



24 August 2004

*Courtesy translation*

Articles 3(4) and 5 of Regulation (EC) No 258/97

**OPINION ON SUBSTANTIAL EQUIVALENCE IN THE CASE OF PLANT STEROL/PLANT STANOL INGREDIENT INTENDED TO BE USED IN FOODS (CARGILL INCORPORATION)**

The National Food Agency has requested Finland's competent food assessment body mentioned in the Novel Foods Regulation (EC) 258/97, the Novel Food Board, to examine the issue of the substantial equivalence of Cargill Incorporation's plant sterol/plant stanol ingredient with similar ingredients intended to be added to food and approved to be placed on the market within the EU. The Board has examined the matter at its meeting of 24 August 2004.

The Board states that the plant sterol ingredient of Cargill Inc. is considered to fulfil the conditions set out in Commission Decisions 2004/333/EC – 2004/336/EC<sup>1</sup> as concerns both the plant sterol/plant stanol content and the purity of the plant sterols/plant stanols used. The source of plant sterols/stanols in the sterol ingredient produced by Cargill Inc. is tall oil from which the plant sterol/plant stanol substance is refined and the end product itself is in crystalline form. The ingredient under evaluation primarily corresponds to the ingredient concerned by Commission Decision 2004/334/EC<sup>2</sup>.

The Board states that the labelling of products with added plant sterol ingredient shall be made in accordance with Regulation (EC) No 608/2004<sup>3</sup>. The Novel Food Board also states that the amount of plant sterols/plant stanols proposed to be added to the foods is to be consistent with the amounts set out in Commission Decisions 2004/333/EC – 2004/336/EC.

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<sup>1</sup> OJ L 105 (2004), P. 40-51

<sup>2</sup> OJ L 105 (2004), P. 43-45

<sup>3</sup> OJ L 97 (2004), P. 44-45



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### Detailed examination of documents

The Board has examined the request submitted by Cargill Inc. and containing justification for equivalence of Cargill's plant sterol/plant stanol ingredient with plant sterol/plant stanol ingredients already approved to be placed on the market (Commission decisions 2004/333/EC — 2004/336/EC). In particular, Cargill Inc. has proposed that the plant sterol ingredient produced by Pharmaconsult Oy Ltd. (Commission decision 2004/334/EC) should be used as basis for comparison. Cargill also invokes the Opinion of the Scientific Committee on Food dated 4 April 2003<sup>4</sup> as an argument in support of the comparison.

### *Composition*

The source of plant sterol/plant stanol in the ingredient produced by Cargill Inc. is tall oil. Tall oil is used as a plant sterol source for some sterol ingredients that are approved to be placed on the market (Multibene® by Pharmaconsult Oy Ltd. and Diminicol® by Teriaka Ltd), and also in Benecol® by Raisio Oy Ltd. that already is on the market. In the submitted document, Cargill Inc. has proved that its product corresponds, as to its plant sterol content, to the ingredient produced by Pharmaconsult Oy Ltd. Also the production method presented by Cargill is similar to that used by Pharmaconsult Oy Ltd. and described in the SCF Opinion dated 4 April 2003. The documents submitted by Cargill Inc. contain data on the plant sterol/plant stanol profile of the ingredient based on four different batches and a comparison of its composition with both the requirements laid down in Commission decisions and the composition set out in the SCF Opinion of 4 April 2003. As to its plant sterol/plant stanol content, the ingredient can be stated to meet the specifications as contained in Annexes 2 to Commission Decisions 2004/333/EC – 2004/336/EC.

### *Purity and concentration levels for undesirable compounds*

Cargill Inc. has submitted certificates of analysis proving the purity of the plant sterol ingredient, such as certificates on residual heavy metals and pesticide residues, PAHs, dioxins and PCBs. As to above contaminants, the sterol ingredient can be regarded as being of food grade.

### *The use and nutritional effect of the plant sterol ingredient*

The material contains a description of food products in which Cargill Inc.'s plant sterol ingredient may be used. Cargill Inc. states that it may manufacture or order to be manufactured foods to which the plant sterol ingredient is added, or that it may deliver the ingredient to other manufacturers of foodstuffs.

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<sup>4</sup> Opinion of the Scientific Committee on Food on an application from MultiBene for approval of plant-sterol enriched foods, [http://europa.eu.int/comm/food/fs/scf/out\\_191\\_en.pdf](http://europa.eu.int/comm/food/fs/scf/out_191_en.pdf)



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The plant sterol ingredient concerned is intended for use in groups of foodstuffs mentioned in Commission Decisions 2004/333/EC — 2004/336/EC, such as

- Yellow fat spreads excluding cooking or frying fats and spreads based on butter or other animal fat
- Salad dressings, mayonnaise and spicy sauces (single portions)
- Milk-type drinks, milk-type drinks with fruit and/or cereals, milk-based fruit drinks, fermented milk type products, soy drinks
- Cheese type products

Products with the added plant sterol ingredient produced by Cargill Inc. can be assumed to replace other similar plant-sterol enriched products in the diet, and the use of the products concerned by the application is thus not anticipated to result in additional nutritional concern. As for metabolism, both the plant sterol ingredient and the food matrices correspond to products that are approved to be placed on the market or to products already on the market.

The plant sterol ingredient will be added to single portion packages so that the total daily intake of sterols will not exceed 3g. On the basis of the size of the package, the amount of plant sterols will be set at 1g or 3g/portion. These amounts correspond to those criteria set out in Commission Decisions 2004/333/EC–2004/336/EC. Cargill Inc. states that the labelling of the products concerned is intended to be made in accordance with the conditions laid down in the Commission Regulation (EC) No 608/2004.