Safety Assessment of Superba™ Krill Oil (Extension of use)

Name of Applicant: Aker BioMarine Antartic AS

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Novel Food Classification: 1.2.(e)

Introduction

A novel food application for the extension of the possible uses of Superba™ krill oil was submitted to the Food Safety Authority of Ireland (FSAI) by Aker BioMarine Antartic AS from Norway in accordance with *Article 4* of the novel food Regulation (EC) No. 258/97. The application was accepted by the FSAI on September 12th, 2014.

The novel ingredient (Superba™ krill oil) is a source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Superba™ krill oil is already on the EU market since 2009 based on an opinion by the Finnish authorities on its substantial equivalence to Neptune krill oil which was initially assessed by the UK authorities and EFSA followed by an authorisation by Commission Decision 2009/752/EC. The applicant wishes to extend the use of their krill oil to align the DHA and EPA use from Superba™ krill oil with that from a microalgal source which was authorised through Commission Implementing Decision 2014/463/EC following a positive EFSA safety opinion.

Though already on the EU market, Superba™ krill oil is considered novel for the purpose of this application due to the extension of uses requested by the applicant. It is classed by the applicant as novel in accordance with *Article 1.2(e)* of the novel food Regulation (EC) No 259/97; "Foods and food ingredients consisting of, or isolated from, plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe use". The application dossier was prepared pursuant to Commission Recommendation 97/618/EC and in order to assess wholesomeness, Superba™ krill oil was considered most appropriately to fall into Class 2.2 "Complex novel food from non-GM source; the source of the NF has no history of food use in the Community".

Safety Assessment

The overall safety of Superba™ krill oil currently on the EU market is not addressed here as the composition of the krill oil and the production process used will not change. The toxicological profile of the krill oil does not change significantly as a result of the extended uses proposed.

The main aspects of this novel food application that are addressed from a safety perspective relate to potential increase in overall intake levels of DHA and EPA as well as the consumption levels of astaxanthin. The proposed extension of use includes new food groups to which Superba^{TM} krill oil would be added, as well as an increase of levels in some existing food groups. The new food groups (sweet biscuits and cooking fats) are already allowed to contain microalgal DHA and EPA rich oil and therefore Superba^{TM} krill oil will simply represent an alternative source of DHA and EPA rich oil which should not result in an increase in overall intake.

The applicant wishes to increase the DHA and EPA levels available from Superba^{TM} krill oil in supplements to 3g/daily dose and to 450 mg/daily dose for pregnant and lactating women. Increases are also requested in foods for energy restricted diets for weight reduction (to 250 mg/100g) and non-alcoholic beverages (to 80 mg/100g). The applicant concludes that while these alterations will increase EPA and DHA availability from Superba^{TM} krill oil, it should not result in a significant overall increase in DHA and EPA intake. Potential health claims are put forward by the applicant as reasons for requesting some of the extensions of use but health claims are not considered in this report.

The applicant provides intake estimates for EPA and DHA from the novel ingredient based on UK NDNS data and concludes that the 5g/day tolerable upper intake level recommended by EFSA will not be exceeded or even reached if this extension of use is authorised. The applicant notes that its proposed increase of DHA and EPA in high dose supplements to 3g/day is in line with the EFSA opinion in 2014 that supplements providing 3g/day of DHA and EPA are safe in terms of the potential to exceed the tolerable upper intake level of 5g/day.

The other safety issue addressed is the potential increase in astaxanthin intake as a result of its content in Superba^{TM} krill oil. The applicant states that the astaxanthin level in Superba^{TM} krill oil is similar to that in Neptune krill oil which was previously assessed by EFSA in 2009. However, EFSA published an opinion in 2014 on the safety of astaxanthin rich supplements that were the subject of a novel food application. In that EFSA opinion, the NDA panel concluded that the safety of the novel supplements for which a maximum daily intake of 4 mg of astaxanthin was recommended had not been established. This conclusion was reached on the basis of an ADI of 0.034 mg/kg bw (2.38 mg per person per day for a 70 kg adult) for astaxanthin that had been established previously by the FEEDAP panel of EFSA. The applicant calculates that the intake of astaxanthin from the high dose (3g/day DHA and EPA) supplements containing Superba^{TM} krill oil would equate to 2 mg/daily dose which is significantly less than the EFSA ADI. In addition, the applicant specifies that achieving supplements with 3g/day dosage will be difficult from a practical perspective and that most supplements will deliver in the region of 500mg/day of DHA and EPA which would deliver approximately 0.34 mg/day of astaxanthin. It is difficult to envisage a scenario where intakes of astaxanthin from foods supplemented with Superba^{TM} krill oil would pose a safety risk in terms of exceeding the ADI for astaxanthin. The applicant notes that a portion of some fish can deliver a significant level of naturally occurring astaxanthin.

Conclusions

Though its safety has not previously been assessed under novel food legislation, Superba^{TM} krill oil has legitimately been on the EU market in certain food categories and at permitted levels since 2009 without any evidence of negative health consequences. The applicant is requesting an extension to the currently permitted uses and use levels of this krill oil and therefore a full novel food application is required.

The applicant has identified the additional food types in which they wish to market the food as well as the intended use levels. The highest intended use is for high dose supplements that would deliver 3g/daily dose of DHA and EPA, though most consumers are likely to opt for a 500mg/day dose. The information provided by the applicant does not indicate any safety concerns in regard to the anticipated intake of EPA, DHA or astaxanthin in the context of recent EFSA opinions addressing these components. The novel ingredient is going to provide an alternative source of DHA, EPA and astaxanthin and therefore should not significantly alter overall intakes.

Recommendation

The Food Safety Authority of Ireland has not identified any specific safety concerns associated with the proposed extension of use of Superba^{TM} krill oil in the specified food groups and at the intended use levels. Therefore, the extension of use of Superba^{TM} krill oil meets the criteria for novel food set out in *Article 3.1.* of the novel food Regulation (EC) No 258/97.