Commission Implementing Regulation (EU) 2019/108 of 24 January 2019 authorising the change of specifications of the novel food ingredient lipid extract from Antarctic Krill (Euphausia superba) under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/108

of 24 January 2019

authorising the change of specifications of the novel food ingredient lipid extract from Antarctic Krill (*Euphausia superba*) under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001[(1)], and in particular Article 12 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470[(2)] establishing a Union list of authorised novel foods was adopted.

(3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on the updating of the Union list.

(4) Commission Decision 2009/752/EC[(3)] authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council[(4)], 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. In that Decision, the maximum level of phospholipids was established at 50 %.

(5) Commission Implementing Decision (EU) 2016/598[(5)] authorised, in accordance with Regulation (EC) No 258/97, an extension of use of lipid extract from Antarctic Krill (*Euphausia superba*) as a novel food ingredient to be used in food supplements. In that Decision, the minimum level of phospholipid was established at 35 %.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/108. (See end of Document for details)*

(6) The novel food ingredient 'Antarctic Krill oil rich in phospholipids from *Euphausia superba*' was authorised to be used in certain food categories by the Finnish competent authorities[(6)]. The minimum level of phospholipids was established at 60 %.

(7) The conditions of use for both 'Antarctic Krill oil from *Euphausia superba*' and 'Antarctic Krill oil rich in phospholipids from *Euphausia superba*' are identical and are based on the maximum levels of combined eicosapentaenoic acid and docosahexaenoic acid. However, they differ in the phospholipid content, which is established at a range of 35 % to 50 % for 'Antarctic Krill oil from *Euphausia superba*' and a minimum of 60 % for 'Antarctic Krill oil rich in phospholipids from *Euphausia superba*'. Therefore, the current authorisations do not cover the range of phospholipids in 'Antarctic Krill oil from *Euphausia superba*' between 50 % and 60 %.

(8) On 29 August 2018, the company Aker BioMarine A/S ('the Applicant') made a request to the Commission to change the specifications of the novel food Antarctic Krill oil from *Euphausia superba* within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The applicant requested to increase the maximum phospholipid content from 50 % to less than 60 % thereby covering the range in the phospholipid concentration, which is not currently authorised.

(9) The Commission considers that a safety evaluation of the current application by the European Food Safety Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary on the basis of the fact that if certain levels of a given novel food component have been assessed and determined to be safe, then lower levels of the same component would also be safe. The authorised maximum levels of combined eicosapentaenoic acid and docosahexaenoic acid for both 'Antarctic Krill oil from *Euphausia superba*' and 'Antarctic Krill oil rich in phospholipids from *Euphausia superba*' under Implementing Regulation (EU) 2017/2470 are the same. The proposed change in the phospholipid levels in the specification of the 'Antarctic Krill oil from *Euphausia superba*' does not change the safety considerations that supported its authorisation and the authorisation of the 'Antarctic Krill oil rich in phospholipids from *Euphausia superba*' which concluded that phospholipid levels above and below 60 % are both safe.

(10) The proposed change to the specifications in the phospholipid content will address the gap in phospholipid content between 'Antarctic Krill oil from *Euphausia superba*' and 'Antarctic Krill oil rich in phospholipids from *Euphausia superba*'. Therefore, it is appropriate to amend the specifications of the novel food Antarctic Krill oil from *Euphausia superba* at the proposed level for phospholipids.

(11) The information provided in the application gives sufficient grounds to establish that the proposed changes to the specifications of the novel food ingredient 'Antarctic Krill oil from *Euphausia superba*' comply with Article 12(2) of Regulation (EU) 2015/2283.

(12) Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/108. (See end of Document for details)*

HAS ADOPTED THIS REGULATION:

Article 1

The entry in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283 referring to the novel food 'Antarctic Krill oil from *Euphausia superba*' shall be amended as specified in the Annex to this Regulation.

Article 2

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 January 2019.

For the Commission

The President

Jean-Claude JUNCKER