

Safety Assessment on Krill Protein Hydrolysate Used as an Alternative Source of Protein in Food Supplements and Functional Protein Food and Drinks (RP1290)

Food Standards Agency¹, Food Standards Scotland²

¹ Regulated Products Risk Assessment, Food Standards Agency, UK, ² Risk Assessment, Food Standards Scotland, UK

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FSA Research and Evidence

An application was submitted to the Food Standards Agency and Food Standards Scotland in September 2021 from Aker BioMarine (“the applicant”) for the authorisation of Krill Protein Hydrolysate, as a novel food.

The novel food is a partially hydrolysed protein isolate derived from Antarctic krill (*Euphausia superba*) and is composed of no less than 85% protein on an as-is basis and $\geq 90\%$ protein on a dry matter basis. Krill protein hydrolysate is intended for use as an alternative source of protein in food supplements as defined in the Food Supplements (England, Scotland and Wales) Regulations 2003 for the general population, excluding infants, young children (toddlers) aged up to 3 years and pregnant or lactating women. The novel food is also intended to be used within other food categories such as formulations of functional protein foods and drinks, including bakery wares, isotonic sport drinks and single meal replacements.

To support the Food Standards Agency (FSA) and Food Standard Scotland (FSS) in evaluating the dossier, the Advisory Committee on Novel Foods and Processes (ACNFP) was asked to review the dossier and supplementary information provided by the applicant. The Committee did not consider any potential health benefits or claims arising from the consumption of the novel food, as the sole focus of the assessment is to ensure the food is safe and is not putting consumers at a nutritional disadvantage.

The Committee concluded that the applicant had provided sufficient information to assure that the novel food, Krill Protein Hydrolysate, was safe under the proposed conditions of use. The anticipated intake levels and the proposed uses of the novel food were not nutritionally disadvantageous.

This safety assessment represents the opinion of the FSA and FSS.

This is a joint FSA and FSS publication.



1. Introduction

The ACNFP assessed the food safety risks of Krill Protein Hydrolysate under the proposed conditions of use and its production in line with Article 7 of assimilated Commission Implementing Regulation (EU) 2017/2469. The regulatory framework and the guidance put in place by EFSA for full novel food applications has formed the basis and structure for the assessment (EFSA, 2016).

In September 2021, Aker BioMarine (“the applicant”) submitted a full novel food application for the authorisation of Krill Protein Hydrolysate. The novel food is a partially hydrolysed protein isolate derived from Antarctic krill (*Euphausia superba*). The final consumer product intended for market is a white to cream coloured powder containing not less than 85 g/100 g of protein on an “as-is” basis, along with low levels of residual fat (not more than 1 g/100 g), ash (not more than 7 g/100 g) and moisture (not more than 10 g/100 g).

The applicant intends to market the product as an alternative protein source to plant and animal-based protein in foods and food supplements. The novel food is also intended to be used within other food categories such as formulations of functional protein foods and drinks, including bakery wares, isotonic sport drinks and single meal replacements.

Following the review by the ACNFP in February and June 2023, further information was sought on the production process and toxicology. The final advice from the Committee was agreed at the 169th meeting of the ACNFP. This Committee advice document (CAD) outlines the conclusions of the FSA and FSS on the safety of Krill Protein Hydrolysate as a novel food.

Table 1. Table showing products included in this assessment

Title	Product type	Intended use/s	Intended dose/ intake
Fine Bakery Wares	Novel food	Cereal Bars	5 g/100 g or

Title	Product type	Intended use/s	Intended dose/ intake
			100 mL
Protein products, excluding products covered in category 1.8	Novel food	Isolated proteins and other protein products	90 g/100 g or 100 mL
Flavoured drinks	Novel food	Functional drinks and isotonic sport drinks	8 g/100 g or 100 mL 8 g/100 g or 100 mL
Water, including natural mineral water as defined in Directive 2009/54/EC and spring water and all other bottled or packaged waters	Novel food	Fortified bottled water	5 g/100 g or 100 mL
Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)	Novel food	Single meal replacement for weight reduction	60 g/100 g or 100 mL
Krill Protein Hydrolysate	Novel food	Supplements	25 g/day

2. Assessment

2.1. Identity of the Novel Food

The novel food is sourced from the harvesting of Antarctic krill (*E. superba*) exclusively from the Southern Ocean (Antarctic Ocean) by vessels owned and operated by Aker Krill company. Information on the taxonomy of *E. superba* and the origin of the source are provided below.

- Kingdom: Eukaryote
- Subkingdom: Animalia
- Subphylum: Arthropoda
- Class: Malacostraca
- Order: Euphausiacea
- Family: Euphausiidae
- Genus: Euphausia
- Species: *Euphausia superba*

The novel food, with the trade name KPH, is a partially hydrolysed (<200 Da to 2 kDa in molecular weight) protein isolate composed of ≥85% protein on a g/100g as-is basis and ≥90% protein on a dry matter basis. The remaining 10-15% consists of moisture, ash and fat.

Prior to treatment with food-grade proteases to form the hydrolysate, Antarctic krill are deshelled and processed to either Antarctic krill meal or partially defatted Antarctic krill meal. Analytical information to support the characterisation of the novel food was provided for 15 batches originating from defatted Antarctic krill meal and 5 batches originating from (full fat) Antarctic krill meal, as detailed in Tables 1 and 2 below.

The data and evidence to characterise the novel food has been adequately provided.

2.2. Production Process

The manufacturing of Krill Protein Hydrolysate is performed in two distinct production stages:

- Manufacture of Antarctic krill meal (full fat and defatted); and
- Hydrolysis of the Antarctic krill meal to produce the protein hydrolysate.

Krill Protein Hydrolysate is a partially hydrolysed protein isolate derived from deshelled whole Antarctic krill (*E. superba*) harvested from the Southern Ocean. The potential risk for by-catch of other species was considered in the context of the allergenicity assessment for the presence of fish allergens. The effectiveness of the management measures is explored in section 2.11 (Allergenicity).

Antarctic krill are processed to either Antarctic krill meal or partially defatted Antarctic Krill meal. The two forms of krill meal are used as raw material for enzymatic hydrolysis with food-grade protease(s) to produce Krill Protein Hydrolysate.

The specifications for each of the two precursors were provided. Appropriate control of the degree of hydrolysis has been confirmed in the hazard analysis and critical control points (HACCP) plan provided by the applicant and discussed below. However, it is recommended that the degree of hydrolysis should be included within the specification to reassure that the product is produced consistently.

All processing aids used in the production process are food grade, have a long history of use for these purposes in the UK and EU, and are supported by relevant authorisations. Krill Protein Hydrolysate is produced in registered facilities in accordance with GMP and a HACCP plan and appropriate quality management systems are in place throughout the production process.

A HACCP certificate has been provided. All controls were concluded to be effectively managed, as demonstrated in the compositional data. This HACCP certificate has been produced in terms of current accepted practice as set out in Commission document 2016/C 278/01.

Following initial review by the Committee, the Committee noted inconsistency in the information on the production process. This, coupled with higher levels of enterococci in the products in the stability test, prompted a deeper consideration of the effectiveness of the temperature and other controls on effectively managing microbial hazards.

Further information received indicated that this was an error in the interpretation of the initial results where a confirmational testing to identify enterococci had not been completed. Changes have been made to support use of the method in future. To provide further reassurance the batches in the stability study will be measured at the next timepoint (t=18 months) to confirm the microbial stability for this parameter.

To demonstrate the effective management of the process, further detail was provided on the effectiveness of the microbial control steps. This was verified with the data outlined in [Table 7](#). The applicant has also considered the issue for possible enterococci activity and has confirmed that the use of bile aesculin agar will be implemented from and including the six-month timepoint of the stability study.

The production process has characterised the potential hazards and the corresponding control measures are appropriate.

2.3. Compositional Information

To verify that the compositional analysis provided was accurate and reliable, certification was provided to demonstrate that the laboratories were accredited to perform these analytical studies. Where an in-house analysis was utilised, full methodology and supporting validation documentation were provided.

The final consumer product intended for market is a white to cream coloured powder containing not less than 85 g/100 g of protein on an as-is basis along with low levels of residual fat (not more than 1 g/100 g), ash (not more than 7 g/100 g) and moisture (not more than 10 g/100 g).

A proximate analysis of the novel food has been provided for 9 representative batches. Five of the nine batches were derived from defatted krill meal, whilst the remaining four batches were derived from the full fat krill meal.

The results show that the novel food is mostly comprised of protein, with small amounts of fat, ash and moisture present. Proximate analysis data for the novel food derived from defatted Antarctic krill are displayed in [Table 2](#). Data for the novel food derived from full-fat Antarctic krill meal are displayed in [Table 3](#).

Table 2. Proximate analysis of the novel food derived from defatted Antarctic krill meal

Parameter	Method	Specification level	Batch 012	Batch 013	Batch 014	Batch 017	Batch 040
Water Activity	ISO 21807: 2004/c Hygrometry	≤0.7	0.14	0.12	0.10	0.07	0.26
Moisture Content/ Humidity (g/100g)	EU 152/ 2009/ Gravimetry	≤10 g/100 g	1.4	3.2	2.4	2.6	4.3
Crude Ash (g/100 g)	EU 152/ 2009/ Gravimetry	≤7 g/100 g	3.9	3.4	2.6	3.8	4.4
Protein DM, (g/ 100 g)	Calculation (adjust for moisture content)	≥85-90 g/ 100 g	93.4	95.7	94.7	95.6	92.7
Protein – as-is basis (g/100 g)	EU 152/ 2009/ Kjeldahl (titrimetry)	≥85-90 g/ 100 g	92.1	92.6	92.4	93.1	88.7
Total Fat (g/100 g)	EU 152/ 2009/ Gravimetry	≤1 g/100 g	<0.4a	0.7	0.5	<0.4a	<0.4a

DM = dry matter; EU = European Union; ISO = International Organization for Standardization; ND = not detected.
a. Below the limit of detection. b. Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed. OJ L 54, 26.2.2009, p. 1–130. Available online: <https://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=CELEX%3A32009R0152&qid=1616099200896> (Current Consolidated Version: 16/11/2020).

Table 3. Proximate analysis of the novel food derived from full fat Antarctic krill meal

Parameter	Method	Batch 025	Batch 030	Batch 033	Batch 036
Water Activity	ISO 21807: 2004/c Hygrometry	0.15	0.09	0.08	0.06
Moisture Content/ Humidity (g/ 100 g)	EU 152/ 2009/ Gravimetry	3.0	2.8	2.7	<0.2a
Crude Ash (g/100 g)	EU 152/ 2009/ Gravimetry	3.8	2.8	2.3	6.5
Protein dry matter (g/100 g)	Calculation (adjust for moisture content)	93.6	97.6	97.2	95.1
Protein – as-is basis (g/100 g)	EU 152/ 2009/	90.8	94.9	94.6	94.9

Parameter	Method	Batch 025	Batch 030	Batch 033	Batch 036
	Kjeldahl (titrimetry)				
Total Fat (g/100 g)	EU 152/2009/Gravimetry	<0.4a	<0.4a	0.4	<0.4a

DM = dry matter; EU = European Union; ISO = International Organization for Standardization; ND = not detected.
a. Below the limit of detection. b. Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed. OJ L 54, 26.2.2009, p. 1–130. Available online: <https://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=CELEX%3A32009R0152&qid=1616099200896> (Current Consolidated Version: 16/11/2020).

The composition data demonstrates that the novel food is consistently the same when manufactured with or without full-fat krill meal as the precursor component. The data demonstrates that Krill Protein Hydrolysate exhibits an acceptable batch-to-batch variation, as seen by the consistent proximate analysis results for both precursor components, which highlight no difference in the novel food or additional food safety concerns.

To understand the degree of hydrolysis of the protein, data was presented on the molecular weight distribution of the protein/peptide components in 7 representative batches of the novel food – 4 derived from defatted Antarctic krill meal and 3 from the full fat Antarctic krill meal. The results are presented in [Table 4](#).

Table 4. Molecular Weight Distribution of Peptides for 8 Representative Batches of Krill Protein Hydrolysate

Molecular Weight	Analytical data (% water soluble peptides) Krill Protein Hydrolysate from Defatted Antarctic Krill Meal					Analytical data (% water soluble peptides) Krill Protein Hydrolysate from Full Fat Antarctic Krill Meal	
	Batch 012	Batch 014	Batch 017	Batch 040	Batch 018	Batch 021	Batch 039
>20 kDa	<0.1a	<0.1a	<0.1a	<0.1a	<0.1a	0.3	<0.1a
15 to 20 kDa	<0.1a	<0.1a	<0.1a	<0.1a	<0.1a	<0.1a	<0.1a
10 to 15 kDa	<0.1a	<0.1a	<0.1a	<0.1a	<0.1a	<0.1a	<0.1a
8 to 10 kDa	<0.1a	<0.1a	<0.1a	<0.1a	<0.1a	<0.1a	<0.1a
6 to 8 kDa	<0.1a	<0.1a	<0.1a	0.1	<0.1a	<0.1a	<0.1a
4 to 6 kDa	0.2	0.2	0.1	0.8	0.2	0.3	0.4
2 to 4 kDa	3.1	3.3	2.6	5.8	2.6	3.4	3.5
1 to 2 kDa	9.9	10.2	8.5	14.8	9.3	10.3	10.5

Molecular Weight	Analytical data (% water soluble peptides) Krill Protein Hydrolysate from Defatted Antarctic Krill Meal					Analytical data (% water soluble peptides) Krill Protein Hydrolysate from Full Fat Antarctic Krill Meal	
	Batch 012	Batch 014	Batch 017	Batch 040	Batch 018	Batch 021	Batch 039
500 Da to 1 kDa	20.9	21.1	18.6	24.8	20.3	21.1	21.5
200 to 500 Da	36.9	36.7	35.8	32.1	37.1	36.7	37.3
<200 Da	29.0	28.4	34.4	21.6	30.5	28.0	26.7

Da = Daltons; MW = molecular weight.

a. Below the limit of detection or quantification.

The results demonstrate that Krill Protein Hydrolysate is primarily composed of peptide components ranging from <200 Da to 2 kDa in molecular weight, accounting for greater than 96% of the water-soluble fraction. This indicates the degree of hydrolysis.

The molecular weight distributions of the peptides are similar between batches confirming that the manufacturing process produces a consistent product.

In order to understand the impact of replacing common protein sources with the novel food, a comparison of the amino acid profiles for Krill Protein Hydrolysate to whey protein, casein and pea protein isolate has been provided in [Table 5](#).

Table 5. Comparison of Amino Acid Profiles for Krill Protein Hydrolysate, Whey Protein, Casein and Pea Protein Isolate

Amino Acid	Content (g/100 g of Raw Material)				
	Krill Protein Hydrolysate	Whey Protein	Casein	Pea Protein	Adult Requirement (g/100 g protein)
Protein	88.7 to 94.9	72 to 84	67 to 78	77 to 88	(100)
<i>Histidine</i>	2.3	1.4	2.2	1.6	1.5
<i>Isoleucine</i>	5.1	3.8	3.0	2.3	3.0
<i>Leucine</i>	7.9	8.6	7.8	5.7	5.9
<i>Lysine</i>	8.4	7.1	5.9	4.7	4.5
<i>Methionine</i>	3.1	1.8	2.2	0.3	1.6
<i>Cysteine</i>	0.6	0.8	0.1	0.2	0.6
<i>Phenylalanine</i>	4.5	2.5	3.1	3.7	3.8
<i>Tyrosine</i>	4.2	2.4	3.4	2.6	3.8
<i>Threonine</i>	4.8	5.4	3.5	2.5	2.3
<i>Tryptophan</i>	1.1	-	-	-	0.6
<i>Valine</i>	5.4	3.5	3.0	-	3.9

Amino Acid	Content (g/100 g of Raw Material)				
	Krill Protein Hydrolysate	Whey Protein	Casein	Pea Protein	Adult Requirement (g/100 g protein)
Alanine	5.7	4.2	2.0	-	-
Arginine	5.9	1.7	2.1	5.9	-
Aspartic acid	11.7	-	-	-	-
Glutamic acid	14.8	-	-	-	-
Glycine	4.4	1.5	1.2	2.8	-
Proline	3.7	4.8	6.5	3.1	-
Serine	4.2	4.0	3.4	3.6	-

- = not reported or established; italics indicates the essential amino acids (NASEM, 2019). a. Mean results of analytical data provided for 9 batches of Krill Protein Hydrolysate. b. Values reported by Gorissen et al. (2018). c. Based on reported Food and Agriculture Organization of the United Nations/World Health Organization adult essential amino acid requirements (WHO, 2002) reported as g/100 g protein recognizing that Krill Protein Hydrolysate, whey protein, casein and pea protein amino acid values are provided as g/100 g raw material where the protein content varies as indicated in the table. d. Considered to be conditionally essential by the Institute of Medicine but included in italics for completeness (NASEM, 2019). e. Analytical results for Krill Protein Hydrolysate refer to cysteine + cystine.

The results indicate that relative to whey protein, casein and pea protein, Krill Protein Hydrolysate exhibits similar levels of essential amino acids on a g/100 g basis.

Additionally, the applicant has referenced the total essential amino acids content for whey protein, casein and pea protein on a protein basis as 43, 34, and 30% respectively, as estimated by Gorissen *et al.*, (2018). By comparison, based on the analytical data for the 9 representative batches of Krill Protein Hydrolysate (mean protein content 92.7% as-is), the total essential amino acids content of the novel food was calculated to be 42.6%.

A heavy metals analysis of nine independent batches has been provided. [Table 6](#) shows the heavy metal analysis for 5 batches of the novel food derived from defatted krill meal and [Table 7](#) shows the heavy metal analysis of 4 batches of the full fat krill meal derived version of the novel food.

Table 6. Heavy metal analysis of five independent representative batches of Krill Protein Hydrolysate derived from defatted krill meal

Parameter	EU Limit (mg/kg wet wt) ^a	Krill Protein Hydrolysate from defatted krill meal [Batch Numbers]				
		Batch 012	Batch 013	Batch 014	Batch 017	Batch 040
Arsenic (mg/kg)	-	0.16	0.20	<0.1	0.13	0.24
Cadmium (mg/kg)	0.5 ^b	0.038	0.013	<0.01	<0.01	-
Mercury (mg/kg)	0.05 ^c	<0.005	<0.005	<0.005	<0.005	<0.005

Parameter	EU Limit (mg/kg wet wt) ^a	Krill Protein Hydrolysate from defatted krill meal [Batch Numbers]				
		Batch 012	Batch 013	Batch 014	Batch 017	Batch 040
Lead (mg/kg)	0.5 ^d	<0.05	<0.05	0.073	<0.05	<0.05

- = not measured; wt = weight.

a. Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. OJ L 364, 20.12.2006, p. 5–24. Available online: <https://eurlex.europa.eu/legalcontent/EN/ALL/?uri=CELEX:32006R1881&qid=1469459335477> (Latest Consolidated Version: 14/10/2020).

b. Limit for crustaceans. c. Limit for fishery products including crustaceans which applies to muscle meat from appendages and abdomen. d. Limit for crustaceans: muscle meat from appendages and abdomen.

Table 7. Heavy metal analysis of four independent representative batches of Krill Protein Hydrolysate derived from full fat krill meal

Parameter	EU Limit	Batch 025	Batch 030	Batch 033	Batch 036
Arsenic (mg/kg)	-	0.22	<0.1	<0.1	<0.1
Cadmium (mg/kg)	0.5	0.072	0.05	0.014	0.039
Mercury (mg/kg)	0.05	<0.005	<0.005	<0.005	<0.005
Lead (mg/kg)	0.5	-	-	<0.05	<0.05

- = not measured/established for arsenic;

a. Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. OJ L 364, 20.12.2006, p. 5–24. Available online: <https://eurlex.europa.eu/legalcontent/EN/ALL/?uri=CELEX:32006R1881&qid=1469459335477> (Latest Consolidated Version: 14/10/2020).

b. Limit for crustaceans. c. Limit for fishery products including crustaceans which applies to muscle meat from appendages and abdomen. d. Limit for crustaceans: muscle meat from appendages and abdomen.

The results show that the levels of heavy metals (arsenic, cadmium, mercury, lead) consistently remain below specified EU limits. The Committee notes that while limits for arsenic in crustaceans and fishery products are not established under Commission Regulation (EC) No 1881/2006, it is widely recognised that arsenic in seafood is predominantly present in the less toxic organic rather than inorganic form (Codex, 1999; EFSA CONTAM Panel, 2009). EFSA considered 0.1 mg/kg to be a realistic value for inorganic arsenic in seafood when estimating human dietary exposure (EFSA CONTAM Panel, 2009). The presence of arsenic in the novel food has been tested; the values in the batches tested were well below this level.

Microbiological analysis of nine individual batches has been provided. The product conforms to the limits set out within the specification of the novel food. As the novel food is derived from either of the two precursor krill meals, individual tables for novel foods produced from each have been provided in order to demonstrate the microbiological composition for the representative batches of Krill Protein Hydrolysate derived from either precursor meal. [Table 8](#) details the microbiological analysis from five representative batches of Krill Protein Hydrolysate derived from the defatted Antarctic krill meal precursor.

Table 8. Microbiological analysis of five independent representative batches of Krill Protein Hydrolysate derived from defatted Antarctic krill meal

Parameter	Specification	Batch 012	Batch 013	Batch 014	Batch 017	Batch 040
Aerobic plate count (CFU/g)	≤10,000	>15000	860	4000	3000	27
Coliform (CFU/g)	≤100	90	<10	40	<10	<10
<i>Clostridium perfringens</i> (CFU/g)	≤100	<10	<10	<10	<10	-
<i>Listeria monocytogenes</i> (/25g).	Absent in 25 g	Absent	Absent	Absent	Absent	-
<i>Salmonella</i> (/25 g)	Negative ^c	Absent	Absent	Absent	Absent	Absent
<i>Escherichia coli</i>	10 MPN/g ^b	Absent	Absent	Absent	Absent	Absent
Yeasts and Moulds (CFU/g)	≤100	-	30	-	-	-
Yeasts (CFU/g)	≤100	<10	<10	<10	<10	<10
Moulds (CFU/g)	≤100	10	<10	<10	<10	<10

- = not measured; CFU = colony forming units. a. Commission Regulation 2073/2005: Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. OJ L 338, 22.12.2005, p. 1–26. Available online: <https://eurlex.europa.eu/legalcontent/EN/TXT/?qid=1548801125816&uri=CELEX:32005R2073> (Latest Consolidated Version: 08/03/2020). b. Limit for shelled and shucked products of cooked crustaceans and molluscan shellfish. Units MPN/g. c. Limit for cooked crustaceans and molluscan shellfish.

[Table 9](#) details the microbiological analysis from four representative batches of Krill Protein Hydrolysate derived from the full-fat Antarctic krill meal precursor.

Table 9. Microbiological analysis of four independent representative batches of Krill Protein Hydrolysate derived from full fat Antarctic krill meal

Parameter	Specification	Batch 025	Batch 030	Batch 033	Batch 036
Aerobic plate count (CFU/g)	≤10,000	23,000	16,000	8,000	48,000
Coliform (CFU/g)	≤100	<10	<10	<10	<10
<i>Clostridium perfringens</i> (CFU/g)	≤100	-	-	-	-
<i>Listeria monocytogenes</i> . (/25 g)	/25 g	Absent	Absent	Absent	Absent
<i>Salmonella</i> (/25 g)	Negative	Negative	Negative	Negative	Negative
<i>Escherichia coli</i> (CFU/g)	<10	<10	<10	<10	<10
Yeasts and Moulds (CFU/g)	≤100	30	<10	<10	<10
Yeasts (CFU/g)	≤100	-	-	-	-
Moulds (CFU/g)	≤100	-	-	-	-

- = not measured; a. Commission Regulation 2073/2005: Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. OJ L 338, 22.12.2005, p. 1–26. Available online: <https://eurlex.europa.eu/legalcontent/EN/TXT/?qid=1548801125816&uri=CELEX:32005R2073> (Latest Consolidated Version: 08/03/2020). b. Limit for shelled and shucked products of cooked crustaceans and molluscan shellfish. Units MPN/g. c. Limit for cooked crustaceans and molluscan shellfish.

Samples from 11 different batches of Krill Protein Hydrolysate were analysed for the following marine biotoxins as detailed in [Table 10](#): paralytic shellfish poison (PSP), amnesic shellfish poison (ASP), diarrhetic shellfish poison (DSP, including all forms of okadaic acid (OA) and dinophysistoxins (DTX) together), yessotoxins (YTX), and azaspiracids (AZA). Additionally, 6 different batches of Krill Protein Hydrolysate were analysed for pectenotoxin toxin (PTX).

All results were below the limit of quantification for all biotoxins assessed.

The data presented indicate the novel food and any risks present were appropriately characterised.

2.4. Stability

The stability of Krill Protein Hydrolysate over a 24-month period was tested for three representative batches. The novel food was stored at 25°C and 60% relative humidity. Testing was conducted at 1, 2, 3, 6, 9, 12, 18 and 24 months.

A second test was conducted under accelerated conditions at 40°C and 75% relative humidity. Interim results to 12 months were available for three representative batches of Krill Protein Hydrolysate.

In both studies the parameters measured in the stability studies include total crude protein on an as-is basis and a dry matter basis, and microbiological testing. The Committee requested further information regarding the presence of enterococci in the provided stability samples. Enterococci will be measured in the accelerated study (t=18 months) to confirm the stability for this parameter; albeit the levels of observed enterococci fall far below the specification limits established, as would be expected in a dry material.

The results demonstrate the long-term stability of the novel food over a 12 and 24-month period, under both real-time and accelerated conditions. On this basis, the data does not indicate significant changes in the novel food, manufactured with full-fat or defatted krill meal, over 24 months.

No studies to evaluate the stability of Krill Protein Hydrolysate in food matrices have been undertaken.

2.5. Specification

The specifications for the novel food are outlined in [Table 11](#) below.

As the novel food can use either of the two identified source materials, the requested novel foods specification and the associated parameters remain the same regardless of the source material used. As discussed in Section 2.2 (Production Process) and 2.3 (Composition), the variability of

Table 10. Marine Biotoxin Analysis for 11 Representative Batches of Krill Protein Hydrolysate

Parameter	LOQ	Batch 30	Batch 33	Batch 39	Batch 43 (DF)	Batch 44 (DF)	Batch 56 (DF)	Batch 58 (DF)	Batch 59 (DF)	Batch 60 (DF)	Batch 102 (DF)	Batch 103 (DF)	Method
DSP (µg OA ekv./kg)	20	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	M-AL. 10
YTX (µg YTX ekv./kg)	100	<100	<100	<100	<100	<100	<100	<100	<100	<100	<100	<100	M-AL. 10
AZA (µg AZA ekv./kg)	20	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20	M-AL. 10
PTX (µg PTX ekv./kg)	30	<30	<30	<30	<30	-	-	-	-	-	<30	<30	M-AL. 10
PSP (µg STXdiHCl ekv./kg)	120	<120	<120	<120	<120	<120	<120	<120	<120	<120	<120	<120	M-AL. 12
ASP (µg DA ekv./kg)	2500	<2,500	<2,500	<2,500	<2,500	<2,500	<2,500	<2,500	<2,500	<2,500	<2,500	<2,500	M-AL. 11

- = not measured; ASP = amnesic shellfish poison; AZA = azaspiracids; DA = domoic acid; DF = defatted; DSP = diarrhetic shellfish poison (i.e., including all forms of OA and dinophysistoxins together); ekv. = equivalents; LOQ = limit of quantification; OA = okadaic acid; PSP = paralytic shellfish poison; PTX = pectenotoxin (PTX was previously included in the marine biotoxin panel from the reference laboratory, as PTX was grouped with OA toxins in Regulation (EC) No 853/2004/10; however, the EFSA Panel on Contaminants in the Food Chain (EFSA CONTAM Panel, 2009a) concluded that “because PTX-group toxins do not share the same mechanism of action as OA-group toxins they should not be included in the regulatory limit for OA-group toxins”. Based on this recommendation, the reference laboratory removed the PTX-group toxins from the marine biotoxin panel. As a result, data on PTX toxins are only available for earlier batches of Krill Protein Hydrolysate); STXdiHCl = saxitoxin di-hydrochloride equivalents; YTX = yessotoxins.

Table 11. Specifications for Krill Protein Hydrolysate

Parameter	Specification Value	Analytical Method
Characterisation and Identity		
Appearance	White to cream coloured powder	Visual Observation
Proximate Analysis		
Water activity	≤0.7	NF ISO 18787:2017
Moisture content/humidity	≤10 g/100 g	Commission Regulation (EC) No 152/2009a / ISO 6496
Protein	Protein, as-is ≥85 g/100 g Protein, DM basis ≥90 g/100 g	Kjeldahl Method and adjusted calculations to account for moisture content
Total Fat	≤1 g/100 g	Commission Regulation (EC) No 152/2009
Crude Ash	≤7 g/100 g	Commission Regulation (EC) No 152/2009
Total Carbohydrate, as water soluble carbohydrates	<0.05g/100 g	UV-VIS Spectrophotometer (internal method)
Fibre	<2.0g/100g	AOAC 985.29; Eurofins AA210
Microbiological Analyses		
Aerobic Plate Total Count	≤10,000 CFU/g	NF EN ISO 4833-1
<i>Salmonella</i>	Absent in 25 g	NMKL 71/NordVal 023
<i>Escherichia coli</i>	≤10 CFU/g	AOAC 991.14/NordVal017
Yeasts	≤100 CFU/g	NMKL 98/ AFNOR 3M01/13-07/14
Moulds	≤100 CFU/g	NMKL 98/ AFNOR 3M01/13-07/14
Heavy Metals		
Inorganic Arsenic	0.1 mg/kg	ICP-MS
Cadmium	0.1 mg/kg	ICP-MS
Mercury	0.5 mg/kg	ICP-MS
Lead	0.3 mg/kg	ICP-MS
Mineral Analysis		
Magnesium	≤5500 mg/kg	EN 13805:2014, EN ISO 11885m:2009
Selenium	≤3.5 mg/kg	EN 13805m:2014, EN ISO 17294m:2016 /ICP-MS
Fluoride	≤25 mg/kg	ASU L 49.00-7:2000-07, mod

ISO = International Organization for Standardization,

the composition of the novel food was queried and whether the novel food could be produced consistently. The updated composition of the novel food and specifications supports the conclusion that the novel food can be produced consistently.

The ACNFP concluded that the information provided is sufficient for the specification of Krill Protein Hydrolysate and appropriately characterises the novel food.

2.6. History of Use

There is no history of use for the novel food in the UK. There is a history of krill consumption globally. Information on cultural patterns of consumption across the globe is extensive. Use of Antarctic krill oils and protein hydrolysates from other sources is well documented in the UK. However, whilst lipid extracts from *E. superba* have been permitted for use as a novel food in the UK and EU since 2009, the protein hydrolysate form of Antarctic krill has not previously been marketed, nor consumed to a significant degree in the UK. The krill protein is therefore considered novel and requires authorisation in the UK before it is placed on the market.

Information on other krill derived products authorised under the novel food regulation in the UK and EU were provided. A lipid extract from Antarctic krill *Euphausia superba* was authorised for use as a novel food in 2009 under Decision 2009/752/EC. The uses authorised included food supplements, dairy products and breakfast cereals. Phospholipid-rich oil extracted from Antarctic krill was authorised by the Finnish authorities in 2015 for a range of products including dairy products, bakery products and food supplements based on the DHA and EPA content of the novel food. An extension of use was authorised in 2016 to increase the use levels in food supplements.

The history of use does not indicate any areas for concern.

2.7. Proposed Uses

Krill Protein Hydrolysate is intended for use as an alternative source of protein in food supplements at a maximum of 25 g per day, as defined in the Food Supplements (England) Regulations 2003 and associated provisions in the nations of GB, for the general population. The novel food is also intended to be used within other food categories such as formulations of functional protein foods and drinks, including bakery wares, isotonic sport drinks and single meal replacements.

This novel food is intended as an alternative to plant and animal-based proteins currently used for the same purpose. [Table 12](#) details the intended uses, and the use levels based on the FoodEx2 Food Classification System.

The target population for foods containing Krill Protein Hydrolysate is the general population. Products containing Krill Protein Hydrolysate will not be targeted towards infants and young children (toddlers), aged up to 3 years, and pregnant or lactating women. The applicant states that products containing the novel food will be labelled accordingly to reflect these restrictions. The exposure has been also calculated for these populations

Table 12. Representative Food Categories Used for the Intake Assessment of Krill Protein Hydrolysate Based on the FoodEx2 Food Classification System

Specific food category	FoodEx2 group name ^a	Max. Level of Hydrolysed Krill Protein (g/100 g or 100 mL) ^b
Fine Bakery Wares	Cereal Bars	5
Protein products, excluding products covered in category 1.8	Isolated proteins and other protein products	90
Flavoured drinks	Functional drinks and isotonic sport drinks	8 8
Water, including natural mineral water as defined in Directive 2009/54/EC and spring water and all other bottled or packaged waters	Fortified bottled water	5
Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)	Single meal replacement for weight reduction	60
Food Supplements (England) Regulations 2003 and associated provisions in the nations of GB	-	25 g per day

EFSA = European Food Safety Authority; EU = European Union; Max. = maximum.

a. Proposed uses and use levels of Krill Protein Hydrolysate were matched with the FoodEx2 food categorisation system developed by EFSA. b. The maximum use level was applied in the assessment to account for the “worst-case” scenario.

and shows that should the novel food be used for these groups it would represent a significant contribution to their protein consumption coming from a single protein source.

The estimated level of exposure to the novel food was determined using the representative levels for each food category against the total population. The mean intakes for each food category by population group were used as the final values. These values were calculated from the use of the Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data, as established by the EFSA Scientific Committee (EFSA SC, 2012). The data is presented in [Table 13](#) for food use and 14 for food supplement use.

Table 13. Estimated Daily Intake of Krill Protein Hydrolysate from Representative Food Uses and Use Levels other than food supplement Based on the EFSA Comprehensive Database in Different Population Groups

Population Group	No. of surveys ^a	Intakes of Krill Protein Hydrolysate (g/person/day)		Intakes of Krill Protein Hydrolysate (g/kg bw/day)	
		Mean Range	High Level Range	Mean Range	High Level Range ^b
Infants (≤11 m)	8 (0)	<0.1	-	<0.1	-
Toddlers (12 to 35 m)	17 (5)	<0.1 to 0.1	0.6 to 1.6	<0.1	0.1 to 0.2
Other children (3 to 9 y)	26 (7)	<0.1 to 0.6	0.4 to 3.0	<0.1	<0.1 to 0.2
Adolescents (10 to 17 y)	26 (5)	<0.1 to 5.1	0.8 to 45.4	<0.1 to 0.1	<0.1 to 0.9

Population Group	No. of surveys ^a	Intakes of Krill Protein Hydrolysate (g/person/day)		Intakes of Krill Protein Hydrolysate (g/kg bw/day)	
Adults (18 to 64 y)	35 (12)	<0.1 to 3.4	1.0 to 44.0	<0.1	<0.1 to 0.6
Pregnant and lactating women	6 (1)	<0.1 to 0.8	3.2	<0.1	0.1
Elderly (65 to 74 y)	23 (0)	<0.1 to 1.3	-	<0.1	-
Very elderly (≥75 y)	11 (0)	<0.1 to 2.7	-	<0.1	-

bw = body weight; EFSA = European Food Safety Authority; m = months; y = years. a. Number of surveys in which individuals within the population group were identified to be consumers of the food groups of interest. Number of surveys with a statistically reliable number of consumers (used to calculate high level intakes) are presented in parentheses. b. Results are not presented for values that were not statistically reliable (n<60).

Table 14. Estimated Daily Intake Per Kilogram Body Weight of Krill Protein Hydrolysate from food supplements at the proposed maximum daily dose of 25 g/day

Population group	Mean Body Weights ^a	Estimated Intake based on proposed use levels (mg/kg bw/day) ^b
Other children (3 to 9 years)	23.1	1082
Adolescents (10 to 17 years)	43.4	576
Adults (18 to 64 years)	73.9	338
Elderly (65 to 75 years)	76.0	329
Very elderly (≥75 years)	71.2	351

bw = body weight. a. EFSA Scientific Committee (European Food Safety Authority Scientific Committee). 2012. Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal, 10, 2579 [32 pp]. Available online: <https://www.efsa.europa.eu/en/efsajournal/pub/2579>. b. Calculation: Proposed Maximum Daily Dose (g/day) / values from the column Mean Body Weights x 1,000.

Krill Protein Hydrolysate in food supplements are not intended to be used if other foods with added proteins are consumed on the same day, in order to not over-consume the novel food compared to other sources of protein in the diet.

The applicant has considered the impact of adding the novel food to the diet via the proposed representative uses stated above and the proposed supplemental use of a maximum dose of 25 g/day. The anticipated 95% intake of the novel food via conventional food uses ranges from 5.1 g/person/day at the mean and 45.4 g/person/day at the high-level for representative use groups and 329 mg/kg body weight/day in elderly (body weight of 76.0 kg) to 1,082 mg/kg body weight/day in other children (body weight of 23.1 kg) through supplemental use.

2.8. Absorption, Distribution, Metabolism and Excretion (ADME)

No ADME studies were conducted on the novel food.

The novel food is derived from Antarctic krill (*E. superba*) and specified at $\geq 85\%$ and $\geq 90\%$ protein on a g/100 g as-is and dry matter basis, respectively. The amino acid profile is comparable to and consistent with the Antarctic krill meal on a relative scale. The amino acid profile itself and the corroborating evidence provided by the applicant highlights that Krill Protein Hydrolysate demonstrates an availability of amino acids following ingestion that is comparable to whey and soy protein isolates, and a nutrient profile that is comparable to casein and whey proteins ([Table 5](#)). It is anticipated that the novel food will be processed in a similar manner as other dietary proteins via normal physiological processes.

2.9. Nutritional Information

A summary of the proximate analysis of Krill Protein Hydrolysate can be found in the composition section in [Table 2](#) for the novel food derived from one precursor and [Table 3](#) for the other. In practice, both meet a common specification for the novel food. The nutrient analysis of Krill Protein Hydrolysate is characterised primarily by protein with low levels of fat present.

No specific protein digestibility analysis has been commissioned by the applicant for the novel food such as DIAAS or PDCAAS. As part of the literature review and weight of evidence approach to the toxicological data, a digestibility study on krill meal in mink was (Krogdahl et al., 2015) was provided.

The investigators concluded that Aker BioMarine's krill meal has a similar nutritional value to fish meal and is not associated with any adverse effects on growing mink at levels of up to 8% dry matter, equivalent to 12 g/kg body weight/day for females and 15 g/kg body weight/day in males.

As the intended use of the novel food is as a protein source, the contribution of the novel food in the context of total protein intake was assessed. An exposure calculation was done for all age groups. [Tables 13](#) and [14](#) above in section 2.7 represent the different age groups and the total intake of protein as calculated.

Mean and high-level consumer-only intakes of Krill Protein Hydrolysate were estimated to be greatest for adolescents at 5.1 g/day and 45.4 g/day, respectively. These results were calculated as part of the weight of evidence approach where several nutritional studies analysing high protein

intakes were reviewed and deemed relevant to the novel food. Under the representative conditions of use, Krill Protein Hydrolysate will contribute to, but not alter, total daily protein intakes from all sources

It is recognised that the novel food could represent a substantive fraction of daily protein requirements. However, the reported levels fall under the tolerated levels put forward in the average requirement for protein established by the European Food Safety Authority based on nitrogen balance data (EFSA NDA Panel, 2012).

Krill Protein Hydrolysate is intended to be a direct replacement for other plant and animal-derived proteins such as whey protein, casein and pea protein in the proposed food categories. The comparison of the novel food to these sources of protein is explored in [Table 5](#) and indicates they have similar levels of essential amino acids.

The novel food has the potential to act as a source of essential amino acids, meeting or exceeding the requirements laid down by the WHO (WHO, 2002) for protein sources on a g/100 g protein basis for all individual amino acids. As demonstrated by the applicant, the typical values reported for other protein isolate products (whey, casein and pea), in comparison to the novel food, demonstrates that the novel food could be a potential replacement in an individual's diet.

Due to the conservative nature of the exposure calculation methodology provided, Krill Protein Hydrolysate is unlikely to replace all other protein sources at the maximum levels sought in the proposed conditions of use.

The mineral intakes (including inorganics) as contributed from Krill Protein Hydrolysate were assessed against the nutrient reference values (NRVs) established in Annex XIII of Regulation (EU) No 1169/2011 and the Upper Intake Levels (ULs) as established by EFSA.

At the mean level intake of Krill Protein Hydrolysate, the estimated contribution of minerals to established Nutrient Reference Values (NRVs) was low, ranging from 0.02% for potassium to 15.08% for selenium, and none of the mineral levels exceeded the ULs as established. However, for the high-level intake of Krill Protein Hydrolysate, some of the minerals would be considered significant contributors to the NRV including calcium (50.17%), magnesium (52.67%), copper (66.31%), selenium (195.20%), and iodine (61.60%). Therefore, actual exposure to minerals from the novel food ingredient would be lower than estimated based on the estimated contribution calculated via the mean level intake of Krill Protein Hydrolysate.

The levels of aluminium and tin in Krill Protein Hydrolysate were low or below the level of detection and were not considered a safety concern.

As Krill Protein Hydrolysate contains measurable levels of vitamins riboflavin (B2), niacin (B3), biotin (B8), folate (B9) and cyanocobalamin (B12) that are below the EU values established by EFSA, IOM and Annex XIII of Regulation (EU) No 1169/2011, the novel food ingredient will not make a significant contribution to dietary vitamin intake under the intended conditions of use.

Moreover, where ULs are established, none of the B vitamins would exceed this level under the most conservative levels of intake of 45.4 g/day in adolescents. Thus, Krill Protein Hydrolysate is not anticipated to impact vitamin intake under the proposed conditions of use.

The presence of fibrous components found in crustaceans such as chitin, and the potential effects of these components, was initially queried. In response to questions on the appropriate characterisation of the novel food analysis, a detailed discussion surrounding the removal and potential for anti-nutritive components as part of production was provided for chitin and chitosan levels in the novel food for 8 batches of the novel food, five using the defatted krill meal and 3 with the full fat krill meal precursor. The results of the pyrolysis–gas chromatography–mass spectrometry (Py-GC-MS) showed all values were below the limit of quantification of the test of 0.2%.

Based on the further information the Committee concluded that the processes adequately demonstrated the reliability and accuracy of fibrous component removal. Similarly testing was undertaken for astaxanthin, astaxanthin esters and canthaxanthin, and all samples tested were below the limit of quantification of 2 mg/kg.

Taking the analytical data into account for the representative Krill Protein Hydrolysate batches, the applicant demonstrates that levels of protein, amino acids, vitamins and minerals are within acceptable levels and do not highlight a potential concern. The novel food was considered not nutritionally disadvantageous.

2.10. Toxicological Information

Toxicological studies were provided and performed to support the safety assessment of Krill Protein Hydrolysate, using a weight of evidence approach for the subchronic toxicology that was initially queried by the Committee. The respective study reports contained within the body of evidence are either published or unpublished and claimed as proprietary data. The Committee considers the dataset as essential in the assessment of the safety of the novel food.

2.10.1. Genotoxicity

In vitro genotoxicity testing of krill protein hydrolysate was conducted under GLP conditions and according to the following OECD guidelines: *in vitro* bacterial reverse mutation test (OECD TG 471) and *in vitro* mammalian cell micronucleus test (OECD TG 487). This approach is recommended by the UK Committee on Mutagenicity and is also the basis of guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283, as retained in UK law.

The *in vitro* bacterial reverse mutation test (Šoltésová, 2021a [unpublished, confidential and proprietary]) was conducted with aliquots of the vehicle control, positive controls, or Krill Protein Hydrolysate solutions (at concentrations of 5, 15, 50, 150, 500, 1,500, or 5,000 µg/plate) incubated with *Salmonella typhimurium* strains TA98, TA100, TA1535, or TA1537, or *Escherichia coli* strain WP2 uvrA (pKM101). Treatments were prepared in pairs in the presence and absence of metabolic activation (liver S9 preparations).

No increase in revertant colonies was seen with Krill Protein Hydrolysate compared to controls. It was concluded that the hydrolysed krill protein was non-mutagenic at concentrations up to and including 5,000 µg/plate, in the absence or presence of metabolic activation.

An *in vitro* micronucleus test (Šoltésová, 2021b [unpublished, confidential and proprietary]) exposed cells to 1,250, 2,500 or 5,000 µg/mL Krill Protein Hydrolysate for 3 hours in the presence and absence of S9 metabolic activation (short-term exposure) and for 20 hours in the absence of S9 only (long-term exposure). No increase in micronuclei compared to controls was observed. It was concluded that hydrolysed krill protein was non-clastogenic and non-aneugenic in the absence or presence of metabolic activation up to the highest concentration of 5,000 µg/mL.

2.10.2. Subchronic Toxicity

Due to the long and established history of use of krill as a traditional food in South Asian countries, the applicant has approached the toxicological evidence portion of the application process by providing supporting evidence of the safety of Krill Protein Hydrolysate under the intended conditions of use via a weight of evidence approach. The approach utilises published works that either use the novel food as a test material or similar products that are either krill-based or already authorised novel foods containing krill from the *E. superba* species.

After the initial review of the weight of evidence approach, further information was sought from the applicant to understand the relevance of the study to the novel food seeking authorisation.

The applicant has provided numerous tabulated studies and datasets from 90-day subchronic studies that use either the novel food or related krill test items. Each selected study included an attached associated discussion of their relevance, whereby a description of the source material, compositional analysis comparison and the degree of relevance to the novel food was provided as well as an indication of the weight the evidence provided to the assessment. A literature review on the toxicity of krill-containing products was also carried out.

The studies identified by the applicant were considered consistent with the toxicological profile identified for the particular materials tested in the differing types of studies. The studies provided included a 90-day subchronic toxicity study.

Three subchronic studies were highlighted as the main supporting studies for the weight of evidence approach. In a GLP OECD 408 and U.S. FDA Redbook-compliant repeat dose study (Berge et al., 2015), groups of Han Wistar rats (10/sex/group) were fed diets containing either 8% soybean oil (control) or 3% soybean oil plus 9.67% krill powder (Aker BioMarine Superba™ krill powder containing ~52% fat and 42% protein; corresponding to 5% krill oil) for 13 weeks. The soybean oil and casein contents of the diet containing krill powder were adjusted to maintain consistent lipid and protein levels relative to the control diet.

The no observed adverse effect level (NOAEL) was concluded by investigators to be 9.67% in the diet, the highest dose tested, corresponding to 5,357 mg krill powder/kg body weight/day for males and 6,284 mg krill powder/kg body weight/day for females. On the basis that krill powder contained 42% protein, the equivalent krill protein intakes were approximately 2,250 mg/kg body weight/day in males, and 2,640 mg/kg body weight/day in females.

The weight of evidence approach was accepted as providing a basis for the toxicological safety of the novel food. No concerns were identified.

2.10.3. Human Studies

Human clinical trials were conducted with the precursor ingredient to the novel food. The precursor was produced using the *Euphausia superba* species of krill, to demonstrate relevance to the novel food. The applicant has provided two human trials.

A single centre, open label clinical study using the applicant's krill powder meal was conducted on 11 healthy non-smoking males between 30 and 56 years of age with a body mass index (BMI) of 30 to 35 kg/m² (Berge et al., 2013). The intention of this study was to investigate the effect of a krill powder on overweight male subjects with an emphasis on peripheral endocannabinoid concentrations.

Subjects in the treatment group were asked to restrict intakes of fatty fish and seafood meals to only once per week and not to consume these foods 48 hours before a clinical visit. The consumption of cholesterol-reducing products and lipid supplementations were prohibited. Data was collected via physical assessment, blood samples and vital sign measurements and ECG during all routine visits. No adverse effect related safety concerns were reported during the trial.

A randomised, double-blinded, placebo-controlled intervention study in male and female subjects was conducted primarily to compare the incidence and type of adverse events after ingestion of a krill powder produced from *E. superba* source material (Sarkkinen et al., 2018). The krill powder test item's composition contained a minimum of 55% protein and a maximum of 25% fat. Maize starch was used as a placebo. Doses of 4 g/day were given to the participants who were overweight, and with elevated blood pressure.

Subjects were required to fast for 10 to 12 hours before blood was taken on Day 0 and 56 and analysed for routine clinical chemistry, haematology (blood count, serum thyrotropin, serum creatinine, plasma gamma-glutamyl transferase, blood glucose, aspartate transaminase and plasma concentrations of LDL-cholesterol, HDL-cholesterol, total cholesterol, and triacyl glycerides).

Over the course of the study, 80 adverse events were reported by study subjects: 50 in the placebo group and 30 in the krill powder group. None of the adverse events were considered serious and only 12 were considered possibly related to the test article; minor gastrointestinal symptoms (flatulence, heartburn and diarrhoea) were the most commonly reported effects. The mean value of all measured haematology variables remained within reference values in all study subjects and there were no observed significant changes in blood pressure or lipid values.

It was concluded that no adverse effects-related safety concerns attributable to the test item were reported during the trial. The results were noted and considered confirmatory to the wider evidence on the safety and tolerability of the novel food.

2.11. Allergenicity

The novel food is derived from krill, a crustacean shellfish, one of the main groups of allergenic foods in the UK and EU for which allergen labelling is mandatory. The assessment of allergenicity was based on the *Euphausia superba* species of krill. Therefore, in line with Annex II of Regulation 1169/2011, the novel ingredient would be labelled as containing crustaceans (Antarctic krill) and products thereof to reflect the potential risk for those with shellfish allergies.

Since the krill used as the source material for the novel ingredient originates from wild-caught krill the potential for co-catch of fish also major allergenic foods were considered. The potential for unintended allergens, namely by-catch of fish species, has been considered by the applicant as part of their production process. The proportion of by-catch to crustacean (using the Eco-Harvesting method, the total % by-catch as recorded by CCAMLR observers (kg by-catch per total Antarctic krill catch (kg)) from 2019 to 2022 was less than 0.3% and typically below 0.1%) confirmed that other fish species were effectively removed from all batches of the novel food precursor via mechanical meshes and further sorting of the catch prior to entering the production facility.

The potential presence of unintended allergens via by-catch of fish species is expected to be low.

It was noted that the novel food is intended to be added as an ingredient into foods that would not be expected to normally contain crustaceans. Risk managers should consider how to support those with a crustacean allergy avoiding the novel food.

3. Discussion

The novel food is Krill Protein Hydrolysate derived from Antarctic krill, which consists of $\geq 85\%$ and $\geq 90\%$ crude protein on an g/100 g as-is and dry matter basis, respectively.

Krill Protein Hydrolysate is manufactured by a two-stage production process involving the manufacturing of Antarctic krill meal (either full fat or defatted), and hydrolysis of the Antarctic krill meal to produce the protein hydrolysate where the yield is a white to cream coloured powder meal with a high percentage of protein.

Krill Protein Hydrolysate is intended to be used as a food supplement at a maximum of 25 g/day, as well as in a range of functional protein foods and drinks including bakery wares, isotonic sport drinks and single meal replacements. The novel food is intended to be used as an alternative source of protein in supplements and the represented food categories. The novel food ingredient is not expected to increase the overall consumption of protein from foods in the UK population.

A weight of evidence approach was used to support the toxicological safety of the novel food. The NOAELs for similar Krill Protein Hydrolysate in a single subchronic rat study, reported in the literature, range between 2,250- 2,640 mg/kg BW/day. As the applicant did not commission their own 90-day subchronic study on the specific protein hydrolysate, the basis of these values was provided from studies on Krill powder. The materials

in the study, while not the same composition as the novel food, were considered relevant due to the protein content. However, these were not specifically protein hydrolysates.

The toxicological evidence presented did not indicate the potential for toxicological concern for the novel food. The weight of evidence approach was accepted as appropriate to support the safety of this novel food.

The maximum daily intake of Krill Protein Hydrolysate from the supplement was calculated on a body weight basis. For consumers classed as the elderly to children between 3 and 9 years of age, the calculated values ranged from 392 – 1,082 mg/kg bw/day. These values were derived from the maximum dose of 25 g/day and the default body weights for the children, adolescent, adult, the elderly, and the very elderly sub-populations of 23.1 kg, 43.4 kg, 73.9 kg, 76.0 kg and 71.2 kg, respectively (EFSA, 2012).

The novel food is comprised primarily of crustaceans/shellfish (one of the main food allergens) that causes IgE-mediated food allergies. It was confirmed that in line with Annex II of Regulation 1169/2011, the novel ingredient would be labelled as containing crustaceans (Antarctic krill) and products thereof to reflect the potential risk for those with crustacean shellfish allergies. The proposed uses include foods where crustaceans would not normally be used, suggesting a potential risk for crustacean allergic consumers.

The potential for the presence of by-catch of other species was explored and the steps to minimise exposure considered in the allergenicity risk assessment.

4. Conclusions

The FSA and FSS have undertaken the assessment of Krill Protein Hydrolysate and concluded that the novel food is safe under the proposed conditions of use and does not pose a safety risk to human health. The proposed uses are not considered nutritionally disadvantageous.

These conclusions were based on the information in the novel food dossier submitted by the applicant plus the supplementary information and could not have been reached without the following data claimed as proprietary by the applicant:

- *in vitro* bacterial reverse mutation test (Šoltésová, 2021a [unpublished, confidential and proprietary]).
- *in vitro* micronucleus test (Šoltésová, 2021b [unpublished, confidential and proprietary]).

Abbreviations

Abbreviation	Definition
ACNFP	Advisory Committee on Novel Foods and Processes
Da	Dalton
HDL	High-density lipoprotein
FSA	Food Standards Agency
FSS	Food Standards Scotland
kDa	Kilodalton
KPH	Krill Protein Hydrolysate
LOD	Limit of detection
LDL	Low-density lipoprotein
NRV	Nutrient Reference Value
NOAEL	No observed adverse effect level

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