



GOED

MONOGRAPH

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DEFINITIONS

Omega-3 fatty acids, EPA and DHA, consist of the all *cis* forms of 5, 8, 11, 14, 17-eicosapentaenoic acid and 4, 7, 10, 13, 16, 19-docosahexaenoic acid, respectively. Omega-3 fatty acid products may be found with DHA as the predominant fatty acid, EPA as the predominant fatty acid or mixtures of DHA and EPA in varying combinations.

The content of omega-3 EPA and DHA is expressed as free fatty acid equivalents on a weight/weight basis, as mg EPA per gram or mg DHA per gram when available as single sources of omega-3. If a mixture of EPA and DHA exist in the product, the total omega-3 EPA and DHA content may be expressed individually and as total mg EPA and DHA per gram (*see Fatty Acids section below*).

For other Omega-3 Fatty Acids see Fatty Acid Analysis Methods (*see Guidance on Methods*).

A Food Approved antioxidant may be added to enhance product stability.

SCOPE

Applicable to omega-3 EPA and DHA fatty acids obtained from marine, plant or microbial sources, esterified (or re-esterified) as triglycerides, or esterified as ethyl esters.

Applicable to:

- ¶ Bulk refined oil products sold as ingredients
- ¶ Refined finished liquid oils and finished encapsulated oils intended for use as dietary supplements or food
- ¶ Minimally-processed triglyceride oils for sale as ingredients, finished liquid oil products, or as encapsulated oils for use as dietary supplements or foods

Not applicable to:

- ¶ Formulations and special delivery systems (including solid forms such as microencapsulation)
- ¶ Oils with a total omega-3 content below 10% wt/wt
- ¶ Oils that are destined to be refined prior to sale
- ¶ Other minimally-processed oils rich in phospholipids, wax esters, glycolipids, or other naturally-occurring lipids distinct from triglycerides

The specifications described herein apply throughout the stated lifetime (shelf-life) of the product.

A separate document called the Guidance Documents contains Guidance on Methods and Technical Guidance Documents. The Guidance on Methods provides technical guidance on methods useful for GOED members. A set of Technical Guidance Documents provides technical guidance on specific and recommended test methodologies and quality parameters for a number of EPA- and/or DHA- containing product classes currently covered under the GOED Monograph. Guidance on Methods and Technical Guidance Documents will be periodically updated.

EPA/DHA-containing product classes currently covered by this GOED Monograph are:

- ¶ Refined EPA and/or DHA Omega-3 Oil Triglycerides
- ¶ EPA and/or DHA Omega-3 Oil Ethyl Ester Concentrates
- ¶ EPA and/or DHA Omega-3 Oil Triglyceride Concentrates
- ¶ Cod Liver Oil
- ¶ Tuna Oil
- ¶ Green-Lipped Mussel Oil
- ¶ Salmon Oil
- ¶ Anchovy Oil
- ¶ Skate Liver Oil
- ¶ Minimally-Processed Triglyceride Oils
- ¶ Flavored Oils¹

Note: ¹Flavored Oils fall under the scope of this GOED Monograph if the underlying oil that was flavored falls within the scope of the GOED Monograph. In case of interference of the flavor with the tests for oxidation, please find technical guidance in the Technical Guidance Document on Flavored Oils (Guidance Documents).

CHARACTERISTICS

Long chain omega-3 EPA and DHA products are generally liquids at ambient temperature. The color varies from colorless, pale, light-yellow to orange. The products have a characteristic odor ranging from bland to mild fish-like and are derived from crude oils produced under hygienic conditions sufficient for products intended for human consumption.

IDENTIFICATION

Examine the chromatograms obtained in the assay for long-chain omega-3 EPA and DHA. The presence of EPA and/or DHA based on retention time comparison to authentic reference standards establishes the identity of the product. In the case of bulk refined oils sold as ingredients, the identity and its country or countries of manufacture, should be clearly stated

on its certificate of analysis.

GENERAL TESTS

Whenever you use a 3rd party laboratory for any analyses, be sure that the 3rd party laboratory uses validated methods. The 3rd party laboratory should be accredited for the specific analysis being carried out, and have an internationally-recognized laboratory accreditation, for example ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories."

Oxidation

Peroxide value (PV). Maximum: 5 meq/kg; AOCS Official Method Cd 8b-90 / Ph.Eur. method 2.5.5 "Peroxide Value"

p-Anisidine value¹ (pAV). Maximum: 20; AOCS Official Method Cd 18-90 / Ph.Eur. method 2.5.36 "Anisidine Value"

TOTOX¹ Maximum: 26 (result of calculation; (2x PV) + pAV)

Note: ¹ Not applicable to flavored oils due to inaccuracies with the *para*-anisidine method; see Technical Guidance Document on flavored oils.

Environmental Contaminants

PCBs, Dioxins, Furans and Dioxin-like PCBs²

All environmental contaminants must be analyzed with methods validated for the matrix used.

PCBs. Maximum: 0.09 mg/kg

Total PCBs should be expressed on a weight/ weight basis as a sum of all 209 congeners. Note that it is not necessary to report all 209 individual congeners to verify compliance.

PCDDs and PCDFs. Maximum 1.75 pg WHO- PCDD/F-TEQ/g

Dioxin limits include the sum of 2,3,7,8-substituted polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organization (WHO) toxic equivalents using WHO-toxic equivalent factors (TEFs). This means that analytical results relating to 17 individual dioxin congeners of toxicological concern are expressed in a single quantifiable unit: TCDD toxic equivalent concentration or TEQ. The name and TEF values

are listed in the 2005 WHO Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds.

Dioxin-like PCBs. The level of total Dioxin-like PCBs is set at 3 pg/g (WHO-TEQ).

The total "dioxin-like" PCBs should be expressed as the sum of Non-ortho PCB congeners 77, 81, 126, and 169 and Mono-ortho PCB congeners 105, 114, 118, 123, 156, 157, 167, and 189. The name and TEF values are listed in the 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds.

Total Dioxins, Furans and Dioxin-like PCBs. Maximum 3 pg WHO-TEQ/g.

Note: ² For compliance with California's Proposition 65, consumer products should also ensure they do not contain more than 90 ng of PCBs per labeled daily serving.

Heavy Metals

All heavy metals must be analyzed with methods validated for the matrix used.

Lead (Pb):	Less than 0.05 mg/kg
Cadmium (Cd):	Less than 0.1 mg/kg
Mercury (Hg):	Less than 0.1 mg/kg
In-organic Arsenic (As):	Less than 0.1 mg/kg

The determination of the detection limit (DL) and quantitation limit (QL) for heavy metals are described in EU commission regulation No. 333/2007. Results below the detection limit are suggested to be reported as the actual value of the measured detection limit, and results between the DL and QL are suggested to be reported as actual values.

Fatty Acids

EPA and DHA

The assay used for quantitative determination of EPA and DHA content in omega-3 products is applicable to triglyceride and ethyl ester product forms with results expressed as mg DHA/g and mg EPA/g after correction to free fatty acid equivalents. In addition to the use of free fatty acid equivalents, which permit comparison of products between GOED members and production technologies, GOED members can express EPA and DHA content of their product according to their needs and following the recommendations of the following table.

<i>Oil type</i>	<i>GOED analytical method</i>
Triglycerides (TG)	Calculated as FFA or as TG
Ethyl Esters (EE)	Calculated as FFA or as EE

EPA and DHA should be measured using one of the four recommended methods provided in the Guidance on Methods (*Description of Tests - A. Fatty Acid Analysis Methods*).

Individual GOED members can use other methods than described here, when validated against the GOED Fatty Acid method. GOED member companies are responsible to have performed the necessary validations of the fatty acid method they employ for quantitative analysis of fatty acid composition and content, according to ICH Guidelines for Validations of APIs. It is the individual company's responsibility if they use other methods and they should confirm this to GOED. They should participate in a yearly proficiency test.

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