COMMISSION IMPLEMENTING DECISION (EU) 2016/598
of 14 April 2016

authorising an extension of use of 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

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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) Commission Decision 2009/752/EC (2) authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of lipid extract from Antarctic Krill (Euphausia superba) as a novel food ingredient to be used in certain foods and foodstuffs.

(2) On 11 December 2009, the company Aker BioMarine Antarctic AS notified the Commission about the intention to place on the market a lipid extract from Antarctic Krill (Euphausia superba) based on an opinion by the competent food assessment body of Finland on its substantial equivalence to a lipid extract from Antarctic Krill (Euphausia superba) authorised by Decision 2009/752/EC.

(3) On 15 September 2014, the company Aker BioMarine Antarctic AS made a request to the competent authorities of Ireland for extension of uses of lipid extract from Antarctic Krill (Euphausia superba) as a novel food ingredient.

(4) On 23 December 2014, the competent food assessment body of Ireland issued its initial assessment report. In that report, it came to the conclusion that the extension of uses of lipid extract from Antarctic Krill (Euphausia superba) meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(5) On 22 January 2015, the Commission forwarded the initial assessment report to the other Member States.

(6) Reasoned objections were raised within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97. The applicant consequently modified the request concerning the food categories proposed. This change and additional explanations by the applicant alleviated the concerns to the satisfaction of the Member States and the Commission.

(7) Directive 2002/46/EC of the European Parliament and of the Council (3) lays down requirements for food supplements. The use of lipid extract from Antarctic Krill (Euphausia superba) should be authorised without prejudice to the requirements of that legislation.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Lipid extract from Antarctic Krill (Euphausia superba) as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses defined and at the maximum levels established in Annex II without prejudice to the specific provisions of Directive 2002/46/EC.

Article 2

The designation of a lipid extract from Antarctic Krill (*Euphausia superba*) authorised by this Decision on the labelling of the foodstuffs containing it shall be ‘lipid extract from the crustacean Antarctic Krill (*Euphausia superba*)’.

Article 3

This Decision is addressed to Aker BioMarine Antarctic AS, PO Box 496, NO-1327 Lysaker, Norway.

Done at Brussels, 14 April 2016.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission
ANNEX I

Specification of a lipid extract from Antarctic Krill (Euphausia superba)

Description: To produce lipid extract from Antarctic Krill (Euphausia superba), milled Antarctic Krill is subjected to an extraction with ethanol. Proteins and krill material are removed from the lipid extract by filtration. The ethanol and residual water are removed by evaporation.

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saponification value</td>
<td>Not more than 185 mg KOH/g</td>
</tr>
<tr>
<td>Peroxide value (PV)</td>
<td>Not more than 2 meq O₂/kg oil</td>
</tr>
<tr>
<td>Moisture and volatiles</td>
<td>Not more than 0.6 (%)</td>
</tr>
<tr>
<td>Phospholipids</td>
<td>Not less than 35 % w/w</td>
</tr>
<tr>
<td>Trans-fatty acids</td>
<td>Not more than 1 % w/w</td>
</tr>
<tr>
<td>EPA (eicosapentaenoic acid)</td>
<td>Not less than 15 % of total fatty acids</td>
</tr>
<tr>
<td>DHA (docosahexaenoic acid)</td>
<td>Not less than 7 % of total fatty acids</td>
</tr>
</tbody>
</table>

(1) Expressed as water activity at 25 °C.

ANNEX II

Authorised uses of a lipid extract from Antarctic Krill (Euphausia superba)

<table>
<thead>
<tr>
<th>Food category</th>
<th>Maximum content of combined DHA and EPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food supplements as defined in Directive 2002/46/EC.</td>
<td>3 g per day for general population</td>
</tr>
<tr>
<td></td>
<td>450 mg per day for pregnant and lactating women</td>
</tr>
</tbody>
</table>

Note: All food products containing DHA- and EPA-rich oil from Antarctic Krill should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC).