

LETTER  
Placing on the market  
of a novel food

Courtesy translation

Control Department  
Product Safety Unit

Pvm/Datum/Date  
18.11.2015

Dnro/Dnr/DNo  
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Ref: Regulation (EC) N:o 258/97, Article 4 (2), first indent

**SUBJECT: PHOSPHATIDYLSERINE MANUFACTURED FROM FISH PHOSPHOLIPIDS  
(ENZYMOTEC LTD)**

This letter is to inform of the results of the review procedure carried out on the novel food application "Phosphatidylserine from Fish Phospholipids" that has been submitted to the Finnish Food Safety Authority Evira pursuant to Articles 4 and 6 of Regulation (EC) No 258/97.

Enzymotec submitted on 1 December 2014 to the Finnish Food Safety Authority Evira an application concerning novel foods pursuant to Regulation (EC) No 258/97. The application concerned phosphatidylserine manufactured from fish phospholipids. Phosphatidylserine is to be used as a food ingredient in conventional foods, food supplements and dietary foods for special medical purposes in the same way as analogous phosphatidylserine extracted from soya, as it is notified to the Commission Decision 2011/513/EU, Annex II.

Evira submitted the application on 19 December 2014 to the Finnish Novel Food Board that carries out food assessments for performance of the initial assessment referred to in Article 6. The Novel Food Board submitted to Evira on 17 June 2015 the initial assessment report, which stated that the phosphatidylserine manufactured from fish phospholipids fulfils the requirements for safety under Article 3(1) of the Novel Food Regulation (EC) No 258/97. The board also noted that as the product may be assumed to be a concern for consumers suffering from fish allergy, the package labelling of foodstuffs that contain phosphatidylserine manufactured from fish must indicate the source of the product, fish, in the way proposed by the applicant.

The Commission forwarded the initial assessment report to all Member States on 3 July 2015. No reasoned objections were presented within the period of 60 days confirmed in Regulation (EC) No 258/97, Article 6(4), on the use of phosphatidylserine manufactured from fish phospholipids as a novel food ingredient as presented in the application. Germany, United Kingdom and Poland raised questions which Enzymotec Ltd has on 19 October 2015 replied in a manner that has satisfied the Member States concerned.

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Taking the above into consideration, phosphatidylserine manufactured from fish phospholipids meets the requirements laid down in Regulation (EC) No 258/97, Article 3(1) when the placing on the market of the oil concerned meets the following criteria:

1) The specifications of the phosphatidylserine product manufactured from fish phospholipids:

Parameter	Phosphatidylserine product (powder)
Moisture	less than 5 %
Phospholipids	not less than 75 %
Phosphatidylserine	not less than 35 %
Glycerides	less than 4 %
Free L-serine	less than 1 %
Tocopherols	less than 0.5 % <sup>1</sup>
Peroxide value	less than 5 meq O <sub>2</sub> /kg

<sup>1</sup>Tocopherols may also be added as antioxidants according to Commission Regulation (EU) No 1129/2011.

2) Phosphatidylserine manufactured from fish phospholipids can be used to supplement the following food categories in the presented maximum level of phosphatidylserine product\* in foods:

Food use	Level of phosphatidylserine in foods (maximum level)
Beverages based on yoghurt	50 mg/100 ml
Powders based on milk powders	3500 mg/100 g (equivalent to 40 mg/100 ml ready to drink)
Foods based on yoghurt	80 mg/100 g
Cereal bars	350 mg/100 g
Chocolate based confectionary	200 mg/100 g
Foods for special medical purposes	in compliance with Commission Directive 1999/21/EC (as amended)
Food supplements	300 mg/daily dose as recommended by the manufacturer

\*Phosphatidylserine product contains a minimum of 35 % of phosphatidylserine.

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3) The labelling of the products shall include a note that the product is derived from fish lecithins ("derived from fish lecithin").

Enzymotec Ltd is authorised to place on the market phosphatidylserine manufactured from fish phospholipids for use as a novel food ingredient according to the above presentations.

A copy of this letter is submitted to the Commission for valid publication and forwarding to all Member States.

Senior Inspector, Head of Section

Pirkko Kostamo

Senior Inspector

Sanna Viljakainen

ENCLOSURE

Initial assessment by Finnish Novel Food Board (courtesy translation)

FOR INFORMATION

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