



CL 2015/23-FO
July 2015

TO: Codex Contact Points
Interested International Organisations

FROM: Secretariat, Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme
00153 Roma, Italia

SUBJECT: Request for comments at Step 6 on the draft Standard for Fish Oils

DEADLINE: 30 September 2016

COMMENTS:	To:	Copy to:
	Malaysian Secretariat for CCFO Food Safety and Quality Division Ministry of Health Malaysia E-mail: cfo_malaysia@moh.gov.my	Secretariat Joint FAO/WHO Food Standards Programme Viale delle Terme di Caracalla 00153 Rome, Italy email : codex@fao.org

BACKGROUND

1. The 24th Session of the Committee on Fats and Oils (CCFO24) considered the proposed draft Standard for Fish Oils and noted that substantial progress had been made but that a few issues needed to be further discussed and that the information in Table 1 needed to be strengthened with additional data.
2. CCFO24 agreed to forward the proposed draft Standard to the Commission for adoption at Step 5.¹
3. As requested by CCFO24, [CL 2015/5-FO](#) Part B, point 4 was issued asking for:
 - Additional information on the fatty acids profiles of anchovy and krill oils; and
 - Proposals for alternative texts in Section 7.3 "Other Labelling Requirements".
4. CCFO24 also agreed to establish a physical Working Group (pWG), chaired by Switzerland, open to all members and observers, working in English only and meeting immediately prior to CCFO25 to:
 - Consider the replies to the Circular Letter (CL 2015/5-FO);
 - Consider comments submitted at Step 6 (subject to adoption at Step 5 by CAC38); and
 - Prepare a report for consideration by the Plenary.
5. CAC38 adopted the proposed draft Standard for Fish Oils at Step 5, noting the reservations of the Delegations of Chile, Peru and Panama.²

REQUEST FOR COMMENTS

6. Codex members and observers are invited to submit comments at Step 6, as directed above, on the draft Standard for Fish Oils (see Annex I).
7. Comments should be submitted through the Codex Contact Point or recognized international organizations having observer status with the Codex Alimentarius Commission. Comments should be in accordance with the general guidance for the provision of comments (Annex II) and presented in Word file to facilitate their analysis and compilation.
8. Members and observers which have submitted technical comments at Step 5 are reminded to resubmit their comments in response to this CL.

¹ [REP15/FO](#) para. 47 and Appendix III

² [REP15/CAC](#) paras 65-70 and Appendix IV

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)³. 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, refining and purification and have to comply with section 3.1, as applicable, as well as with sections 4, 6.1 and 7.

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 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 genus *Brevortia* (*Clupeidae*).

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

2.2 **Fish oils (unnamed)** are derived from 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.

2.3.1 **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.

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

2.5.2 **Highly concentrated fish oil** contains greater 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.

³ *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 **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** contains 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 greater 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)

Samples falling 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 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.

3.2.1 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 3.2.2 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) ⁴	≤ 26

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	≤ 30 mg KOH/g
Peroxide value	≤ 5 milliequivalent of active oxygen/kg oil

3.3 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

4. Food Additives

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

⁴ Total oxidation value (ToTox) = 2 x Peroxide value + Anisidine value

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 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 for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

7. Labelling

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.]

The content of EPA and DHA [shall/may] be given for all fish oils covered by this Standard .

8. Methods of Analysis and Sampling

8.1 Sampling

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

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-91 (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)	Cod Liver (Section 2.3.1)	Tuna (Section 2.1.2)	Krill (Section 2.1.3)	Menhaden (Section 2.1.4)	Salmon oil (Section 2.1.5)	
						Wild	Farm
C14:0 myristic acid	5.0-11.5	2.0-6.0	ND-5.0	6.4-13.0	8.0-11.0	2.0-4.5	1.5-5.5
C15:0 pentadecanoic acid	ND-1.5	ND-0.5	ND-2.0	NA	ND-1.0	ND-1.0	ND-0.5
C16:0 palmitic acid	13.0-22.0	7.0-14.0	14.0-24.0	17.0-24.6	18.0-20.0	12.0-16.0	6.5-12.0
C16:1 (n-7) palmitoleic acid	5.0-12.0	4.5-11.5	ND-12.5	2.1-8.9	9.0-13.0	4.5-6.0	2.0-5.0
C17:0 heptadecanoic acid	ND-2.0	na	ND-3.0	NA	ND-1.0	ND-1.0	ND-0.5
C18:0 stearic acid	1.0-7.0	1.0-4.0	ND-7.5	NA	2.5-4.0	2.0-5.0	2.0-5.0
C18:1 (n-7) vaccenic acid	na	2.0-7.0	ND-7.0	8.4-21.7	2.5-3.5	na	na
C18:1 (n-9) oleic acid	5.0-17.0	12.0-21.0	10.0-25.0	NA	5.5-8.5	16.0-18.0	30.0-47.0
C18:2 (n-6) linoleic acid	ND-3.5	0.5-3.0	ND-3.0	0.7-2.1	2.0-3.5	1.5-2.0	8.0-15.0
C18:3 (n-3) linolenic acid	ND-7.0	ND-2.0	ND-2.0	0.1-4.7	ND-2.0	ND-1.0	3.0-6.0
C18:3 (n-6) γ -linolenic acid	ND-5.0	na	ND-4.0	NA	ND-2.5	ND-1.0	ND-0.5
C18:4 (n-3) stearidonic acid	ND-5.0	0.5-4.5	ND-2.0	1.0-8.1	1.5-3.0	1.0-2.5	0.5-1.5
C20:0 arachidic acid	na	na	ND-2.5	NA	0.1-0.5	ND-0.5	0.1-0.5
C20:1 (n-9) eicosenoic acid	ND-4.0	5.0-17.0	ND-2.5	NA	ND-0.5	4.5-6.0	1.5-7.0
C20:1 (n-11) eicosenoic acid	ND-4.0	1.0-5.5	ND-3.0	NA	0.5-2.0	na	na
C20:4 (n-6) arachidonic acid	ND-2.0	ND-1.5	ND-3.0	NA	ND-2.0	0.5-1.0	ND-1.2
C20:4 (n-3) eicosatetraenoic acid	ND-2.0	ND-2.0	ND-1.0	NA	na	1.0-2.0	0.5-1.0
C20:5 (n-3) eicosapentaenoic acid	5.0-26.0	7.0-16.0	2.5-9.0	14.3-24.3	12.5-19.0	6.5-9.5	2.0-6.0
C21:5 (n-3) heneicosapentaenoic acid	ND-4.0	ND-1.5	ND-1.0	NA	0.5-1.0	ND-1.0	na
C22:1 (n-9) erucic acid	ND-5.0	ND-1.5	ND-2.0	NA	0.1-0.5	1.0-1.5	3.0-7.0
C22:1 (n-11) cetoleic acid	ND-5.0	5.0-12.0	ND-1.0	NA	ND-0.1	1.0-1.5	na
C22:5 (n-3) docosapentaenoic acid	ND-4.0	0.5-3.0	ND-3.0	0-0.07	2.0-3.0	1.5-3.0	1.0-2.5
C22:6 (n-3) docosahexaenoic acid	4.0-23.0	6.0-18.0	21.0-42.5	7.2-25.7	5.0-11.5	6.0-8.5	3.0-10.0

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

na = not available

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, members and observers, which are not yet doing so, are requested to provide their comments under the following headings:

- (i) General Comments
- (ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in underlined/bold font and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, members and observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied/pasted into a consolidated document.

In order to reduce the translation work and save paper, members and observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.