of the product described by the present applicant with the existing product is claimed on the basis of (a) close similarities in the source materials and methods of manufacture and (b) analyses confirming that the phytosterol profile falls within the range of the existing product.

## **Conclusion**

5. The Secretariat has amended the draft opinion incorporating the above information (**Annex C**).

## **Committee Action Required**

6. The Committee is asked to consider the applicant's response and whether it is content to agree that substantial equivalence has been established between the phytosterols supplied by Naturis and the phytosterols marketed by ADM, in accordance with Article 3(4) of Regulation (EC) 258/97.
7. If so, the Committee is asked whether it is content with the text of the proposed draft opinion attached as Annex C.
8. In addition, the Committee is asked if it wishes to review the minor components of phytosterol preparations (in general) at a future meeting.

**ACNFP Secretariat  
May 2008**

## **Annexes attached**

**Annex A:** GC Trace provided by applicant

**Annex B:** Overview of minor components included in phytosterol products already approved under the novel food regulation 258/97

**Annex C:** Naturis phytosterol draft opinion (RESTRICTED)