Report

GOED Conference
Summarized (Key) Presentations

Edited March 2011

GOED EXCHANGE 2011

January 13-14, 2011 . Salt Lake City, Utah U.S.A.






Bringing together experts to dissect and analyze the marketing, regulatory, scientific, quality and innovation issues facing the omega-3 market.

Keynote Speaker

Richard Carmona, M.D.
17th Surgeon General of the United States

Register Online
www.GOEDexchange.com

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GOED

EXCHANGE 2011

Day 1 : Plenary Session

A Challenge to the Omega-3 Industry
Dr. Richard Carmona, 17th Surgeon General of the United States

Market Overview Panel
Christopher Shanahan, Frost & Sullivan
David Sprinkle, Packaged Facts
Greg Stephens, Natural Marketing Institute

Omega-3 Claims: Risk, Substantiation and Enforcement
Devin Domond, US Federal Trade Commission
Gary Coody, US Food and Drug Administration
Nigel Baldwin, Cantox

How Industry Can Leverage the Omega-3 Consortium
Dr. Bruce Watkins, University of Connecticut

Sustainability of EPA and DHA Sources
Dr. Michael Crawford, London Metropolitan University
Dr. Simeon Hill, CCAMLR
Kees Lankester, Marine Stewardship Council
Andrew Jackson, International Fishmeal and Fish Oil Organisation

Role of future sources of EPA and DHA
Crop geneticist, TBD (Invited)
Dr. Niels-Henrik Norsker, Wageningen University and Research

Annual GOED Awards Dinner
Keynote Address: Omega-3 Intake in the US Military
Capt. Joseph Hibbeln, National Institutes of Health

Day 2 : Plenary & Breakout Sessions

Roundtable: The Early History of Omega-3 Research
Dr. Jorn Dyerberg, University of Copenhagen (Ret.)
Dr. Bill Lands, National Institutes of Health (Ret.)
Dr. Michael Crawford, London Metropolitan University

Innovative uses of EPA and DHA – Surgery and apraxia
Dr. Robert Martindale, Oregon Health Sciences University
Dr. Claudia Morris, Children's Hospital & Research Center of Oakland

Regulatory Breakout Session: What impact Can Recommended intakes Have in Public Health?
Jacques Delarue, French Agency for Food, Environmental and Occupational Health & Safety
Andrea Mortensen, Omega-3 Centre

Scientific Breakout Session: Using Omega-3 Blood Testing to increase EPA/DHA intakes
Bill Harris, Sanford Health
Penny Kris-Etherton, Pennsylvania State University

Marketing Breakout Session: Can Pharma and Dietary Supplement Omega-3s Coexist?
Naoyuki Tanaka, Nippon Suisan
Andrew Shao, Council for Responsible Nutrition (Invited)

Regulatory Breakout Session: What Role Will a Codex Standard Have in Regulation?
Neil Buck, Industry Working Group
Christina Blummer, Swiss Codex Delegate (Invited)
Paulo Almeida, US Codex Office (Invited)

Scientific Breakout Session: What is the Future of Dementia and Depression Research?
Capt. Joseph Hibbeln, National Institutes of Health
2nd Speaker TBD

Marketing Breakout Session: Using Social Media to Reach Health Consumers
Sylvia Rowe, SR Strategy
John Wayne Zimmerman, eRocketFuel (Invited)
Jeff Hilton, Integrated Marketing Group

Regulatory Status in Major Asian Countries
Takeshi Takeda, Global Nutrition Group

Source Identification in the Detection of Adulteration
Marits Aursand, SINTEF
Andres Marino,UCLM

Future of Omega 3 Functional Foods
Elizabeth Rahavi, International Food Information Council
Ian Newton, Ceres Consulting

Contaminants in Fish Oils
Colin Garrioch, Nutrasource Diagnostics
Fishoilsafety.com (Invited)
Claire Kruger, Spherix

Summary

The conference was set on a two-day closed sessions, addressing regulatory, marketing and sourcing concepts that affect and shapes the fish oil industry as a whole, EPA/DHA in particular.

GOED Conference speakers, and attendees, agreed EPA/DHA to be the current most important market, eventually becoming even larger. Although the EU and Asian markets are steadily growing in importance (volume mostly), EU's regulatory aspects and Asian traditional food and medicine practices will make their market development take longer.

EPA & DHA most important sources remain marine-origin fish oils. Vegetable sources have still a road to transit prior having a truly and long lasting competitive stance against marine-origin EPA/DHA.

Krill oils, although all in consensus to be a new ingredient, it was labeled as the "**star-of-the-show**" by one speaker. Although still small in volume, its >20% CAGR is the most impressive one among all marine-origin lipids.

With the current EPA & DHA consumption trend, with it comes the importance to sort out several concepts, such as (1) is it medical treatment or supplementation? (2) Prevention purposes? (3) can be used as a trauma response ? (4) ARA demolition?

One thing for sure is that regulatory aspects will prevail as the main problem for a healthy growth of the category, more in the EU market.

Regulation, at least in the US, has been sorted out in a much better way, at least for sales volumes, in terms of quality between an Rx and a Dietary Supplement. This will bring more changes for these regulations, but not necessarily an ease of current ones.

The big question…..will pharma and dietary supplements co-exist?

Under the US perspective (1) Rx formulations (under a physicians supervision) are appropriate when provision of EPA and DHA are part of the medical management of very high triglycerides, (2) It may not be appropriate to raise EPA/DHA levels in healthy individuals that do not eat fish, pregnant woman, or a child who hates fish, (3) Insurance reimbursement for Rx n-3 when used for very high TGs.

Nonetheless, there is no 'alternative' physiology, (4) High quality dietary supplements providing the same amount of EPA and DHA in the same ratios showing the same biologic effect as compared to a drug and (5) The only difference will be the label and allowable claims.

The current coexistence of Rx and dietary supplement omega-3 fatty acids has likely benefited both categories through (1) Multiple marketing efforts maximizing consumer awareness (2) Maximized distribution channels and (3) Increased physician and pharmacist awareness and comfort of the category

Rx products continue discrediting dietary supplement omega-3s in an attempt to gain market share, however, dietary supplements will continue to thrive as a category due to (1) The variety and flexibility of dietary supplement omega-3 products and claims (2) The legal and regulatory environment favor the latter (3) Supply chain transparency and (4) Clear consumer preferences.

The success of Rx Omega-3s anyway may be representative of the size and scope of the Rx market and not a result of siphoning sales from DS products.

The biggest threat to the dietary supplement Omega-3 products would be a significant change to USA's DSHEA[1] where DS Omega-3 companies would benefit from being vigilant about protecting supplement regulation as opposed to focusing on the success of Rx products.

[1] Dietary Supplement Health and Education Act

How about risks? and hazards? this is a dilemma that was also addressed, being (1) The purpose for setting specifications is to control risks, not eliminate hazards (2) The absolute absence of a risk can only be proved when it is certain that exposure does not exist (3) The Goal of "**I can't find it so it must be safe**" approach to controlling environmental risks is flawed and (4) Analytically, regulators must link the term "no residue" to a current method of analysis; constrained to a limit of detection.

One speaker urged for a set of fish-oil specifications that may define how the category will look and be traded in the near future, among them (1) Physical and chemical properties, e.g. appearance, odor, taste (2) Fatty acid composition, e.g. EPA, DHA. Mono- di- and tri-glyceride, (3) Environmental contaminants, e.g. PCBs, furans, dioxins and (4) Biological contamination, e.g. E. coli, Salmonella spp., coliforms

On marketing aspects, brand loyalty is significantly important for the category. Omega-3 users are the ones that have the highest brand loyalty. Same users also have the largest desire for good quality and are willing to pay more for it.

And it is end users' awareness what will define how much growth the Omega-3 category will support in the coming 4 to 5 years.

Overall, Omega category main drivers seen to be (1) Brands (2) Private labels (3) BRIC markets (4) Beverages in Europe, Latin America (5) Foodservice, seasonal immunity products (6) Facial and skin care in Asia / Pacific and (7) Pet nutraceutical treats.

In terms of krill biomass and resource condition, it is still based on theoretical requirements although there is currently a precautionary catch limit equals to 9% of stock biomass (in 2000) and the operational catch limit ("**trigger level**") is only 1% of the current estimate of stock size.

Is hemp the new blockbuster ?

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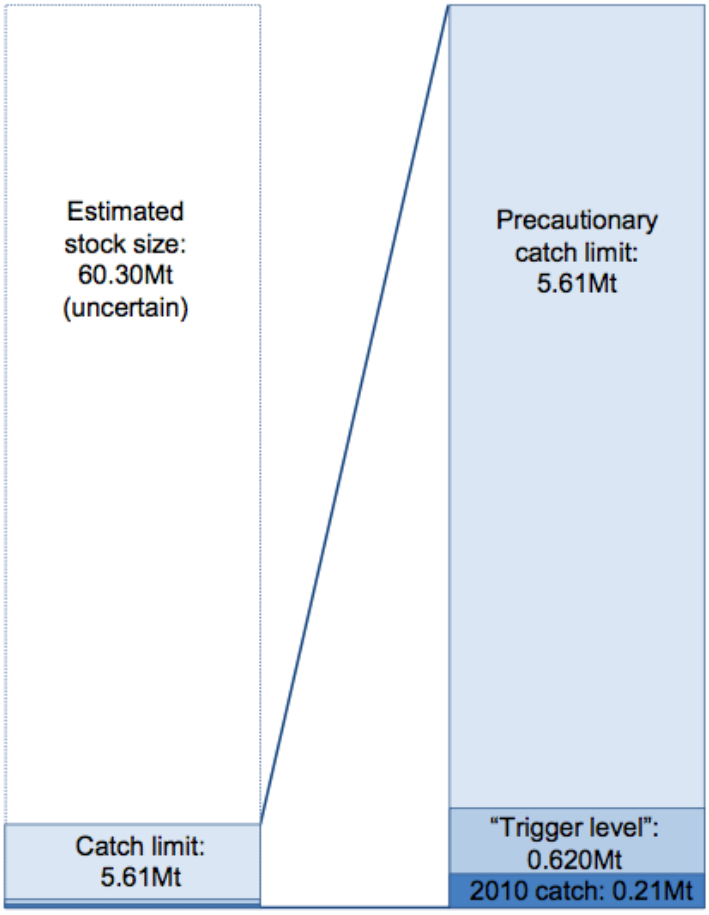
South Antarctic Krill[2] Sustainability

Summarized Concepts [3]:

(1) CCAMLR[4], as a krill fishery supra-national body, acts on consensus and still sees this fishery as a well-managed one.
(2) Current catch levels seen as "sustainable".
(3) Future fishing restrictions will be applied more on a spatial activity rather than a closure of the fishery. Limitations will come from zoning. For example, the risk to predators depends on how much krill is caught and where it is caught.
(4) So far the "**consensus approach**" has worked well and has allowed a good level of understanding. For how long?
(5) Expectations on krill IUU[5] are real, forcing CCAMLR to improve its monitoring and control practices, which today are rather limited.
(6) Krill oil and other **"**extracts**"** are becoming increasingly important.
(7) There is still debate on how South Antarctic Krill synthesize its PUFA's and still it obtains them from its feed (algae) rather own synthesis process.
(8) Several questions remain to be answered and it will take time to find an answer. Among the key ones is how to manage krill fishery;
    a. How much?, still based on theoretical requirements. Current precautionary catch limit = 9.3% of stock biomass (in 2000).
    b. Where?, this issue hasn't been resolved. Until the Commission has defined an allocation of this total catch limit between "**smaller management units**", the operational catch limit ("**trigger level**") is only 1% of the current estimate of stock size[6].
    c. Why hasn't CCAMLR set fine scale catch limit? These limits have been proposed and evaluated but have not been unanimously agreed.

[2] ***Euphausia superba***, Dana
[3] On this presentation.
[4] Commission for the Conservation of Antarctic Marine Living Resources
[5] Illegal, Unreported, Unregulated
[6] There are also "sub-area" catch limits of no more than 45% in any subarea.



There is growing "media and public" concern on resources condition and if there will be constant and sustainable supply of overall marine species, not only krill, to be used as raw material for the EPA/DHA category. This is applicable for various species such as, but not limited to Cod, Mackerel, Sardine, Krill, etc.

Most pressing channels is media coverage and NGO's (e.g. Pew Trust, Greenpeace, ASOC).

Sustainability objectives were defined[7] as the (a) Maintenance of human benefits from fish stocks, (b) Maintaining the ability of fish stocks to replace themselves and (c) Maintaining the integrity of ecosystems. CCAMLR's work on krill was emphasized as a truly supra-national, resource-preservation-oriented conservation work.

Krill fishery is receiving and will receive an even higher attention. More fishing regulations in the form of MPA's[8] and TAC's[9]. So far the krill fishery is seen as a well-managed fishery with catch limits well within CCAMLR's own regulation and well bellow standing biomass. The remaining hurdle is how to define which is the best TAC volume and how to assess the biomass.

"Counting fish is like counting trees, except they are invisible and they keep moving" (John Shepherd)

Main "sustainable" concepts discussed about krill;
(1) Sustainability
(2) Risks
(3) Management

The scientific community is trying to agree on which conservation approach to follow: The ecosystem versus the precautionary approach.

Problems for both:

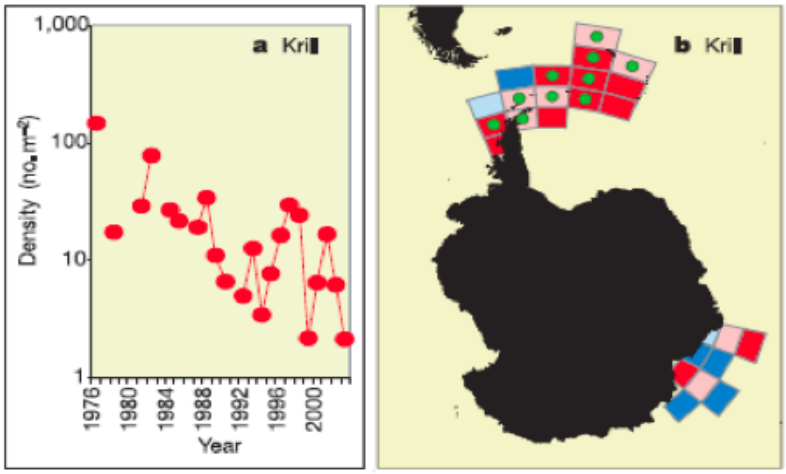
a. Stock size (and productivity) that naturally changes over time.
b. There is more of what is not known rather what it is known.
c. For example, not known about stock size, even less about how these stock sizes will change in the future….and even much less about how the Southern Hemisphere Antarctic Convergence ecosystem works.
d. Therefore there is not certainty on how krill fishing will affect fish stocks and the ecosystem itself.

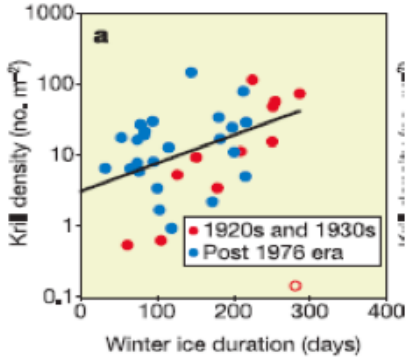
[7] By the British Antarctic Survey (BAS).
[8] Marine Protected Areas.
[9] Total Allowable Catch.

In other words, there are and will always be risks associated with krill fishing and sustainability is about managing and limiting these risks.

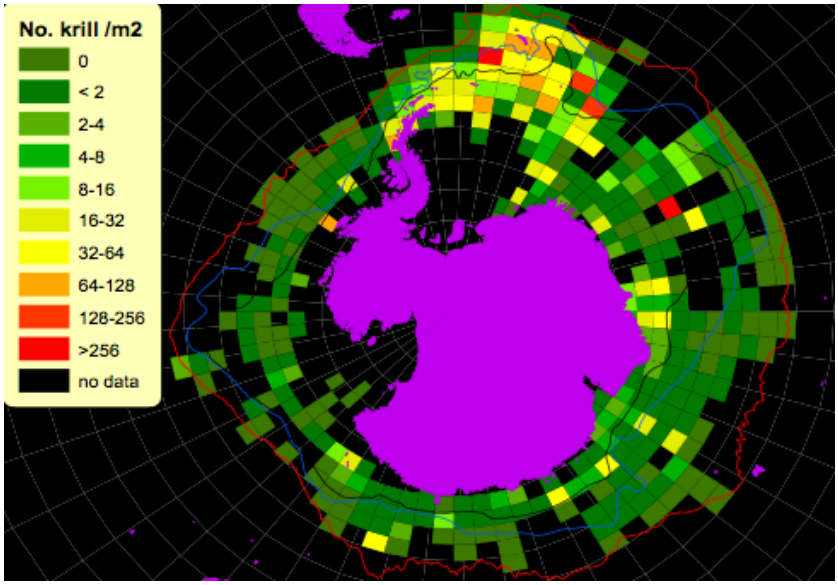
There are no signs that krill fishing will be stopped or even preventing "**other-than-current operators**" to address this fishery. There are strong signs that the krill fishery will remain a healthy and well-managed fishery.

Nonetheless, There is evidence that krill abundance has declined over time and that this is linked to warming seas. While the warming trend is likely to continue, climate change could further reduce krill abundance.





Krill Fishing is currently been targeted on very few places within the same fishing region….and changes will come.

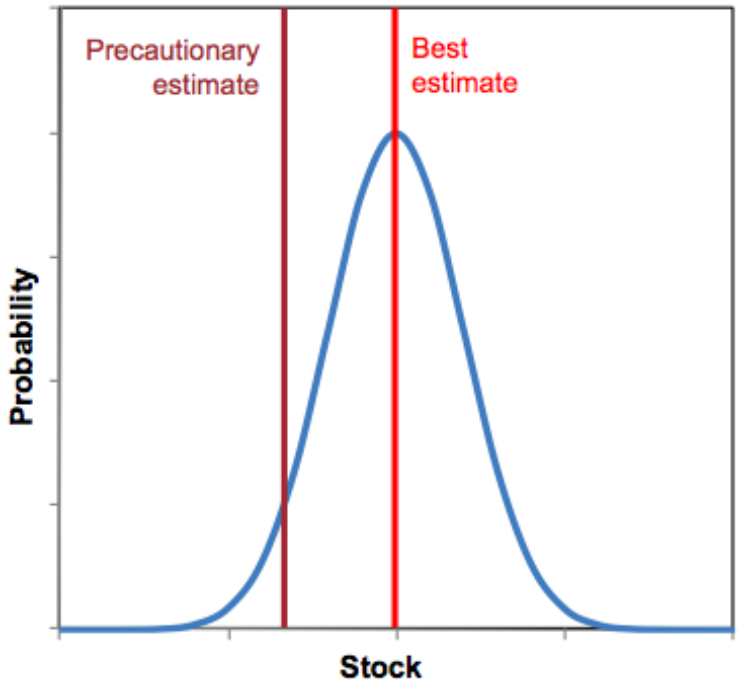


Probable action plan: Limit krill fishing to certain areas (fishing zones), volumes and timing. It is known that current krill catch takes place on few and limited areas and CCAMLR will prevent this to remain this way.

Current fishing effort may increase ("substantially" some say) in which case there will be a "***trade***" discussion between catch (reward to the operator) and fishing effort. It will force CCAMLR for stricter control, enforce control/survey and prevent massive fishery effort as well as IUU[10] krill fishery, the latter non- existent at this time.

Not having krill IUU fishing and CCAMLR's consensus approach on all its decision, krill fishery is still seen as a "healthy way of obtaining healthy biological-rich compounds".

[10] Illegal, Unreported, Unregulated.



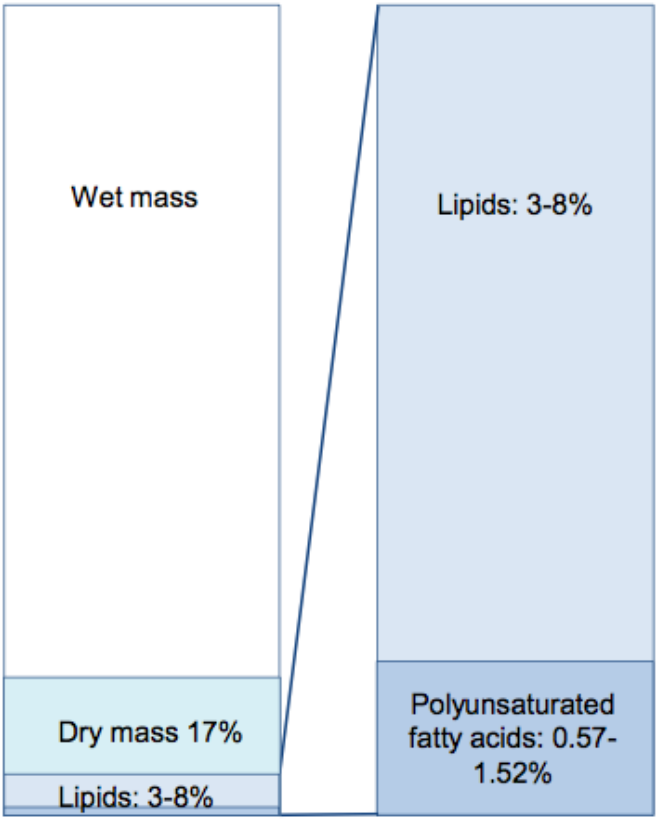
The ***Precautionary*** approach deals with uncertainty by using low risk strategies (i.e. with a low risk of long-term ecological impact). This usually means catching less than the best estimate would suggest.

The Ecosystem Approach (to Fisheries in general) recognizes that fished stocks are part of complex ecosystems. It generally requires management that recognizes multiple objectives.

The Johannesburg Declaration on Sustainable Development (2002) called for the widespread implementation of the ecosystem approach by 2010.

It is expected (by the speaker) that the ***Ecosystem*** approach will prevail over the precautionary one. Its implication on the krill fishery means that it will not affect operator's work on the krill fishery in the short term. It will also require closer monitoring of which operators works in this area and what it is manufacturing and how its fishing practices are taking care of.

Regarding krill's lipid count, polyunsaturated fatty acids constitute around 20% of lipids and about 1% of total wet mass.



"Other" perspectives about krill fishing

- "The massive uncertainties regarding krill biology… mean that… **CCAMLR's existing management regime cannot be considered precautionary**." Greenpeace (*GRL-TN-01-2009*)

- "[eco-labelling] falsely advertises the message that all krill are sustainably caught and that consuming krill-based omega 3 supplements or purchasing farmed salmon raised on krill meal is okay. **Nothing could be further from the truth**." Gerald Leape (*Pew Environment Group*) (*www.prnewswire.com*)

- "much of the krill caught is destined not for consumer purchase but for fishmeal, to feed factory-farmed fish, pigs and chickens. We propose that **any fishery undertaken for fishmeal should not be viewed as responsible or sustainable**". Jacquet et al (2010) *Nature*

- [Chinese krill fishing is] "**just wrong**" Willie Mackenzie, Greenpeace (*www.publicservice.co.uk*)

Marine Lipids Category (as a whole)

Summarized Concepts[11]:

(1) Krill oil was labeled as the …."**star of the show**" due to;
   a. Strong and steady growth on market awareness.
   b. Market growth (in volume).
   c. Category allocation still to be fully "categorized".

(2) Food fortification, please !

(3) End users' overall awareness growing but still more work is required.

(4) The entire marine-EPA/DHA category is facing a strong growth curve.

(5) Several challenges remain on how the "message is conveyed to the customer.

(6) More medical and scientific working support is required.

All key category indicators show to be on an "***emerging***" condition. All critical measurement areas are either "growing" or remain "stable", while the only "decreasing" factor is the "**de-concentration**" of the market, where there are more and more players involved.

While Frost & Sullivan estimates volume CAGR % 2010~2015 at 12%, other sources indicate this value might be ***twice as much*** considering past 10-years trend.

[11] On this presentation, by speaker.

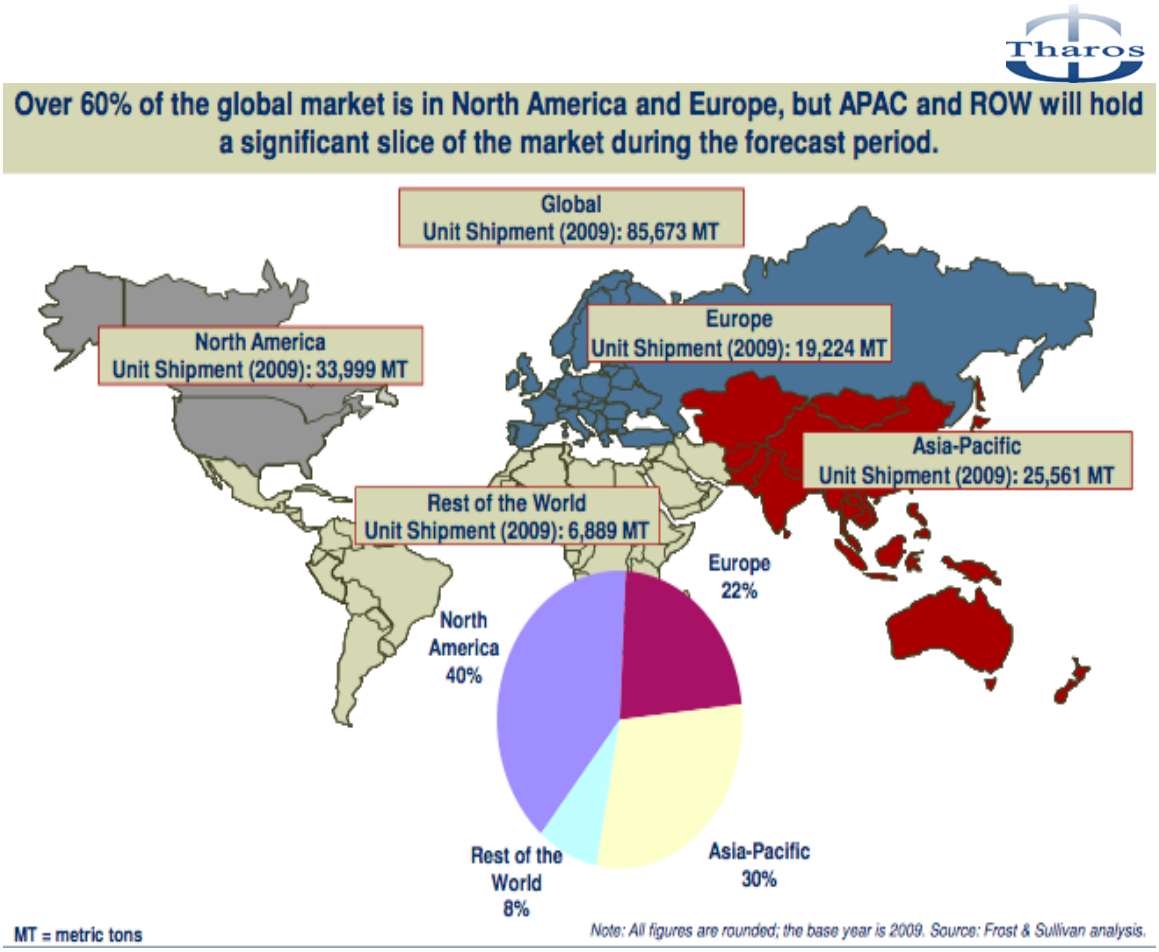
EPA and DHA Omega-3 Ingredients Market: Market Engineering Measurements (World, 2009 Base Year)

Measurement Name	Measurement	Trend
Global omega-3 ingredients market age	Growth	Increasing
Global omega-3 ingredients market revenues, $US millions (2009)	$1,447.5	Increasing
Global omega-3 revenues likely CAGR, % (2010 - 2015)	12.0 %	Stable
Global omega-3 market volume demand, metric tons (MT) (2009)	85,673	Increasing
Global omega-3 volume demand likely CAGR, % (2010 - 2015)	11.5 %	Increasing
Global omega-3 average price per kilogram, $ US (2009)	$16.90	Increasing
Market concentration (% of market revenues controlled by top three competitors), (2009)	38.6 %	Decreasing

Note: All figures are rounded Source: Frost & Sullivan analysis.

Source: Frost and Sullivan

Out of this total, although USA still leads (revenue & volume); Asia Pacific (APC) and Rest of the World (ROW) are growing at a faster rate depending on which specific market is analyzed. It is expected that this market will overtake the US as the main Omega-3 market destination.



Source: Frost and Sullivan

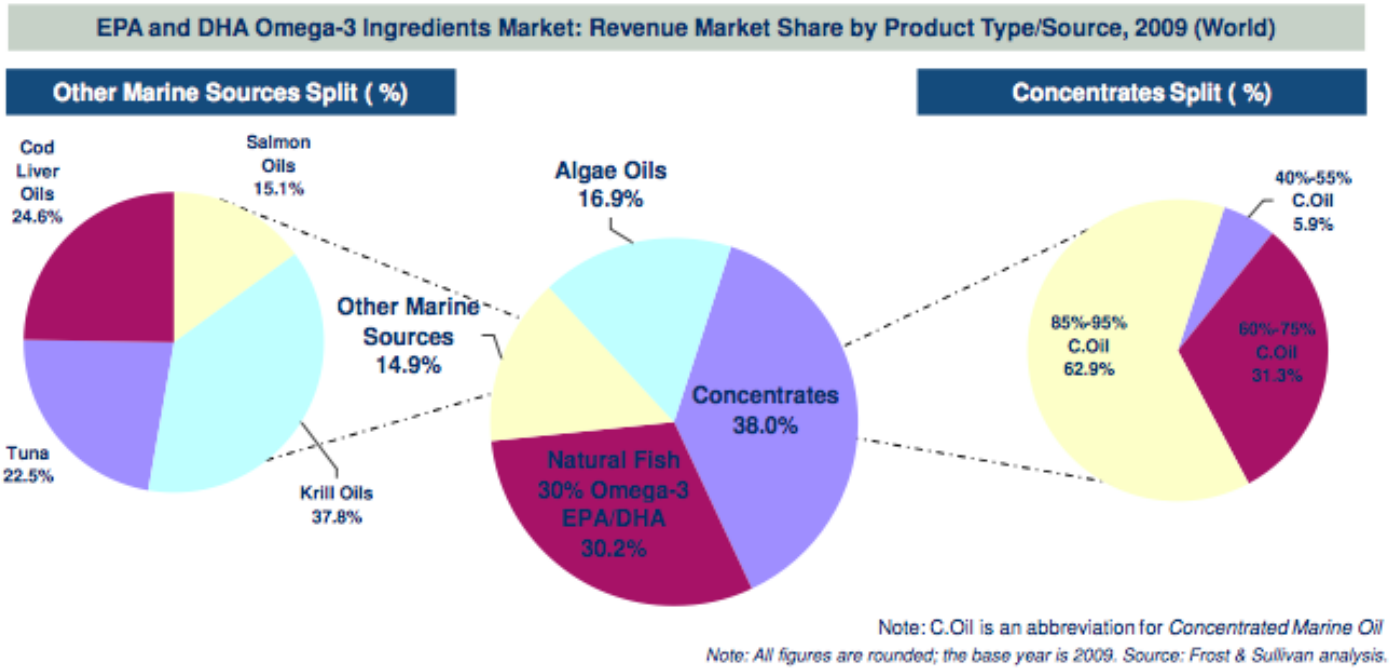
In terms of global revenues, concentrates have the largest share of the market due to its favorable pricing in highly price insensitive market channels (i.e. pharmaceuticals).

Algae oil also continues to hold a significant share of global revenues due to its dominance in the infant formula sector and its rapid growth in the food and beverage and animal feed sectors[12].

[12] MARTEK was one of GOED's Conference main sponsors.

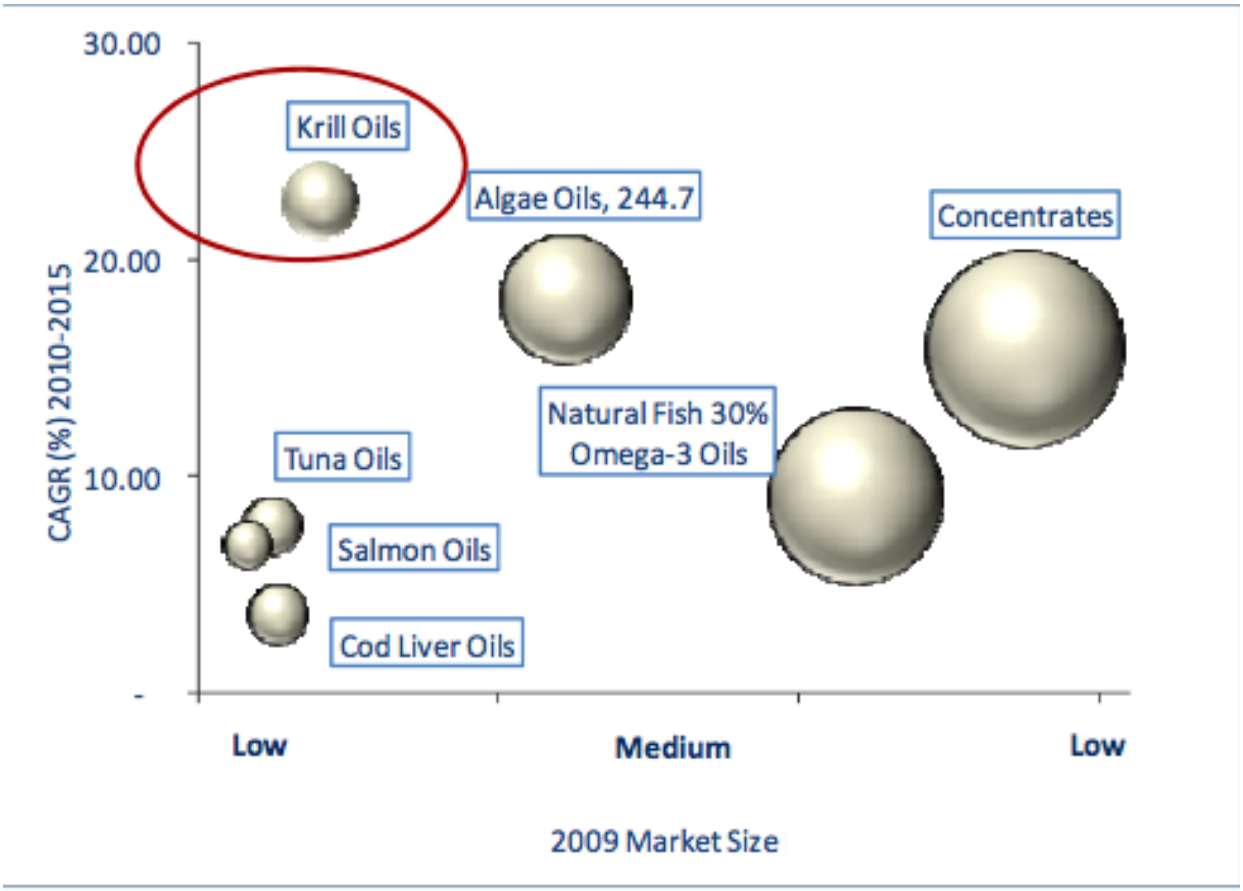
And krill oil appears for the first time on stat's and market data due to its strong growth curve, market awareness, customers demand and request from the market to have Frost & Sullivan's monitor this ingredient. Just two years ago (2009) krill oil was not at the forefront of any major conference speech, less on market data collection.

In the last three years, krill oil has taken over market share from known cod liver oil, salmon oil and tuna oil.



Krill oil demand (in volume and revenue) will get stronger and stronger. This trend is going to be maintained and strengthen by newcomers and world market interest on its supply, supply that it is to become stable and of the highest quality. Krill oil by all means leads on market awareness.

In terms of "***Revenue Growth Opportunities***" by product type, krill oils have seen the greatest push forward due to the segment's successful product differentiation strategy in the dietary supplements market.



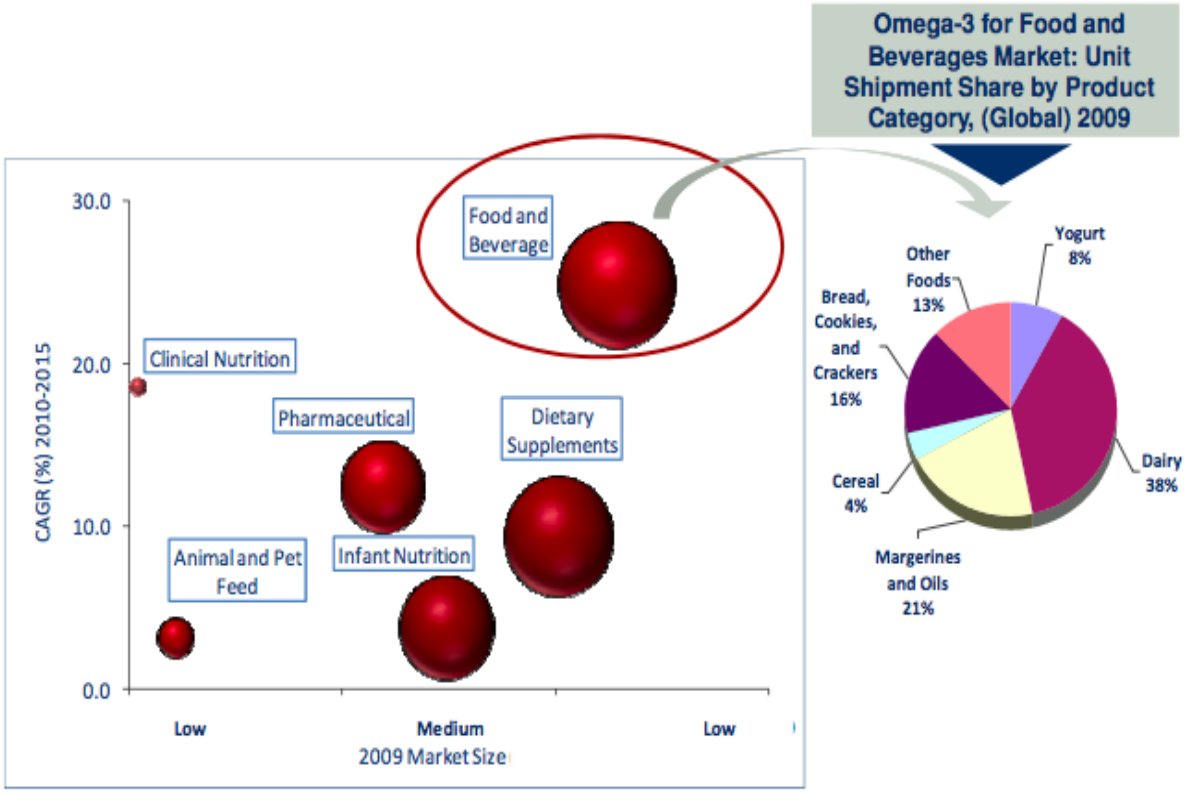
Remark: On the market size line, the last "low" should read "high" due to speaker typo error.

If the krill oil category is going to be sustained, as well as for the entire omega-3 category, scientific research is considered to be the backbone among all growth factors. It increases awareness among consumers, which, in turn, drives the demand for Omega-3. Its product attributes have also increased consumer's willingness to pay for Omega-3 and convinced governments around the world that it is something important for its population's long-term health and wellness.

Following is the summary of the key growth factors for the category, where scientific research is the backbone within all growth factors. Quality needs to be monitored, as it is other key-differentiating factor.

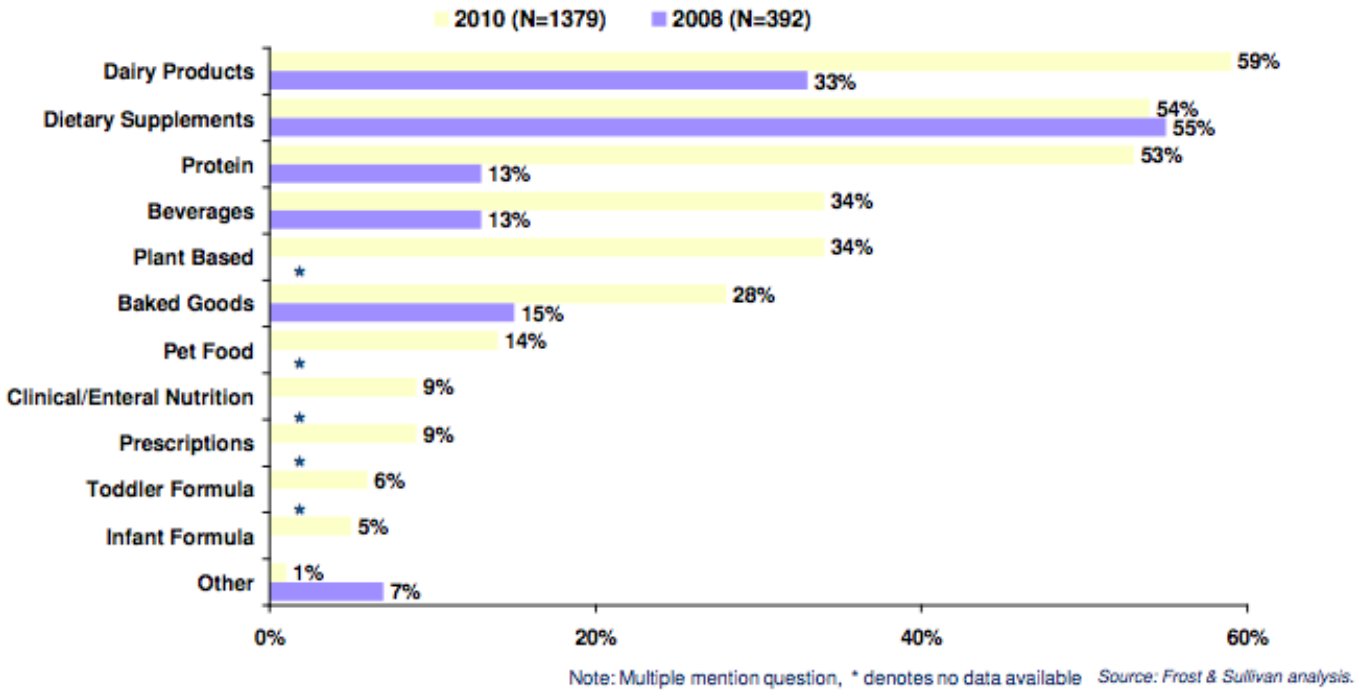
Source: Frost & Sullivan

Which is then the revenue growth opportunities by end-application? by all means food & beverage applications is the clear area of focus going forward.



Source: Frost & Sullivan
Remark: On the market size line, the last "low" should read "high" due to speaker typo error.

Regarding the specific opportunities in the food & beverage (F&B) space, the highest proportion of consumers report that dairy products, supplements, and protein sources are their key sources of omega-3 products. The chart bellow answers the question, indicating which of the following types of products fortified with Omega-3 nutrients do consumers use daily/weekly:



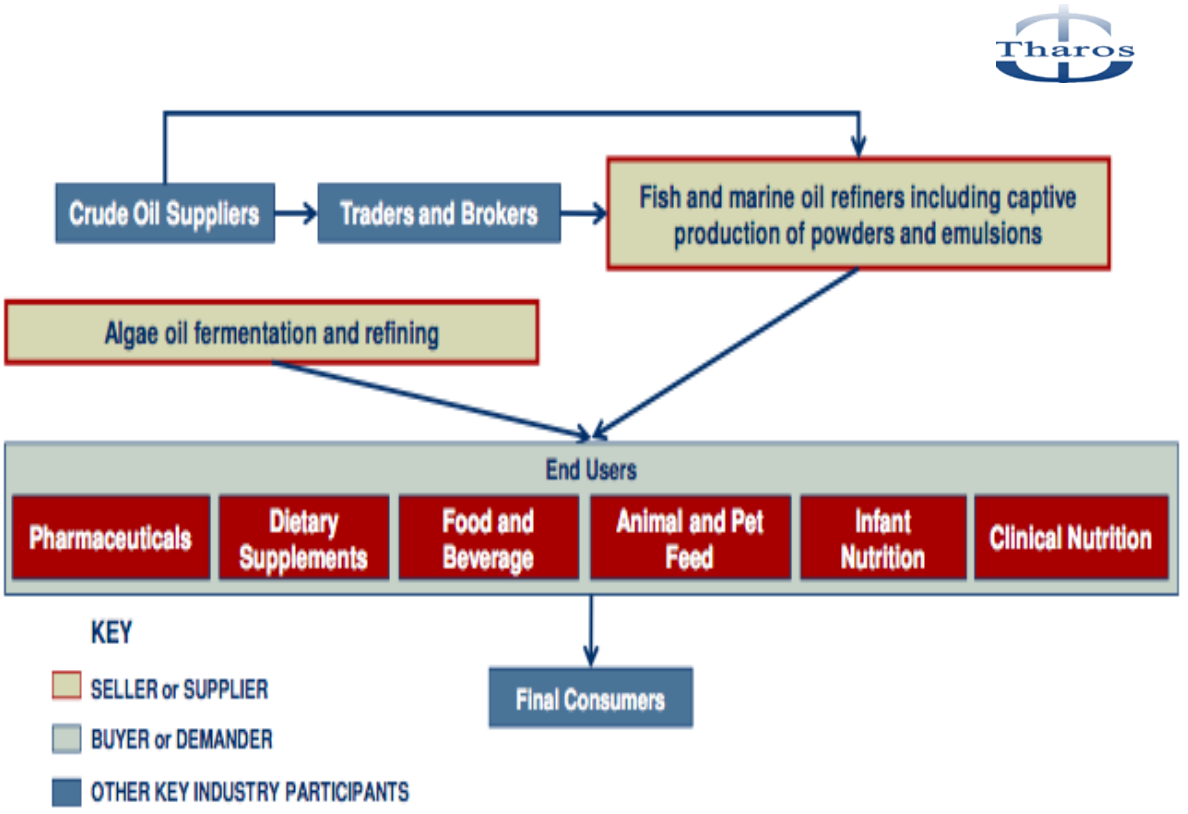
Who will benefit from these trends? Frost & Sullivan expects that suppliers of powders from refined oils and algae will see significant growth in the food & beverage space.

1. Omega-3 marine oil represents the largest product category within the food and beverage EPA and DHA Omega-3 ingredients market.
2. Omega-3 powder sourced from fish oils has made significant strides in the technology front and has played a role in enhancing the use of fish oils in a wider range of applications.
3. Algae oils have been successfully penetrating the food and beverage market due to increasing consumer awareness about the health benefits of DHA, hence many food and beverage manufacturers have incorporated this ingredient in their product.

In the period 2009 ~ 2010, refined oils for emulsions for F&B (refined oils for F&B applications, first converted into a higher valued oil emulsions), took around world's 0,5% of the EPA and DHA Omega-3 ingredients market for food and beverages in terms of revenue market share by technology.

On the same revenue comparison, oils for F&B, algae oils for F&B, and refined oil for powder for F&B (refined oils for food and beverage applications converted into a higher valued powdered products), took worlds 52%, 17% and 31%, respectively.

With respect to the value chain, this has not changed much on the last several years, regarding on the demand for refined marine and algae oils supplied to key end-user segments (World 2009). There is a possibility this value chain to change, depending on how deep marketing positioning goes for the entire category and supply situation. Intermediates are on a tight situation.

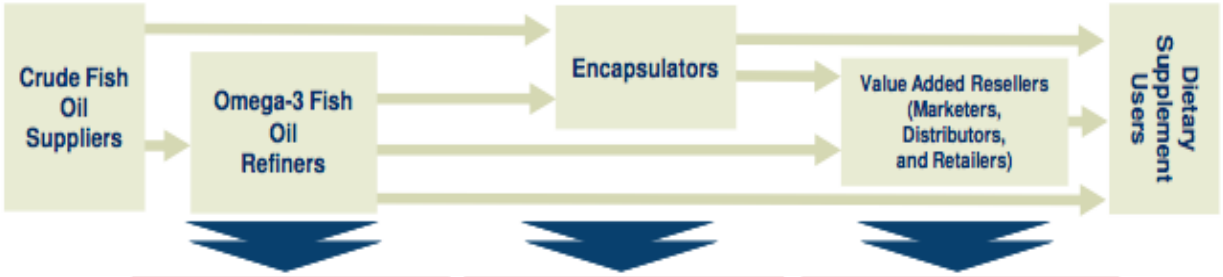


Source: Frost & Sullivan analysis.

On this respect, Frost & Sullivan presented the case for the US market. It presented a case study for the "**North American Omega-3 Ingredients for Dietary Supplements Value Chain**". Undoubtedly, margins are better further down the value chain, but the hidden costs of increased competitive rivalry rise.

Krill oil marketing positioning within the value chain will define its CAGR and surely its long-term sustainability. So far krill oils are traded using a limited number of options, mostly through value added retailers. This will change as more agreements are put in place along the entire chain, not only focused on a limited number of resellers.

North America Omega-3 EFAs for Dietary Supplements Value Chain



	Omega-3 Fish Oil Refiners	Encapsulators	Value Added Resellers
Sector Sales	$215 million	$388 million	$912 million
Average Gross Margin	Not applicable	44.5%	57.5%
Market Power	Number of competitors: > 35 C4 ratio*: 57% HH index**: 1571	Number of competitors: > 40 C4 ratio*: 42% HH index**: 956	Number of competitors: > 200 C4 ratio*: 29% HH index**: 344

Note: All figures are rounded; the base year is 2009. Source: Frost & Sullivan analysis.

Core Concepts for the Krill Oil Category

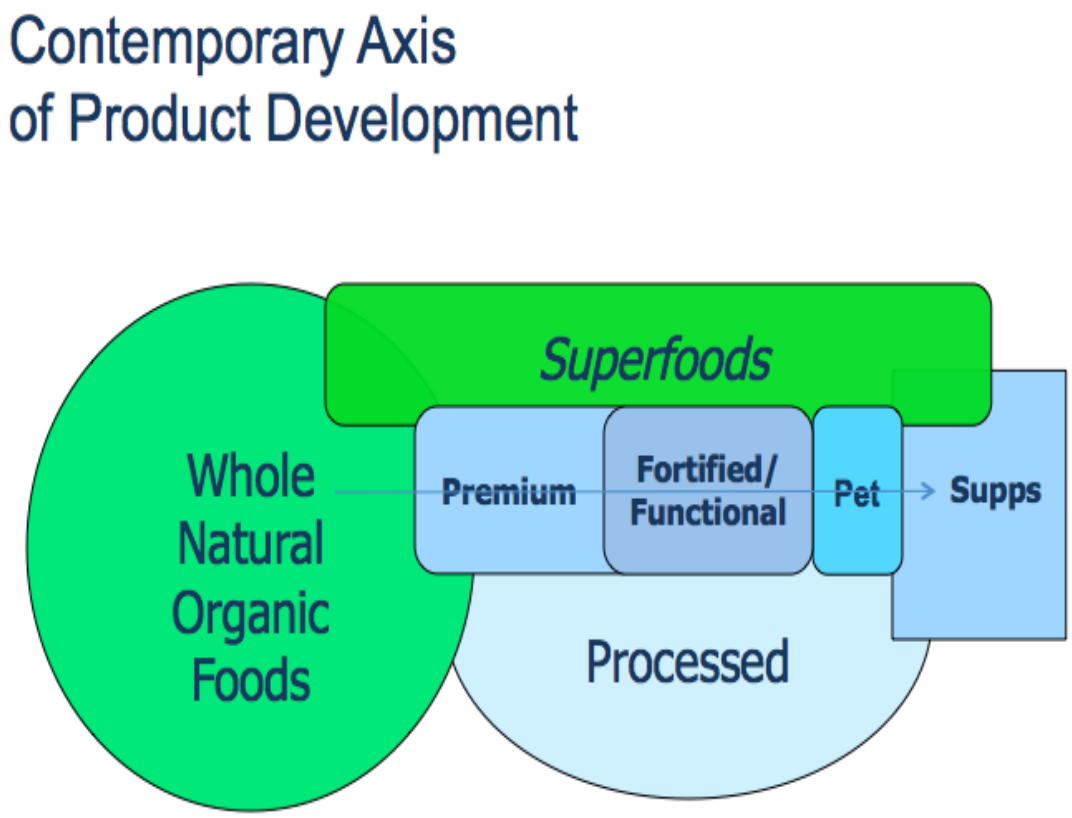
1. Krill oil seen as the "raising star" and a "blockbuster" in terms of volume growth rate (CAGR) within the marine lipid category, and in terns of price within the entire EPA/DHA category.
2. Krill oil still traded on small volumes and needs to accomplish a larger traded volume to be considered a real supply opportunity.
3. Sustainability matters gaining momentum. Surveyors may not be the only solution but in parallel to "country-of-origin" surveillance.

Overall for the Krill Oil Category

1. Larger players entering the playing field.
2. Mergers and Acquisitions "may" reshape the industry.

The Ω-3 Category[13]

Market Research Group[14] described what they define as the "***the new food-supplement continuum***" and how this continuum will shape the category growth and how, eventually, krill oil may workout its "product proposal" to the market.



[13] Most ideas come from GOED presentation from Mr. David Sprinkle, Research Director, www.MarketResearch.com

[14] www.MarketResearch.com

On the above, "The Hartman Group" believes the fertile area for product developers and marketers lie somewhere in the middle of this continuum, in the form of enhanced functional foods, which are inherently functional foods with cultural relevance on which the nutrients or ingredients that **resonate** today are added.

Specifically on sales of Omega-3-Enhanced food and beverage products, for the period 2003-2012 (US$M dollars), www.MarketResearch.com estimates between US$5 and US6 billion for the period 2009 ~ 2010 with a cup above US$8 billion in sales for 2012, compared to the around US$1 billion in sales for the ingredient itself.

2003 Sales	2007 Sales	CAGR 2003-2007	2012 Projected Sales	CAGR 2003-2012
$685	$4,572	60.7%	$8,165	31.7%

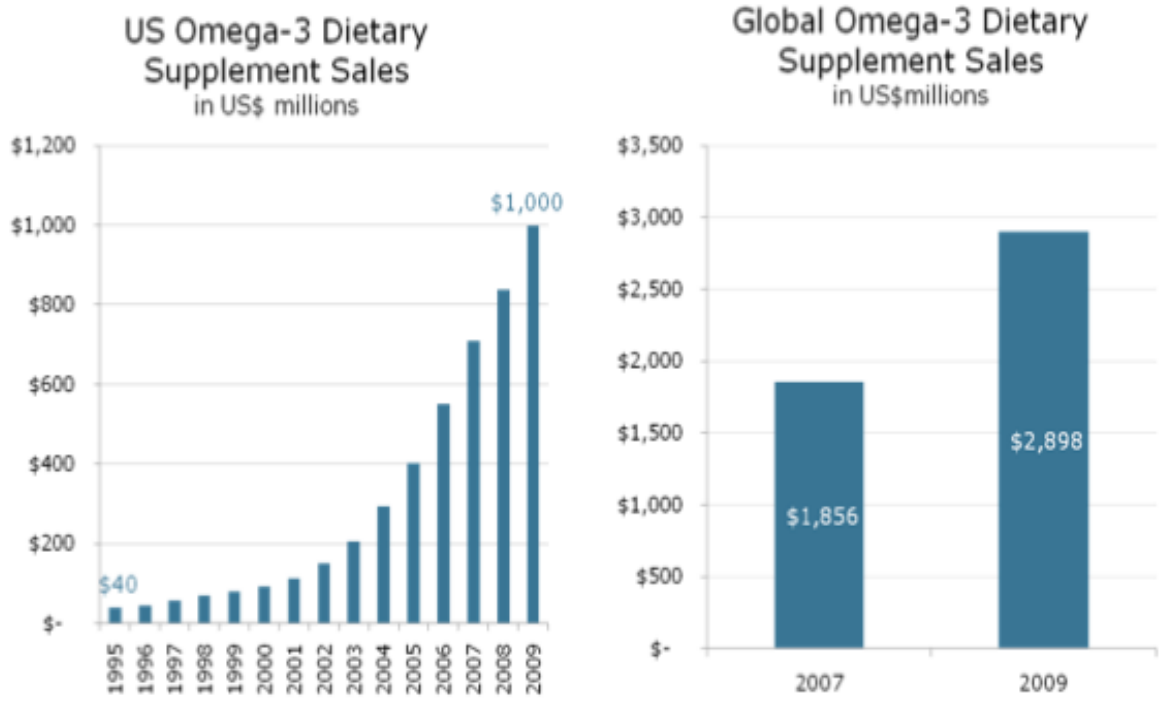
Source: Packaged Facts, *Omega Fatty Acids: Trends in the Worldwide Food and Beverage Markets* (2009)

More specifically about global sales of Omega-3-Enhanced DHA/EPA Food and Beverage Products for the period 2003-2012 (in US$M dollars), EPA/DHA Enhanced Products will take around 50% of the overall sales of Omega-3-Enhanced food and beverage products, for the period 2003-2012.

	Sales	Percent Change
2012	$4,397	17.8%
2011	$3,734	21.9%
2010	$3,062	26.2%
2009	$2,426	32.4%
2008	$1,832	65.6%
2007	$1,106	--

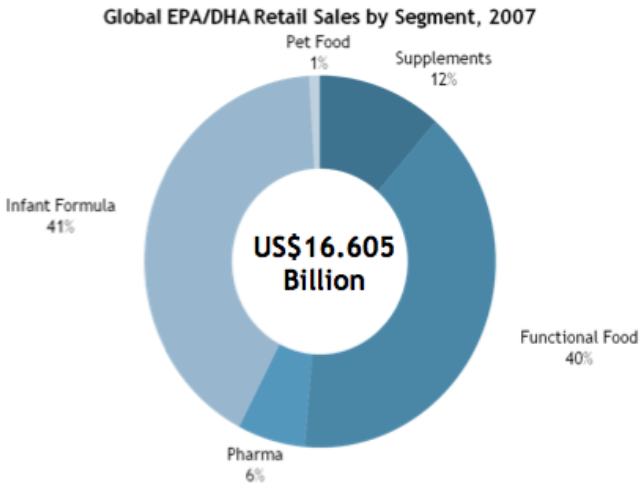
Source: Packaged Facts, *Omega Fatty Acids*
***Trends in the Worldwide Food and Beverage Markets* (2009)**

GOED's sales data is in line with Packaged Facts data



Source: GOED

From this data, GOED estimates that that the Global EPA/DHA market value of around US$1,3 billion by 2007 was taken mostly by functional foods and supplements. This is at the ingredient level while at retail sales jump over ten times that much.



Source: GOED, Datamonitor, Frost and Sullivan, Leatherhead, CERES Consulting

For krill oil, PL[15] content is one of its main attributes[16].

[15] Phospholipids

[16] As well as its carotene content as discussed on the Conference.

Regarding the global omega product introductions for the period 2001-2010, private levels (PL) are gaining strong momentum (based on High Omega/High DHA claims)

	Total	Food	Bev	Supp	Pet	PL
2010	756	511	55	54	87	**47**
2009	708	468	52	33	103	**36**
2008	725	470	49	63	116	**35**
2007	661	442	41	61	61	**35**
2006	530	324	31	72	78	**28**
2005	389	240	16	61	57	**6**
2004	235	135	14	44	37	**3**
2003	182	99	7	21	47	**3**
2002	128	75	4	11	32	**2**
2001	88	58	1	8	13	**1**

Source: Product Launch Analytics, a Datamonitor Service Packaged Facts, *Omega Fatty Acids. Global Market Trends (March 2011)*

In every year, from 2002 until 2010, the growth change year-to-year of global omega Product Introductions has outpaced the "All High" category, with a pick of 12% growth for the year 2009 to 2010 for "High Omega" versus 2% for the "All High" category, sustaining the category strong growth curve.

The Global Omega Product Introductions by manufacturer (2008/10) shows that this trend is not confined to few corporations, rather present on large, mid and small-sized corporations, in a wide spectrum of end-products, such as food, beauty, pet, beverages, private levels, etc.

Global Omega Product Introductions by manufacturer (2008/10)

	Total	Top Categories
Unilever	35	Spreadable Fats (10); Dressings (11)
Nestle	29	Pet Food (10); Ready Meals (5); Milk (4)
Mars	24	Pet Food (20)
J.R. Simplot	22	Canned Fish/SF (15); Chilled Fish/SF (6)
L'Oreal	20	Facial Care (7); Lip Make-Up (6)
George Weston	16	Bread & Rolls (5)
H.J. Heinz	16	Canned Fish/SF (12)
Hain Celestial	16	Baby Snacks (3); Cereal Bars (3)
Altria Group (Kraft)	11	Crackers (3); Cookies (2); Potato Chips (2)
Drs. Foster & Smith	11	Pet Food (11)
EQT Scandanavia	11	Chilled Fish/SF (9)
Alimentos Granix	10	Crackers (6); Cookies (4)
Kellogg	10	Fz Pizza (3); Cereal (2); Cereal Bars (2)
Safcol Australia	10	Canned Fish/SF (7)

Source: Product Launch Analytics, a Datamonitor Service Packaged Facts, *Omega Fatty Acids (March 2011)*

Private Label

Nestle


新
PURINA
DOG CHOW
康多乐
亮丽被毛
成犬犬粮 ADULT
Net Content 14 千克/kg
DOG CHOW
康多乐


PURINA
ONE
NEW SMARTBLEND
SALMON & TUNA FLAVOR


Mon Petit
1歳まで
子ねこ用
総合栄養食
まぐろスープ
40g


PURINA
Mon Petit
GOLD

Unilever

Research shows that including Omega 3 polyunsaturated fats in your diet helps to maintain heart health as part of a diet low in saturated fats and cholesterol when substituted for other foods high in saturated fats. Omega 3s are found in Hellmann's® Real Mayonnaise.

The global Omega product introductions by geographic regions have the US and Canada at the top of the league (45% for 2010), almost double to second ranked Europe.

If the UK, added to Canada and some countries within the "Oceania" Region[17], all these have the same introduction performance as the EU as a whole (23% for 2010).

Omega Product Introductions by Geographic Region

Geographic Region	% Of Total	# Of Reports
USA/Canada	45%	341
Europe	23	172
UK / Canada / South Africa / Australia / NZ	*23*	*170*
Latin America	16	119
Asia-Pacific	14	106
Middle East and Africa	3	20

Source: Product Launch Analytics, a Datamonitor Service Packaged Facts *Omega Fatty Acids (March 2011)*

If the "introduction" analysis is split within by specific countries, USA leads, no doubt. NAFTA region as a whole has a significant share while South America shows a very promising growth trend in a very short period of time.

[17] South Africa, Australia and New Zealand

Global Omega Product Introductions by Country (2004/05 vs. 2009/10)

Country	2004/05	2009/10
United States	49%	40%
Canada	13	10
Australia	5.1	4.7
United Kingdom	3.8	4.4
Mexico	0.3	3.2
Chile	--	2.2
Spain	2.9	2.2
Argentina	1.6	2.1
France	3.2	2.1
Colombia	--	1.8
Finland	2.8	1.6
Sweden	0.9	1.6

Source: Product Launch Analytics, a Datamonitor Service from Packaged Facts
Omega Fatty Acids (March 2011)

South America has more to do with "food" introductions rather pet and beverage product introductions.

Industry Distribution for Global Omega Product Intros by Geographic Region, 2008-2010

Region	Food	Bev	HBC	Pet
USA/Canada	54%	9%	20%	18%
Europe	73%	**4%**	13%	10%
UK / Canada / South Africa / Australia / NZ	58%	7%	24%	11%
Latin America	83%	**4%**	**3%**	11%
Asia-Pacific	77%	6%	**8%**	8%
Australia/NZ	83%	5%	**4%**	7%
China/SE Asia/Japan	73%	8%	**9%**	9%

Source: Product Launch Analytics, a Datamonitor Service from Packaged Facts
Omega Fatty Acids (March 2011)
Remark: HBC = Health Care and Beauty

By categories, there is not a single category left behind on the Omega-3 introduction, be they for the heart, brain, baby food, beauty and others. Almost all large food corporations follow this trend within their business model. Companies such as Nestle, and others to follow, have created specialized food divisions focused on a "**health and wellness**" approach rather a pure food-indulgence one.

In the US/Canada region for example, pet food lead the trend:

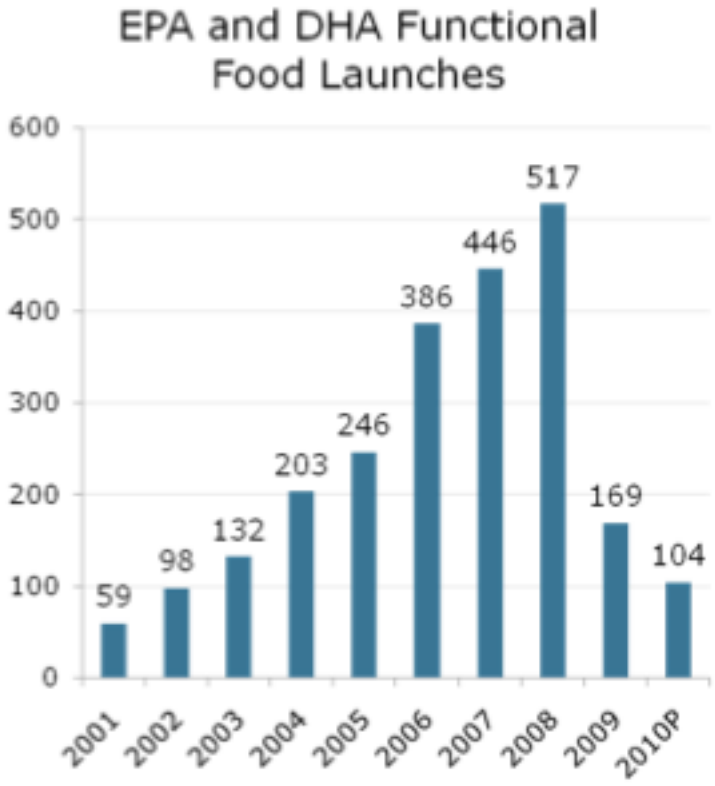
US/Canada Omega Product Introductions by Segment - 2004/05 vs. 2009/10

Product Category	% in 2004/05	% in 2009/10
Pet Food	13.0%	12.3%
Supplements	14.7	7.1
Fish and Fish Products	10.0	4.8
Facial Care	--	4.7
Breakfast Cereals	2.1	4.5
Cereal Bars	9.0	4.4
Bread and Rolls	3.0	3.1
Functional Drinks	1.5	3.1
Baby Snacks	0.9	2.6
Beverage Concentrates	--	2.3
Body Care	0.3	2.2
Dressings	1.3	2.1
Milk	2.2	2.0

Source: Product Launch Analytics, a Datamonitor Service Packaged Facts, Omega Fatty Acids (March 2011)

GOED recent data anyhow shows a slower introduction trend for EPA & DHA in the past few years. Why?

1. Economic uncertainties.
2. Uncertainty about health claims situation.
3. Top-selling products and brands keep selling and growing at the expense of weaker brands.
4. Private level products gaining market share.



Source: GOED

Which are some of this brands/products success stories?

Product (Country)	GOED sales estimates (local currencies)	US equivalent sales (adj. for population)
George Weston Tip Top UP Omega-3 Bread (Australia)	AU$71.4 million	$1,036 million
Puleva Omega-3 Milk (Spain)	€110 million	$684 million
Danone Danino yogurts (Canada)	C$25 million	$209 million
Maruha Nichiro Foods' Resara Sausages (Japan)	¥6.2 billion	$185 million
Ajinomoto Mainichi DHA cooking oil (Japan)	¥4.2 billion	$125 million
Minute Maid Enhanced Juice (United States)	$100 million	$100 million
Smart Balance omega-3 spreads (United States	$70 million	$70 million
Whitewave Silk Plus DHA soymilk (United States)	$65 million	$65 million
Kagome DHA Yogurt (Japan)	¥2.1 billion	$63 million
Pharmalogica's Smartfish juice (Norway)	NOK 10 million	$57 million

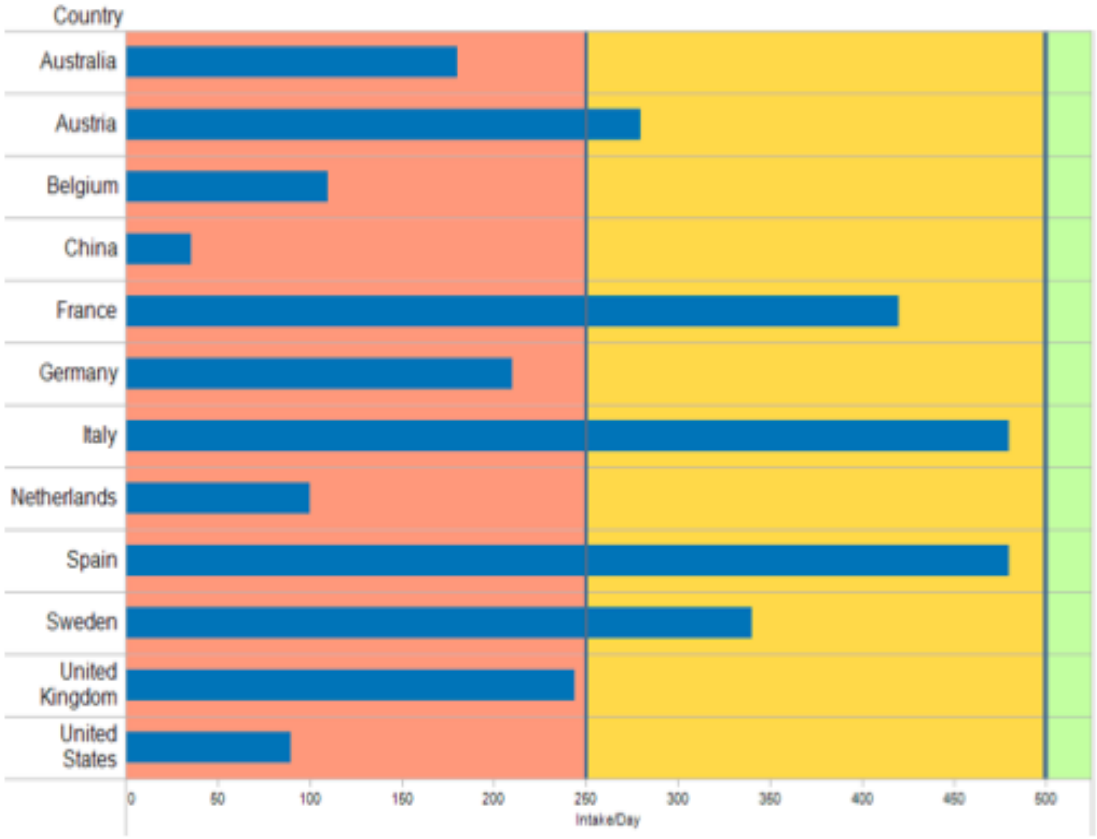
Source: Ceres Consulting

And even though Omega3's may look a new product, more expensive per dose compared other well known supplements (e.g. Vit C), not even with agreed RDI's, Omega-3 still shows a growing market and customers increased awareness and demand.

Active	Global Revs (RM)	TPA	Discovery	Cost/Kg	Cost/Dose	Essential	RDA	Level
LC PUFA	$1,300	85,000	HB's 1970's	$10.00	3-4 c	Qualified Yes	2012?	~500mg.
Vit. C	$1,400	120,000	1932	$8.00	0.005c	Yes	1941	60-100mg

Source: Ceres Consulting

The RDI is an aspect that needs to be resolved, and soon. There is still a major deficiency problem among countries between the EPA & DHA intakes versus international recommendations.



Source: GOED, Ceres Consulting.

Regarding food categories, brands abound on the Omega-3 trend, either on EPA/DHA or ALA, being the former the leader compared ALA products introductions.


Huevos Enriquecidos con
Omega 3


Bella Rosa
OMEGA-3
parmesan


Yoghurt
Omega 3


CABOT
50% REDUCED FAT CHEDDAR CHEESE
with Omega-3 DHA


OMEGA Pro
NATUREGG


novo!
OMEGOL
AKTIV


St-Hubert
Oméga 3
St-Hubert
Oméga 3


Equilibre
"Multifruits
& Oméga 3"


FARM PRIDE
Free Range Omega 3
700


SMART BALANCE
Omega-3


omega 3
1L
Carrefour


NEW
HORIZON
ORGANIC
DHA OMEGA-3
1%
organic
CHOCOLATE
LOWFAT MILK


Omegarella


JOHN WEST
NEW
Tuna
steak
100%
Omega 3
Rich in Omega 3
in Sunflower Oil


Jif
Omega-3
CREAMY


DONG WON
오메가-3


Nestlé
Omega
plus


Dark
Chocolate Squares
70% Cocoa
with
Omega-3
A Delicious Source of
Antioxidants and Omega-3


umego!
umego!
umego!


OMEGA 3
OMEGA 3


NIEUW
Omega 3
Iglo
50%


equia
Omega-3


GRATIS!
Majonez Kielecki
Omega 3
Majonez
KIELECKI
Omega 3
ATIS! GRATIS! GRAT


PULEVA
OMEGA 3
con Nueces

Global Omega Product Introductions: DHA/EPA vs. ALA Claims, 2001-10

Country	DHA/EPA	ALA
2010	255	108
2009	224	57
2008	268	59
2007	154	36
2006	113	17
2005	151	13
2004	74	8
2003	34	1
2002	8	--
2001	11	--

Source: Product Launch Analytics, a Datamonitor Service Packaged Facts, Omega Fatty Acids (March 2011)


100% NATURAL
Heart Healthy Salmon
Keta Salmon


JOHN WEST
4x tuna
multipack
CHILLI
JOHN WEST
tuna
CHILLI
EASY LUNCH IDEAS


Saupiquet
Filets de
Maquereaux
SAUCE BLANCHE À L'ANETH
NOUVEAU!


NUEVO
12 LATAS
Calvo®
FORMATO AHORRO
Atún Claro
en aceite vegetal
12x80g


OMEGA-3
PEÑA
STEAK
TUNA
in vegetable oil
80g e


Mackerel Fillets in olive oil
Delicius
rich in
OMEGA 3
Delicius
PROCESSED ON THE FISHING SPOT
125 g


PURINA
DARLING
Taste & Love
NEW
FORMULA
OMEGA


Becel
Becel

Jardin BiO
mayonnaise

Vibe
CARDIOVITA
AVENA

Extra Virgin

CUIDADO DIARIO

SONTI MIX
OMEGA 3

Super Light

Active Lifestyle
Angel Hair

Bella Rosa
OMEGA-3
parmesan

All Natural
HEART HEALTHY
100% Sunflower Oil

오메가3
&칼슘

PYRAMID
hjärtan
endast 0,3 g salt
och Omega 3

OMEGA Pro
NATUREGG


Smart
SHOT
GINKGO
OMEGA 3


EINSTEIN
EINSTEIN
DHA


Devondale
Smart
OMEGA-3s
WITH LONG CHAIN OMEGA-3 DHA & EPA*
NO PRESERVATIVES
1 LITRE


Active Lifestyle
PREMIUM
LIGHT
Orange Juice Beverage
Helps Support Brain Function
with DHA Omega-3*


Nestlé
Juicy Juice
DHA
Brain Development
grape


NEW!
SMART SALMON


Cookie Time
Fudge
Brownie
SMART COOKIE


MR.
BRAIN
脳トレパン


de Vinch
DHA

Will hemp a new blockbuster on the Omega-3-related industry?

Although industrial hemp production remains illegal in much of the U.S., the market for hemp products is flourishing. Hemp seed is the edible part of the hemp plant, and it packs quite a significant nutritional load: A great source of Essential Fatty Acids (EFAs), it has a good 3:1 ratio of Omega-6 Linoleic Acid and Omega-3 Linolenic Acid, both of which are known for strengthening the immune system, bettering cognitive function and promoting healthy skin, hair and eyes. Its balance of amino acids shows to be nutritionally competitive to soybeans, human milk and cow's milk. In the US, it is seen as a healthful booster from nut bars to milk to salad dressing.


nemp hearts


hemp dream


NEW! NEW! NEW!
HEMP MILK
CHOCOLATE
ORIGINAL
VANILLA


Tharos
Silver Hills
Hemptation


GOOD HEMP
Original
NATURAL SOURCE OF OMEGA 3


GOOD
MAYONNAISE
HEMP SEED OIL
GOOD
MAYONNAISE
HEMP SEED OIL


GOOD
HEMP SEED OIL
GOOD
HEMP SEED OIL


GOOD
DRESSING
GOOD
GOOD

Although in the US the pet's category has a significant share of new Omega-3 related products introductions, babies and kids are the ones that have a large share of current work on product development and probably lead coming product introductions.


DHA
키큰아이


DHA
특허출원
참치에서 추출한 천연
DHA
똑똑한우유


kids


Dumex
Dugro
3-6
tahun
Bahagia


Fish Patties


Danio


Zac'O Mega
Raspberry


100% All Natural
Yummy
Chicken Breast Fries
CHICKEN BREAST PATTY FRITTERS WITH RIB MEAT
450 mg OMEGA 3


Nestlé
Omega


vaalia
Kids


Jungle
energy
bar


POPUMZ


HAPPYBITES
fish bites
SECRET SAUCE


12x
Honey
bikkies

Where krill oil has shown a very active market penetration is on the supplements and personal care category within the many brands that actively approach this niche.

Tharos

MEG-3®
trust the source®

life's DHA™
HEALTHY • BRAIN • EYES • HEART

EPAX®
MARINE OMEGA-3 FORMULA

The speaker's proposed market opportunities rely on brands, category and locations, where pet's diminish its lead in favor of food/human applications.

Main drivers

1. Unilever, Mars, Kellogg, Nestle, other
2. Private label
3. BRIC markets
4. Beverages in Europe, Latin America
5. Foodservice, seasonal immunity products.
6. Facial and skin care in Asia / Pacific
7. Pet nutraceutical treats

Convey the Message

What drives the current consumer behavior and the required marketing message?

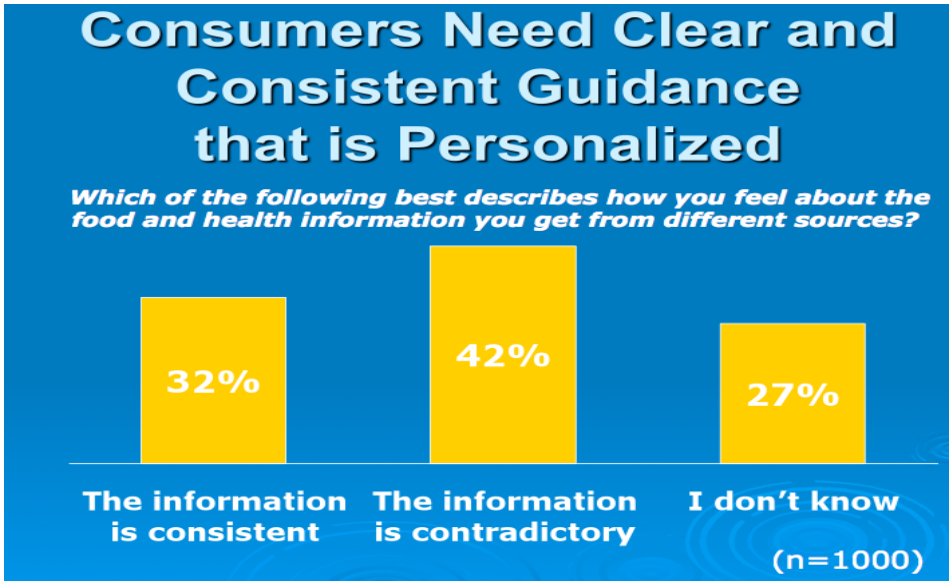
1. Time
2. Taste
3. Cost
4. Health Confusion

It is "**confusion**" currently one of the predominant condition that reigns among the Omega-3 market, even more dramatic for krill oils. Once this aspect is better addressed, the effect on krill oil sales will increase even more compared current CAGR [18].

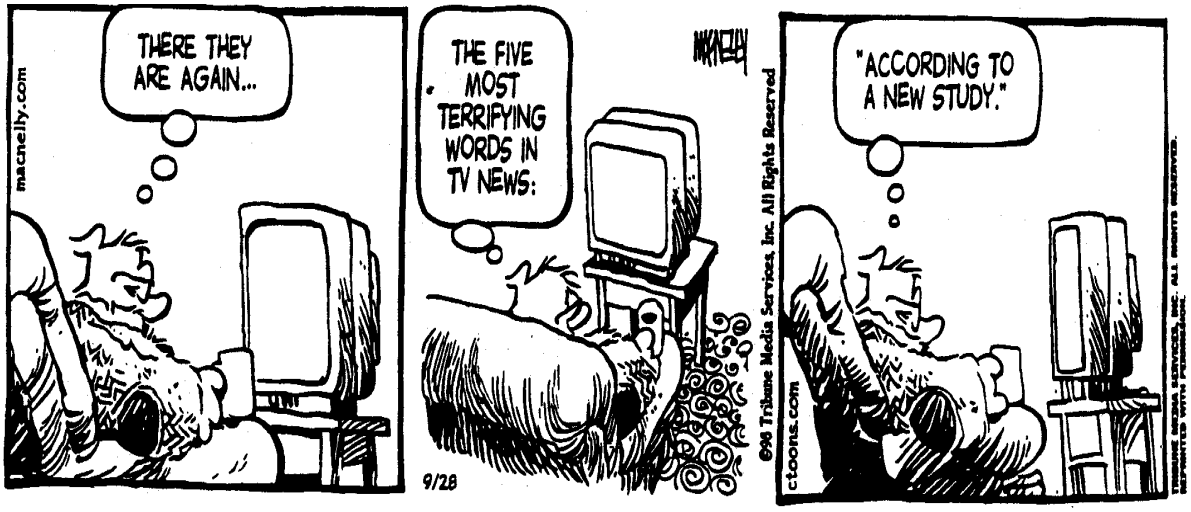
As a reference, in 2010, close to 200.000 links pop-up when Omega-3/longchain fatty acids were searched.

How well krill oil benefits and its medical properties are linked to human health? Does science and R&D serve my needs? are scientific recommendations valuable and suit to follow ?.....questions that are widespread among end-users. Companies that are better positioned to "properly convey the message" will thrive on their sales.

[18] Sylvia Rowe, SR Strategy


Consumers Need Clear and Consistent Guidance that is Personalized
Which of the following best describes how you feel about the food and health information you get from different sources?
32%
42%
27%
The information is consistent
The information is contradictory
I don't know
(n=1000)

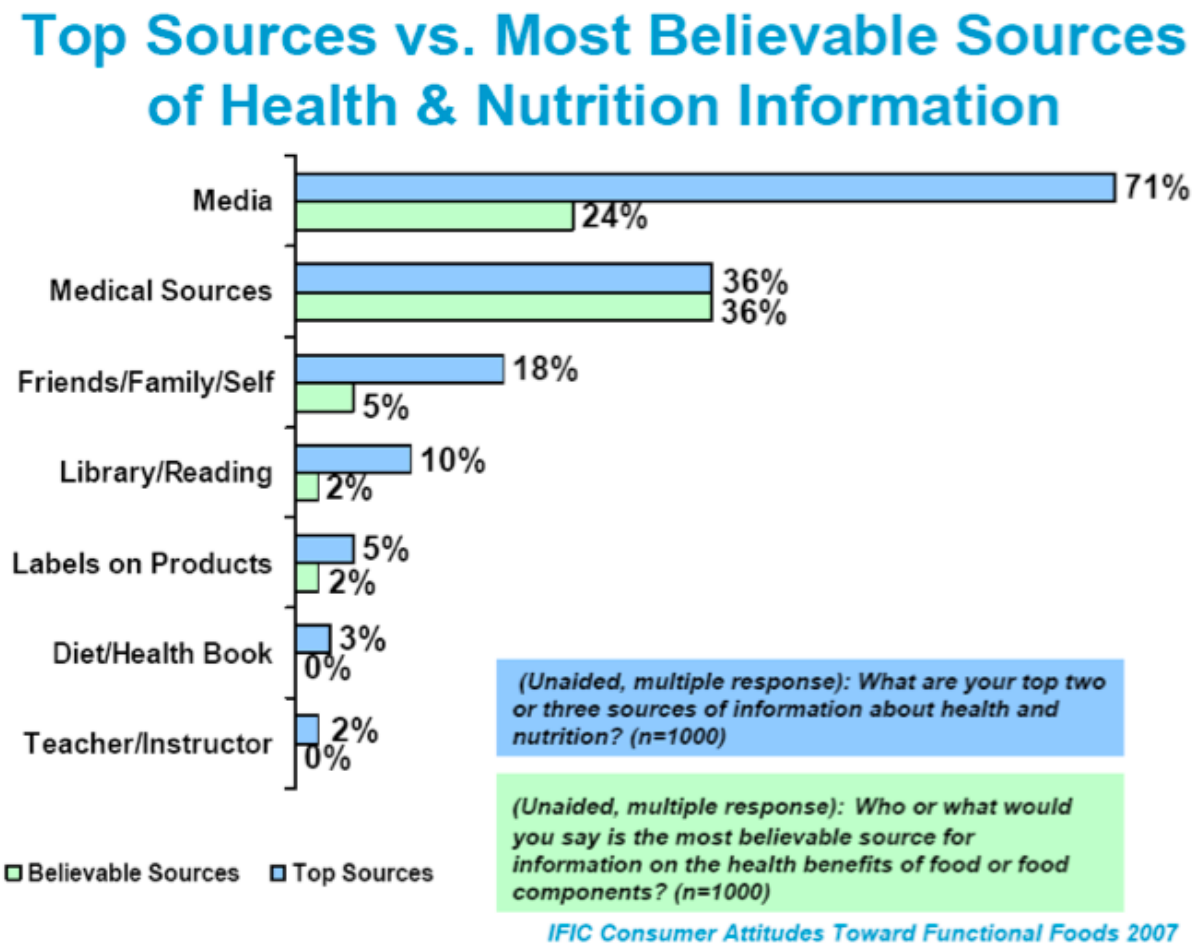

SUPERMARKET
"The American Heart Association endorses this product, but it has a warning label from the National Cancer Institute."

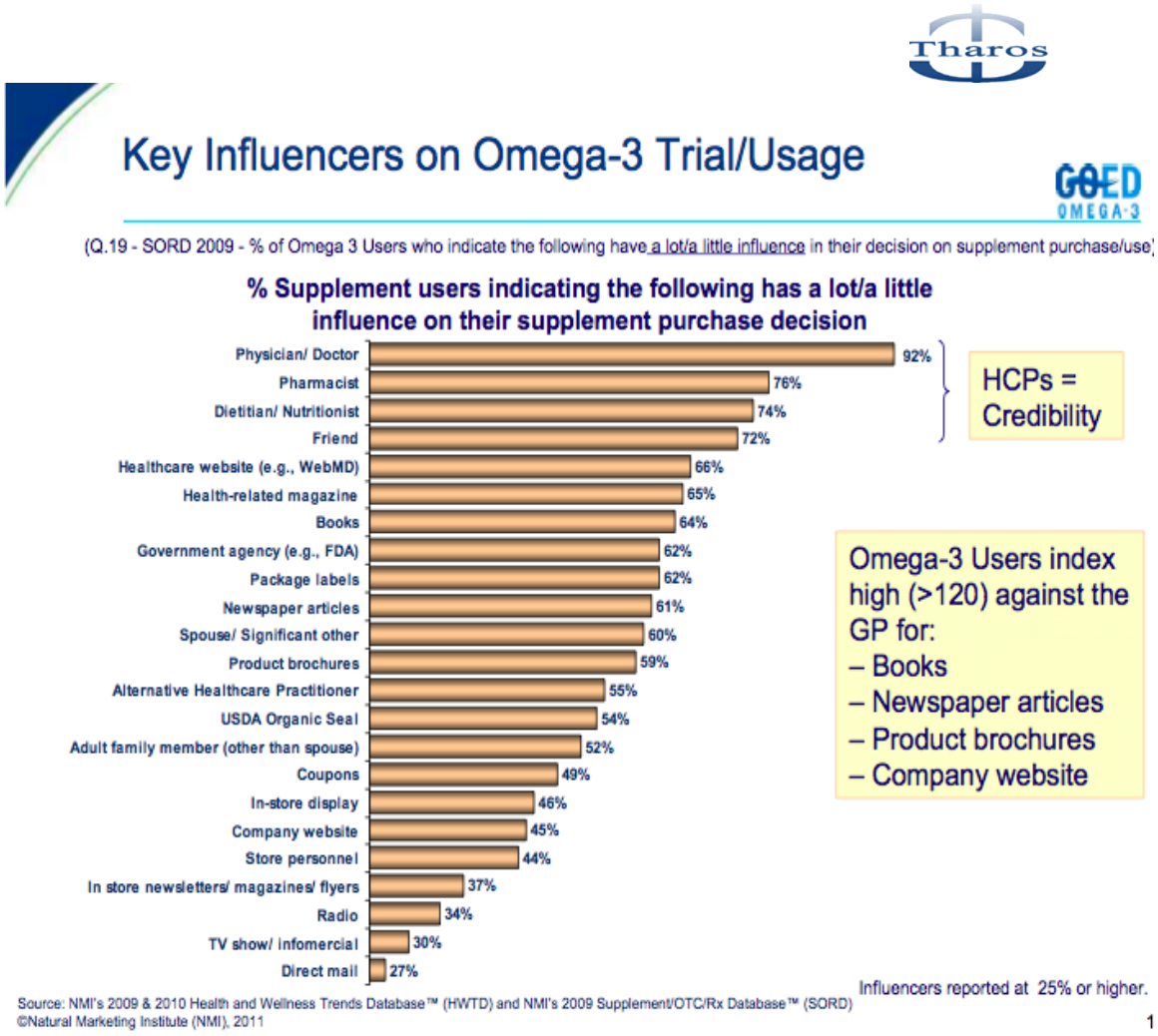


Nonetheless end-buyer's apprehensions on the "medical message" remain one of the key leading sources of information and a true decision making channel (for the US market at least).

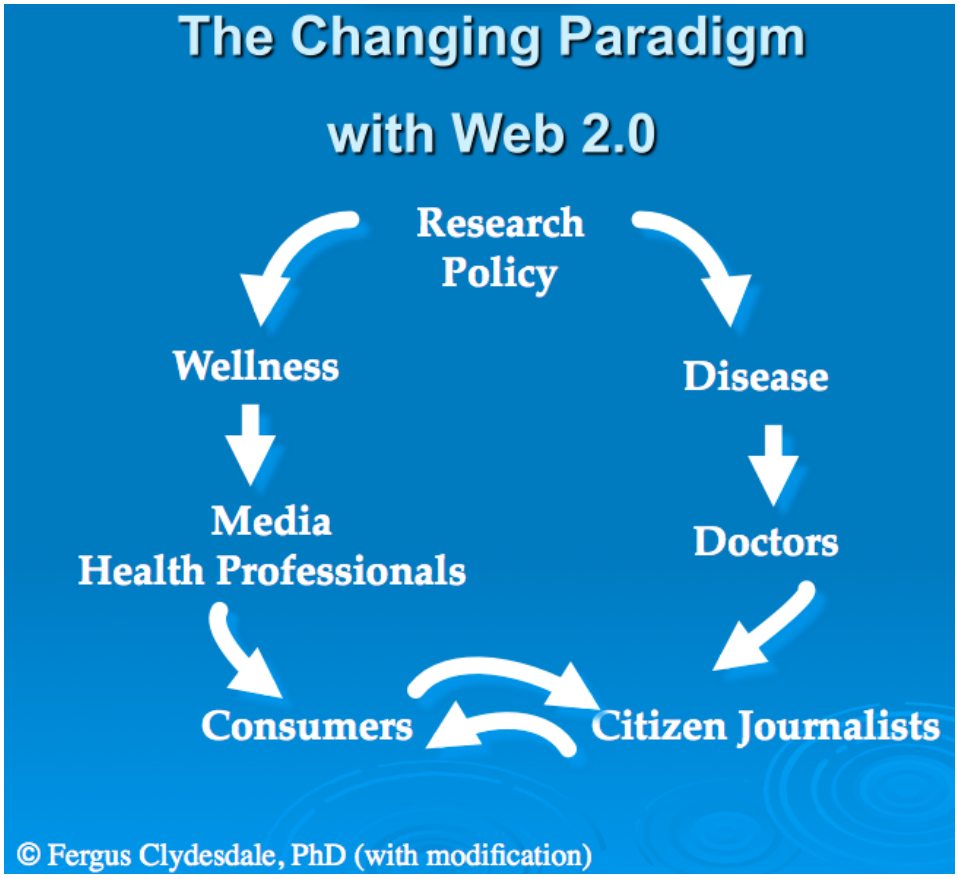
For krill oil, the "**mouth-to-mouth**" conveying message remains so far an important source of information. Although media, medical and research data provides valuable information, it is the "**others**" (e.g. Blogs) that have captive readers and follow their recommendations. It is also valid for other sources of food and specifically for Omega-3 end products.

On this respect, IFIC's awareness and influencers is in line with NMI's data.





Source: NMI 2010

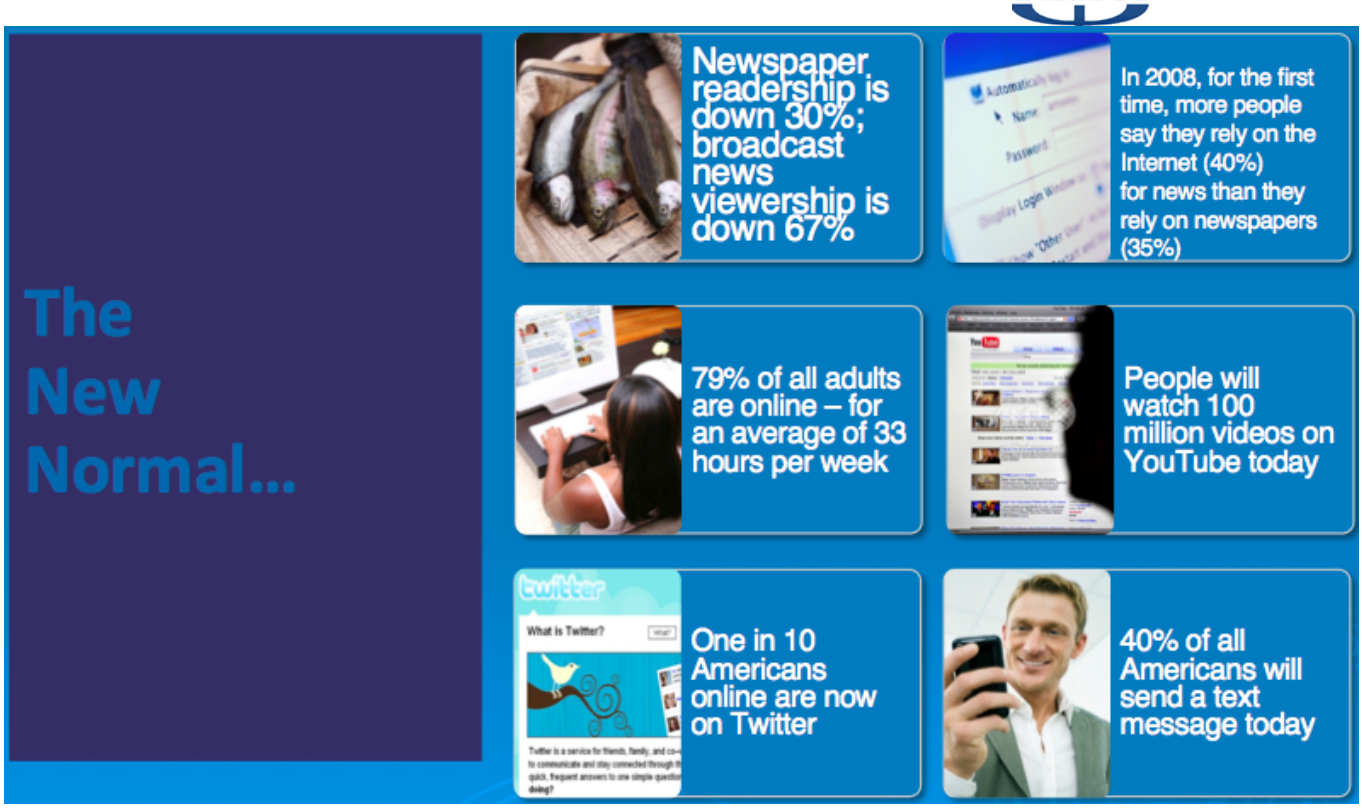


Source: NMI 2010

On a world that praises the "fast" and "immediate" message, the 24-hours coverage, if the product message is not properly packaged and delivered, there are few chances of success for every cost unit spent on advertisement.

In this "media" environment, it is expected that "social media" grabs a larger share of the "message" about new products and benefits of existing ones. The social media landscape has arrived to change the way products are marketed, even more important than the product itself.

Source: NMI 2010

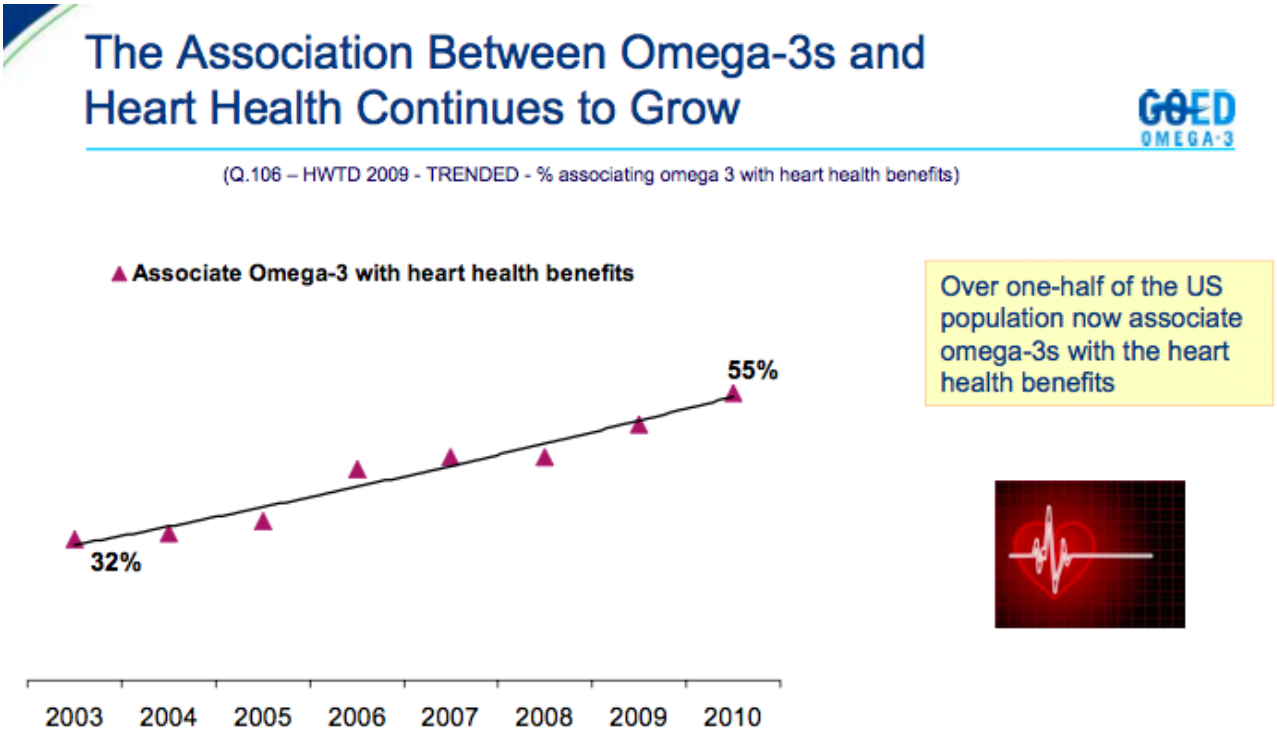


Source: NMI 2010

The new ground rules for communicating consider;

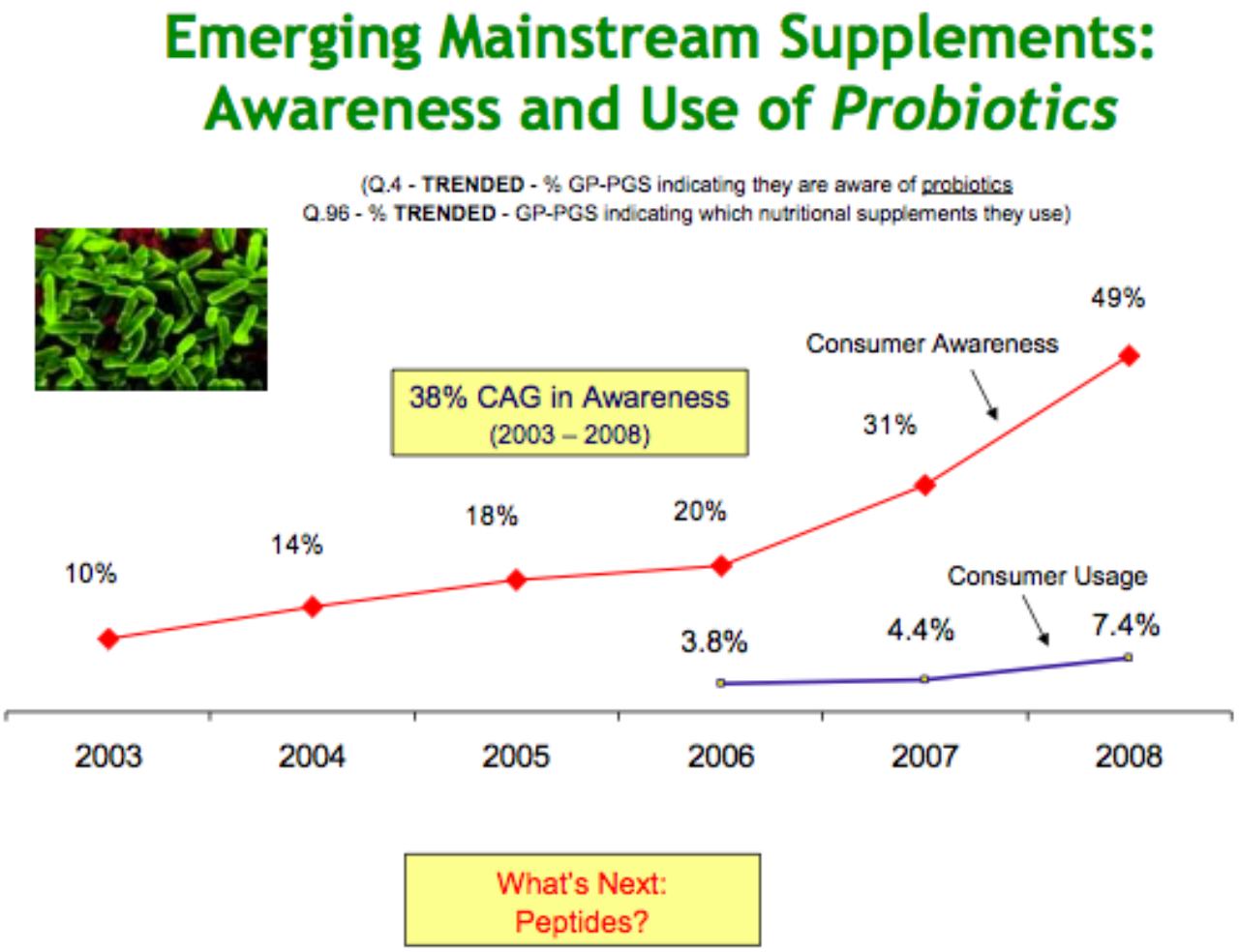
1. Communications must be structured so as to be "heard" above the media-environment.
2. The immediate information environment must be taken into account and messages structured and delivered accordingly.
3. Communicators must have respect for and exploit the increasingly foreshortened "news cycle".
4. Messaging must conform to new media ***style*** of communication.
5. Multiple information channels must be employed simultaneously, traditional as well as new media channels.

No matter the current "apparent" confusion among shoppers, it remains solid the link between fish oil and Omega-3's in respect to health aspects, either heart or other heath benefits. It also leads on awareness and growing demand. This is a "nice" paradox; no matter the confusion, Omega-3 product is facing a growing demand curve……until when?



Source: NMI's 2009 & 2010 Health and Wellness Trends Database (HWTD) and NMI's 2009 Supplement/OTC/Rx Database (SORD)

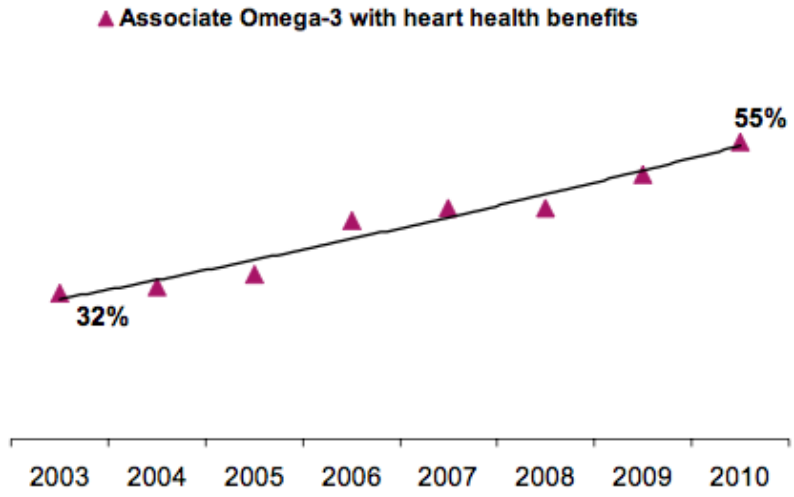
Ceres Consulting work confirms the awareness' importance and growing incidence in all major categories.



Source: Ceres Consulting.

The Association Between Omega-3s and Other Benefits in Increasing Too

(Q.106 – HWTD 2009 - TRENDED - % associating omega 3 with heart health benefits)



Association of Omega-3s with Other Health Issues	
Cognitive Function	34%
Cancer	26%
Anti-Aging	24%
Immune Health	23%
Skin Health	21%
Eye Health	17%
Inflammation	15%
Joint Health	14%
Weight Mgt.	13%
Don't Know	**29%**

Source: NMI's 2009 & 2010 Health and Wellness Trends Database (HWTD) and NMI's 2009 Supplement/OTC/Rx Database (SORD)

Consumers Interest in Omega-3s is Supported by Multiple Attitudes & Behaviors

(Q.61 - HWTD 2010 - % GP indicating what they would like to get more of in their diet)

% of consumers indicating that of the foods and beverages they consume, they wish they could get more…

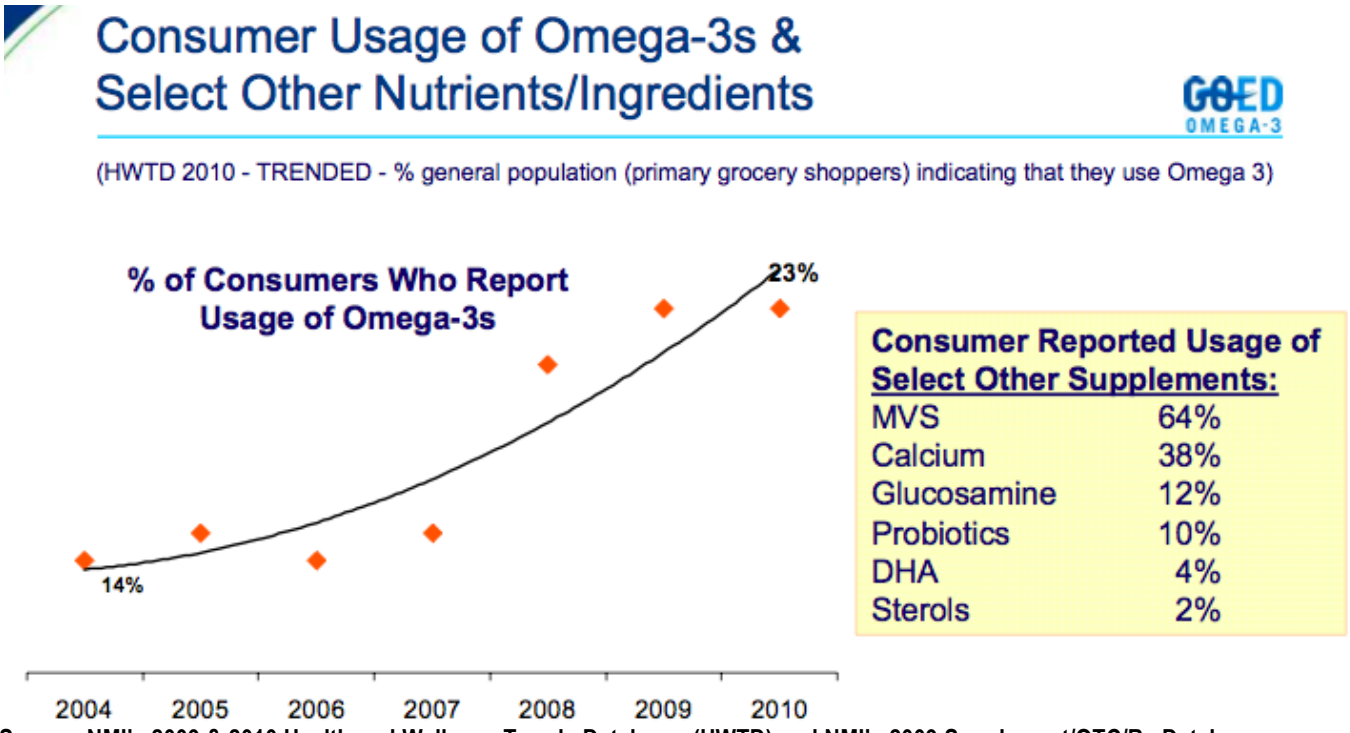
- ✓ 59% Fiber
- ✓ 56% Antioxidants
- ✓ 56% Vitamins/Minerals
- ✓ 54% Calcium
- ✓ **52% Omega-3s**
- ✓50% Vitamin D
- ✓48% Water
- ✓47% Protein

In fact…

- 25% of US consumers feel their diets are "deficient in Omega-3s"
- Over half (53%) report that they feel it is important that their store stock foods enriched with omega-3s

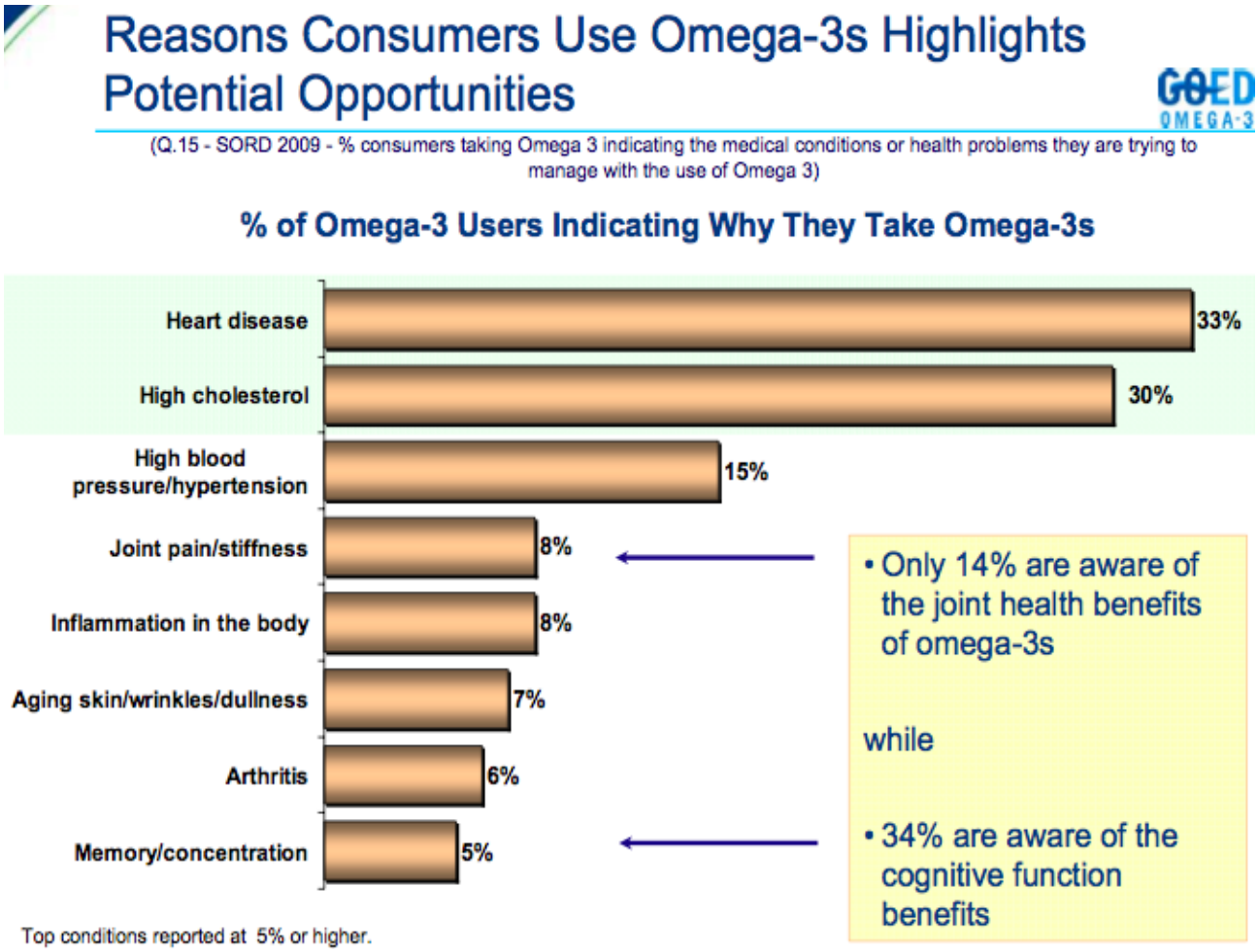
Source: NMI's 2009 & 2010 Health and Wellness Trends Database (HWTD) and NMI's 2009 Supplement/OTC/Rx Database (SORD)

Already, nearly one-quarter of the US adult population reports using omega-3s in 2010. Additionally, this same consumers report to be taking multivitamins, calcium sources and probiotics, among other supplements.



Source: NMI's 2009 & 2010 Health and Wellness Trends Database (HWTD) and NMI's 2009 Supplement/OTC/Rx Database (SORD)

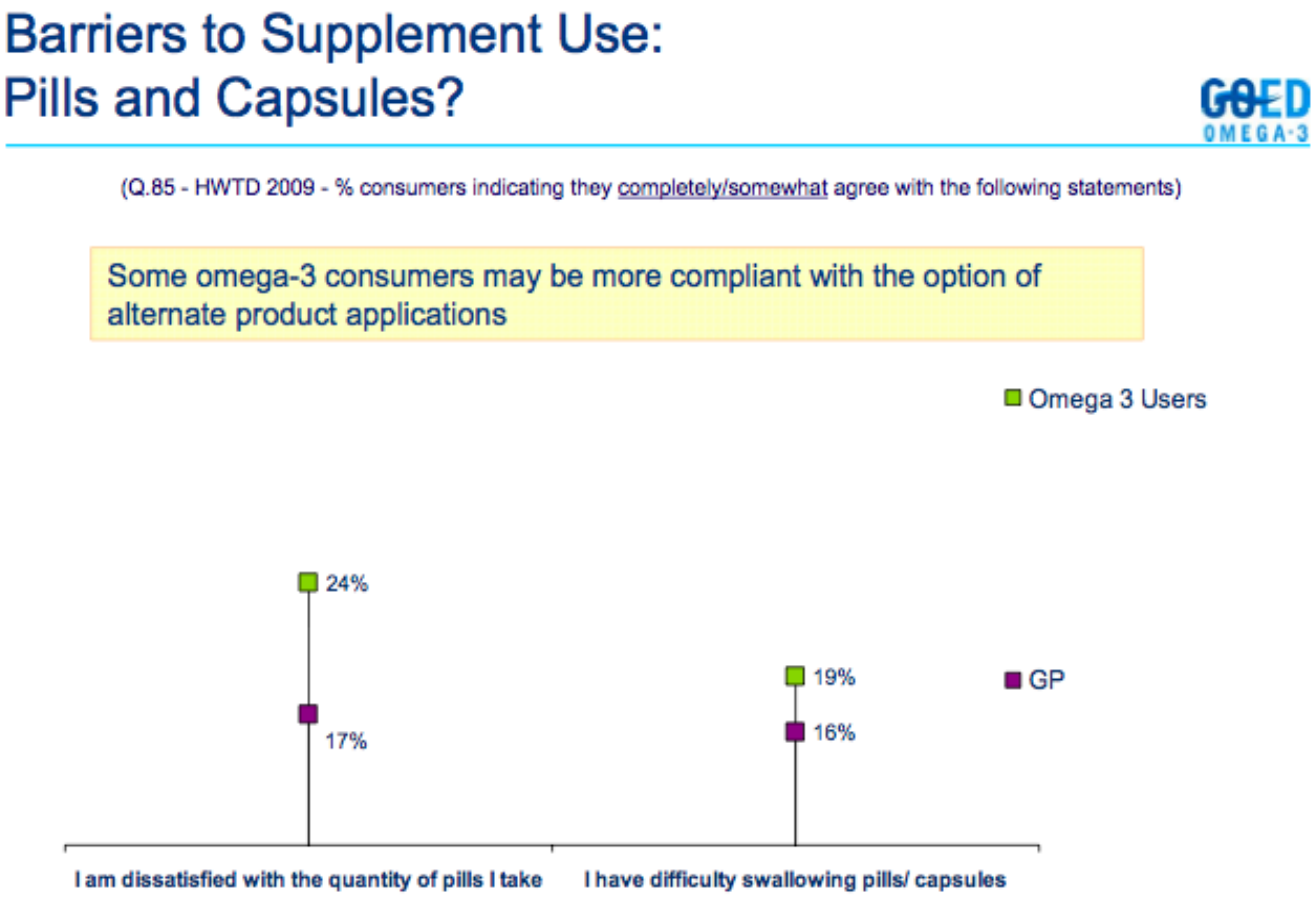
As a whole, consistent within all GOED speakers, heart disease, cholesterol and high blood pressure are leading reasons on Omega-3 consumption.



Source: NMI's 2009 & 2010 Health and Wellness Trends Database (HWTD) and NMI's 2009 Supplement/OTC/Rx Database (SORD)

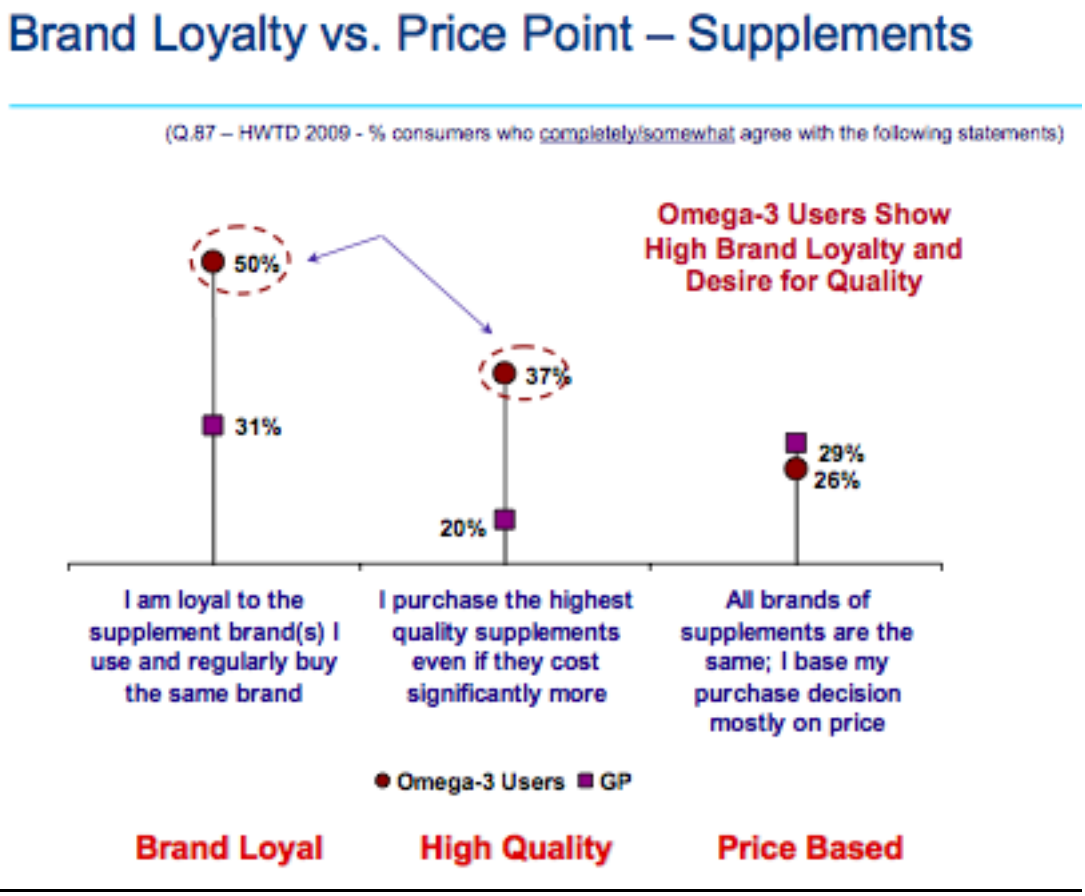
One of NMI's most interesting pieces of research has to do with the way Omega-3 is ingested, how it affects current demand and eventually how it can be improved for a larger market penetration.

It is the comparison between pills and capsules, where the amount of pills to take has a relevant value within the category consumption.



Source: NMI's 2009 & 2010 Health and Wellness Trends Database (HWTD) and NMI's 2009 Supplement/OTC/Rx Database (SORD)

Brand loyalty is other of recent NMI's research. Once more, Omega-3 users are the ones that have the highest brand loyalty. These same users also have the largest desire for quality and may have a significant effect for krill oil as new ingredient. Omega-3 consumers pay more and want more for each unit value.



Source: NMI's 2009 & 2010 Health and Wellness Trends Database (HWTD) and NMI's 2009 Supplement/OTC/Rx Database (SORD)

Per NMI's research, compared to the general population, Omega-3 users exhibit a higher interest in supplement forms for prevention/treatment of heart disease. Indexed to the general population (GP), those concerned about preventing memory/concentration problems prefer supplement forms vs. food or beverage applications

Claims – Article 13 & 14

Regarding the EU Claim process….no doubt it is perceived as a real nightmare! This process was outlined at GOED conference although there is no consensus on its long terms implications, where an EFSA opinion is just the beginning of the process.

Specifically on foods, summarizing

a) Regulation 1924/2006 on nutrition and health claims made on foods.
b) 3-tier health claims submissions.
    - General function claims–aka Article13.1claims
    - "New function" and/or proprietary – aka Article 13.5
    - Disease Risk Reduction or Children's Health–w/out proprietary–aka Article 14 claims
c) The European Food Safety Authority (EFSA) being responsible for scientific review and opinion.
d) A positive EFSA opinion does not secure an authorized claim and a negative opinion does not mean a claim will be rejected.
e) EU Commission in cooperation with Member States responsible for authorization of claim wording and conditions of use.

One thing for sure is to expect an authorized DHA claim by mid-2011. And for the future and beyond regarding the Article 13;

a) Article 13.4 procedure under development.
b) Claims that benefit from the further assessment procedure.
c) Modifying generic claims already authorized.
d) Claims that have previously received a negative opinion.

Regarding the status of N-3 LCPUFA Claims

a) Many claims have already been submitted and reviewed under Articles 13 and 14.
b) Strong science behind n-3 LCPUFA claims evident in numerous positive opinions/pending claims.
c) So far no claims have entered into legislation despite positive opinions dating back as far as spring 2009.
d) Vote taken at 6th December 2010 meeting of the Commission's Standing Committee on the Food Chain and Animal Health (SCFCAH) on Draft Commission Regulation authorizing and refusing authorization of Article 14 claims

On DHA, Article 14 Claims Pending Authorization

a) "DHA contributes to the normal visual development of infants up to 12 months of age" - 0.3% DHA in formula and contribute to 100 DHA mg AI (15/30%) in complementary foods for 7-24 months
b) "DHA maternal intake contributes to the normal development of the eye of the fetus and breastfed infants"
c) "DHA maternal intake contributes to the normal brain development of the fetus and breastfed infants" – 200 mg DHA supplementary intake in addition to adult AI of 250 mg DHA+EPA.

Article 14: Positive EFSA Opinion on DHA and Visual Development

Applicant	Mead Johnson Nutritionals (EFSA Q 2008 211) (EFSA Q 2008 688) (EFSA Q 2008 689)
Details of Exposure	DHA and Arachidonic acid (ARA) from single cell oils Lipil® Enfamil® Premium
Target Population (stated by applicant)	Infants/children, birth to 3 years of age
Claim Wording (stated by EFSA)	DHA contributes to the visual development of infants
Conditions of Use (stated by EFSA)	In order to bear the claim, a formula should contain at least 0.3% of the total fatty acids as DHA. Such amounts can be easily consumed as part of a balanced diet. The target population is infants (breastfed or formula-fed), from birth up to 12 months.
Proprietary status	Positive opinion required consideration of proprietary data

Article 14: Negative EFSA Opinion for Maternal DHA Supplementation

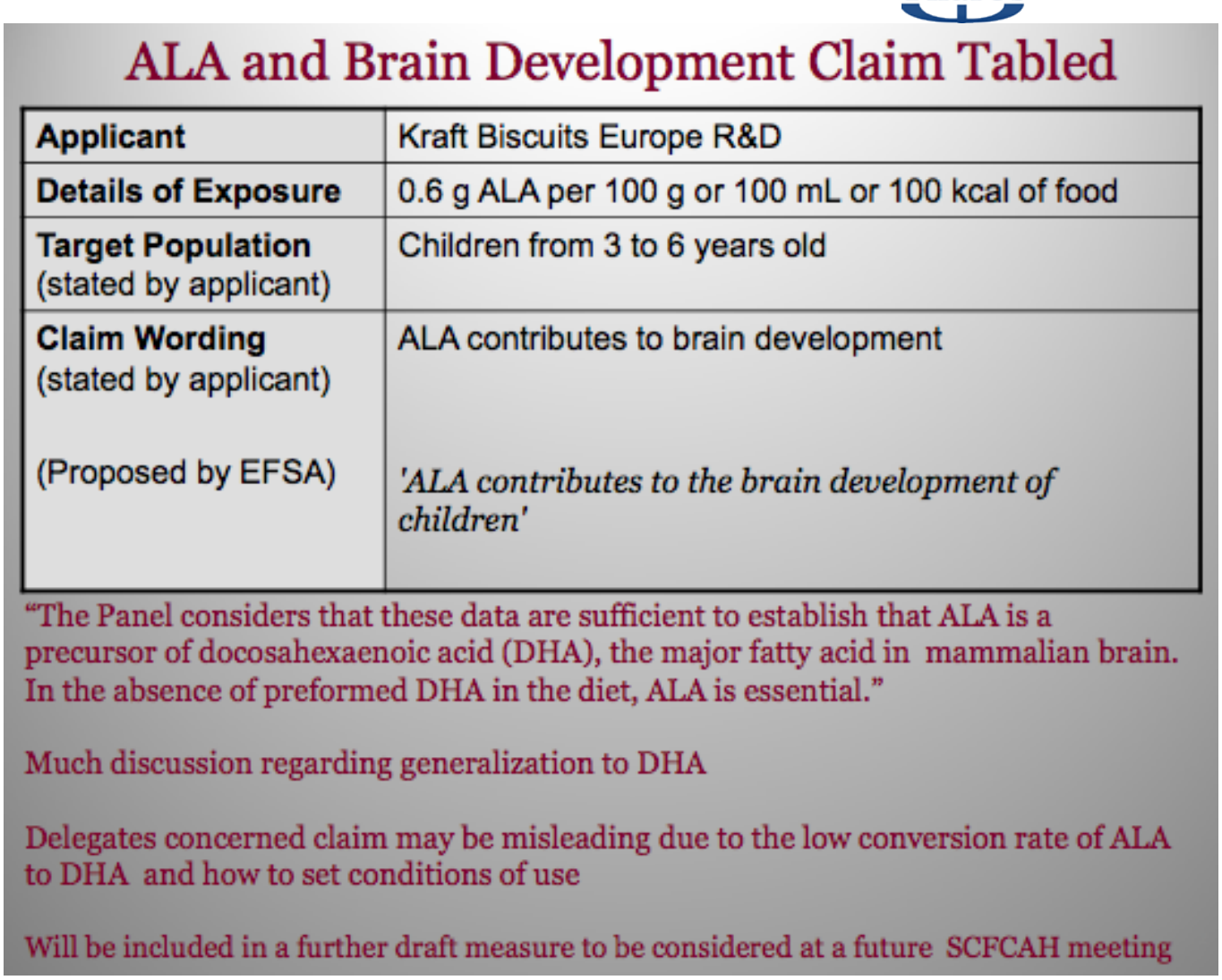
Applicant	Merck Selbstmedikation GmbH (EFSA Q 2008 675) (EFSA Q 2008 773)
Details of Exposure	DHA from tuna oil
Target Population (stated by applicant)	Pregnant and lactating women
Claim Wording (stated by applicant)	DHA is important for early development of the eyes in the foetus (unborn child) and infant. Maternal DHA supply contributes to the child's visual development. DHA is important for early development of the brain in the foetus (unborn child) and infant. Maternal DHA supply contributes to the child's cognitive development.

Article 14: Negative EFSA Opinion on Optimal Brain Development

Applicant	Mead Johnson Nutritionals (EFSA Q 2008 212) (EFSA Q 2008 690) (EFSA Q 2008 691)
Details of Exposure	DHA and ARA from single cell oils Lipil® Enfamil®
Target Population (stated by applicant)	Birth to 3 years of age
Claim Wording (stated by applicant)	DHA and ARA/Lipil/Enfamil contribute to the *optimal brain development* of infants and young children

Factors contributing to negative opinion:

heterogeneity of evidence with regard to study design, outcome measures, consistency of benefit and benefit extension beyond early life



Article 13 Claim reviewed up to date

a) 31 January 2008 - Member States submitted national lists – (44.000 entries)
b) May 2010 – EFSA publishes consolidated database (4.637 main entry claims)
c) First batch: October 2009 – includes DHA+EPA for blood pressure and triglycerides
d) Second batch: February 2010
e) Third batch October 2010 – includes mix of DHA and DHA+EPA claims.
f) Finalization of the assessment: end of 2011
g) No Article 13 claims authorized to date and Community Register not established

Opinion Results for Cardiovascular n-3 LCPUFA Article 13.1 Claims

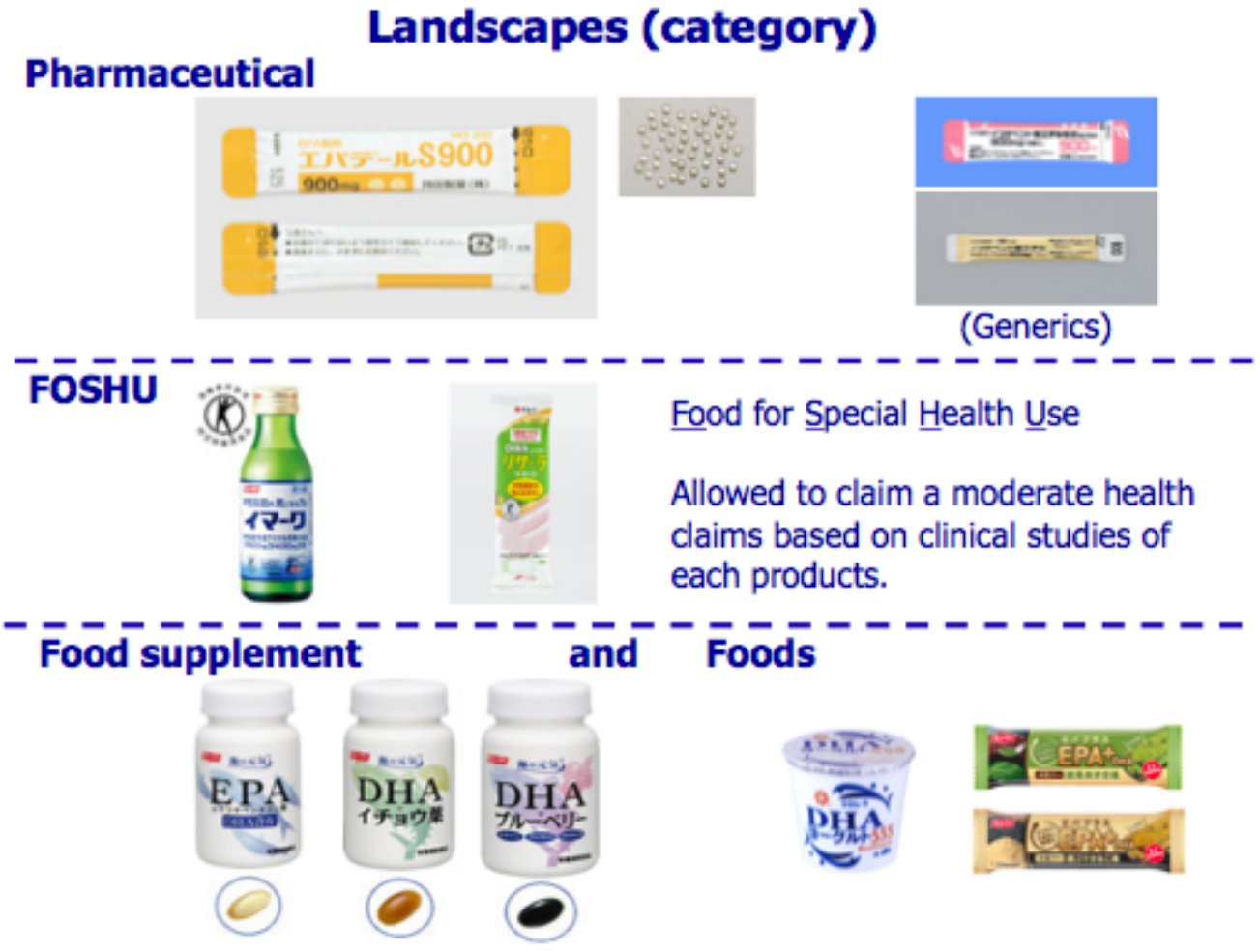
Opinion Outcome	Claim (Biomarker)	Proposed Condition of Use
Positive	DHA+EPA and Maintenance of **blood pressure**	~3 g per day
Negative	DHA+EPA and Maintenance of normal **HDL-cholesterol** levels	N/A
Positive	DHA +EPA Maintenance of normal **triglyceride** levels	~2-4 g per day
Negative	DHA+EPA and Maintenance of normal **LDL-cholesterol** levels	N/A
Positive	DHA and maintenance of normal **triglyceride** concentrations	2 g per day
Positive	DHA+EPA and **cardiac function**	250 mg per day

Opinion Results for N-3 LCPUFA Neural Article 13 Claims

Opinion Outcome	Health Relationship	EFSA Specified Claim Language	EFSA Specified Condition of Use
Positive	Brain Health and Function	DHA contributes to the maintenance of normal brain function	250 mg DHA
Positive	Visual Health and Function	DHA contributes to the maintenance of normal vision	250 mg DHA

Can Pharma and Dietary Supplements Co-Exist?

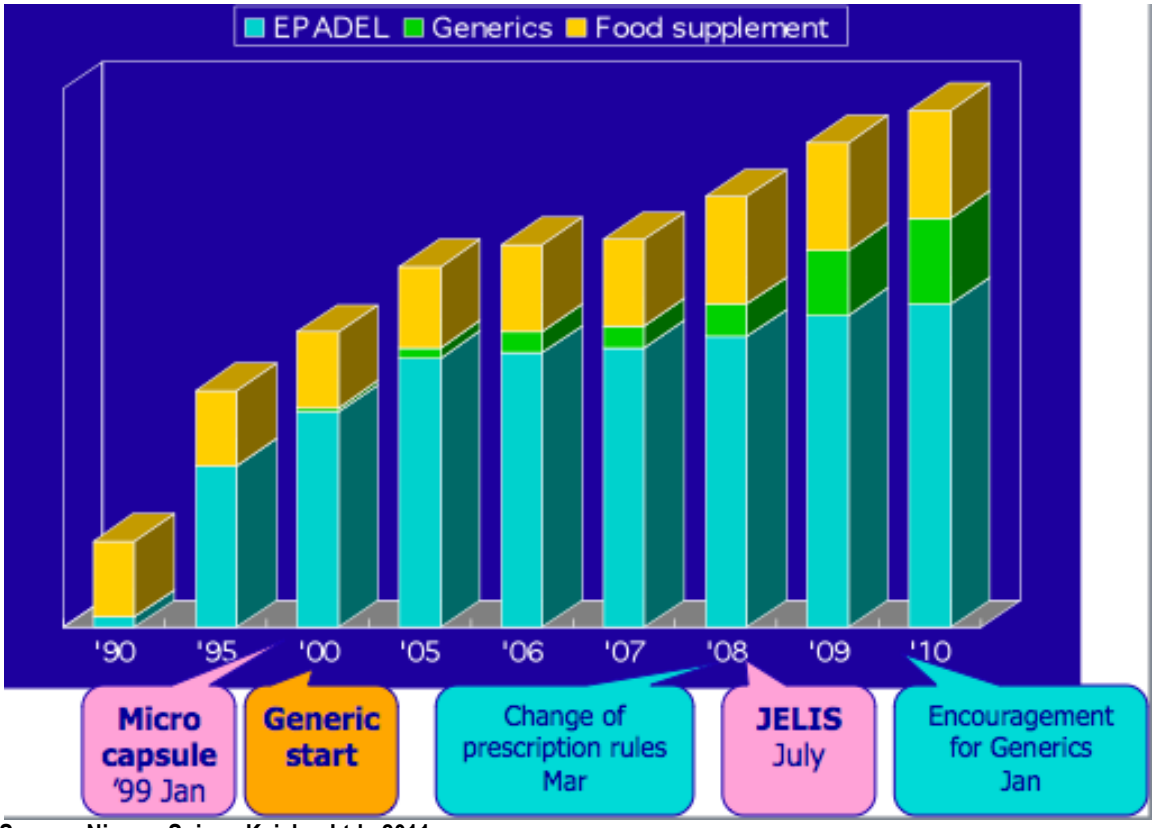
At least the Japanese experience say that this is possible, where the market value of food supplements is still outpaced by the pharma category for EPA & DHA (values in ¥).



Source: Nippon Suisan Kaisha, Ltd., 2011 (EPADEL experience)

Source: Nippon Suisan Kaisha, Ltd., 2011

The Japanese market growth for pharma applications has to do with the change on regulations and economic reasons, valid for the EPADEL product.



Source: Nippon Suisan Kaisha, Ltd., 2011

Why this change;

1. Regulatory changes EE for pharma and TG for food supplements.
2. Marketing diversity EPA for heart health and DHA for the brain and eyes.
3. Economical reasons

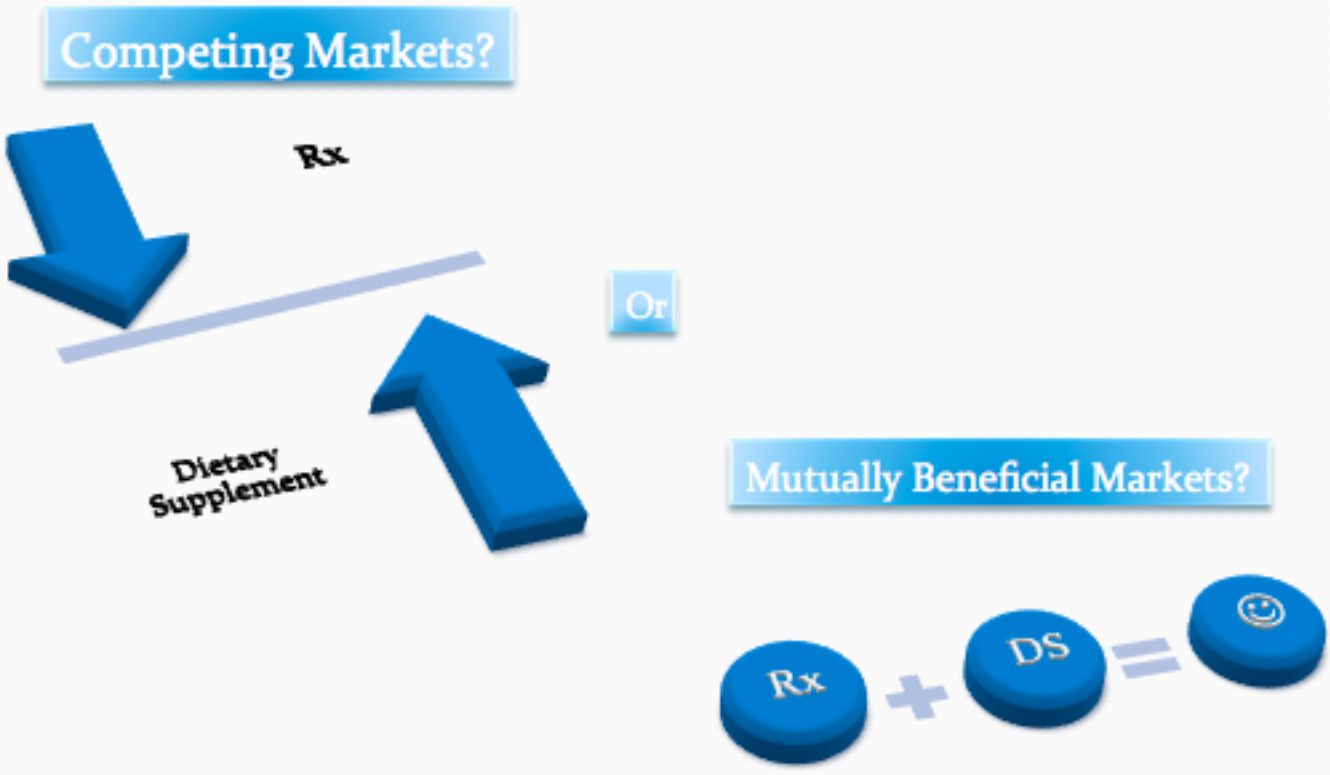
According to Dr. Duffy MacKay, N.D., from the Council for Responsible Nutrition (CRN) in Washington, D.C., in the US both can also and do co-exist. In the United States Omega-3 fatty acids are sold as dietary supplements and by prescription.

In the US, currently the two categories co-exist

- Omega-3 - a strong dietary supplement category
- Omega-3 Rx - a 'blockbuster drug'

Dr. MacKay sustains that both categories should co-exist on a mutual enhancing way.

Source CRN



The sustaining factor for this comes form the composition of each and the question of what is the difference between Rx and dietary supplement omega-3 products? where there is not such difference, rather a matter of terminology. **The distinction between a supplement and a drug is largely an exercise in regulatory linguistics and it is not a function of biological activity.**

Dr. MacKay expanded his views on terminology and the regulatory language.

A product is defined by it 'intended use'

a) Drug = articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

b) Dietary supplement = a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet.

Therefore, identical material can exist both as a dietary supplement and a drug. Each regulatory category is associated with its own set of rules, guidelines, regulations, and oversight divisions within the FDA.

On Rx products' compositions and claims

Strict specifications for purity, potency, and composition

1. Single Rx composition is pre-approved by the Food and Drug Administration (FDA) for specific therapeutic indication (claim).
2. Completed FDA drug approval (phase I, II, and III clinical trials) - Establishes safety and efficacy for approved product.
3. Manufactured under drug GMPs.
    a. Designed to ensure that the product is consistently manufactured to specific composition, purity, and stability.
    b. Food GMPs>Supplement GMPs>Drug GMPs.

Rx Omega-3

"One-gram capsule contains 465 mg EPA and 375 mg DHA"

a. 84% EPA and DHA ethyl ester derived from fish body oil.
b. Approved to lower very high triglycerides.
c. Protected by intellectual property portfolio.
d. PubMed search would suggest a desire to expand to other cardiovascular indications: secondary prevention of post MI, statin combo therapy, cognitive indications, etc.

On Dietary Supplements' compositions and claims

1. Manufacturers are not tied to one type of finished product
    a. Specifications for purity, potency, and composition are set by each manufacturer
    b. Multiple sources - fish, algae, krill, squid, shark, etc
    c. Multiple forms - EE, native TG, re-esterified TG, phospholipids, etc
    d. Multiple concentrations and ratios of EPA/DHA
2. Manufactured under supplement GMPs.
3. Not allowed to make drug claims - can't claim to treat, cure, mitigate, or prevent disease.
4. Allowed to make approved health claims or structure function claims.
5. Not limited to any specific claims
    a) DS claims only requirement is to be supported by reliable and competent scientific evidence.
    b) Claims submitted to FDA within 30 days of marketing.
    c) Drugs can not be marketed for unapproved claims (off-label use).

In the US, the Dietary Supplement Health and Education Act (DSHEA) protects the dietary supplement omega-3 category;

1. Multiple forms of EPA and DHA were marketed as dietary supplements before an omega-3 product was approved as a drug in the United States
2. Omega-3 dietary supplements manufactured and marketed according to DSHEA do not have any additional limitation imposed by the presence of Rx omega-3
3. Patent laws present legal limitations to composition and claims, but apply equally for Rx and DS forms with patent protection - Patent protection is responsibility of patent holder

Regarding distributions practices in the US depending if Rx or Dietary Supplement, there are differences among them;

Rx

1. Prescribed by healthcare provider.
2. Dispensed by pharmacists.
3. Covered by insurance.
4. Relatively expensive.
5. Marketing emphasis (differential advantage).
6. Meets all of the efficacy, safety and manufacturing standards for FDA approval.
7. Approved for treatment of very high TGs.
    a. Other applications would be 'off label' - Not clinically proven to be the correct dose, concentration or form for off label use (also contradicts its own marketing emphasis)
    b. May not be reimbursed?

Dietary Supplements

1. Retail, mass, chain drug, internet, direct sellers, functional food, formula, etc.

2. Manufacturers and marketers have options for….
    a. Source, form, and delivery system - Not limited to one product and one indication.
    b. How and who it is marketed to
        i. Not limited to a single diseased population.
        ii. Can be promoted for 'preventive' and 'off label' uses.
        iii. Can be promoted for nutrient content.
3. Marketing emphasis flexibility
    a. Quality, freshness, taste, lack of contaminants.
    b. Environmental impact, social impact, etc.
    c. Different characteristics will appeal to different audiences.

Dr. MacKay concludes about the "**Symbiotic Relationship**" between Rx and DS's, and the reasons for it while there is also a "**Parasitic Relationship"**

On the contributing "**Symbiotic Relationship**" issues

1. Consumer omega-3 awareness is elevated
    a. Direct to consumer drug advertising.
    b. Recommendations and discussions by physicians.
    c. Dialogue from the medical/scientific world spills over into mainstream media.
2. Additional consumer omega-3 exposure
    a. Omega-3 impressions in consumer media
    b. Friend or colleague given a prescription.
    c. Health policy recommendations (AHA, APA).
3. The coexistence of Rx and Dietary Supplement omega-3 products results in parallel efforts to increase public awareness while maximizing distribution channels and claims that can be made for EPA and DHA.
4. The possibility for additional therapeutic indications (drug claims) fuels continued clinical research and expands the body of scientific evidence for omega-3 fats.

Supplemental Reading

Omega 3 as dietary supplement
Can co-existence of pharma and dietary omega-3s benefit the industry?

CRN's Dr. Mackay presented an overview of the two categories and outlined differences in regulatory standards, distribution channels and allowable marketing claims. He pointed out that Omega-3's prescribed as a drug, although subjected to more stringent GMPs and strict specifications for purity and potency in their composition, ***do not differ*** from omega-3 dietary supplements in their biological activity.

A drug is defined as a substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, whereas a ***dietary supplement is defined as a product taken by mouth that contains a 'dietary ingredient' intended to supplement the diet***. As noted, these definitions do not prevent the same material from existing as both a dietary supplement and a drug.

While the currently available omega-3 drug Lovaza can make the approved therapeutic claim to "***lower very high triglycerides***" it ***cannot make the multiple structure-function claims*** (considered off-label use) that dietary supplements can make, including claims concerning eye health, prenatal health and immune function. Thus while Lovaza can claim it is "the only FDA-approved fish oil," dietary supplements have considerable marketing flexibility and can appeal to multiple audiences for multiple reasons.

Mr. Tanaka affirmed Mr. Mackay's conclusions and presented data from Japan showing how omega-3 dietary supplements and pharmaceuticals have co-existed for 20+ years and are even produced by the same company.

Omega-3 public safety specification standard moves forward

Setting a specification standard for safe levels of contaminants in omega 3s requires understanding the hazard and correctly measuring exposure in order to assess risk.

Dr. Claire Kruger, CEO and director of Health Sciences at Spherix, outlined a conceptual equation for evaluating public safety:

Hazard + Exposure = Risk

Kruger explained: "We need to understand the hazard, we need to marry that understanding with the degree of exposure, and then we can assess the risk." Kruger emphasized that public safety relies on controlling the risk of exposure, not on eliminating the hazard.

Dr. Kruger also voiced the necessity for setting the new standard at a level considered safe for the most sensitive sub-populations, in this case prenatal fetuses and infants.

Dr. Kruger's core concepts were summarized as follows regarding risk versus hazzard:

1. Purpose for setting specifications is to control risk, not eliminate hazard.
2. The absolute absence of risk can only be proved when it is certain that exposure does not exist.
3. The Goal of "I can't find it so it must be safe" approach to controlling environmental risks is flawed. It depends upon the relationship between analytical capabilities to detect the presence of a chemical and the magnitude of the health risks it poses.
4. Analytically, regulators must link term "no residue" to a current method of analysis; constrained to a limit of detection

The proposed set of fish-oil specifications was;

1. Physical and chemical properties
2. Fatty acid composition
3. Environmental contaminants
4. Biological contamination

(1) Physical and chemical - properties such as appearance (color/clarity), odor, taste, density, moisture, acid value, peroxide value, p-anisidine value, iodine value, stability to oxidation.

(2) Chemical characterization such as fatty acid composition (EPA, DHA, mono- di- and tri-glyceride, free fatty acid), unsaponifiable, saponification value.

(3) Environmental contaminants such as pesticides (per each batch or analyzed periodically for quality control), heavy metals such as arsenic, mercury, lead. Some products included cadmium and others even include iron, nickel and copper. PCBs, dioxins, furans, benzo(a)pyrene (BaP)

(4) Biological contamination such as yeast/mold, standard aerobic plate count, Enterobacteriaceae, *E. coli*, Salmonella spp., coliforms, Coagulase positive staphylococcus, *Bacillus cereus* (biological parameters are not often included)

Dr Kruger's approach on risk and hazard

Instead of → How much risk is allowable
Substitute → How much hazard is possible

Levels of PCBs and Dioxins were presented for several fish oils.

Product	Total PCBs	Dioxins/Furans
Menhaden oil (21CFR184.1472):	-	-
ω-3 triglycerides concentrate (GRN 200)	90 ppb	2 pg WHO-TEQ /g
Tuna fish oil (GRN193)	3.5 pg WHO-TEQ/g [a]	1.5 pg WHO-TEQ/g
Salmon oil (GRN 146)	12 pg WHO-TEQ/g [a]	2 pg WHO-TEQ/g
Fish oil (GRN138)	2.0 ppm [b]	c
Tuna oil (GRN109; GRN97)	0.1 ppm	d
Small fish body oil (GRN102; GRN98)	-	-
Marinol ω-3 concentrate (GRN105)	0.1 ppm	e
DHA-rich tuna oil (GRN94)	Not detected [f]	Not detected [f]

a. For PCBs similar to dioxins
b. The highest total PCB content in the batch data was 0.01 ppm (or 10 ppb), about 1/20 of the specification established.
c. Specifications were not established. Individual dioxin and furan were tested showing a highest level of about 3 ppt.
d. Specifications were not established. Batch analysis showed highest level of total dioxin/furans of 1 ng TEQ/kg (i.e., 1 pg WHO-TEQ/g)
e. Two samples showed low levels of dioxins and furans of 0.18 and 0.13 pg/g (WHO-TEQ), assuming that any non-detected congeners were present at their respective limits of detection.
f. The detection limit for PCBs (Arochlor 1254) was 0.0168 ppm. The detection limits for each dioxins were provided in Appendix A which is not available to access.

Product	Total PCBs	Dioxins/Furans
Menhaden oil (21CFR184.1472):	-	-
ω-3 triglycerides concentrate (GRN 200)	490,000 pg	11 pg WHO-TEQ
Tuna fish oil (GRN193)	36 pg WHO-TEQ	15.5 pg WHO-TEQ
Salmon oil (GRN 146)	180 pg WHO-TEQ	30 pg WHO-TEQ
Fish oil (GRN138)	100,000 pg	
Tuna oil (GRN109; GRN97)	850,000 pg	8.5 pg WHO-TEQ
Small fish body oil (GRN102; GRN98)	-	-
Marinol ω-3 concentrate (GRN105)	770,000 pg	2.4 pg WHO-TEQ
DHA-rich tuna oil (GRN94)	1,900 pg (Arochlor 1254)	0.08 pg WHO-TEQ

Regarding the daily intake of of PCB's and Dioxins from various sources of fish oils

- Fish oils, GRN 200, GRN193, GRN146, GRN138, GRN109 and GRN105, contained average EPA+DHA levels of 55%, 29%, 20%, 30%, 32.5% and 35%, respectively
- GRAS substances (GRN200, GRN193, GRN146, GRN138, GRN109, GRN102 and GRN105) were proposed for general food uses as menhaden oil (21CFR184.1472). Intake of these fish oils is self-limiting with a total intake of EPA + DHA not to exceed 3.0 gram/person/day in accordance with 21CFR184.1(b)(2).
- Estimated daily intakes of EPA+DHA from proposed uses of GRAS substances, GRN109 and GRN105, were 2.76 and 2.7 g/p/d, respectively.
- DHA-rich tuna oil (GRN94) was proposed for use in infant formula only. One trial showed the intake of DHA-rich oil of 38 mg/kg/d (one month old infant). EDI was calculated based on a 3 kg infant.
- To estimate the daily intake of PCBs, dioxins/furans, limits established for specification were used. If limits were not established, batch data were used. One exception is that, although 2 ppm limit was established for PCBs in the fish oil (GRN138), 0.01 ppm (batch data) was used in calculating EDI.

Mr. Colin Garrioch[19] shared the combined results of past studies conducted on contaminant levels in omega 3s. Although 2010 research results had not yet been analyzed, Garrioch's 2006-2009 combined-study results clearly indicated that most substances tested well below current California and US EPA safety thresholds, not only for PCBs but also for other heavy metals and dioxins.

Mr. Robert Orr[20], pointed out that marine sources measuring above the threshold, although called "fish oil" in the media, were cod liver oil and shark oil, and not oil from anchovies, salmon or other sources commonly used in omega-3 consumer products.

[19] Business Development Manager for Nutrasource Diagnostics Inc.

[20] Chairman of Ocean Nutrition Canada (GOED member)

Regarding new technologies, because contaminant levels do vary from source to source, new forms of measurement for improving the traceability of marine oils were also discussed. Dr. Mrs. Marit Aursand[21] introduced new NMR spectroscopy technology that can authenticate four source variables:

(1) The species of different marine oils,
(2) Their geographical origin,
(3) Whether the source was wild or farmed, and
(4) The process history.

This authentication provides a method for verifying traceability data and improves transparency in the industry. Dr. Aursand stressed that continuing to populate the database with source referents is the next step in accomplishing the overall goal of Norwegian Research Council Project No: 178264, which is to establish a tool for official verification of traceability data on marine crude oils.

While a new GOED-approved specification standard is not yet in place, research needed to set such a standard, establish methods for evaluating risk and track traceability data is all well under way.

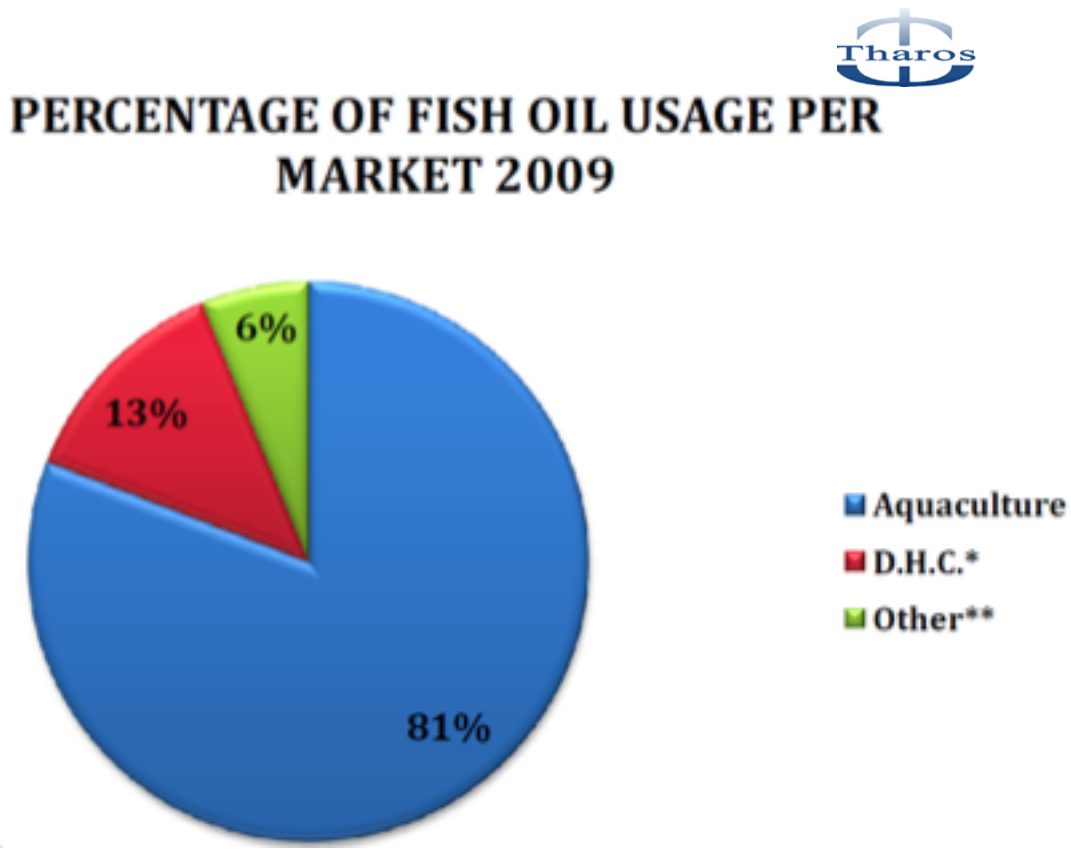
[21] Head of the Processing Technology Group at SINTEF

Fish oil supply, enough?

IFFO Managing Director Dr. Andrew Jackson expects fish oil supplies will become scarcer although depends on fishing regulations. Despite the growth of aquaculture and growing demand from human nutrition the global production of both fishmeal & fish oil has remained fairly static.

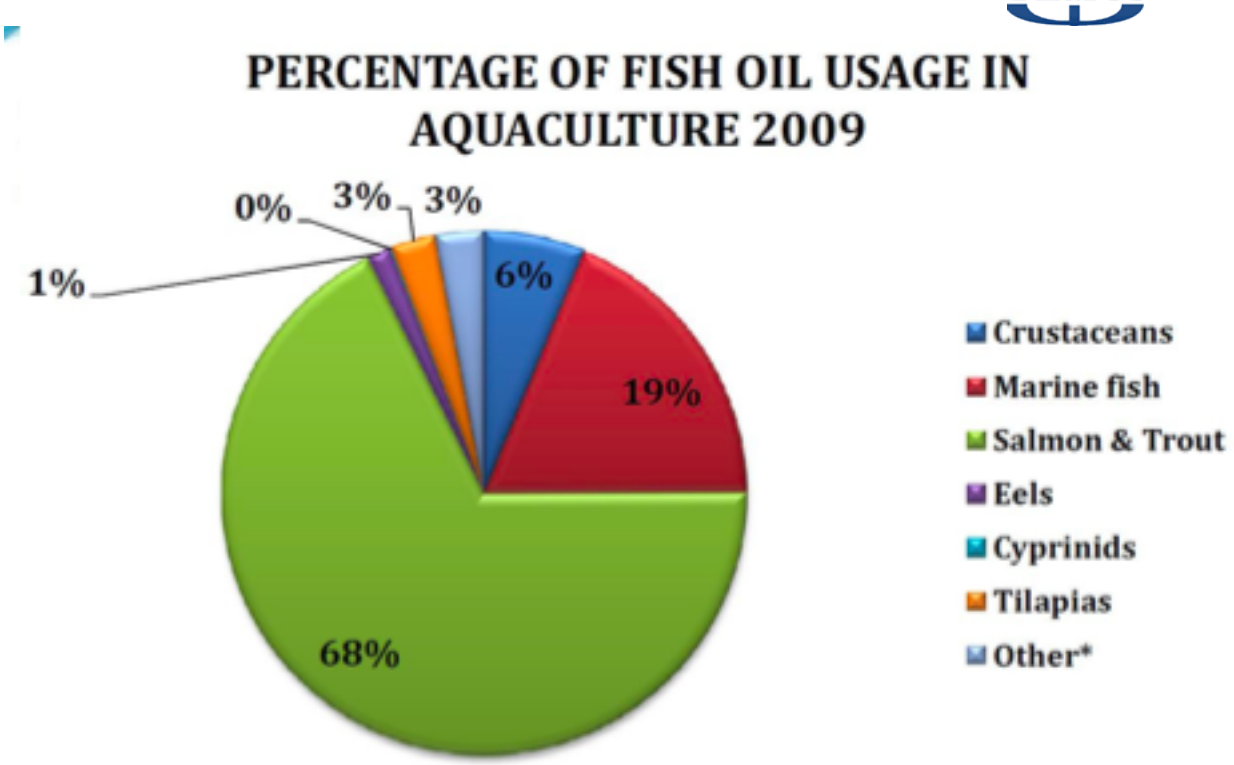
IFFO (International Fishmeal and Fish Oil Organization) is the global trade association representing fishmeal and fish oil producers and related trades. Represents two thirds of world production and 80% of trade in fishmeal and fish oil worldwide with producers in Europe, South America, Africa, USA, China and India.

The scarce situation will be felt more on the aqua business first as its share will diminish in favor of the human-consumption category. From current 80~85% share of fish oils targeting the animal feed-grade consumption, food-grade targeted fish oils will grow significantly.



Source: IFFO
DHC = Direct Human Consumption

If there will be less fish oil for feed applications, salmon farming will be the first to feel the pinch, marine fish closely following.



Source: IFFO

How will this be accomplished?

1. Salmon farming, growing by reducing fish oil inclusion level.
2. Industrial uses, including for hydrogenation decreasing, increasing plant oil inclusion e.g. canola.