

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

PHYTOSTEROLS PRODUCED BY DDO PROCESSING

Issue

Comments have been received on DDO Processing's substantial equivalence dossier during the Food Standards Agency's 21-day public consultation on this document. The Committee is asked to consider these comments and whether it considers that substantial equivalence has been established for this product.

Background

1. An application has been submitted by DDO Processing requesting an opinion from the UK Competent Authority (CA) on the equivalence of their phytosterols (Nutraphyl™) to be used in yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and spicy sauces with phytosterols sold by Forbes Medi-Tech for use in the same range of products.
2. At the November meeting, Members were content in principle that the DDO Processing phytosterols could be considered substantially equivalent to the existing Forbes Medi-Tech phytosterols and agreed that a draft positive opinion should be drafted by the Secretariat (paper ACNFP/74/4).
3. In line with standard practice for the assessment of novel food dossiers, the original request from DDO Processing was published on the Food Standards Agency's website for public comment. One response was received from a company (Annex A) and the issues they have raised are discussed below.
 - (i) **Inadequate analytical method** - The Secretariat has approached the applicant about these comments and is awaiting a response from them.
 - (ii) **Beta-sitosterol level** - At the November meeting, Members agreed that the composition of DDO Processing phytosterols with a slightly higher upper limit of 87% for beta-sitosterol did not prevent this product being considered "substantially equivalent" to Forbes Medi-Tech phytosterols with an upper limit of 80% for beta-sitosterol.
 - (iii) **Use of heptane in sterol purification process and safety of its residual levels** - The Secretariat notes that the use of heptane as a solvent for the extraction of foods and food ingredients is not authorised under Directive 88/344/EEC (as amended). Further information is being sought on this point and will be provided at the meeting. The manufacturing method used by Forbes Medi-Tech involves the use of a mixture of methanol and methyl ethyl ketone at a similar stage in the purification process.
 - (iv) **No data on levels of impurities** - The purity of DDO Processing phytosterols is above 99% which complies with the purity criteria set in Commission Decision 2004/845/EC for tall oil derived phytosterols. Annex A

refers to an SCF opinion (13 March 2003) on a variety of plant sterol-enriched foods which does not mention heavy metals such as mercury and cadmium and notes that benzpyrene and 15 other polycyclic hydrocarbons were undetectable in samples of phytosterol products extracted from tall oil. The SCF concluded that *“Any contamination of the sterol mixture with non-sterol constituents from crude tall oil, however, should be avoided. Consequently, phytosterol preparations derived from tall oil should contain more than 99% sterols/stanols and comply with the maximum limits of the Council Directive on extraction solvents (EC, 1992) and the recommendations on potential contaminants in the Report of the Committee on smoke flavourings (SCF, 1993).”* No criteria have been set for undesirable components in other authorised phytosterol products, including those manufactured by Forbes Medi-Tech, although information on relevant contaminants was provided as part of that company’s revised application dossier, reviewed by EFSA in 2003.

Committee Action Required

4. The Committee is asked to consider the public comments made on this application and whether it is content to agree that substantial equivalence has been established between the phytosterols supplied by DDO Processing and the phytosterols marketed by Forbes Medi-Tech, in accordance with Article 3(4) of Regulation (EC) 258/97.
5. If so, the Committee is asked whether it is content with the text of the draft opinion attached as Annex B.
6. If not, the Committee is asked what additional information the applicant should supply in order to demonstrate equivalence.

**ACNFP Secretariat
January 2006**

Annexes attached

Annex A: Public comment

Annex B: Draft opinion (*restricted*)

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Public comment.

**Secretariat
January 2006**

UK Food Standards Agency
Advisory Committee on Novel Foods and Processes (ACNFP)
ACNFP Secretariat
Food Standards Agency
Room 515B Aviation House
125 Kingsway
London WC2B 6NH

January 4, 2006

Re: Notification Dossier, Simplified Procedure for Substantial Equivalence, Phytosterols and Phytosterol Esters for Use as a Novel Food Ingredient In Prior Approved Food Applications. Applicant Manufacturer, DDO Processing, LLC, 3117 Southside Ave., Cincinnati, OH 45204

To the advisory committee,

The applicant has not established equivalence to tall oil sterols approved for use as food ingredients in the European Union. Specifically, we note the following:

1. The analytical method is not adequate to demonstrate that the sterol ingredient meets the approved EU specifications:
 - (a) The method does not detect the "other sterols" components which have a specification of less than 3%.
 - (b) The method overestimates the content of major sterols as shown in the applicants data, expressed as percent of total weight.

Phytosterol		349M4	192M5	194M5	222M5	267M5	271M5
Brassicasterol		0.0	0.0	0.0	0.0	0.0	0.0
Campesterol		6.17	6.05	6.15	5.92	5.62	5.54
Campestanol		0.79	0.83	0.71	0.84	0.74	0.78
Stigmasterol		0.84	0.48	0.82	0.8	0.78	0.91
Beta Sitosterol		83.76	83.09	86.27	83.11	81.95	81.75
Sitostanol		10.48	10.53	10.02	11.1	10.31	10.77
Total Detected		102.04	100.98	103.97	101.77	99.4	99.75

In four of the six batches analyzed, the total content exceeds 100%. The applicant has also not taken into consideration the water content of the sterols in the analysis. This correction will add at least 0.9% to the purity estimate depending on the water content of the sterols at the time of manufacture. If the minor sterols content which is very likely in the range of 2% is also taken into consideration, the over-estimate is even higher.

- (c) The beta-sitosterol component is out of the approved specification of "less than 80%" in all batches.
2. The purification process for the sterols uses heptane, a solvent, to our knowledge not previously used in the preparation of tall oil sterols. The safety of tall oil sterols was established by extensive toxicology studies as well as human clinical

studies with sterols purified by solvents other than heptane. The heptane solvent is not authorized for use in the production of foodstuffs and food ingredients (Directive 88/344/EC as amended). Although solvents not included in the Annex of this Directive may be used in the production of "nutritional additives", a category of food ingredients which may encompass phytosterols, their level in the final foodstuff must be such as to not endanger human health (see Article 1 of Directive).

The applicant has not provided information about the residual levels of heptane in the product and their implications for human health.

3. The applicant has not provided any data on the levels of certain impurities in the sterols; specifically, cadmium, mercury and polyaromatic hydrocarbons, identified by the Scientific Committee on Food as an impurities of concern (see SCF Report on Smoke Flavourings, June 25, 1993 and SCF Report of 13 March 2003, Opinion of the Scientific Committee on Food on Applications for Approval of a Variety of Plant Sterol-Enriched Foods and EFSA Journal 15,1-12, 2003). In the Novel Foods applications which are the basis for Commission Decisions, 2004/336/EC, and 2004/845/EC, data was also provided on the content of polychlorinated biphenyls, and residues of over 43 pesticides and herbicides. All potential impurities were below the limits of detection of the methods applied.

In our opinion, until the above deficiencies are addressed, the tall oil sterols and tall oil sterol esters described in the notification cannot be considered equivalent to those approved for food use in the European Union.

With best regards

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