

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda item 4

CRD2

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FATS AND OILS

25<sup>th</sup> Session

Kuala Lumpur, Malaysia, 27 February - 3 March 2017

#### REPORT OF THE WORKING GROUP<sup>1</sup> ON THE PROPOSED DRAFT STANDARD FOR FISH OILS

##### *Introduction*

1. At its 24<sup>th</sup> session the CCFO had agreed to establish a physical Working Group (pWG), chaired by Switzerland open to all Members and Observers, meeting immediately prior to its 25<sup>th</sup> session to consider
  - a. replies to those issues identified by the committee (REP15/FO: para 44; CL 2015/05-FO), and
  - b. comments on the whole standard at Step 6 (CL 2015/23-FO).
2. Before revising the standard in the light of the comments submitted, the chair of the working group reminded that the standard applies to fish oils as such that will be used as ingredients in food and in food supplements. The standard does not address these foods or food supplements when they contain fish oils.

##### *Revision of the standard*

3. The pWG considered the documents submitted in response to both circular letters<sup>2</sup>, discussed possible revisions, and revised the draft standard section by section (see Annex I) accordingly. Data on the fatty acid composition of anchovy oil, krill oil, and wild salmon oil had been provided and ranges in Table 1 were adjusted accordingly.

##### *Recommendation I*

4. The pWG recommends to the 25<sup>th</sup> session of the CCFO to consider the revised Draft Codex Standard for Fish Oils (Annex I) including the updated Table 1 and to propose to the CAC for final adoption as Codex standard at Step 8 of the procedure.

##### *Named fish oils from farmed fish*

5. With respect to Sections 3.1, 7.1 and Table 1 the pWG noted that named fish oils from farmed fish would be expected to differ in their fatty acid composition from those obtained from the wild populations of the same species. As consumers should be informed about possible differences between fish oils obtained from farmed or wild fish of the same species, it was agreed that when including any new named fish oil from farmed fish species it should be dealt with in the same way as oil from farmed salmon:
  - a. agree on a separate entry in Table 1, and
  - b. the label shall specify the source of the raw material (wild, farmed).

##### *Recommendation II*

6. The pWG recommends to take note of this agreement for future reference.

##### *Authenticity of fish oils*

7. The pWG discussed in detail the difficulties using only the fatty acid ranges of Table 1 as measure to determine compliance of a fish oil with Section 2.1 of the standard. Specifically, the positive verification of the fish species used as raw material may not always be unequivocal. It was agreed that current practice to refer to supplementary information from traceability and certification systems could assist stakeholders (industry, control authorities).

<sup>1</sup> Codex Secretariat; Codex members: Brasil, Canada, Chile, European Commission, Germany, India, Japan, Korea, Malaysia, Norway, Peru, Switzerland, Thailand, UK, USA; Codex observers: AOCS, GOED, IADSA, IFFO, ISDI

<sup>2</sup> CX/FO 17/25/4rev1, CX/FO 17/25/4 Add.1, CRD 4, CRD 8, CRD 17, CRD 18

8. The pWG noted that the format for Codex commodity standards does not foresee to address such issues within the standard. The Codex Secretariat informed the pWG that CCFICS was currently addressing by means of a discussion paper the emerging issues of food integrity/food authenticity.

### ***Recommendation III***

9. Recognizing the importance of the issue which cannot be addressed within the current discussion of the draft standard, the pWG recommends that this topic should be considered separately e.g. by means of a discussion paper that outlines the problem and identifies those elements from traceability and certification systems that would encourage good practice and assist in applying the fish oil standard. Such a discussion should be done in close coordination with the ongoing work at CCFICS.

### ***Astaxanthin in krill oil***

10. The pWG noted that the USP-NF monograph specified for astaxanthin a minimum content in astaxanthin of 0.01% but members were not sure whether all krill oil would meet this requirement.
11. The pWG agreed that data on the astaxanthin content of krill oil samples should be collected with a view to discuss an additional essential composition criterion for krill oil in Section 3.2 of the standard.

### ***Analytical methods***

12. The pWG took note that CCMAS had endorsed at its 38<sup>th</sup> session the sampling plan and all analytical methods except the methods for arsenic and lead, and the methods for phospholipids.
13. With respect to arsenic and lead appropriate methods would be developed once the CCCF had finalized its work on maximum levels for these contaminants which would commence once the standard on fish oils is finalized and adopted.
14. With respect to phospholipids the options to determine total phosphorus and applying a conversion factor, or determining phospholipids were considered. Although conversion factors are being used in practice, participants were not aware of one that would be suitable for fish oil and could be recommended.
15. According to members current practice for determination of total phospholipids is an NMR-based method as the one proposed by the USP-NF Monograph. AOCS is considering the validation of this method and may adopt it in the near future.
16. The PWG noted that for concentrated and highly concentrated fish oil methods for determination of triglycerides were needed. Three methods were identified for inclusion in Section 8 of the draft standard which shall be forwarded to CCMAS for consideration and possible endorsement.

### ***Recommendation IV***

- a) The CCFO is asked to inform CCCF that the work on the fish oil standard is finished and reiterate the request to consider maximum levels for arsenic and lead for inclusion into the GSCTF and related methods of analysis Attention should be paid by CCCF to the presence of organic arsenic in fish oils.
- b) The CCMAS shall be informed that the methods used for determination of total phospholipids are based on qualitative and quantitative NMR analysis such as the one included in the revised USP-NF monograph. Conversion factors for total phosphorus content are not available.
- c) The Section 8.8 of the draft standard was revised and CCMAS is asked to consider and endorse the proposed NMR-based method
- d) The Section 8.9 of the draft standard contains a new entry for determination of triglycerides in concentrated fish oil. The CCMAS is asked to consider the proposed methods for endorsement.

**DRAFT CODEX STANDARD FOR FISH OILS**  
**(at Step 6 of the Procedure)**

## 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)<sup>3</sup>. 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.

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<sup>3</sup> *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) <sup>4</sup>	≤ 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.

<sup>4</sup> 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
<b>Antioxidant</b>		
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
<b>Emulsifier</b>		
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 Hygienic Practice for the Storage and Transport of Edible Oils and Fats 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, 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

*Note: Once the standard is adopted, the entries in this section will be replaced by the following wording:*

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.

#### Sampling

ISO 5555: Animal and vegetable fats and oils – Sampling - ENDORSED

Provisions	Method	Principle	Type	Status
Fatty acid composition	ISO 5508	Gas chromatography	III	Endorsed
	ISO 12966-2	Gas chromatography	III	Endorsed
	AOCS Ce 1b-89	GLC	III	Endorsed
	AOCS Ce 1i-07	Capillary GLC	III	Endorsed
	AOCS Ce 2b-11	Alkali hydrolysis	III	Endorsed
	AOCS Ce 1a-13	Capillary GLC	III	Endorsed
	AOCS Ce 2-66	Preparation of methyl esters by fatty acids	III	Endorsed
Acid value	AOCS Ca 5a-40 AOCS CD 3D-63 ISO 660 NMKL 38 European Pharmacopeia 2.5.1 Type I	Titration	I	Endorsed
Peroxide value	AOCS Cd 8b-90 ISO 3960 NMKL 158	Titration	I	Endorsed
	European Pharmacopeia 2.5.5 (Part B Iso-octane as solvent)			Endorsed
P-Anisidine value	AOCS Cd 18-90	Spectrophotometry	I	Endorsed
Vitamin A	European Pharmacopoeia Monograph on Cod Liver Oil (Type A), monograph 01/2005:1192, with LC end-point 2.2.29.	LC	III	Endorsed
	EN 12823-1(Determination of vitamin A by high performance liquid chromatography - Part 1: Measurement of all-E-retinol and 13-Z-retinol)	LC	III	Endorsed
Vitamin D	European Pharmacopoeia Monograph on Cod Liver Oil (Type A), monograph 01	LC	III	Endorsed
	EN 12821 (Determination of vitamin D by high performance liquid chromatography - Measurement of cholecalciferol (D3) or ergocalciferol (D2))	LC	III	Endorsed
	NMKL 167 (Cholecalciferol (vitamin D3) and Ergocalciferol (vitamin D2). Determination by HPLC in foodstuffs).	LC	III	Endorsed

<b>Provisions</b>	<b>Method</b>	<b>Principle</b>	<b>Type</b>	<b>Status</b>
Phospholipids	USP 39-NF 34 (Krill oil): Content of total phospholipids by qualitative and quantitative NMR Analysis			For endorsement
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 11d96 (Mono- and diglycerides determination by HPLC-ELSD)			For endorsement

**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 oil (Section 2.1.5)		Cod Liver (Section 2.3.1)
					Wild	Farm	
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) $\gamma$ -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



## DRAFT CODEX STANDARD FOR FISH OILS

(Version 2015 compared with 2017 with changes underlined changes)

### 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)<sup>5</sup>. 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. The content of phospholipids should be at least 30 w/w %.

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, a single species of fish other than the ones listed in Section 2.1 or are a mixture of fish oils derived from specified and/or unspecified raw materials. This includes also mixtures with fish liver oils.

2.3.4 **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.

2.3.12 **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 may be derived from the livers of one fish other than those used for named fish liver oils or more are a mixture of named fish liver oils and/or single species of fish liver oils.

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), at least 50 w/w % of fatty acids are in the form of triglycerides.

<sup>5</sup> *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.

- 2.5.2 **Highly concentrated fish oil** contains ~~more~~<sup>greater</sup> than 50 w/w % fatty acids as sum of EPA and DHA, ~~at least 50 w/w % of fatty acids are in the form of triglycerides.~~
- 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.
- 2.6.1 **Concentrated fish oil ethyl esters** ~~contain~~<sup>contains</sup> 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~~<sup>greater</sup> 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~~<sup>Samples falling</sup> within the appropriate ranges specified in Table 1, ~~are in compliance with sections 2.1 and 2.3 of this Standard.~~ 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.

#### 3.3.2 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.

#### 3.3.2.1 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 <del>oxygen</del> <sup>oxygen</sup> /kg oil
Anisidine value	≤ 20
Total oxidation value (ToTox) <sup>6</sup>	≤ 26

#### 3.3.2.2 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	≤ <del>4530</del> mg KOH/g
Peroxide value	≤ 5 milliequivalent of active <del>oxygen</del> <sup>oxygen</sup> /kg oil

#### 3.43 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

<sup>6</sup> 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.

### 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.

## 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
<b>Antioxidant</b>		
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
<b>Emulsifier</b>		
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 Hygienic Practice for the Storage and Transport of Edible Oils and Fats 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 product shall be labelled in accordance with the *General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985).~~ 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, 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 shall be given.~~

~~or~~

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~~ may be given if required by country of retail sale ~~for all fish oils covered by this Standard.~~

## 8. Methods of Analysis and Sampling

*Note: Once the standard is adopted, the entries in this section will be replaced by the following wording:*

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.

### 8.1 Sampling

ISO 5555: Animal and vegetable fats and oils ~~---~~ Sampling - ENDORSED

<u>Provisions</u>	<u>Method</u>	<u>Principle</u>	<u>Type</u>	<u>Status</u>
<u>Fatty acid composition</u>	<u>ISO 5508</u>	<u>Gas chromatography</u>	<u>III</u>	<u>Endorsed</u>
	<u>ISO 12966-2</u>	<u>Gas chromatography</u>	<u>III</u>	<u>Endorsed</u>
	<u>AOCS Ce 1b-89</u>	<u>GLC</u>	<u>III</u>	<u>Endorsed</u>
	<u>AOCS Ce 1i-07</u>	<u>Capillary GLC</u>	<u>III</u>	<u>Endorsed</u>
	<u>AOCS Ce 2b-11</u>	<u>Alkali hydrolysis</u>	<u>III</u>	<u>Endorsed</u>
	<u>AOCS Ce 1a-13</u>	<u>Capillary GLC</u>	<u>III</u>	<u>Endorsed</u>
	<u>AOCS Ce 2-66</u>	<u>Preparation of methyl esters by fatty acids</u>	<u>III</u>	<u>Endorsed</u>
<u>Acid value</u>	<u>AOCS Ca 5a-40</u> <u>AOCS CD 3D-63</u> <u>ISO 660</u> <u>NMKL 38</u> <u>European Pharmacopeia 2.5.1 Type I</u>	<u>Titration</u>	<u>I</u>	<u>Endorsed</u>
<u>Peroxide value</u>	<u>AOCS Cd 8b-90</u> <u>ISO 3960</u> <u>NMKL 158</u>	<u>Titration</u>	<u>I</u>	<u>Endorsed</u>
	<u>European Pharmacopeia 2.5.5 (Part B Iso-octane as solvent)</u>			<u>Endorsed</u>
<u>P-Anisidine value</u>	<u>AOCS Cd 18-90</u>	<u>Spectrophotometry</u>	<u>I</u>	<u>Endorsed</u>
<u>Vitamin A</u>	<u>European Pharmacopoeia Monograph on Cod Liver Oil (Type A), monograph 01/2005:1192, with LC end-point 2.2.29.</u>	<u>LC</u>	<u>III</u>	<u>Endorsed</u>
	<u>EN 12823-1 (Determination of vitamin A by high performance liquid chromatography - Part 1: Measurement of all-E-retinol and 13-Z-retinol)</u>	<u>LC</u>	<u>III</u>	<u>Endorsed</u>
<u>Vitamin D</u>	<u>European Pharmacopoeia Monograph on Cod Liver Oil (Type A), monograph 01</u>	<u>LC</u>	<u>III</u>	<u>Endorsed</u>
	<u>EN 12821 (Determination of vitamin D by high performance liquid chromatography - Measurement of cholecalciferol (D3) or ergocalciferol (D2))</u>	<u>LC</u>	<u>III</u>	<u>Endorsed</u>
	<u>NMKL 167 (Cholecalciferol (vitamin D3) and Ergocalciferol (vitamin D2). Determination by HPLC in foodstuffs).</u>	<u>LC</u>	<u>III</u>	<u>Endorsed</u>

<u>Provisions</u>	<u>Method</u>	<u>Principle</u>	<u>Type</u>	<u>Status</u>
<u>Phospholipids</u>	<u>USP 39-NF 34 (Krill oil): Content of total phospholipids by qualitative and quantitative NMR Analysis</u>			<u>For endorsement</u>
<u>Triglycerides</u>	<u>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 11d96 (Mono- and diglycerides determination by HPLC-ELSD)</u>			<u>For endorsement</u>

### 8.2—~~Determination of fatty acid composition~~

According to applicable ISO methods including: ISO 5508 and ISO 12966-2 (Animal and vegetable fats and oils -- Analysis by gas chromatography of methyl esters of fatty acids) or AOCS methods including: Ce 1b-89 (Fatty acid composition of Marine Oils by GLC), Ce 1i-07 (Determination of saturated cis-, monounsaturated, and cis-polyunsaturated fatty acids in Marine Other Oils containing long chain Polyunsaturated Fatty Acids (PUFAs) by Capillary GLC), Ce 2b-11 (Direct Methylation of Lipids in Foods by Alkali Hydrolysis), Ce 1a-13 (Determination of Fatty Acids in edible oils and fats by capillary GLC) and Ce 2-66 (Preparation of Methyl Esters of Fatty Acids)

### 8.3—~~Determination of arsenic~~

According to AOAC 952.13 (Silver Diethyldithiocarbamate Method); AOAC 942.17 (Molybdenum Blue); or AOAC 986.15 (Spectroscopy/Atomic Absorption Spectroscopy).

### 8.4—~~Determination of lead~~

According to AOAC 994.02 (Atomic Absorption Spectroscopy); or ISO 12193 (Animal and vegetable fats and oils -- Determination of lead by direct graphite furnace atomic absorption spectroscopy); or AOCS Ca 18c-94 (Determination of Lead by Direct Graphite Furnace Atomic Absorption Spectrophotometry).

### 8.5—~~Determination of acid value~~

According to AOCS Ca 5a-40 (Free Fatty Acids), AOCS Cd 3d-63 (Acid Value); ISO 660 (Animal and vegetable fats and oils -- Determination of acid value and acidity); European Pharmacopoeia 2.5.1 (Acid value).

### 8.6—~~Determination of peroxide value~~

According to AOCS CD 8b-90 (Peroxide Value Acetic Acid Isooctane Method); ISO 3960 (Animal and vegetable fats and oils -- Determination of peroxide value -- Iodometric (visual) endpoint determination); European Pharmacopoeia 2.5.5 (Peroxide value).

### 8.7—~~Determination of p-anisidine value~~

According to AOCS Cd 18-90

### 8.8—~~Determination of vitamin A~~

According to PhEur 2.2.29 liquid chromatography, monograph Cod liver oil (type A).

### 8.9—~~Determination of vitamin D~~

According to PhEur 2.2.29 liquid chromatography, monograph Cod liver oil (type A).

### 8.10—~~Determination of phospholipids~~

According to AOCS Ca 12b-92 (Phosphorus by direct graphite furnace atomic absorption spectrometry); AOCS Ca 12a-02 (Colorimetric determination of phosphorus content in fats and oils); Ca 20-99 (Analysis for phosphorus in oil by inductively coupled plasma optical emission spectroscopy).

**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 oil (Section 2.1.5)		Cod Liver (Section 2.3.1)
					Wild	Farm	
C14:0 myristic acid	<u>2.7</u> -11.5	ND-5.0	<u>5.0</u> -13.0	8.0-11.0	2.0- <u>5.0</u>	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	<u>4.0-12.6</u>	ND-12.5	<u>2.5-9.0</u>	9.0-13.0	<u>4.0</u> -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	<u>1.7-3.7</u>	ND- 7.0	<u>4.7-8.1</u>	2.5-3.5	<u>1.5-2.5</u>	NA	2.0-7.0
C18:1 (n-9) oleic acid	<u>3.6</u> -17.0	10.0-25.0	<u>6.0-14.5</u>	5.5-8.5	<u>8.0-16.0</u>	30.0-47.0	12.0-21.0
C18:2 (n-6) linoleic acid	ND-3.5	ND-3.0	<u>ND-3.0</u>	2.0-3.5	1.5- <u>2.5</u>	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- <u>2.0</u>	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- <u>2.0</u>	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- <u>4.0</u>	0.5-1.5	0.5-4.5
C20:0 arachidic acid	ND- <u>1.8</u>	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	<u>2.0-10.0</u>	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- <u>2.5</u>	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- <u>3.0</u>	0.5-1.0	ND-2.0
C20:5 (n-3) eicosapentaenoic acid	5.0-26.0	2.5-9.0	14.3- <u>28.0</u>	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- <u>4.0</u>	NA	ND-1.5
C22:1 (n-9) erucic acid	ND- <u>2.3</u>	ND-2.0	<u>ND-1.5</u>	0.1-0.5	<u>ND-1.5</u>	3.0-7.0	ND-1.5
C22:1 (n-11) cetoleic acid	ND- <u>5.6</u>	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	<u>ND-0.7</u>	2.0-3.0	1.5-3.0	1.0-2.5	0.5-3.0
C22:6 (n-3) docosahexaenoic acid	4.0- <u>26.5</u>	21.0-42.5	<u>7.1-15.7</u>	5.0-11.5	<u>6.0-14.0</u>	3.0-10.0	6.0-18.0

ND = non-detect, defined as ≤0.05%

NA = not applicable or available