

LETTER

Replaces letter dated  
8.5.2015

Courtesy translation

Control Department  
Product Safety UnitPvm/Datum/Date  
13.5.2015Dnro/Dnr/DNo  
1698/0935/2014

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

**SUBJECT: PHOSPHOLIPID-RICH OIL EXTRACTED FROM ANTARCTIC KRILL (EUPHASIA SUPERBA) AS A NOVEL FOOD INGREDIENT (ENZYMOTEC LTD)**

This letter is to inform you of the results of the review procedure carried out on the novel food application you have submitted to the Finnish Food Safety Authority Evira pursuant to Articles 4 and 6 of Regulation (EC) No 258/97.

Enzymotec submitted on 20 February 2014 to the Finnish Food Safety Authority Evira an application concerning novel foods pursuant to Regulation (EC) No 258/97. The application concerned the placing on the market of phospholipid-rich oil extracted from Antarctic Krill (*Euphasia superba*) for use in foods and food supplements as a source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). According to the application, the oil is to be used in all the food categories and use concentrations for which equivalent oils rich in EPA and DHA derived from algae or krill have been approved for use in the EU. The application further requested that the permitted daily use level in food supplements be increased to a total combined level of 3000 mg of EPA and DHA.

Evira submitted the application on 6 March 2014 to the Finnish Novel Food Board that carries out food assessments for performance of the initial assessment referred to in Article 6. The Board requested the applicant to provide further information concerning the specification and microbiological quality of the product as well as the assessed intake of phospholipids and nutritional impacts. The applicant submitted the requested further details on 30 June 2014.

The Novel Food Board submitted to Evira on 30 October 2014 the initial assessment report, which stated that the phospholipid-rich crustacean krill oil fulfils the requirements for safety under Article 3(1) of the Novel Food Regulation (EC) No 258/97. The

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Board considered it important that the foods containing the product derived from krill are labelled to show their potential allergenicity in line with the requirements of Regulation (EU) 1169/2011 on the provision of food information to consumers.

The Commission forwarded the initial assessment report to all Member States on 3 December 2014. No reasoned objections were presented within the period of 60 days confirmed in Regulation (EC) No 258/97, Article 6(4), by the Commission or the Member States on the use as a novel food ingredient of Enzymotec Ltd's phospholipid-rich oil produced from Antarctic Krill (*Euphausia superba*) as presented in the application. You have on 1 April 2015 provided to the comments made by the Member States (Germany, Hungary, United Kingdom, Ireland) replies in a manner that has satisfied the Member States concerned.

Based on the initial assessment, it is confirmed that the application concerning phospholipid-rich oil produced from Antarctic Krill (*Euphausia superba*) 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) Phospholipid-rich crustacean krill oil meets the following specifications:

Parameter	Phospholipid-rich oil
Saponification value	Not more than 230 mg KOH/g
Peroxide value (PV)	Not more than 0.5 meq O <sub>2</sub> /kg
Moisture and volatiles	Not more than 0.9 % w/w
Phospholipids	Not less than 60 % w/w
Trans fatty acids	Not more than 1 %
EPA (eicosapentaenoic acid)	Not less than 9 % w/w
DHA (docosahexaenoic acid)	Not less than 5 % w/w

2) The labelling of products containing phospholipid-rich crustacean krill oil shall include the designation "lipid extract from the crustacean Antarctic Krill (*Euphausia superba*)".

3) Phospholipid-rich crustacean krill oil can be used to supplement the following food categories in the presented maximum combined DHA + EPA contents:

Food category	Maximum EPA+DHA content
Bakery products (breads, bread rolls) including sweet biscuits	200 mg/100 g
Breakfast cereals	500 mg/100 g
Nutrition bars (muesli, cereal bars)	500 mg/100 g

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Cooking fats	360 mg/100 g
Dairy products except milk-based drinks (incl. Yoghurts, unripened cheese/fromage frais)	200 mg/100 g
Dairy analogues except drinks	200 mg/100 g
Cheeses and cheese analogues	600 mg/100 g
Non-alcoholic beverages, incl. milk-based drinks	80 mg/100 ml
Spreadable fats and dressings	600 mg/100 g
Food supplements - general population - products intended for pregnant and lactating women	3000 mg/daily dose 450 mg/daily dose
Dietary foods for special medicinal purposes	According to the special dietary requirements of persons for whom the products are intended.
Food intended for use in energy restricted diets for weight restriction	250 mg/meal replacement
Other foods for particular nutritional uses as defined by Directive 2009/39/EC excluding infant and follow-on formula	200 mg/100 g

Enzymotec Ltd is authorised to place on the market phospholipid-rich crustacean krill oil 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

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ENCLOSURE

Initial assessment by Finnish Novel Food Board

FOR INFORMATION

European Commission, Sirkku Heinimaa  
Ministry of Agriculture and Forestry of Finland/Novel Food Board,  
Leena Mannonen  
Intertek Scientific Regulatory Consultancy, Danika Martyn and Nigel  
Baldwin