

LETTER

Control Department
Product Safety UnitPvm/Datum/Date
2.2.2012Dnro/Dnr/DNo
1596/0935/2011RNI CONSEIL
Ms Carole Kohler
2 square Lafayette
49000 Angers
FRANCE

On behalf of Neptune Technologies & Bioressources Inc (Canada)

Ref.: Regulation (EC) N:o 258/97, Article 4, Paragraph 2, first list point

MATTER: EXTENSION OF USES OF OIL (NEPTUNE KRILL OIL (NKO®)) MANUFACTURED FROM ANTARCTIC KRILL (EUPHASIA SUPERBA)

The purpose of this letter is to inform you of the outcome of the review procedure conducted in compliance with Articles 4 and 6 of Regulation (EC) No 258/97 regarding the request you have submitted to Finnish Food Safety Authority Evira for the extension of the uses of NKO[®] oil manufactured from Antarctic Krill (*Euphasia superba*):

RNI CONSEIL submitted on 31 January 2011 on behalf of Neptune Technologies & Bioresources Inc. to Finnish Food Safety Authority Evira a novel food request as referred to in Regulation (EC) No 258/97. The request pertained to the extension of the uses of the oil (NKO[®]) extracted from Antarctic Krill (*Euphausia superba*) to bakery products, nutrition bars, non-alcoholic beverages as well as milk-based drinks and dairy analogue drinks. A request was also made to increase the maximum use level of the oil for food supplements. Evira forwarded the request for the initial assessment referred to in Article 6 to the Novel Foods Board that carries out food assessments.

The Finnish Novel Food Board issued on 5 May 2011 to Evira an initial assessment report, which concluded that the extension of the uses of the NKO[®] oil to bakery products, nutrition bars and non-alcoholic beverages, including milk-based drinks and dairy analogue drinks, fulfils the requirements laid down regarding safety in Paragraph 1 of Article 3 of Regulation (EC) No 258/97. The Board further concluded that an increase of the level of NKO[®] oil for food supplements to the extent that the total daily use level of Eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) rises to 250 mg/day would fulfil the requirements of the Regulation.

The Commission sent the initial assessment report to all the member states.

No reasoned objections to the extension of the uses of the NKO[®] oil as presented in the request were received from the Commission or member states within the period of 60 days laid down in Paragraph 4 of Article 6 of Regulation (EC) No 258/97.

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The comments made by the member states have been forwarded to you for information and you have on 27 January 2012 provided your replies to them.

It is confirmed on the basis of the initial assessment report that the request for the extension of the uses of NKO[®] oil fulfils the requirements laid down in Paragraph 1 of Article 3 of Regulation (EC) No 258/97, provided the placing of this oil on the market fulfils the following requirements:

- 1) NKO[®] oil meets the requirements laid down in Annex I to Commission Decision 2009/752/EY¹ regarding composition.
- 2) The labelling of products containing NKO[®] oil shall display the designation "lipid extract from the crustacean Antarctic Krill (*Euphausia superba*)".
- 3) In addition to what is presented in Annex II to Commission Decision 2009/752/EC, the uses of NKO[®] oil can be extended to the following product groups:

Product group	Maximum use level of DHA and EPA
Bakery products (breads and rolls)	200 mg / 100g
Nutrition bars	500 mg / 100g
Non-alcoholic beverages Milk-based drinks Dairy analogue drinks	60 mg / 100 ml
Food supplements	250 mg per daily dose recommended by manufacturer

Neptune Technologies & Bioresources Inc. can on the basis of the aforesaid extend the uses of the lipid extract from Antarctic Krill (*Euphausia superba*) referred to in Commission Decision 2009/752/EC previously adopted by the Commission on request of the Company.

This letter will be published on the web site of Evira. A copy of the letter will be submitted to the Commission for forwarding to all the member states and for appropriate publication.

Senior Officer, Head of Section

Pirkko Kostamo

Senior Office

Sanna Viljakainen

¹ Commission Decision authorising the placing on the market of a lipid extract from Antarctic Krill (*Euphausia superba*) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. EUVL L 268, 13.10.2009, pp. 33-34.