Quality Assurance Report
December, 2010

Bench marking overview

Introduction:

Today there are three main Producers of krill oil in the market, Producer A, Producer B and Producer C. Producer C is the company Mercola.com uses for their source of krill oil.

Producer C has taken the initiative to closely examine quality parameters and compliance with labeled specifications in krill oil manufactured by the three main producers. Very strict protocol was applied to ensure the impartial testing of the different brands. Analytical tests were done by third party laboratories.

Results and methodology:

Compliance with the label claims by vendors: The active ingredients of krill oil, which all Producers are committed to, are phospholipids, EPA, DHA, total omega-3 and astaxanthin level. Krill oil samples were tested by services specializing in 3 main areas: phospholipids, EPA, DHA and omega-3 fatty acids, and freshness indicators. While Producer A showed deviation from levels of astaxanthin and omega-3 fatty acids (DHA, EPA), Producer C and Producer B met the labeled specifications.

Stability of krill oil: Results obtained show that while Producer C and Producer B have similar levels of intact phospholipids, Producer B has a much higher level of lyso-phospholipids.

Safety and freshness: Producer C's krill oil has shown non-detectable levels of TMA in all three samples, and was always under the safety threshold. Average TMA results for Producer A were border line with the safety threshold. Highest levels were found for Producer B, with TMA levels reaching the value of 34 mg TMA/100 g oil. Results obtained for TVN levels displayed a similar trend.

Main conclusions:

1. Producer A consistently fails to adhere to its label claim for both astaxanthin, DHA, EPA and total omega-3 fatty acids.
2. Producer B's krill oil is highly unstable.
3. Producer B's krill oil has a foul smell, indicating a potentially unsafe product for human consumption.

1. Introduction

1.1 Krill Oil Producers

Today there are three main Producers of krill oil in the market, Producer A, Producer B and Producer C. Krill oil is distributed in the USA market by many branded companies who are buying krill oil from the above listed Producers.

1.2 Quality assurance in Producer C

Process of krill oil requires specialized knowledge of chemistry, analytical testing and process engineering in order to maintain the highest level of purity, stability and organoleptic properties. Producer C is committed to the best quality of its products and therefore has an active process development unit which works constantly to improve the product. Producer C's process development team has developed specialized know-how in key parameters such as the manufacturing process and raw material handling to ensure a high quality, fresh and stable product to their customers.

1.3 Bench marking

Producer C decided to perform bench mark testing by comparing its own product to the two other krill oil producers. Producer C has tested various quality safety and freshness parameters of 9 commercial brands. The results of the different analyses are described in this report in the following order:

Chapter 1: Compliance with the label claims by vendors
Chapter 2: Stability
Chapter; 3: Safety and freshness

The products were sent to third party, well established laboratories for analysis of levels of astaxanthin, omega-3 fatty acids, phospholipids and lysophosphatidylcholine, and freshness/safety indicators (TMA, TVN and TMOA)

1.4 Study protocol

Producer C has taken the following steps to assure that the bench marking report is impartial and is blinded to the krill oil samples tested:

a. Producer C sent a representative to purchase 9 commercially available krill oil packages. Three different brands for each of the main krill Producers.
b. The 9 packages were sent to a third party CPA. The CPA and her employees were instructed to do the following steps as to ensure that the analytical labs were blinded to the branded companies and the Producers' identity:
    i. Verify that all packages were intact and sealed
    ii. Open the packages and transfer all capsules to different pack ages as displayed in figure 1.
    iii. Send the newly packaged capsules to certified third party analytical laboratories as detailed in figure 1.
    iv. To instruct the certified laboratories regarding the required analytical tests that should be performed.

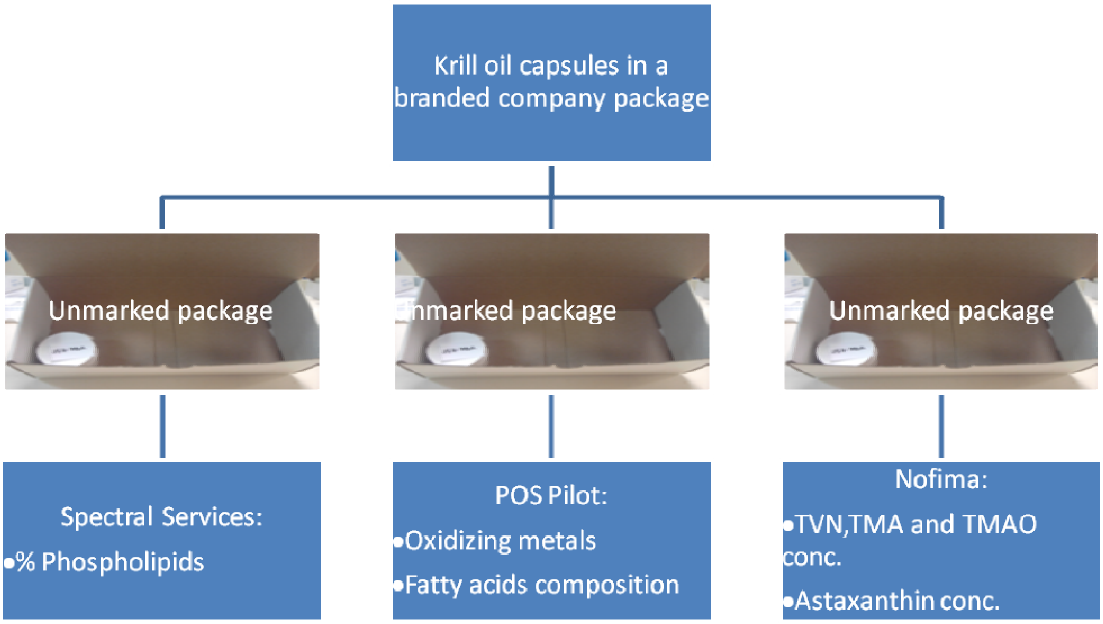


Figure 1: Flow chart of the different steps taken to ensure independent analysis of krill oil samples

1.5 Analytical laboratories

The laboratories chosen to perform the analytical tests were are well known in their field and have vast experience with marine and fish lipids.

Lab 1 utilizes standard methodologies of AOCS, AOAC, ISO, IUPAC, ASTM, AACC and internally developed methods. Furthermore, their analysis quality is monitored both internally and through a variety of national and international test programs.

Lab 2 is an independent private laboratory and offers spectroscopy as a scientific service, especially for organic substances. Their team specializes in modern techniques of NMR-spectroscopy and chromatography as well as mass-spectroscopy of organic substances. Lab 2 is both GMP- and GLP-certified and is approved by the US Food and Drug Administration (FDA), FEI-Nr. 3008542737.

Lab 3 specializes in fishery related analysis. It is an acceptable 3rd party laboratory for fish products quality and is considered as one of the most reliable analytical authority in northern Europe for marine products including fish oils. Lab 3's quality system for the analytical laboratory is based on the ISO 17025 standard and the laboratory is accredited by Norwegian Accreditation with accreditation number TEST 045.

2. Results and discussion

2.1 Compliance with the label claims by vendors

The active ingredients of krill oil, which all manufacturers are committed to, are phospholipids, EPA, DHA total omeg-3 and astaxanthin level. Recently, Consumer Labs, an independent laboratory, published a comprehensive report tha tested the compliance of certain krill products with specifications. 24 products were tested, including two krill oil brands produced by Producer C and Producer A. Producer B's krill oil was surprisingly absent from this report.

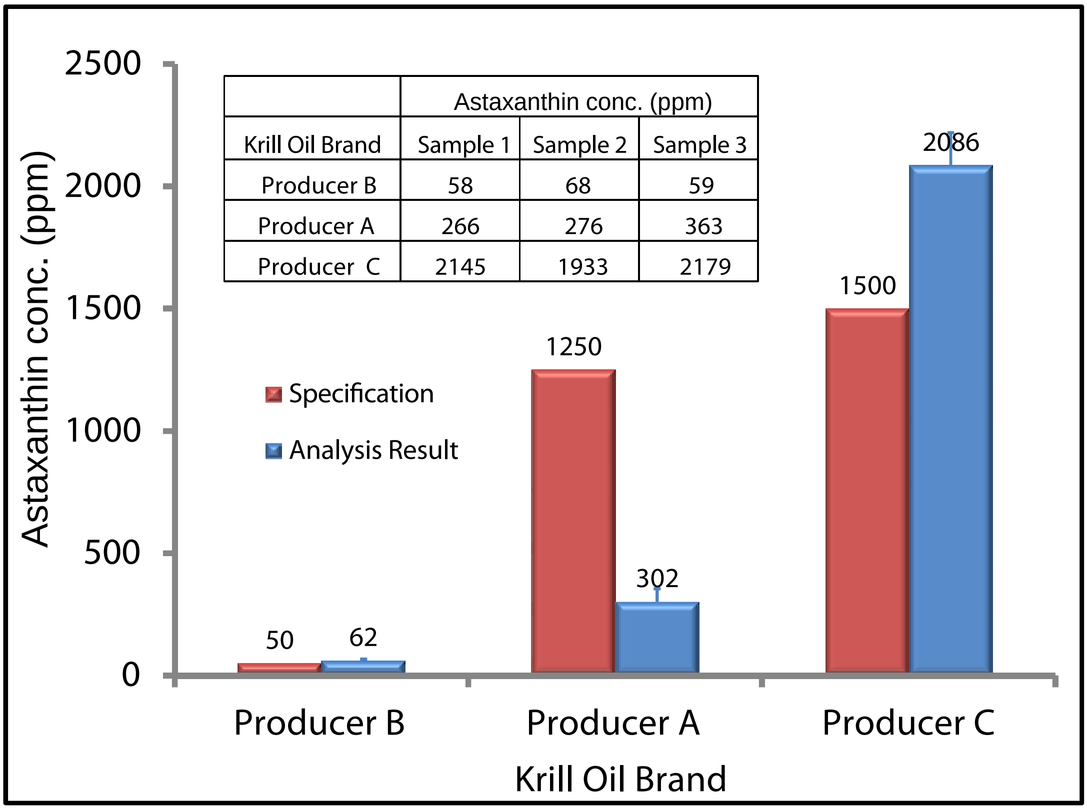
The first Chapter describes the tests results for the compliance with specifications of the three main active ingredients in krill oil, astaxanthin, total omega-3 content (mostly EPA and DHA) and phospholipids, in 9 commercial brand (3 from each producer).

2.1.1 Astaxanthin

Krill oil contains a unique and very potent antioxidant called astaxanthin. Astaxanthin is one of the most potent natural antioxidants known to man, making it one of the most desirable and important components in the krill oil supplements.

Due to astaxanthin reactivity; assurance of its stability requires very unique production technology. There are two general methods for analyzing the astaxanthin content of a product: Spectrophotometric analysis and High Pressure Liquid Chromatography (HPLC) analysis. The limitation of Spectrophotometric assay method is that, in addition to astaxanthin, other carotenoids are falsely included as astaxanthin in the results3. The most technically sound and accurate method for determining the astaxanthin content of a product is by HPLC analysis, which is the method used by Lab 3.

Figure 2: Astaxanthin concentration in krill oil samples compared with specifications



Astaxanthin levels were measured by Lab 3 using an HPLC (Lab 3 A23) Figure 2 displayed the average result of astaxanthin level for each of the Producers (blue column) and the level specified on the label for each of the krill oil samples (red column). Actual astaxanthin level in each of the 9 samples tested is displayed in the insert (small table). Both Producer C and Producer B are in compliance with the specifications as stated on the product label. However, while Producer C is in compliance with specifications of 1500 ppm, Producer B's specification is for 50 ppm only.

Producer A's krill oil results on the other hand demonstrate a significant deviation from the specified level for all tested samples. Instead of a labeled level of 1500 ppm, the actual astaxanthin levels show an average of 300 ppm (actual astaxanthin amount is only about 20% of specified).

2.1.2 Omega-3 (DHA/EPA)

Omega-3 fatty acids are long chain polyunsaturated fatty acids, and are a very important component of krill oil. Omega-3 fatty acids in krill oil are attached to phospholipids, unlike in fish where they are attached to triglycerides.

Krill oil samples were tested by Lab 1 (method: AOAC 969.33 prep, AOAC 996.06 quant. Modified). Analysis results for total omega-3 fatty acid in krill oil samples from Producer B, Producer A and Producer C levels are displayed in table 1.

Table 1: level of EPA, DHA and total omega-3 for krill oil from Producer B, Producer A and Producer C

	EPA (mg per 1000mg serving)		**DHA (mg per 1000mg serving)**		**Total Omega 3 (mg per 1000mg serving)**	
Krill oil brand	**Label**	**Analysis**	**Label**	**Analysis**	**Label**	**Analysis**
Producer B	115.0	126±7.6	65	69±2.5	230	232±8.3
Producer A	**150.0**	**107±3.6**	**90**	**61±2.5**	**300**	**206±7.7**
Producer C	150.0	169±11.6	90	119±16.9	300	335±28.5

The analysis results clearly indicate that Producer C's krill oil has presented the highest level of EPA, DHA as well as total omega-3. Producer B's krill oil omega-3 levels (EPA, DHA and total) was in compliance with their specifications as labeled on the product, however, Producer A's krill oil failed to meet the specifications in levels of EPA, DHA and total omega-3. These results are in agreement with the results published by Consumer Labs regarding omega 3 content in Producer A’s krill oil.

2.1.3 Phospholipids

In contrast to traditional omega-3 supplements on today’s market, which are based on omega-3 fatty acids attached to triglycerides (such as cod liver oil and fish oil) or bound as ethyl esters, krill oil contains a high proportion of omega-3 fatty acids conjugated to phospholipids. Krill oil EPA/DHA are considered highly bio-available, based on preclinical studies that have shown that omega-3 fatty acids attached to phospholipids are delivered to different organs such as the brain and liver more efficiently.

The phospholipid structure of the EPA and DHA in krill oil makes them much more absorbable. Phospholipids content in krill oil produced by the different producers is present in figure 3. The results show that all the tested products are in compliance with their specifications.

2.2 Stability

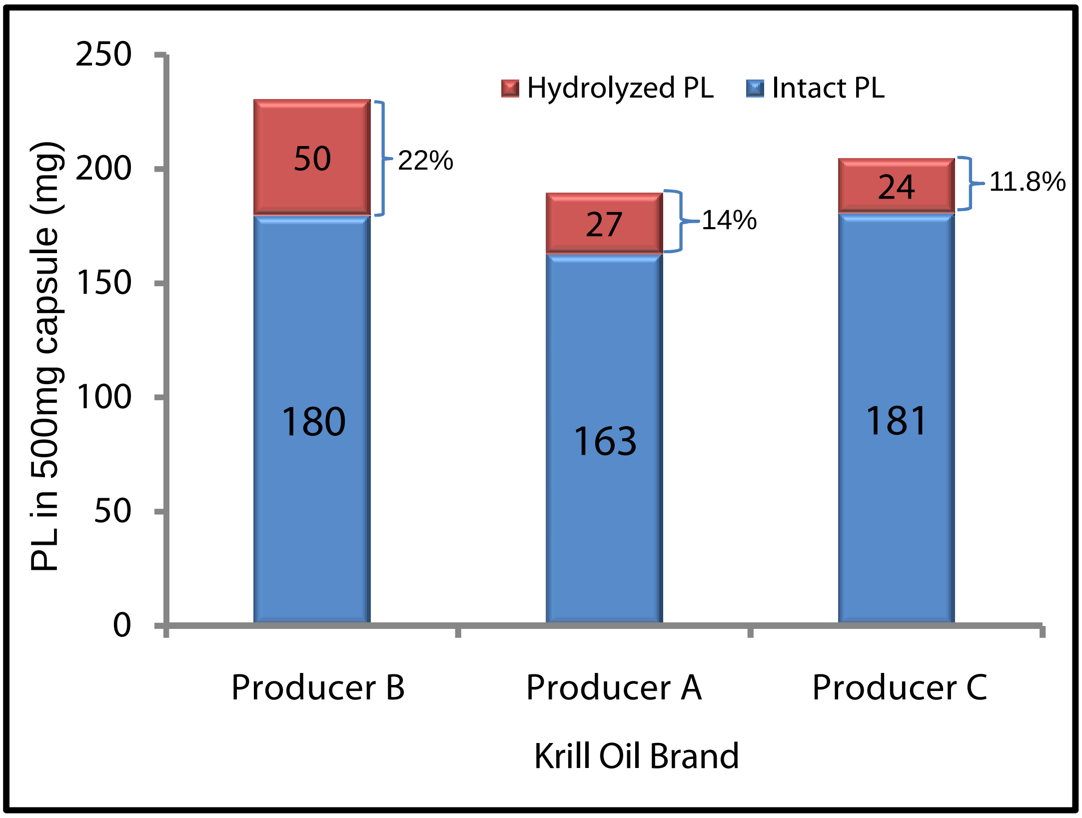
The processing of krill oil requires specialized knowledge of chemistry and process engineering in order to maintain appropriate purity, stability, and quality. Krill oil stability and quality were tested. Producer C has tested the lysophospholipids content and oxidation potential that can lead to lipids oxidation.

2.2.1 <u>Lyso-phospholipids as an indicator to quality and stability</u>

Phosphatidylcholine (PC) is the most abundant phospholipid present in krill oil. PC is comprised of two fatty acids and a choline head group attached to its glycerol backbone. However, PC can be subject to degradation when one of the fatty acids is detached from the glycerol

back bone, leading to the formation of lyso PC, a degradation product of the original PC. This degradation process may occur to all phospholipids present in the krill oil (such as PE). Therefore, high levels of lysophospholipids in the product indicate either the use of degraded krill raw material, in which the phospholipids are already degraded, or improper and uncontrolled manufacturing process. High lyso-phospholipids levels typically go hand in hand with high levels of free fatty acid. It should be noted that lyso-phospholipids are a non-toxic substance and can only be used as an indicator for stability and quality testing.

Figure 3: Lyso-phospholipid content compared with total phospholipids

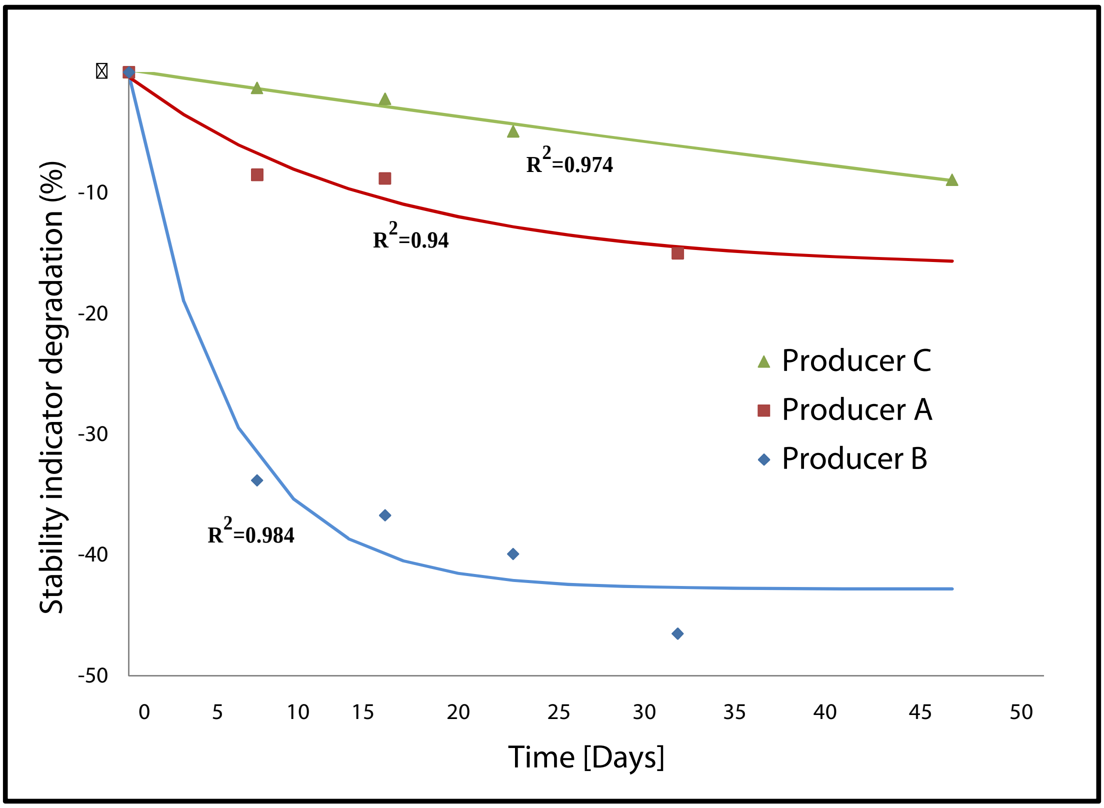


Lab 2 received nine krill oil samples for testing, three from each of the producers. They tested the samples for phospholipids composition using 31PNMR The results are shown in figure 3. Lab 2 provided detailed reports of all the different phospho-lipids present in each of the krill samples. The blue bars in figure 3 represent the total phospholipids (that are attached to two fatty acids chains) and the red bars represent lyso-phopholipids. The results show that while Producer C and Producer B have similar levels of intact phospholipids, Producer B has a much higher level of lyso-phospholipids, suggesting that they either use degraded krill raw material, or have a problematic manufacturing process that may cause phospholipids hydrolysis. Producer C's krill oil contains the lowest concentration of lyso-phopholipids.

2.2.2 Stability of krill oil and its susceptibility to oxidation

In order to demonstrate the stability of krill oil and its susceptibility to oxidation and compare between suppliers, astaxanthin was used as an indicator for oxidation atatus assessment. Astaxanthin is highly reactive (therefore a very potent antioxidant) and will potentially be consumed more rapidly than other natural antioxidant in the presence of peroxides and other oxidants. In this experiment, bulk amounts of krill oil produced by Producer C, Producer A and Producer B and tested stability of astaxanthin were used.

Figure 4: Degradation profile of the stability indicator following accelerated conditions incubation (40ºc).



In this experiment (presented in figure 4) similar concentrations of astaxanthin (same producer and LOT number) were added into Producer C, Producer A and Producer B krill oils (same expiration date). The stability study was carried out in accelerated conditions (40ºc). The results demonstrate that following one week, astaxanthin levels in Producer B's krill oil degraded significantly, (33.8% decrease) compared to Producer C's krill oil (only 1.3% decrease). These results suggest that Producer B's product is highly unstable due to the presence of oxidants. There is high likelihood that this is a fundamental result of the purification process currently in use. The results also demonstrate that Producer As's astaxanthin levels degraded much faster than in Producer C's (8.5%

decrease for Producer A's krill oil compared with only 1.3% decrease for Producer C's krill oil) following only one week.

2.3 Safety and its indicators (levels of TMA, TVN and TMAO)

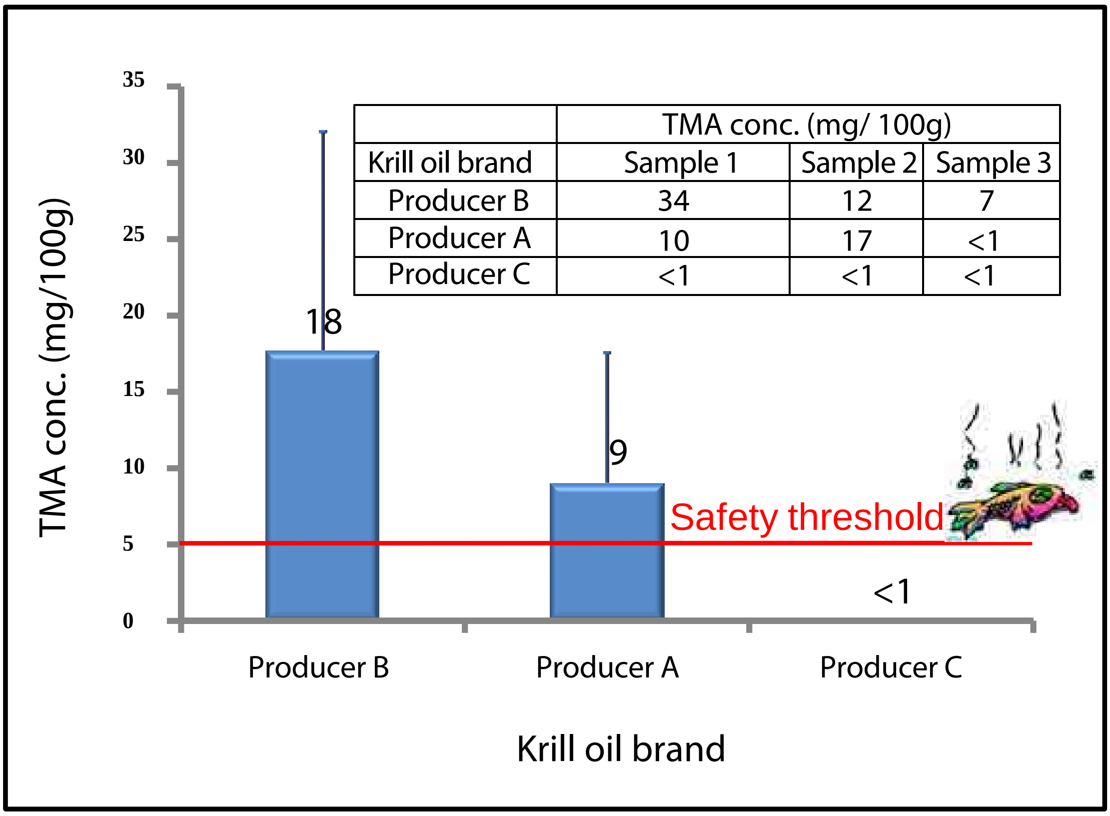
Freshness indicators:

Trimethylamine oxide (TMAO) is a natural and nontoxic substance found in marine species of fish, shellfish and crustaceans. Tri Methyl Amine (TMA) is a degradation product of choline and TMAO and is responsible for the characteristic 'fishy' odor of rotting fish. TMA has been extensively discussed as a spoilage index for commercial fish [4].

An additional index for spoilage is the total volatile basic nitrogen (TVN) which includes TMA, ammonia and other basic nitrogenous compounds. Thus, the most common chemical parameters for assessing the freshness of fish are the determination of both TVN and TMA.

Although the significance and limitations of these chemical indices have been underscored by several authors, they have been widely used as a freshness index because of their close correlation with the organoleptic score[4].

Figure 5: TMA concentration in krill oil samples



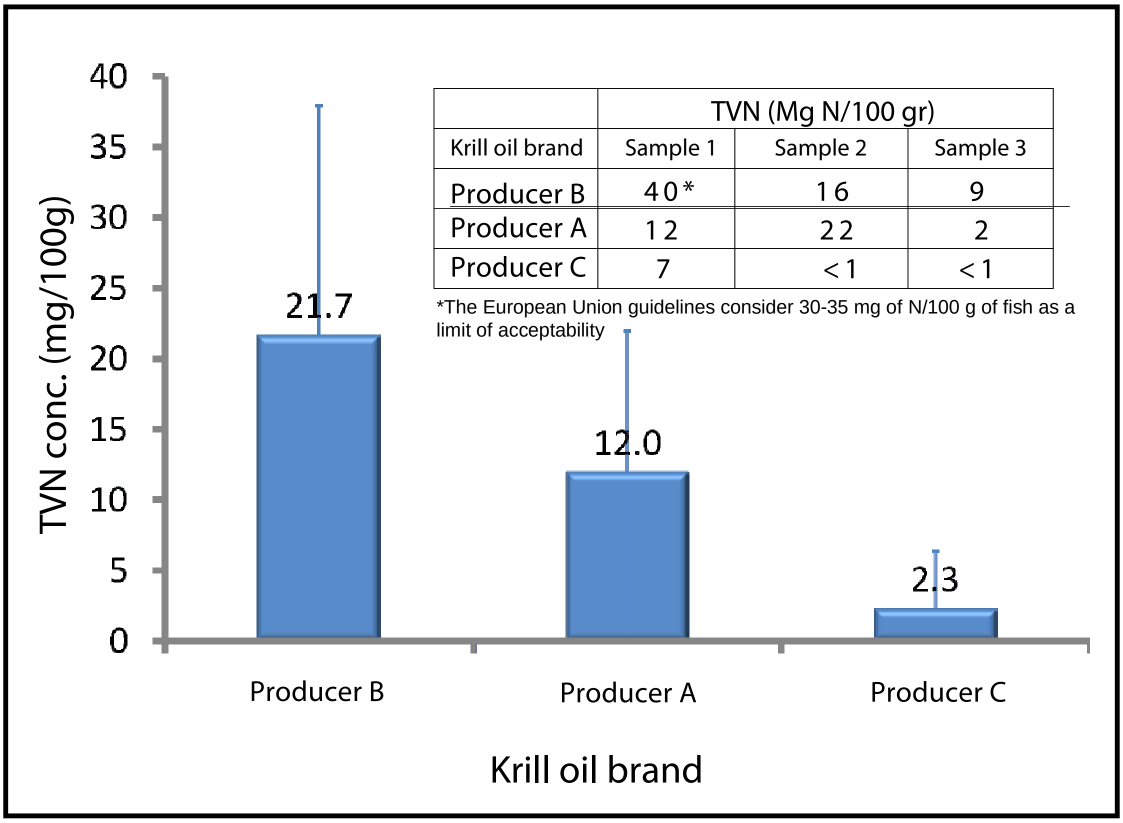
	TMA conc. (mg/ 100g)		
Krill oil brand	Sample 1	Sample 2	Sample 3
Producer B	34	12	7
Producer A	10	17	<1
Producer C	<1	<1	<1

Level of TMA

Concentration of TMA was tested by Lab 3 (method: Lab 3 A47). The result of the average TMA concentration with SD are shown in Figure 5 with the safety threshold which was determined from 5 to 10 mg/100 g for fresh fish5. Producer C's krill oil showed non-detectable levels of TMA in all three samples, and was always under the safety threshold. Average TMA results for Producer A is 9 mg TMA/100g oil, (borderline with the safety threshold), and one of the samples reached a much higher level of 17mg TMA/100g oil. However, the highest levels were found for Producer B, with TMA levels reaching the value of 34 mg TMA/100 g oil. These results show that all three samples of Producer B's krill oil and two of Producer A's krill oil were found to be spoiled. In contrast, Producer C's krill oil showed no spoilage signs in all tested batches.

In a well-described biochemical reaction, choline is known to easily degrade to TMA. This is one reason why ingesting high levels of free choline can lead to "fishy" breath, "fishy" bowel gas, or "fishy" stools. As excess choline is broken down in the gut, TMA is formed, with its attendant fishy odor. TMA can also form when the choline portion of phosphatidylcholine breaks down in storage or processing. Thus, the presence of TMA in a finished product suggests degradation (of the choline portion) of phosphatidylcholine.

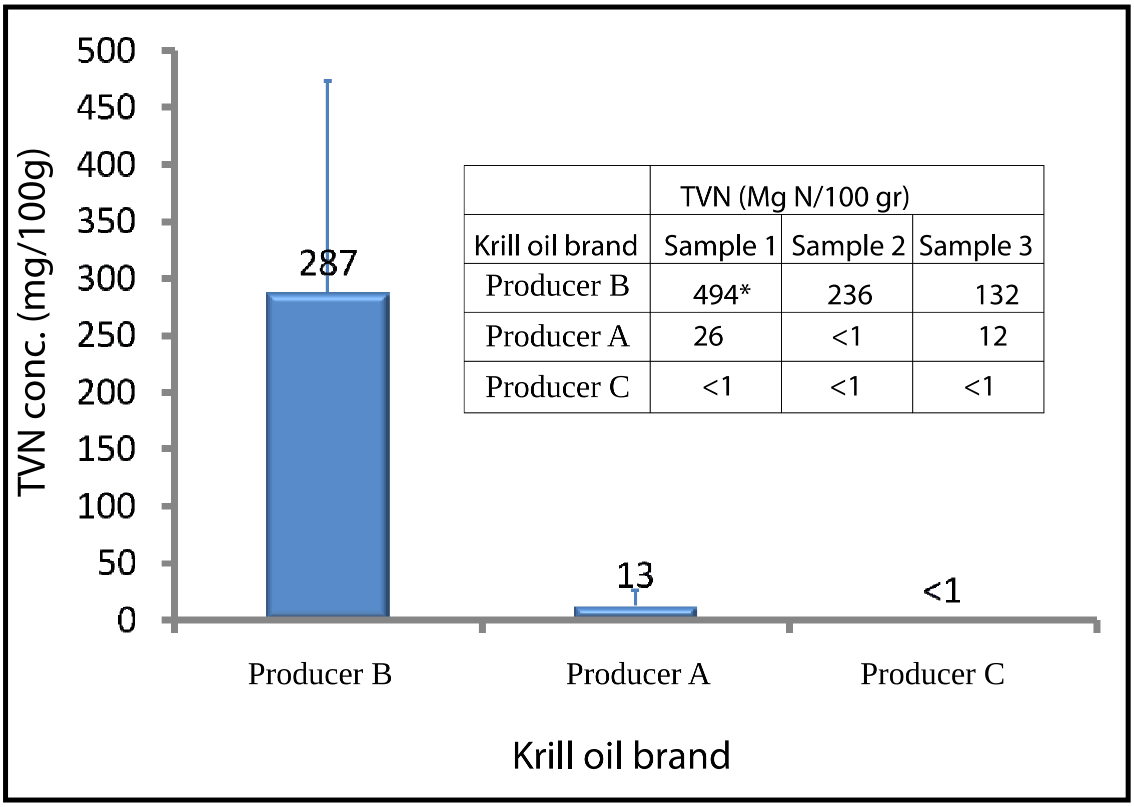
Figure 6: TVN concentration in krill oil samples



	TVN (Mg N/100 gr)		
Krill oil brand	Sample 1	Sample 2	Sample 3
Producer B	40*	16	9
Producer A	12	22	2
Producer C	7	< 1	< 1

According to Commission Decision 95/149/EC, unprocessed fishery products shall be regarded as unfit for human consumption when TVN levels exceed 35 mg N/100 gram. Though the commission decision relates to unprocessed fishery products, TVN levels were tested in all krill oil samples by Lab 3 (method: Lab 3 A47). Results are shown in figure 6 suggesting that the lowest levels of TVN were found in Producer C's krill oil. Two out of three samples of Producer C had undetectable levels of TVN and the third one had 7 mg N/100 g oil. Krill oil samples produced by Producer A showed slightly higher levels of TVN, but were still below the limit as set by the European Union. Producer B's samples had the highest average for TVN level and one of them exceeded the acceptability limit set by the European Union. It is quite clear that Producer B's krill oil is contaminated with undesired chemical degradation products that may be formed due to the use of improper or non-fresh raw materials and uncontrolled process.

Figure 7: TMAO concentration in krill oil samples



	TVN (Mg N/100 gr)		
Krill oil brand	Sample 1	Sample 2	Sample 3
Producer B	494*	236	132
Producer A	26	<1	12
Producer C	<1	<1	<1

Though levels of TMAO are not considered a health risk, TMAO is the precursor for TMA. Therefore, when TMAO is present in high levels, we can expect a consequent elevation in TMA levels.

TMAO levels were tested by Lab 3 (method: Lab 3 A47), on three batches of krill oil from the three producers. Figure 7 displays the results of these tests. Producer C's TMAO are under the detection limits. Producer A's krill oil had higher levels, with an average of 13 mg N/100g oil, however, Producer B's krill oil displayed very high levels, over 2000% more than Producer A. This troubling result suggests that Producer B's krill oil, containing high level of TMA and TVN will further degrade and accumulate extreme amounts of the two compounds as well as other contamination nitrogen compounds.

3. Conclusions

Producer C took the initiative to closely examine quality parameters and compliance with labeled specifications in krill oil manufactured by the three main producers: Producer A, Producer B and Producer C. To assure the impartial testing of the different brands, the entire process from purchasing the different krill oil packages, opening the sealed bottles, transferring the capsules into unlabeled containers and sending to analytical laboratories was all done by a third party.

- **Producer A consistently fails to adhere to its label claim**

The results obtained by the analytical laboratories were presented in this report and the conclusions are very clear. None of the krill oil samples manufactured by Producer A were in compliance with their reported specifications. Producer A's samples did not meet the specified levels of the majorcomponents of krill oil, both astaxanthin and omega-3 fatty acids (EPA, DHA and total omega-3 fatty acid) in each and every one of the samples. On the contrary, krill oil samples produced by Producer C and Producer B were in compliance with reported specification for phospholipids, omega-3 (EPA, DHA and total omega-3 fatty acids) and astaxanthin.

- **Producer B's krill oil is highly unstable**

The phospholipids composition analysis results obtained by Lab 2 show that while Producer C and Producer B have similar levels of intact phospholipids, Producer B has much higher level of lyso-phospholipids, suggesting that Producer B may either be using degraded krill raw material, or using a manufacturing process that may cause phospholipids hydrolysis. It should be noted that Producer C's krill oil was found to have the lowest concentration of lyso-phopholipids. It was found that 33% of the astaxanthin in Producer B's krill oil was degraded 1 week following incubation under accelerated conditions. These results strongly support the fact that Producer C's krill oil is significantly more stable.

- **Producer B's krill oil has a foul smell, indicating a potentially unsafe product for human consumption**

Lastly, we have also tested freshness indicators and found that krill oil manufactured by Producer C has the lowest (in most cases un-detectable) limits TMA, TVN and TMAO. In contrast, the krill oil produced by Producer B showed very high concentration of TMA, TVN and TMAO indicating spoilage and in one case even unfit for human consumption according to the Commission Decision 95/149/EC.

As mentioned before, processing of krill oil requires specialized knowledge of chemistry and process engineering in order to maintain appropriate purity, stability, and odor control. There are three key process control elements requiring specialized know how to ensure that a high purity product is provided to our customers. Any potential client considering the purchase of bulk krill oil is advised to employ a third party laboratory to analyze for the presence and amount of the analysis that are the subject of this memorandum. These are:

1) Trimethylamine (TMA)
2) Total volatile nitrogen (TVN)
3) Trimethylamine oxide (TMAO)

And finally, a comment regarding freshness….

A member of the 49th Congress (1885) articulated the need for regulation when he said that: "In ordinary cases the consumer may be left to his own intelligence to protect himself against imposition. By the exercise of a reasonable degree of caution, he can protect himself from frauds… and can impose a penalty upon the fraudulent vendor. As a general rule the doctrine of laissez faire can be applied. Not so with many of the adulterations of food. Scientific inspection is needed to detect the fraud, and scientific inspection is beyond the reach of the ordinary consumer. In such cases, the Government should intervene."

4. References

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