

## ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

## ANTARCTIC KRILL OIL

## Issue

Members are asked whether the applicant company's response to the UK's comments and objections to the marketing of Antarctic krill oil as a novel food ingredient provide the necessary reassurance that the product is safe and can be authorised as a novel food ingredient.

## Background

1. Antarctic krill oil is a whole lipid extract of the crustacean *Euphasia superba* (Antarctic Krill) and is an opaque reddish oil with an intense seafood odour. The applicant intends to market Antarctic krill oil as a novel food ingredient (NI), for use in a number of food categories as a source of omega-3 fatty acids and in food supplements.
2. On 20 February 2007, the European Commission forwarded to Member States the Finnish Competent Authority (CA)'s initial opinion on the application, which had been submitted by Neptune Technologies and Bioresources Inc. made under Article 4(1) of Regulation (EC) No 258/97, for the authorisation of Antarctic krill oil as a novel food ingredient.
3. The Committee considered the application and the Finnish initial opinion at the March 2007 meeting (ACNFP/81/2). Members were unable to agree with the positive opinion of the Finnish CA and concluded that additional information is required before the assessment of the safety of the NI can be concluded. Members raised a number of comments and objections which formed the basis of the UK response to this application (**Appendix A**). These related to:
  - (i) **Intake:** Members were concerned that no estimates of consumption by children had been provided. Children would be, by body weight, the highest consumers of the NI.
  - (ii) **Labelling:** Members queried the proposed labelling regime (coagulopathy advice, vegetarian labelling)
  - (iii) **Allergy.** Members offered an alternative labelling suggestion, and requested information on the likely levels of allergenic proteins.
  - (iv) **Environmental impact:** Members commented on the likely impact of increased fishing.
  - (v) **Food Hygiene:** Members highlighted the requirement to additionally comply with Regulation (EC) 853/2004.
  - (vi) **History of consumption:** References to history of consumption are limited and insufficient to demonstrate the safety of the oil

4. Seven other Member States also commented on, or objected to the Finnish initial opinion. The applicant has sought to respond to all Member States' concerns (**Appendix B**).

### **Applicant's response**

5. The applicant's responses to the Committee's concerns are set summarised below.

#### **(i) Intakes**

Appendix B p.18-19

6. The applicant has amended the proposed food categories and maximum levels of addition so that the resulting levels of DHA and EPA would harmonise with those approved for DHA-rich oil from the microalgae *Schizochytrium sp.* (Commission Decision 2003/427/EC of 5 June 2003). The applicant has provided revised proposed uses in Table IX.2-1 where combined maximum DHA and EPA levels replace the maximum DHA levels in the DHA rich oil.
7. The applicant states that the recommended daily intakes for DHA and EPA fish and/or fish oil apply to the whole population and are not defined on a per kg/bodyweight basis. The applicant highlights the UK Scientific Advisory Committee on Nutrition recommends an intake of 450 mg of DHA/EPA per day (1 portion of oily and 1 portion of white fish per week) (SACN, 2004). The applicant estimates for food products with a specified maximum level per portion of 200 mg combined DHA and EPA per day, a child would have to consume 15 daily portions to reach the 3 g per day upper safe limit. If 100 g portions are assumed, then this would represent 1.5 kg of food, or twice the total daily food consumption of a small child.
8. The NI is intended to be used as an alternative to DHA-rich oil or fish oil in existing DHA/EPA fortified food products and food supplement products. Food supplements will be labelled in accordance with Directive 2002/46/EC which includes an indication of the portion of the product recommended for daily consumption and a warning not to exceed the stated recommended daily dose. The applicant is of the view that the labelling criteria provide additional risk-management procedures so as to ensure that excessive consumption of DHA/EPA from multiple sources, including the NI, would be unlikely to occur.

#### **(ii) Labelling**

Appendix B p. 21

9. Members may wish to note that another Member State was of the view that the applicant's proposed warning addressed to people suffering from coagulopathy or under anti-coagulant treatment was excessive, as the FDA identified the lowest dose of omega-3 fatty acids having a detectable effect to be 3 g per day in a healthy subject: One portion of a food containing the NI in the dose proposed by the applicant provides only 0.139 g of omega-3 fatty acids.

10. The applicant confirms that intakes from food uses are much lower, and less likely to exceed 3 g per day, than intakes from food supplements and therefore only proposes to label food supplements with the warning that those suffering coagulotherapy or under anti-coagulant treatment should speak to their doctors.
11. Regarding the Committee's comment that the product is clearly labelled as being of fish (animal origin) to show that it is not suitable for vegetarians, the applicant proposes to label the NI as being of crustacean (shellfish) origin (see (iii) below).

### **(iii) Allergy**

Appendix B p.25

12. The applicant notes that, according to Directive 2003/89/EC, the NI is required to be labelled as being made from crustaceans. The applicant additionally proposes to use the term "shellfish" as follows: "contains oil made from crustaceans (shellfish – Antarctic Krill)"
13. The applicant states that there is no established threshold value for crustacean allergens and so quantification of the tropomyosin content compared to that of shellfish is of minimal value. Three production batches of the NI were analysed for the possible presence of shellfish allergens. A shellfish allergen assay (ELISA) was performed on the protein extract. The results were negative for tropomyosin or potentially allergenic fragments in the three batches of NI analysed (Table 1.4-1). An independent laboratory also tested three production batches of the NI for shellfish allergens using the alternative PCR methodology. No allergen was detected in any of the batches.
14. The applicant is of the view that the clear labelling that has been proposed, as mandated by Directive 2003/89/EC, is the best risk management measure for the NI and highlights that this Directive makes no special provision for children in the labelling for any allergen, including peanuts.

### **(iv) Environmental Impact**

Appendix B p.51

15. The applicant states that the Antarctic krill fishing industry is controlled by the Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR, 2007), which aims to protect the Antarctic ecosystem from the consequences of overexploited marine animals such as great whales. The population of krill in the Antarctic is estimated at around 150 million tonnes and currently the worldwide harvest is less than 0.1% of the allowed fishing quota of 6 million tonnes. At full capacity the applicant anticipates that they will require only 1,000 tonnes of krill per annum.

### **(v) Hygiene regulation for foods of animal origin**

Appendix B p.50

16. The applicant has provided a site licence (Appendix 6) for the manufacture of the NI issued by the Canadian Ministry of Health under the Authority of Section 22 of

the Canadian Natural Health Product Regulations. It has also provided a Certificate of Registration of a Fish Processing Establishment issued by the Canadian Food Inspection Agency (Appendix 6). The applicant notes that it is registered with the EU Number 5111 as an approved Third Country establishment for the production of fish and fishery products (CIRCA, 2007).

17. The applicant states that the NI intended for the European Market is currently supplied by New Zealand and South Korean companies and has provided the full list of boats from these countries which are currently approved for the import of fishery products in the EU in Appendix 7.

#### **(vi) History of consumption of krill**

Appendix B p.22

18. The applicant states that the history of consumption when consumption of krill began in the 1970s in Japan, Russia and the Ukraine, and more recently in France, Poland and the US. The applicant presents the annual tonnage of harvested krill (for all uses) from 1980 to 2003 in Table XIII.4-2. In 1989 it was reported that more than 50% of the world's annual krill catch was being directed, either as tinned or frozen krill meat, for human consumption.
19. The applicant states that the NI has been available for purchase in the US since October 2003 and in Japan, Korea, Singapore, and Hong Kong since December 2004. The recommended intake of the NI in North America and Asia is 1-2 softgel capsules/day, with each softgel containing 500 mg of the NI. Over the last 4.2 years 55,000 kilograms of Neptune Krill Oil has been sold, which is equivalent to approximately 110 million individual softgel capsules (of 500 mg). This equates to 151,000 years of consumption, or 36,000 people consuming 2 capsules per day continuously for 4.2 years<sup>1</sup>. Throughout this time no serious adverse events have been reported.
20. The applicant has provided in Table XIII.4-3 a summary of the results of the analysis of lipid classes, fatty acids and sterols on samples of fish and seafood and compositional data representing the average values from the analysis of three production lots of the NI in order to compare the content with common marine species. The applicant states that the data suggest that the consumption of the NI provides similar nutritional value as fish that have been commonly consumed around the world. The applicant is of the view that taking into account the history of consumption of krill oil since 2002, supported by sales data and the fact that phospholipids are commonly consumed on a daily basis in the form of food of marine origin and dietary supplements, it can be concluded that the key components of the NI have been traditionally consumed and do not pose a safety concern.

#### **Committee Action Sought**

21. The Committee is asked whether the applicant's responses are sufficient to adequately address their earlier comments and objections.

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<sup>1</sup> The figures in this and the preceding sentence replace the incorrect figures given in Appendix B

22. Members are also asked whether there are any other issues that they wish to comment on arising from the applicant's response to points raised by other Member States.

23. The Committee's comments will be used to inform the Agency's position in future discussions regarding this novel ingredient at meetings of the Standing Committee on the Food Chain and Animal Health.

**Secretariat  
September 2007**

Appendices attached:

Appendix A: Letter to the Commission with the ACNFP's comments on the Finnish Competent Authority's Initial opinion

Appendix B: Applicant's response of 6<sup>th</sup> August 2007 (Restricted)



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**Letter to the Commission with the ACNFP's comments on the Finnish  
Competent Authority's Initial opinion.**

**Secretariat  
September 2007**



**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**

**RESTRICTED**

**Applicant's response of 6th August 2007**

**Secretariat  
September 2007**