High value (food) ingredients from Danish organic mussels

Market potential, regulatory barriers and go-to-market strategy

Summarizing report

(based on presentation at MuMiPro final meeting, October 30th 2020)

Henrik Uth, Engredo ApS

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Introduction to high value ingredients

High value ingredients are mainly foodstuffs containing concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination. An example is omega-3 fatty acids, found in multiple marine organisms, but extracted and used as a high value ingredients to enrich a certain food with omega-3, or delivered in dosage forms such as capsules, tablets and other (food supplements). The overall supply chain for omega-3 fatty acids are presented below.

Anchovy and Sardine fishery South America

Crude oil production (10-20% omega-3)

Algae oil biomass from fermentation or other technologies

Crude oil production

Cod, herring, mussel, squid, seal, salmon, trout, and other.

Crude oil production

Krill oil fishery in the Southern Ocean (Antarctic).

Main player Aker Biomarine AS (Norway)

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Crude oil/meal production on the vessels

Refining and processing at factories in USA (+).

Omega-3 (food and pharma) refineries in USA, Europe, Asia with different technologies (chemical refining, Co2 extraction and other)

Range of EPA, DHA concentrates on different forms (triglycerides, ethyl esters, phosphoplids, free fatty acids) containing various EPA/DHA levels, f.ex.:

18% EPA / 12% DHA, 33% EPA / 22% DHA, Up to >95% EPA/DHA

Production of food supplements and functional foods

(contract manufacturers, brand owners)

Capsules, tablets, liquids, enriched foods and drinks

Use and recommendations of omega-3 fatty acids

Short - and long chain polyunsaturated fatty acids (PUFA's) are so called essential fatty acids, which must be ingested, because the human body can not synthesize them and they are needed for human health.

The WHO (World Health Organization) recommends dietary intake of PUFA's from fatty fish, through regular consumption (minimum twice /week) of **fatty fish** – for maintaining cardiovascular health.

In case dietary intake for PUFA's from fatty fish, for one or the other reason, is not consumed – supplementation, by way of food supplements or enriched foods (functional foods) is an alternative.

EFSA (European Food Safety Authority) have proposed daily label reference intake values of:

- 2 gram omega-3 short-chain PUFA (ALA)
- 250 mg omega-3 long-chain PUFA (EPA + DHA)

An important parameter in the marketing and sales of high value ingredients, is the ability to communicate the health effects following ingestion of a particular ingredient. In 2006, the European Commission introduced a regulation to oversee and govern the use of health claims (defined such as a claim that suggests or implies that a relationship exists between a food category, a food or one of its constituents and human health).

EFSA have proposed – and European Commission have approved – health claims liking the intake of EPA and DHA omega-3 fatty acids to:

- Cardiovascular health and blood pressure
- Brain health
- Eye health

See further details in table 1. As such, in this context, having a biomass (that being of fish, algae, krill, mussel or other origin) with a high level of EPA and DHA is valuable, when looking at supply chain needs (based on the end consumer demand).

EU regulation (EC) 1924/2006 and (EC) 432/2012 defines the process for approval health – and nutritional claims in the European Union.

Table 1 - Omega-3 (EPA/DHA) related health claims approved and corresponding intake levels of EPA/DHA.

Eicosapentaenoic acid and docosahexaenoic acid (EPA/DHA)	EPA and DHA contribute to the normal function of the heart	The claim may be used only for food which is at least a source of EPA and DHA as referred to in the claim SOURCE OF OMEGA 3 FATTY ACIDS as listed in the Annex to Regulation (EC) No 1924/2006. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of EPA and DHA.
Docosahexaenoic acid and Eicosapentaenoic acid (DHA/EPA)	DHA and EPA contribute to the maintenance of normal blood pressure	The claim may be used only for food which provides a daily intake of 3 g of EPA and DHA. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of EPA and DHA. When the claim is used on food supplements and/or fortified foods information shall also be given to consumers not to exceed a supplemental daily intake of 5 g of EPA and DHA combined.
Docosahexaenoic acid (DHA)	DHA contributes to maintenance of normal brain function	The claim may be used only for food which contains at least 40 mg of DHA per 100 g and per 100 kcal. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of DHA.
Docosahexaenoic acid (DHA)	DHA contributes to the maintenance of normal vision	The claim may be used only for food which contains at least 40 mg of DHA per 100 g and per 100 kcal. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of DHA.
Docosahexaenoic acid and Eicosapentaenoic acid (DHA/EPA)	DHA and EPA contribute to the maintenance of normal blood triglyceride levels	The claim may be used only for food which provides a daily intake of 2 g of EPA and DHA. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of EPA and DHA. When the claim is used on food supplements and/or fortified foods information shall also be given to consumers not to exceed a supplemental daily intake of 5 g of EPA and DHA combined.
Docosahexaenoic acid (DHA)	Docosahexaenoic acid (DHA) maternal intake contributes to the normal brain development of the foetus and breastfed infants.	Information shall be given to pregnant and lactating women that the beneficial effect is obtained with a daily intake of 200 mg of DHA in addition to the recommended daily intake for omega-3 fatty acids for adults, i.e.: 250 mg DHA and EPA. The claim can be used only for food which provides a daily intake of at least 200 mg DHA
Docosahexaenoic acid (DHA)	Docosahexaenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age.	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 100 mg of DHA. When the claim is used on follow-on formula, the food shall contain at least 0,3 % of the total fatty acids as DHA.

EU regulatory framework

Novel foods (relevant for starting material (mussels) and processing technology)

When considering launching "new" food products in the EU, regulation (EC) 2015/2283 must be evaluated. If a product is considered a novel food (as evaluated by the competent authorities) and hence, falls under the said regulation, it's safety must be documented, evaluated (EFSA) and legally approved.

A Novel Food is defined as food that had not been consumed to a significant degree by humans in the EU before 15 May 1997, when the first Regulation on novel food came into force. 'Novel Foods' can be newly developed, innovative food, food produced using new technologies and production processes, as well as food which is or has been traditionally eaten outside of the EU.

Examples of Novel Food include new sources of vitamin K (menaquinone) or extracts from existing food (Antarctic Krill oil rich in phospholipids from *Euphausia superba*), agricultural products from third countries (chia seeds, noni fruit juice), or food derived from new production processes (UV-treated food (milk, bread, mushrooms and yeast). Source: https://ec.europa.eu/food/safety/novel_food_en

The two main considerations, when arguing for the "non-novel food" classification (and hence out of scope of the novel food regulation) of mussel oil and – protein from Danish blue mussels, as high value ingredients, are:

1) Justifying that fat – and proteins of Danish blue mussels have been consumed prior to May, 1997.
2) Justifying that fat – and proteins of Danish blue mussels, are not produced using new technologies and production processes (post May, 1997) and that comparable products (fish oil) have already been placed on the market.

Following dialogue with the Danish Food Authorities, it has been established that solid argumentation, based on assumptions from the proof on concept manufacturing process (oil and protein extraction) performed in MuMiPro, along with general argumentation within the frames of the novel food regulation, needs to submitted to the Danish Food Authorities, for pre-evaluation.

Following dialogue with the Danish Food Authorities, it is considered likely that mussel oil and – protein, prepared as such, from Danish blue mussels, will not be considered a novel food, but it is important to underline that when and if a commercial scale production is to be set up, a very important parameter, is to seek regulatory clearance (by way of non-novel food classification) before any investments are made, since the alternative is a full EU novel food application. Such a process includes conducting safety and toxicology studies, and a following process of application and evaluation by EFSA. A significant investment, estimated not to be below 4 million DKK, with a timeline for approval of 2-3 years.

What makes mussel oil interesting?

RMIT University of Melbourne has compared fatty acid found in Green Lipped Mussel (Perna Canaliculus) to that of the Tasmian Blue Mussel (Mytilus edulis)

The study suggests that the Tasmania blue mussel has (naturally) an even higher content of omega-3 fatty acids that the Green Lipped Mussel. This is interesting since high value oil and protein, from Green Lipped Mussel are sold widely in the world market and blue mussels as such may have the same potential.

Lipid, FA, and Sterol Composition of New Zealand Green Lipped Mussel *(Perna canaliculus)* and Tasmanian Blue Mussel *(Mytilus edulis)*

Karen J. Murphy[a,*], Ben D. Mooney[b], Neil J. Mann[a], Peter D. Nichols[b], and Andrew J. Sinclair[a]
[a]RMIT University, Melbourne, Victoria 3001, Australia, and [b]CSIRO Marine Research, Hobart, Tasmania 7001, Australia

ABSTRACT: The lipid, FA, and sterol composition of the New Zealand green lipped mussel (NZGLM, *Perna canaliculus*) and of the Tasmanian blue mussel (TBM, *Mytilus edulis*) were compared using TLC–FID and GC–MS. The respective mussel species were obtained from three different sites in both New Zealand (NZ) and Tasmania. Lipid class distribution of both mussel species was characterized by a high proportion of phospholipid (PL, 57–79%) and TG (10–25%), FFA (7–12%), and sterols (ST, 12–18%). The NZGLM had higher proportions of TG, FFA, and ST ($P < 0.01$), whereas the TBM had a higher proportion of PL ($P < 0.01$). There were higher proportions of total PUFA, saturated FA, n-3 FA, and hydroxy and nonmethylene-interrupted FA ($P < 0.05$) in the TBM compared with the NZGLM. The major FA in the NZGLM were 16:0 (15–17%), 20:5n-3 (14–20%), and 22:6n-3 (11–17%). The same FA dominated lipids in the TBM, although there were significantly higher proportions of 16:0 ($P = 0.000$) and 22:6 n-3 ($P = 0.003$) and lower proportions of 20:5n-3 ($P = 0.0072$) in the TBM. A novel PUFA, 28:8n-3, was detected in both mussels with higher amounts in the TBM, which probably reflects a greater dietary contribution of dinoflagellates for this species. Cholesterol was the dominant sterol in both mussels. Other major sterols included brassicasterol, 22-methylcholesterol, *trans*-22-dehydrocholesterol, and desmosterol. There were significant differences ($P < 0.05$) between the NZGLM and TBM for 12 of the 20 sterols measured. Six sterols showed significant site differences for the NZGLM, and 10 for the TBM. The differences in the FA and sterol composition between the two species may be due to the diet of the NZGLM being more diatom-derived and the diet of the TBM having a greater dinoflagellate component.

Paper no. L8863 in *Lipids 37*, 587–595 (June 2002).

Molluscs are divided into seven classes; however, literature on their lipid composition is only available for a select group, one being the bivalvia (1). The New Zealand green lipped mussel (NZGLM), *Perna canaliculus* [not to be confused Hong Kong as investigated by Ching *et al.* (2), Li *et al.* (3), and Chong *et al.* (4)], is a bivalve marine mussel native to New Zealand (NZ), from the molluscan family Mytilidae, found in the deep-sea beds in the Hauraki Gulf in NZ's North Island waters (5,6). It is distinguished from other bivalve species by the presence of a bright green stripe around the posterior ventral margin of the shell and its distinctive green lip, which is visible on the inside of the shell. The flesh and ligaments of the NZGLM tend to be larger than those of the common blue mussel found in Tasmanian waters and referred to in this study as the Tasmanian blue mussel (TBM). It possesses a shape similar to the common blue mussel *(Mytilus edulis)* and can exceed 120 mm in size (6). The external color of the TBM can vary from blue to purple or black. It is found in coastal waters off the southern coast of Australia, spreading from the lower west to the lower east coast and into Tasmanian waters. TBM vary in size up to 130 mm; however, they are more commonly found to be less than 90 mm in size (7).

Lipid constitutes around 2% of the wet weight in the blue mussel (7–9) of which approximately 75% is structural lipids (10). Depending on season and/or the life cycle of the mussel, lipid content and composition may vary. During various stages of the life cycle, particularly in female mussels, the blue mussel is able to synthesize 16:0 and 18:0 and their derivatives *de novo* (10). Other biochemical changes in the mussel may result from variability in metabolic activity, location, sex, and spawning (11).

Mytilus edulis and *P. canaliculus*, like several other marine organisms such as molluscs in general and fish, not only are low in dietary cholesterol but also contain cholesterol-lowering phytosterols (12) and abundant n-3 PUFA, particularly the long-chain FA such as 22:6n-3 and 20:5n-3 (1); this is unlike most terrestrial organisms, which are rich in n-6 FA

Table 2 – lipid composition green lipped mussel vs blue mussel

	Perna canaliculus (NZGLM)	Mytilus edulis (TBM)
Lipid composition	60 % PL, 22% TG, 12% FFA	**74 % PL**, 13% TG, 7% FFA
DHA (C 20:5)	17,9%	14,6%
EPA (C 22:6)	13,5%	21,2%
Total omega-3	37,1%	41,5%

What makes mussel oil interesting?

In MumiPro it was evaluated whether a comparable content of omega-3 fatty acids are found in the Danish (organic) mussel. As such, a full fatty acid analysis of the fat component of Danish (organic) mussels from the MumiPro project were analyzed at DTU.

Table 2 – lipid composition green lipped mussel vs blue mussel

Fatty Acid	Kode-1 %		Kode-2 %		Kode--3 %		Kode-4 %		Kode-5 %		Kode-6 %	
	Average	StDev	Average	StDev	Average	StDev	Average	StDev	Average	StDev	Average	StDev
8:0	-	-	-	-	-	-	-	-	-	-	-	-
10:0	-	-	-	-	-	-	-	-	-	-	-	-
12:0	-	-	-	-	-	-	-	-	-	-	-	-
13:0	-	-	-	-	-	-	-	-	-	-	-	-
14:0	1,81	0,07	1,77	0,02	1,88	0,02	1,79	0,01	1,79	0,04	1,76	0,00
14:1	1,75	0,13	1,61	0,02	1,78	0,03	1,60	0,02	1,57	0,06	1,63	0,01
15:0	0,39	0,02	0,41	0,01	0,41	0,00	0,40	0,00	0,40	0,01	0,40	0,00
16:0	12,10	0,61	12,58	0,03	12,35	0,02	12,53	0,02	12,53	0,36	12,64	0,00
16:1 (n-7)	7,50	0,33	7,74	0,13	8,18	0,08	7,90	0,02	7,77	0,31	7,45	0,06
16:2 (n-4)	0,66	0,02	0,76	0,03	0,88	0,05	0,79	0,05	0,68	0,10	0,71	0,01
16:3 (n-4)	0,16	0,01	0,28	0,01	0,27	0,02	0,30	0,02	0,25	0,08	0,29	0,01
17:0	0,60	0,05	0,69	0,00	0,73	0,00	0,70	0,02	0,63	0,10	0,75	0,00
17:1	-	-	-	-	-	-	-	-	-	-	-	-
16:4 (n-3)	1,50	0,07	1,30	0,01	1,52	0,00	1,44	0,04	1,34	0,07	1,47	0,02
18:0	2,60	0,25	2,70	0,03	2,70	0,06	2,73	0,01	2,43	0,06	2,77	0,06
18:1 (n-9)	1,99	0,15	2,14	0,01	2,07	0,04	2,14	0,01	1,98	0,04	2,17	0,00
18:1 (n-7)	1,22	0,04	1,11	0,08	1,07	0,01	1,16	0,00	1,07	0,27	1,01	0,01
18:2 (n-6)	1,29	0,10	1,31	0,03	1,21	0,08	1,31	0,01	1,42	0,06	1,32	0,05
18:2(n-4)	0,53	0,07	0,64	0,01	0,62	0,00	0,65	0,00	0,63	0,01	0,59	0,02
18:3 (n-6)	-	-	-	-	-	-	-	-	-	-	-	-
18:3 (n-4)	0,40	0,05	0,49	0,02	0,49	0,01	0,50	0,00	0,45	0,01	0,41	0,01
18:3 (n-3)	1,44	0,11	1,41	0,02	1,29	0,01	1,49	0,01	1,48	0,01	1,41	0,01
18:4 (n-3)	3,84	0,25	3,55	0,04	3,60	0,01	3,65	0,02	3,70	0,06	3,63	0,05
18:5 (n-3)	-	-	-	-	-	-	-	-	-	-	-	-
20:0	0,65	0,03	0,64	0,01	0,65	0,02	0,67	0,00	0,60	0,05	0,66	0,01
20:1 (n-9,n-11)	2,40	0,04	2,41	0,01	2,26	0,06	2,31	0,01	2,36	0,04	2,42	0,02
20:1 (n-7)	2,85	0,11	2,99	0,01	2,82	0,03	2,87	0,00	2,90	0,00	2,86	0,01
20:2 (n-6)	0,65	0,08	0,64	0,02	0,54	0,01	0,60	0,00	0,64	0,03	0,60	0,00
20:3 (n-6)	0,39	0,07	0,35	0,01	0,29	0,00	0,33	0,00	0,37	0,03	0,31	0,00
20:4 (n-6)	1,12	0,03	1,12	0,01	1,07	0,01	1,04	0,01	1,02	0,09	1,07	0,01
20:3 (n-3)	0,10	0,01	0,14	0,01	0,11	0,00	0,13	0,00	0,18	0,09	0,13	0,02
20:4 (n-3)	0,35	0,07	0,35	0,00	0,32	0,00	0,34	0,00	0,40	0,07	0,36	0,00
20:5 (n-3)	20,29	1,16	21,44	0,05	21,19	0,10	20,90	0,10	20,58	0,36	20,48	0,06
22:1 (n-11)	-	-	-	-	-	-	-	-	-	-	-	-
22:1 (n-9)	-	-	-	-	-	-	-	-	-	-	-	-
21:5 (n-3)	0,90	0,05	0,87	0,00	0,92	0,00	0,91	0,01	0,97	0,05	0,92	0,00
22:2	-	-	-	-	-	-	-	-	-	-	-	-
22:3	-	-	-	-	-	-	-	-	-	-	-	-
22:4	-	-	-	-	-	-	-	-	-	-	-	-
22:5 (n-3)	0,93	0,19	1,03	0,09	1,10	0,02	1,19	0,03	1,11	0,18	1,10	0,03
22:6 (n-3)	11,72	0,70	12,61	0,12	11,99	0,11	11,21	0,07	12,28	0,06	12,50	0,05
24:1 (n-9)	0,05	0,03	0,04	0,01	0,08	0,02	0,09	0,02	0,14	0,07	0,09	0,01
22:0	-	-	-	-	-	-	-	-	-	-	-	-
24:0	-	-	-	-	-	-	-	-	-	-	-	-
Sum	82,18	4,52	85,14	0,32	84,41	0,43	83,67	0,24	83,68	1,21	83,90	0,06

	Danish (organic) MuMiPro mussels (fat)
DHA (C 20:5)	~ 21%
EPA (C 22:6)	~ 12%
Total omega-3	40,6%

Market analysis, products and insights

Products - an industry benchmark (Green lipped mussel) - AROMA New Zealand Ltd.

AROMA are manufacturing and supplying mussel oil and mussel powder/protein under brands such as GlycOmega® and Greenshell®. Manufacturing process somewhat comparable to proof-of-concept model used in MumiPro, whereby two main products are manufactured.

<u>GlucOmega® (oil)</u>

A product consisting of 99,1 g/100g fat (oil)

DHA level of 12,3g /100g, EPA level of 19,4g /100g, DPA level of 1,0g /100g - ALA level of 3,4g /100g

Sold in 18 kg plastic containers, flushed with nitrogen.

Pricing: 5kg (MOQ): 2.075€/kg, 10kg: 2.025€/kg (CIP, Vejle, Denmark)

<u>GlycoOmega® Plus (powder) – two grades</u>

A product consisting of 53,4 g/100g crude protein, total fat of 11,5g/100g and omega-3 of 3,5g/100g

Sold in 20 kg aluminium foil bags.

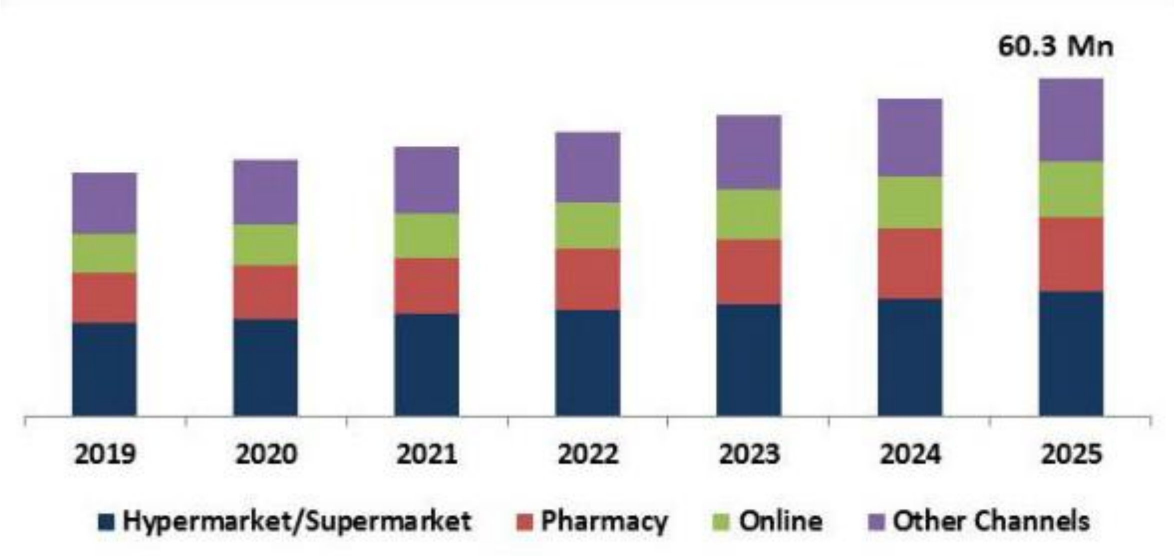
Pricing (standard grade): 20 kg (MOQ): 47,50€/kg, 100kg: 40,50€/kg

Pricing (no heat): 20 kg (MOQ): 66,00€/kg, 100kg: 62,50€/kg

"For the GlycOmega standard grade green shelled mussel powder the mussels are heat shucked to extract the meat. The meat is dried by using a flash dryer where the product is exposed to high temperature for a very short period of time (2-3 minutes). For GlycOmega Plus no heat is added at time of shucking. The product is freeze dried. GlycOmega Plus has clinical studies proving its efficacy"

Expected market size and development

Some industry analysts predict a growing market for mussel oil, such as f.ex. Kbv research with its report on the Global Mussel Oil (NZ coastal green-lipped mussel) market size growing from around $43 million in 2019 to $60.3 Million by 2025. A market growth of 5.51% CAGR (compound annual growth rate) during the forecasted period.



The main threat to market development, are consumers shifting towards a vegan lifestyle along with global warming, ocean pollution and exploitation of the oceans by human activities have significantly disturbed oceanic biodiversity, and hence potentially lead to decline in mussel count in the ocean. [Sustainable organic mussel farming – MuMiPro – the alternative]

Source, kbv research:

Global Mussel Oils Market By Application (Dietary Supplements, Processed Food, Biopharmaceutical, Pet Food & Veterinary and Beauty & Online) By Distribution Channel (Hypermarket/Supermarket, Pharmacy, Online and Other Channels) By Region, Industry Analysis and Forecast, 2019 - 2025

Market leaders

Mussel oil and – protein, as high value ingredients, used for human consumption are based on green lipped mussel biomass, as explained earlier. The market leaders are all New Zealand.

Maclab

https://www.maclab.co.nz (through/with Pharmalink extracts Ltd., including brand “Lyprinol®”, the main brand with clinical research)

Waitaki Biosciences

https://www.waitakibio.com (Pernatech® mussel powder / oil)

Aroma New Zealand Limited

https://aromanz.nz/ (Glycomega® and Glucomega® Plus, mussel oil and powder)

New products and go-to-market strategy

In “teknisk rapport om muslingemel og olie”, produced by DTU Food, Forskningsgruppen for fødevareproduktionsteknologi, it was discussed how and using which technologies, oil and protein can be extracted from Danish (organic) blue mussels.

It’s clear that the two new (main) high value ingredients, which could be developed from Danish (organic) blue mussels would be:

1) A natural (non-fractionated / non-concentrated) oil, rich in omega-3 (around 40%).
   This product can then have several ways to market, as branded / non-branded bulk material for further formulation, or as finished product in f.ex. soft gelatin capsules.
2) A natural (non-fractionated / non-concentrated) protein powder, utilizing the rest of the mussel (when the fat has been extracted), as a branded / non-branded bulk material for further formulation, or as finished product in f.ex. tablets, capsules or other delivery forms.

To produce a solid go-to-market strategy however, additional data needs to be evaluated, since the price and final composition (by way of fatty acid composition, amino acid profile) will be highly dependent factors such as:

- Supply-chain possibilities (organic mussel biomass access) and scaling (equipment) -> volume human/feed allocation
- Product composition(s) – oil / powder (nutritional categorization), product specifications and consistency
- Regulatory clarification, based on production process (as described earlier)

But bench marking up against the New Zealand world dominance in mussel oil and – powder, a Danish production set-up may be competitive, and with additional USP’s in terms of:

- Environmental sustainability (adding value to nature) and organic certification possible (!!)
- Unique nutritional profile, proteins, fatty acid profile, sterols and more – f.ex. potentially high level phospholipid content, documented to lead to increased absorption (the main rational behind krill oil existence)

Furthermore – local (Danish) access to biomass and production will avoid f.ex. Chinese direct competition (a general price challenge fish oil and many other high value ingredients), at it is the case for the NZ based green lipped mussel companies.

Development and distribution model to follow general market approach of high value branded ingredients