

Application to Amend the Specifications of the Novel Food Ingredient Antarctic Krill Oil from *Euphausia superba* in the European Union

Executive Summary

The European Union (EU) Union List of Novel foods established under *Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017*, as amended includes 2 entries for krill oils:

- Antarctic Krill oil from *Euphausia superba* (*E. superba*); and
- Antarctic Krill oil rich in phospholipids from *E. superba*.

The conditions of use are identical for both entries and are based on the maximum levels of combined eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA); however, there are 2 key differences in the specifications: (1) the Description/Definition for 'Antarctic Krill oil rich in phospholipids from *E. superba*' refers to repeated solvent washings to increase the phospholipid content, while that for 'Antarctic Krill oil from *E. superba*' does not, and (2) the phospholipid content, which is established at 35 to 50% for 'Antarctic Krill oil from *E. superba*' and $\geq 60\%$ for 'Antarctic Krill oil rich in phospholipids from *E. superba*'. **Notably, there is a gap between the 2 ingredients in permitted levels of phospholipids.**

As such, Aker BioMarine A/S ("Aker" hereafter) is submitting this application to request a change in the specifications for 'Antarctic Krill oil from *E. superba*'. Specifically, Aker is **requesting that the phospholipids content for this entry be amended from '35 to 50%' to '35 to 59%'**. This amendment will cover the range of phospholipids possible based on the permitted production process and aligns with the limits established in the United States Pharmacopeia (USP) for phospholipids in 'krill oil'.

Data is provided for Aker's Superba™ Boost krill oil (a representative product) which aligns with the requested specification change for phospholipids (*i.e.*, between 50 and 60% w/w), and **meets all other specification parameters established for Antarctic Krill oil from *E. superba***. Analytical data for 5 to 6 batches have been provided for other compositional parameters, and chemical and microbiological contaminants to demonstrate that the levels in Superba™ Boost krill oil **are aligned with the 2 authorised forms of krill oil, and thus, the levels of individual components, or potential contaminants do not pose a concern for safety.**

Superba™ Boost krill oil is manufactured **consistent with the production process detailed in the Union List** for 'Antarctic Krill oil from *E. superba*'. The 2 production processes are identical with the exception of the concentration of phospholipids through the removal of neutral lipids.

The proposed change to the specifications in phospholipid content will not alter the conditions under which Antarctic krill oil from *E. superba* may be used. The maximum use levels for 'Antarctic Krill oil from *E. superba*' are established on the basis of the combined EPA and DHA content. The higher level of EPA and DHA in Superba™ Boost krill oil, means that lower levels of the oil will be added to foods when compared to the approved forms. **As such, there is no safety concern associated with the anticipated intake of this oil as an alternative to either of the approved forms. We would therefore respectfully suggest that there is no need for a new scientific evaluation by the European Food Safety Authority on this occasion as it is a risk management decision only.**