COMMISSION DECISION

of 10 January 2008

authorising the placing on the market of rice drinks with added phytosterols/phytostanols as novel food under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2008) 6)

(Only the Finnish and Swedish texts are authentic)

(2008/36/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 12 October 2004 the company Teriaka Ltd. Paulig Group made a request to the competent authorities of Finland to place rice drinks with added phytosterols on the market as a novel food or novel food ingredient.

(2) On 12 January 2005 the competent food assessment body of Finland issued its initial assessment report. In that report it came to the conclusion that the rice drinks with added phytosterols are safe for human consumption.

(3) The Commission forwarded the initial assessment report to all Member States on 31 January 2005.

(4) Within the sixty day-period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections to the marketing of the product were raised in accordance with that provision.

(5) Therefore the European Food Safety Authority (EFSA) was consulted on 28 October 2005.

(6) On 15 February 2006 EFSA adopted the 'Statement of the Scientific Panel on dietetic Products, Nutrition and Allergies on a request from the Commission related to a novel food application on rice drinks with added phytosterols'.

(7) In the statement the panel came to the conclusion that there is no reason to believe that the introduction of rice drinks with added phytosterols/phytostanols will increase the risk of overconsumption of phytosterols.

(8) On the basis of the scientific assessment, it is established that rice drinks with added phytosterols/phytostanols comply with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(9) 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 [2] ensures that consumers receive the information necessary in order to avoid excessive intake of additional phytosterols.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Rice drinks with added phytosterols/phytostanols as specified in the Annex may be placed on the market in the Community as a novel food.

Article 2

1. Rice drinks referred to in Article 1 shall be presented in such a manner that they can be easily divided into portions that contain either a maximum of 3 g (in case of 1 portion/day) or a maximum of 1 g (in case of 3 portions/day) of added phytosterols/phytostanols.

2. The amount of phytosterols/phytostanols added to a container of rice drinks shall not exceed 3 g.

[1] OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

[2] OJ L 97, 1.4.2004, p. 44.

Article 3

This Decision is addressed to Teriaka Ltd., Siirakuja 3, 01490 Vantaa, Finland.

Done at Brussels, 10 January 2008.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Specifications of phytosterols and phytostanols for the addition to rice drinks

Definition:

Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids.

Composition (with GC-FID or equivalent method):

< 80 % β-sitosterol

< 15 % β-sitostanol

< 40 % campesterol

< 5 % campestanol

< 30 % stigmasterol

< 3 % brassicasterol

< 3 % other sterols/stanols

Contamination/Purity (GC-FID or equivalent method)

Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.