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Omega-3 oils: Health claims global perspectives

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Where ever you go in the food ingredient world these days you hear of the misery that is apparently facing the industry in regard of health claims. Everyone is against us would be one interpretation of this from an outsider. Yet there is some good stuff going on out there, no more so than for omega-3s. Of course we have known that DHA and EPA are good for you for many years and even the war time generation will refer you to the awful-tasting cod liver oil they were forced to take as children. This article will hope give you a useful update on the specifics of what has been happening in the EU.

OK let's start with the EU. Regulation 1924/2006 on nutrition and health claims made on foods lays down a two tier system for health claims submissions:

- Submission of supporting references only (Article 13.1);
- Submission of a full dossier (Articles 13.5 and 14).

We know by now the European Food Safety Authority (EFSA) applies the same scientific standards to both types of submission, despite the protests that that was not the intention at the outset.

EFSA have now established reference values for omega-3 fatty acids. An adequate daily intake (AI) of 250 mg for EPA + DHA for cardiovascular; 100 mg DHA for infants (>6 months) and young children <24 months. Additionally EFSA have proposed to increase by 100-200 mg preformed DHA in addition to the AI for adults as an adequate supply of n-3 long chain PUFA during pregnancy and lactation (1). These reference values provide a basic framework upon which nutrition and health claims can be based.

The pieces of that framework are now dropping into place.

In the first amendment to the nutrition claims annex of 1924/2006 the criteria for "source" and "high" in long chain omega-3 fatty acids based on 15 and 30% of the AI for cardiovascular (2). This is a nice start. Then there are a series of positive opinions winging their way through the Article 13.1 claims procedure also based on 250 mg per day in one or more daily servings, including DHA and/or EPA and cardiac function (3); DHA and maintenance of healthy brain function (4) and DHA and the maintenance of healthy vision (5). Around 33 claims were originally submitted for long chain omega-3's in one form or another and many have been grouped together. A number are still pending. There have also been two article 13.5 claims rejected so far for fish oil related products.

Meantime the Commission and member states are also discussing three other Article 13.1 claims that have been given positive opinions which require higher doses to claim the effect. DHA and/or EPA requires 2-4 g per day to have a healthy triglyceride maintenance claim (6) and maintenance of healthy blood pressure requires 3 g per day (7). Member States have been discussing these high doses and whether they might be just too high... But at any rate the long chain omega-3 industry looks like it will have nearly a full house of claims far for the general population when the lists are formally adopted.

But what of Article 14 claims for infants and small children, surely the most sought after of all those for DHA at least. Infant formula and follow-on formula are permitted to be fortified with omega-3 and

-6 long chain polyunsaturated fatty acids ("LCs") but only a content claim is permitted for infant formula, which falls out of scope of the nutrition and health claims regulation. But follow-on formula and baby foods are within scope and it is here where the cutting edge science and article 14 applications have been presented to EFSA.

The first claim application from Martek Biosciences (now part of DSM) was made using data from clinical studies in infants from 6 months onwards and EFSA concluded that without earlier study data the evidence was not sufficient. Subsequent applications from Mead Johnson added the data from infants from 0-1 year of age and were successful in obtaining a positive opinion, at least for visual development. Merck have also added maternal consumption to these applications and there have been a total of 28 LC Omega-3 related article 14 claims opinions. EFSA's opinions have been mixed and there have been extensive back and forth communications with the Commission and member states to batten down exactly what EFSA does support in related to the science in this area.

In the end the Commission and Member States have now achieved a qualified majority vote at Standing Committee for the Food Chain and Animal Health (SCFCAH) for the following claims:

- "DHA contributes to the normal visual development of infants up to 12 months of age" (8)

- 0.3% DHA in formula and contribute to 100 DHA mg AI (15/30%) in complementary foods for 7-24 months;

- "DHA maternal intake contributes to the normal development of the eye of the foetus and breastfed infants" (9);
- "DHA maternal intake contributes to the normal brain development of the foetus and breastfed infants" (10)

- 200 mg DHA supplementary intake in addition to adult AI of 250 mg.

It is normally a formality of a 3 month wait for the European Parliament to rubber stamp before publication and EU-wide approval. However, there have been considerable lobby efforts by a number of MEPs and the usual pressure groups opposed to infant and follow-on fortification. However on 6th April the claims finally made it through scrutiny and we can look forward to imminent publication in the Official Journal and EU-wide approval!

Well in summary with the adoption of all of the above claims into EU legislation over the next few months, we have much to look forward to. I hope by the time you read it, it's still be up to date, the regulatory picture changes so fast that it is hard to keep up! Look out for the next issue when I hope to provide you with an up to date review of progress on omega-3 claims around the world. All eyes are on the EU at the moment but the principle of generally accepted scientific evidence is universal as you will see..

REFERENCES

- 1) EFSA "Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol" (EFSA Panel on Dietetic Products, Nutrition, and Allergies/NDA). [Question number: EFSA-Q-2008-466 – Adopted 4 December 2009 by the European Food Safety Authority (EFSA); *EFSA Journal* **2010** 8:1461; Available from: <http://www.efsa.europa.eu/en/scdocs/scdoc/1461.htm>
- 2) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:037:0016:0018:EN:PDF>
- 3) <http://www.efsa.europa.eu/en/efsajournal/pub/1796.htm>
- 4) <http://www.efsa.europa.eu/en/efsajournal/pub/1734.htm>
- 5) <http://www.efsa.europa.eu/en/efsajournal/pub/1734.htm>
- 6) <http://www.efsa.europa.eu/en/efsajournal/pub/1734.htm>; <http://www.efsa.europa.eu/en/efsajournal/pub/1796.htm>; <http://www.efsa.europa.eu/en/efsajournal/pub/1263.htm>
- 7) <http://www.efsa.europa.eu/en/efsajournal/pub/1263.htm>
- 8) <http://www.efsa.europa.eu/en/efsajournal/pub/941.htm>
- 9) <http://www.efsa.europa.eu/en/efsajournal/pub/1006.htm>
- 10) <http://www.efsa.europa.eu/en/efsajournal/pub/1007.htm>

NutraCos news

KRILL-IQ CONTAINS EXCLUSIVE KRILL-DERIVED NUTRIENTS

Krill-IQ launched by **Mercola** introduces for the first time a unique and potent combination of phosphatidylserine derived from Antarctic krill, krill oil, containing omega-3 and Astaxanthin and alpha-GPC, all are exclusive nutrients of **Enzymotec**.

"This launch is a result of almost 2 years of joint efforts to bring consumers the most advanced Krill-derived brain product. This new product features for the first time PS derived from Antarctic Krill – in which both EPA and DHA are conjugated together on the same phospholipids. The product also contains high levels of Omega-3 / Astaxanthin Complex which is originated exclusively from Krill biomass. Besides the phosphatidylserine and omega-3 which are known and acceptable brain nutrients, we have also added our

alpha-GPC active, an Enzymotec exclusive grade" says ELZAPHAN HOTAM, CEO of Enzymotec USA. "We believe this innovative approach to brain health and krill oil is only the beginning of what our companies can do together in the fields of health and nutrition," concludes ELZAPHAN.

Mercola's *Krill-IQ* brings together multiple important elements: phosphatidylserine which was shown to support brain cell and nerve cell function, antioxidants and omega-3 fatty acids to help protect against long-term effects of oxidation and inflammation and GPC that may provide both short-term and long-term effects with solid scientific rationale – for healthy brain functions.

Mercola's website is the number one of the most visited natural health site on the Internet. Mercola's widespread visibility promises to offer exceptional exposure for this revolutionary new product.

Enzymotec is a dynamic biotech company and a leading global developer, producer and supplier of lipid-based

products and solutions. Enzymotec develops, manufactures and markets innovative BioActive ingredients and finished products based on sophisticated proprietary technologies. Enzymotec's products support general health, from cardiovascular to cognitive functions, in the largest therapeutic markets and deliver innovative solutions in three business segments:

- VAYA Pharma – a research-based, specialty pharmaceutical division, dedicated to the discovery, development, manufacture and marketing of innovative, clinically tested, effective and safe lipids based medicines;
- Infant Nutrition – providing lipid compositions that mimic the fat in human milk for the wellbeing of infants;
- BioActive Ingredients – providing premium innovative bioactive ingredients tailored to suit unique needs of pharmaceutical and nutrition industries.

www.enzymotec.com
www.enzybioactive.com