

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

PHYTOSTEROLS FROM NATURIS

Issue

The company Naturis intends to market phytosterols to manufacturers for use as an ingredient in various food categories. The committee is asked to consider whether these phytosterols can be regarded as substantially equivalent to the phytosterols currently marketed by Archer Daniels Midland.

Background

1. Under Article 3(4) of the Novel Foods Regulation (EC) 258/97, the British company Naturis is requesting an opinion from the UK Competent Authority (CA) 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 sold by Archer Daniels Midland (ADM) for use in the same range of products (dossier in **Annex A**).
2. Archer Daniels Midland (ADM) gained authorisation for use of its phytosterols as a novel ingredient in yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products in 2004¹
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 notified the European Commission. In all cases to date, the Commission has required that the applicant first obtain an opinion on equivalence from a Member State. Naturis 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. In line with the standard practice, the application dossier is being placed on the ACNFP's website for a 21-day period of public consultation. Any

¹ Commission Decision 2004/333/EC, 31 March 2004.

comments received during this period will be presented to the Committee at a later date.

Evaluation

Composition

Annex A p.5-8 and p.10-11

6. Naturis sterols are isolated from non-GM soyabean oil and are marketed as a dry, white, free-flowing powder.
7. The manufacturing process is described in page 8 of the application dossier (Annex A). The applicant has not provided a detailed description of the production process used by the US manufacturer of the sterols but states that it is very close to the one used by ADM, which is described in the Scientific Committee on Food's Opinion on ADM's application² as follows:

"The crude oil, which is obtained by pressing or solvent extraction, undergoes a series of refining processes to remove solvents, lecithins, free fatty acids, color bodies, off-odors and off-flavors. In one of these steps, the oil is subjected to steam distillation at reduced pressure (deodorisation) and the resulting distillate contains the sterol fraction. From this fraction, fatty acids, lecithins and other compounds are removed by fractional distillation, ethanolysis/transesterification, distillation and crystallisation from a heptane solution, and the sterols are further purified by recrystallisation using food grade materials and good manufacturing practices. According to the applicant, the extraction and purification steps are standard methods and similar to the procedures used traditionally by the food industry for the production of plant sterols.

"Sterol esters are produced from the sterols using food grade vegetable oil-derived fatty acids or triglycerides and applying standard methods for esterification or transesterification commonly used in the fats and oils industry."

8. The applicant provides specifications for its phytosterols in Table 1. The applicant notes that ADM obtain their sterols from by-products of traditional vegetable oil refining. The starting material described by ADM is commonly a blend of crude edible oils, consisting largely of soy bean oil and lesser amounts of corn, rapeseed and palm oil. The applicant states that their phytosterols are obtained from soyabeans of natural origin and the compositional requirements for their products are strict. They consider that the source used for their product is comprised within that described by ADM. The Secretariat notes that the criteria for establishing substantial equivalence (see paragraph 4 above) do not demand that the new and existing ingredients are from identical sources. The comparison is based on the composition (including undesirable substances) of the final products and their usage.
9. The applicant provides certificates of analysis for four batches of its soyabean oil derived phytosterol (Appendix A of the dossier, summarised in Table 1 below). These data show that the composition of the Naturis product is consistent with EU requirements and that the final product complies with the specification laid down in Commission Decision 2004/333/EC.

² Opinion of the Scientific Committee on Food on an application from ADM for approval of plant sterol-enriched foods (expressed on 4 April 2003), available from http://ec.europa.eu/food/fs/sc/scf/reports_en.html

Table 1

Composition (%)	Commission Decision 2004/333/EC (ADM)	Naturis product (4 batches)
Beta-sitosterol	<80%	55.2-55.7 %
Beta-sitostanol	<15%	3.69- 3.72%
Campesterol	<40%	27.3-27.8 %
Campestanol	<5%	1.3 -1.4 %
Stigmasterol	<30%	3.4-3.6 %
Brassicasterol	<3%	0.0%
Other sterols/stanols	<3%	2.9- 3.0%
Total Sterols	(see note)	93.9-95.1%

Note: The Commission Decision does not impose a limit on the total content of sterols derived from edible vegetable oils. The SCF Opinion mentions that ADM's product has a minimum sterol content of 90%.

(b), (c) Nutritional value and metabolism

Annex A p.13-16

- The composition of the phytosterols manufactured by Naturis and ADM are very similar and there is no information to suggest that their nutritional value or metabolism will differ. No increase in consumer intake above the current amounts of phytosterols is anticipated as the Naturis ingredient will be added to the same products as those already approved in Commission Decision 2004/333/EC.

(d) Intended use

Annex A p.11-13

- Naturis intends that its phytosterols will be used in milk type products, salad dressings (including mayonnaise), fermented milk type products (yoghurts, soya drinks and cheese products), spicy sauces and yellow fat spreads. These products are the same as those authorised to be placed on the market when containing ADM phytosterols.

(e) Levels of undesirable substances

Annex A p.27

- GMP is employed in the manufacturing process described by Naturis. The specification and product data sheet include limits on lead (max. 1 mg/kg) and ash content (max. 0.1%) although no analytical data have been provided to demonstrate that the product complies with these limits.

Additional information

Annex A p.13-15 and p.17-21

- Labelling** Naturis will advise its customers that all products containing its phytosterols must be labelled in accordance with the requirements set in Commission Regulation (EC) No. 608/2004³.
- Safety/Risk assessment** The applicant states that Naturis sterols require low dosage to provide efficacy (800 mg per day) which is well within daily safety limits

³ Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters.

established or recommended by regulatory agencies in Europe and the US. The applicant also states that there are many published safety studies on plant phytosterols demonstrating their low order of toxicity. The projected consumer exposure of Naturis sterols in functional food and nutraceutical applications is consistent with the ranges established with other substantially equivalent phytosterol products already approved and being sold in various countries around the world.

15. **Toxicological information** The applicant notes that the ADI for phytosterols based on animal studies at the highest doses tested and applying a standard 100-fold safety factor was 130 mg/kg/day. This equates to a daily intake of 9.1 g/day for a 70 kg adult. The applicant is of the view that with proper labelling it is unlikely that consumption will exceed 3 g/day even if the sterols and sterol esters are present in multiple and competing novel foods on the market. The Secretariat notes that no regulatory body has established an ADI for phytosterols. EU authorisations for phytosterol products are accompanied by conditions of use, and labelling requirements, that are intended to minimise the possibility that consumers will regularly exceed an intake of 3 g/day. This limit has been set on the basis of human studies which showed that increasing phytosterol intake is associated with a decline in circulating carotenoid levels, and that the cholesterol-lowering effect is maximal at 3 g of phytosterols /day.

Committee Action Required

16. The Committee is asked whether it has any objections or comments to raise or whether it is content to agree that, subject to any comments received during the public consultation, substantial equivalence has been established between phytosterols supplied by Naturis and the phytosterols marketed by ADM, in accordance with Article 3(4) of Regulation (EC) 258/97.
17. If not, the Committee is asked what additional information the applicant should supply in order to demonstrate equivalence.

**Secretariat
November 2007**

Annex attached:

Annex A: Naturis application dossier

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Naturis application dossier.

**Secretariat
November 2007**