

**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**

**PHYTOSTEROLS FROM LIPOFOODS**

**Issue**

Lipofoods has submitted a request for an opinion on the equivalence of their phytosterols. Members were asked to consider this request by postal consultation in November 2006. The Committee is now asked to consider the draft opinion and indicate whether substantial equivalence has been established for this novel ingredient.

**Background**

1. In September 2006, the Food Standards Agency received an application from Lipofoods requesting an opinion from the UK Competent Authority on the equivalence of their phytosterols to be used in yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products, with phytosterols marketed by ADM for use in the same range of products. ADM gained novel food approval for their phytosterols in 2004.
2. The Committee considered this application by postal consultation in November 2006 (ACNFP/80P/1). Some Members commented on the approach taken in the application, where the phytosterol composition of Lipofoods' product was compared with ranges published in the authorisations granted to existing phytosterol products, and not by side-by-side comparison with one or more batches of an existing product. The applicant's approach is however consistent with previous applications examined by the Committee e.g. phytosterols manufactured by Prima Pharm (ACNFP/73/5) and by DDO Processing (ACNFP/74/4).
3. One member highlighted the use of acetone during the refining process. Although this may not be the same solvent as used by the manufacturer of the existing product (ADM), the criteria set out in the novel food regulation 259/86 are based on the composition and usage of the final products. Differences in the manufacturing process do not therefore invalidate the comparison between the two products.
4. One member noted that that the heavy metal analysis was performed on only a single batch of the product.
5. Members were content that in principle Lipofoods' phytosterols could be considered substantially equivalent to the phytosterols marketed by ADM and did not request any further information. A draft opinion has therefore been prepared (Annex 1).

### **Committee Action Required**

6. The Committee is asked whether it is content with the text of the draft opinion attached as Annex 1.
7. If not the Committee is asked what additional information the applicant should supply in order to demonstrate equivalence.

**Secretariat  
January 2007**

### **Annexes attached:**

Annex 1 – Draft Opinion on Substantial Equivalence of Phytosterols Considered  
Under Article 5 of the Novel Foods Regulation