

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON SUBSTANTIAL EQUIVALENCE OF PHYTOSTEROLS CONSIDERED UNDER ARTICLE 5 OF THE NOVEL FOODS REGULATION

Applicant Lipofoods
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Introduction

1. A request was submitted by Lipofoods to the UK Competent Authority, in September 2006, for an opinion on the equivalence of their phytosterols with the phytosterols marketed by Archer Daniels Midland (ADM).
2. ADM gained authorisation for the use of its phytosterols through Commission Decision 2004/333/EC. Lipofoods are therefore seeking a view on equivalence for the use of 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 products¹.
3. According to article 3(4) of (EC) 258/97, the notification procedure applies to "foods or food ingredients ... which on the basis of 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 regarding their:
 - Composition,
 - Nutritional value,
 - Metabolism,
 - Intended use and
 - Level of undesirable substances contained therein."

Evaluation

Composition

4. The applicant is claiming equivalence to the specification of phytosterols set out in Annex 2 of Commission Decision 2004/333/EC. The phytosterols are extracted from non-genetically modified soya bean seeds. They are manufactured in the same way as the approved phytosterol product marketed by ADM, with the exception that the solvent used is acetone and

¹http://eurlex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32004D0333&model=guichett

not heptane. The specification of the product described by the applicant is consistent with that described in Commission Decision 2004/333/EC, as confirmed by analytical data on 5 batches of the product.

Discussion: *The Committee noted that the composition of Lipofoods phytosterols complied with the specification of phytosterols in Commission Decision 2004/333/EC.*

Nutritional Value and Metabolism

5. Evidence suggests that the nutritional value and metabolism of Lipofoods phytosterol ingredient is expected to be the same as those produced by ADM. The anticipated intake of phytosterols is not likely to be increased as the ingredient is to be used in the same range of products already approved for ADM.

Intended Use

6. The applicant intends the ingredient to be used in yellow fat spreads, salad dressing (including mayonnaise), milk type products such as semi skimmed and skimmed milk products, fermented milk products, such as yoghurt, soya drinks, and cheese. These products are the same as those authorised for ADM phytosterols.

Discussion: *The Committee was content that the applicant's product is to be consumed at the same level and in the same range of products as the existing product.*

Levels of Undesirable Substances

7. Limited information on the levels of undesirable substances was given in ADM's application. However, Lipofoods have provided data on the levels of a number of classes of potential contaminants including, polycyclic aromatic hydrocarbons (PAH's), dioxins, herbicides and pesticides, heavy metals, organic solvents and aflatoxins. The applicant claims that all contaminants measured are within acceptable levels and in compliance with EU regulations.

Discussion: *The Committee was content that levels of undesirable substances in this product were not a cause for concern.*

Labelling

8. The applicant states that labelling of the products containing the phytosterols will be in accordance with Commission Regulation (EC) 608/2004 concerning the labelling of foods with added phytosterols.

Additional Information: Toxicology

9. The applicant has given a brief overview of relevant publications looking at the long-term safety of phytosterols. No adverse effects were reported in any of these studies.

Conclusion

10. The Committee is content that the applicant's approach to demonstrating the equivalence of their phytosterols, to be used in conjunction with the existing phytosterol ingredient is consistent with the criteria set out in Article 3(4) of the Novel Food Regulation (EC) 258/97.
11. Therefore phytosterols marketed by Lipofoods can be considered to be substantially equivalent to the existing phytosterol ingredient marketed by ADM.
12. Lipofoods should ensure that the labelling of products containing their phytosterols comply with Commission Regulation (EC) 608/2004 concerning the labelling of foods and added phytosterols.

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