

DRAFT STANDARD FOR FISH OILS**(N09-2011)****(at Step 8)****1. Scope**

This Standard applies to the fish oils described in section 2 that are presented in a state for human consumption. For the purpose of this Standard, the term fish oils refers to oils derived from fish and shellfish as defined in section 2 of the *Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)*¹. This standard only applies to fish oils used in food and in food supplements where those are regulated as foods.

2. Description

Fish oils means oils intended for human consumption derived from the raw material as defined in Section 2 of the *Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)*. Processes to obtain fish oil for human consumption may involve, but are not limited to, extraction of crude oil from raw material and refining of that crude oil. *Fish oils* and *concentrated fish oils* are primarily composed of glycerides of fatty acids whereas *concentrated fish oils ethyl esters* are primarily composed of fatty acids ethyl esters. Fish oils may contain other lipids and unsaponifiable constituents naturally present.

Crude fish oils and crude fish liver oils are oils intended for human consumption after they have undergone further processing, e.g. refining and purification and have to comply with section 3.1, as applicable, as well as with sections 4, 6.1 and 7. Fish oils intended for direct human consumption shall comply with all sections of this standard.

The refined fish oil production process typically includes several steps such as repeated heating at high temperatures as well as alkali/ acid treatments and repeated removal of the water phase. Fish oils may also be subjected to processing steps (e.g. solvent extraction, saponification, re-esterification, trans-esterification).

2.1 Named fish oils are derived from specific raw materials which are characteristic of the major fish or shellfish taxon from which the oil is extracted.

2.1.1 Anchovy oil is derived from *Engraulis ringens* and other species of the genus *Engraulis (Engraulidae)*.

2.1.2 Tuna oil is derived from the species of the genus *Thunnus* and from the species *Katsuwonus pelamis (Scombridae)*.

2.1.3 Krill oil is derived from *Euphausia superba*. The major components are triglycerides and phospholipids.

2.1.4 Menhaden oil is derived from the genera *Brevortia* and *Ethmidium (Clupeidae)*.

2.1.5 Salmon oil is derived from the family *Salmonidae*.

2.2 Fish oils (unnamed) are derived from one or more species of fish or shellfish. This includes also mixtures with fish liver oils.

2.3 Named fish liver oils are derived from the livers of fish and are composed of fatty acids, vitamins or other components that are representative of the livers from the species from which the oil is extracted.

2.3.1 Cod liver oil is derived from the liver of wild cod, *Gadus morhua* L and other species of *Gadidae*.

2.4 Fish liver oil (unnamed) are derived from the livers of one or more species of fish.

2.5 Concentrated fish oils are derived from fish oils described in Sections 2.1 to 2.4 which have been subjected to processes that may involve, but are not limited to, hydrolysis, fractionation, winterization and/or re-esterification to increase the concentration of specific fatty acids.

2.5.1 Concentrated fish oil contains 35 to 50 w/w % fatty acids as sum of C20:5 (n-3) eicosapentaenoic acid (EPA) and C22:6 (n-3) docosahexaenoic acid (DHA).

2.5.2 Highly concentrated fish oil contains more than 50 w/w % fatty acids as sum of EPA and DHA.

2.6 Concentrated fish oils ethyl esters are derived from fish oils described in Section 2.1 to 2.4 and are primarily composed of fatty acids ethyl esters.

¹ *Fish*: Any of the cold-blooded (ectothermic) aquatic vertebrates. Amphibians and aquatic reptiles are not included. *Shellfish*: Those species of aquatic molluscs and crustaceans that are commonly used for food.

2.6.1 Concentrated fish oil ethyl esters contain fatty acids as esters of ethanol of which 40 to 60 w/w % are as sum of EPA and DHA.

2.6.2 Highly concentrated fish oil ethyl esters contain fatty acids as esters of ethanol of which more than 60 w/w % are as sum of EPA and DHA.

3. Essential composition and quality factors

3.1 GLC ranges of fatty acid composition (expressed as percentages of total fatty acids)

Sample of fish oils described in sections 2.1 and 2.3 shall fall within the appropriate ranges specified in Table 1. Supplementary criteria, for example national geographical and/or climatic variations may be considered, as necessary, to confirm that a sample is in compliance with the Standard.

3.2 Other essential compositional criteria

For oil from *Engraulis ringens* (2.1.1) the sum of EPA and DHA has to be at least 27 % (expressed as percentage of total fatty acids).

For krill oils (2.1.3) the content of phospholipids shall be at least 30 w/w %.

Concentrated fish oils (2.5.1) and highly concentrated fish oils (2.5.2) shall contain at least 50 w/w % of fatty acids as sum of EPA and DHA in the form of triglycerides and/or phospholipids.

3.3 Quality parameters

Note: this section does not apply to flavoured fish oils where the added flavourings may interfere with the analytical determination of oxidation parameters.

3.3.1 Fish oils, fish liver oils, concentrated fish oils, and concentrated fish oils ethyl esters (Section 2.1. to 2.6) with the exception of oils dealt with in Section 3.3.2 shall comply with the following:

Acid value	≤ 3 mg KOH/g
Peroxide value	≤ 5 milliequivalent of active oxygen/kg oil
Anisidine value	≤ 20
Total oxidation value (ToTox) ²	≤ 26

3.3.2 Fish oils with a high phospholipid concentration of 30% or more such as krill oil (Section 2.1.3) shall comply with the following:

Acid value	≤ 45 mg KOH/g
Peroxide value	≤ 5 milliequivalent of active oxygen/kg oil

3.4 Vitamins

Fish liver oils except of deep sea shark liver oil (Sections 2.3 and 2.4) shall comply with following:

Vitamin A	≥ 40 µg of retinol equivalents/ml of oil
Vitamin D	≥ 1.0 µg/ml

Losses during processing may be restored (see Section 2.4. of CAC/GL 9-1987) by the addition of:

Vitamin A and its esters

Vitamin D

Maximum levels for vitamins A and D should be in accordance with the needs of each individual country including, where appropriate, the prohibition of the use of particular vitamins.

² Total oxidation value (ToTox) = 2 x Peroxide value + 1 x Anisidine value

Explanatory note: Oxidation of fish oils is a sequential process: following an initial raise of peroxide value, the anisidine value rises. The peroxide value is therefore a parameter for primary oxidation products, the anisidine value for secondary oxidation products. The parameter ToTox, which means "total oxidation of oil", was established to avoid that both of these oxidation products are present at maximum levels. The maximum allowed ToTox value is set separately and lower than the sum of the individual possible maximum limits set for peroxide and anisidine values.

4. Food Additives

Antioxidants, sequestrants, antifoaming agents, and emulsifiers used in accordance with Tables 1 and 2 of the *General Standard for Food Additives* (CODEX STAN 192-1995), in food category 02.1.3 *Lard, tallow, fish oil, and other animal fats* are acceptable for use in foods conforming to this standard.

The following additives may be used in addition:

INS	Additive name	Maximum level
Antioxidant		
300	Ascorbic acid, L-	GMP
304, 305	Ascorbyl esters	2500 mg/kg, as ascorbyl stearate
307a, b, c	Tocopherols	6000 mg/kg, singly or in combination
Emulsifier		
322 (i)	Lecithin	GMP
471	Mono- and di-glycerides of fatty acids	GMP

The flavourings used in products covered by this standard should comply with the *Guidelines for the Use of Flavourings* (CAC/GL 66-2008).

5. Contaminants

The products covered by this Standard shall comply with the Maximum Levels of the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995).

The products covered by this Standard shall comply with the maximum residue limits for pesticides and/or veterinary drugs established by the Codex Alimentarius Commission.

6. Hygiene

6.1 General hygiene

It is recommended that the products covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003), and *Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk* (CAC/RCP 36-1987).

6.2 Microbiological criteria

The products should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21-1997).

7. Labelling

The requirements of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) apply to this standard.

7.1 Name of the food

The name of the fish oil shall conform to the descriptions given in Section 2 of this Standard. For salmon oil the label shall specify the source of the raw material (wild or farmed).

7.2 Labelling on non-retail containers

Information on the above labelling requirements shall be given either on the container or in accompanying documents, except that the name of the food, lot identification and the name and address of the manufacturer or packer shall appear on the container.

However, lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark, provided that such a mark is clearly identifiable with the accompanying documents.

For crude fish oils and crude fish liver oils the label shall indicate that these oils are intended for human consumption only after they have undergone further processing.

7.3 Other labelling requirements

For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D, naturally present or restored, shall be given if required by country of retail sale.

For all fish oils covered by this standard the content of EPA and DHA shall be given if required by country of retail sale.

8. Methods of Analysis and Sampling

For checking the compliance with this standard, the methods of analysis and sampling contained in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) relevant to the provisions in this standard, shall be used

Table 1: Fatty acid (FA) composition of named fish oil and fish liver oil categories as determined by gas liquid chromatography from authentic samples (expressed as percentage of total fatty acids) (see Section 3.1 of the Standard)

Fatty acids	Anchovy (Section 2.1.1)	Tuna (Section 2.1.2)	Krill (Section 2.1.3)	Menhaden (Section 2.1.4)	Salmon (Section 2.1.5)		Cod Liver (Section 2.3.1)
					Wild	Farmed	
C14:0 myristic acid	2.7-11.5	ND-5.0	5.0-13.0	8.0-11.0	2.0-5.0	1.5-5.5	2.0-6.0
C15:0 pentadecanoic acid	ND-1.5	ND-2.0	NA	ND-1.0	ND-1.0	ND-0.5	ND-0.5
C16:0 palmitic acid	13.0-22.0	14.0-24.0	17.0-24.6	18.0-20.0	10.0-16.0	6.5-12.0	7.0-14.0
C16:1 (n-7) palmitoleic acid	4.0-12.6	ND-12.5	2.5-9.0	9.0-13.0	4.0-6.0	2.0-5.0	4.5-11.5
C17:0 heptadecanoic acid	ND-2.0	ND-3.0	NA	ND-1.0	ND-1.0	ND-0.5	NA
C18:0 stearic acid	1.0-7.0	ND-7.5	NA	2.5-4.0	2.0-5.0	2.0-5.0	1.0-4.0
C18:1 (n-7) vaccenic acid	1.7-3.7	ND- 7.0	4.7-8.1	2.5-3.5	1.5-2.5	NA	2.0-7.0
C18:1 (n-9) oleic acid	3.6-17.0	10.0-25.0	6.0-14.5	5.5-8.5	8.0-16.0	30.0-47.0	12.0-21.0
C18:2 (n-6) linoleic acid	ND-3.5	ND-3.0	ND-3.0	2.0-3.5	1.5-2.5	8.0-15.0	0.5-3.0
C18:3 (n-3) linolenic acid	ND-7.0	ND-2.0	0.1-4.7	ND-2.0	ND-2.0	3.0-6.0	ND-2.0
C18:3 (n-6) γ-linolenic acid	ND-5.0	ND-4.0	NA	ND-2.5	ND-2.0	ND-0.5	NA
C18:4 (n-3) stearidonic acid	ND-5.0	ND-2.0	1.0-8.1	1.5-3.0	1.0-4.0	0.5-1.5	0.5-4.5
C20:0 arachidic acid	ND-1.8	ND-2.5	NA	0.1-0.5	ND-0.5	0.1-0.5	NA
C20:1 (n-9) eicosenoic acid	ND-4.0	ND-2.5	NA	ND-0.5	2.0-10.0	1.5-7.0	5.0-17.0
C20:1 (n-11) eicosenoic acid	ND-4.0	ND-3.0	NA	0.5-2.0	NA	NA	1.0-5.5
C20:4 (n-6) arachidonic acid	ND-2.5	ND-3.0	NA	ND-2.0	0.5-2.5	ND-1.2	ND-1.5
C20:4 (n-3) eicosatetraenoic acid	ND-2.0	ND-1.0	NA	NA	1.0-3.0	0.5-1.0	ND-2.0
C20:5 (n-3) eicosapentaenoic acid	5.0-26.0	2.5-9.0	14.3-28.0	12.5-19.0	6.5-11.5	2.0-6.0	7.0-16.0
C21:5 (n-3) heneicosapentaenoic acid	ND-4.0	ND-1.0	NA	0.5-1.0	ND-4.0	NA	ND-1.5
C22:1 (n-9) erucic acid	ND-2.3	ND-2.0	ND-1.5	0.1-0.5	ND-1.5	3.0-7.0	ND-1.5
C22:1 (n-11) cetoleic acid	ND-5.6	ND-1.0	NA	ND-0.1	1.0-1.5	NA	5.0-12.0

C22:5 (n-3) docosapentaenoic acid	ND-4.0	ND-3.0	ND-0.7	2.0-3.0	1.5-3.0	1.0-2.5	0.5-3.0
C22:6 (n-3) docosahexaenoic acid	4.0-26.5	21.0-42.5	7.1-15.7	5.0-11.5	6.0-14.0	3.0-10.0	6.0-18.0

ND = non-detect, defined as $\leq 0.05\%$

NA = not applicable or available

METHOD OF ANALYSIS FOR ENDORSEMENT BY CCMAS

(For inclusion in CODEX STAN 234-1999)

Commodity	Provisions	Method
Fish Oil	P-Anisidine value	European Pharmacopeia 2.5.36
	Phospholipids	USP-FCC10 1S (Krill oil): Content of total phospholipids by qualitative and quantitative NMR Analysis
	Triglycerides	USP 38 (Omega-3 Acid Triglycerides): Content of oligomers and partial glyceride; European Pharmacopoeia 01/2008/1352 (Omega3 acid triglycerides): Oligomers and partial glycerides; AOCS Cd 11d-96 (Mono- and diglycerides determination by HPLC-ELSD)

