

**Q & A about the CRN Voluntary Monograph
on Long Chain Omega-3 EPA and DHA**

1. Is there a standard that identifies high quality long chain Omega-3 EPA and DHA products?

Yes. The Council for Responsible Nutrition (CRN) has sponsored a group of industry leaders to determine a consistent standard for measuring various quality indicators including oxidation, purity, and the amount of EPA and DHA in products, and to set standards for purity and stability of long chain Omega-3 EPA and DHA products. This standard is set forth in a voluntary monograph on long chain Omega-3 EPA and DHA.

2. What industry leaders participated in developing the voluntary monograph?

The CRN Omega-3 Working Group was comprised of 24 suppliers and manufacturers of omega-3 oils. These included a steering committee from Ocean Nutrition Canada, CRN, Croda Oleochemicals, Roche Vitamins Inc., Pronova Biocare a.s., and Denofa. Additional corporate members include Access Business Group, Arista Industries Inc., BASF Corporation, Berg Lipidtech a.s., Bioriginal Food & Science Corporation, Clover Corporation Ltd., ERBL/Coromega, Leiner Health Products, Loders-Croklaan LIPID Nutrition, Marine Nutraceutical Corporation, Maritex a.s., MARTEK Biosciences a.s., Napro Pharma a.s., Nordic Naturals, Omega Protein, Inc., Pharmaline Inc., Seven Seas Ltd., Soft Gel Technologies, Inc. and Spectrum Organic Products Inc.

3. Describe the monograph.

The voluntary monograph applies to long chain Omega-3 EPA and DHA obtained from fish, plant and microbial sources of marine algae. It sets forth rigorous and validated methodology for the assay methods measuring the amount of long chain Omega-3 EPA and DHA, as well as quality standards and limits on environmental contaminants.

4. Do all participants comply with the standards set forth in the monograph? How will compliance be recognized?

Compliance with the monograph is voluntary. Within the trade, products that comply with the monograph will be identified by comparing the certificate of analysis with the standards specified by the monograph. If companies choose to do so, they could highlight compliance with the monograph on the product label or product data sheets.

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5. European monographs have already been developed for omega-3 products. How does this monograph differ?

This monograph specifically focuses on EPA and DHA and uses the *European Pharmacopoeia* assay methods to quantify these two fatty acids. The difference between the two monographs is that the European monograph includes other omega-3 fatty acids, in addition to EPA and DHA.

6. Why is cod liver oil excluded from the monograph?

An official monograph specifically for cod liver oil has previously been presented in the *United States Pharmacopeia*.

7. How are consistent measurements established? What is the process?

Six monographs were considered in establishing the quality standards set forth in this monograph for long chain Omega-3 EPA and DHA products¹. Based on a review of these available assay methods, the European Pharmacopoeia method to quantify EPA and DHA content in omega-3 products was used to provide a simple and uniform measurement of long chain Omega-3 EPA and DHA for product labeling. This method should guarantee at least 100% of stated content claim over the lifetime of the product.

8. What are the proposed standards for quality?

The quality of products is measured by the amount of free fatty acid (acid value), primary oxidation products (peroxide value), and secondary oxidation products (anisidine value) and total oxidation (TOTOX value).

Quality standards for long chain Omega-3 EPA and DHA products will measure: Acid Value, Peroxide Value (PV), Anisidine Value (AN) and TOTOX (a calculation based on $(2 \times PV) + AN$).

The proposed limits for PV (5 meq/kg maximum) and anisidine value (20 maximum) represent the most stringent quality standards established for DHA and EPA products (see referenced monographs on next page)¹.

The creation of a TOTOX value of 26 maximum further tightens quality standards while allowing manufacturers flexibility in individual PV and AN values.

9. What is TOTOX?

TOTOX is a measure of total oxidation calculated as a combined limit of peroxide and anisidine values.

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10. Which environmental contaminants and heavy metals are measured by this monograph?

Environmental contaminants measured are dioxins (PCDDs and PCDFs) and PCBs. Heavy metals measured include Lead, Cadmium, Mercury and Arsenic. The limits set forth in the monograph are consistent with current or emerging European standards and with limits established under California's Proposition 65.

11. What does this mean to me?

It means that when buying long chain Omega-3 products EPA and DHA, you can trust products that meet the standards set forth in this monograph to consistently report accurate amounts of long chain Omega-3 EPA and DHA, to be free of contaminants to a specified level, and to be stable for their labeled period of time.

¹The following monographs (draft or accepted) were considered in establishing quality standards for omega-3 EPA and DHA products: Omega-3-Acid Triglycerides Monograph 1352, *Pharmeuropa* Vol. 12, No. 3, July 2000; Fish Oil, Rich in Omega-3-Acids, *Pharmeuropa* Vol. 12, No. 3, July 2000; Omega-3 Acid Ethyl Esters Monograph 1250, *European Pharmacopoeia – Supplement 2000*; Omega-3-Acid Ethyl Esters 60, *Pharmeuropa* Vol. 12, No. 3, July 2000; Docosahexaenoic Acid Oil, Preview Monograph in *Pharmacopeial Forum* Vol. 26(6) [Nov. – Dec.]; Docosahexaenoic Acid, Preview Monograph in *Pharmacopeial Forum* Vol. 26(6) [Nov. – Dec.]