CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Food and Agriculture Organization of the United Nations
World Health Organization

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STANDARD FOR FISH OILS

CXS 329-2017

Adopted in 2017. Amended in 2021 and 2024.

2024 Amendments

Following decisions taken at the Forty-seventh Session of the Codex Alimentarius Commission in December 2024, Sections 2.1.6 and 3.5 were added as well as a column on calanus oil in Table 1 and amendments were made in Sections 3.2, 3.3.2, 7.2 and 7.3.

2023 Editorial correction

An editorial correction was made to Table 1 to correct “non detect” to “non-detectable” for consistency**.**

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* (CXC 52-2003).[i,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 CXC 52-2003.[1] 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 *Brevootia* and *Ethmidium* (*Clupeidae*).

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

2.1.6 *Calanus oil* is derived from the species *Calanus finmarchicus.* Calanus oil consists mainly of wax esters.

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

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

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

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* (Section 2.1.1) the sum of EPA and DHA has to be at least 27 percent (expressed as percentage of total fatty acids).

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

For calanus oil (Section 2.1.6) the content of wax esters shall be at least 80 w/w percent.

Concentrated fish oils (Section 2.5.1) and highly concentrated fish oils (Section 2.5.2) shall contain at least 50 w/w percent 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)[ii]	≤ 26

3.3.2 Fish oils with a high phospholipid concentration of 30 percent or more such as krill oil (Section 2.1.3) and fish oils with a high wax ester concentration of 80 percent or more such as calanus oil (Section 2.1.6) 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 *General principles for the addition of essential nutrients to foods* (CXG 9-1987)[2] 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.

3.5 Other compounds

Maximum levels of astaxanthin in calanus oil (Section 2.1.6) shall comply with regulations of the country of retail sale.

[ii] 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* (CXS 192-1995),[3] 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 flavourings used in products covered by this standard should comply with the *Guidelines for the use of flavourings* (CXG 66-2008).[4]

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* (CXS 193-1995).[5]

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* (CXC 1-1969),[6] the *Code of practice for fish and fishery products* (CXC 52-2003),[1] and *Code of hygienic practice for the storage and transport of edible fats and oils in bulk* (CXC 36-1987).[7]

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* (CXG 21-1997).[8]

7. LABELLING

The requirements of the *General standard for the labelling of pre-packaged foods* (CXS 1-1985)[9] and of the *Guidelines on nutrition labelling* (CXG 2-1985)[10] 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

The labelling of non-retail containers should be in accordance with the *General standard for the labelling of non-retail containers of foods* (CXS 346-2021).

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 calanus oil (Section 2.1.6), the maximum intake level of astaxanthin shall be declared if required by the country of retail sale in accordance with the acceptable daily intake established for different age groups by competent authorities.

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* (CXS 234-1999)[11] 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)		Calanus oil (Section 2.1.6)	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	12.7–17.1	2.0–6.0
C15:0 pentadecanoic acid	ND–1.5	ND–2.0	NA	ND–1.0	ND–1.0	ND–0.5	0.1–0.9	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	7.9–12.9	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	3.2–8.1	4.5–11.5
C17:0 heptadecanoic acid	ND–2.0	ND–3.0	NA	ND–1.0	ND–1.0	ND–0.5	0.3–1.2	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	0.4–1.5	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	0.3–0.8	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	2.3–4.2	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	0.7–1.5	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	1.1–3.5	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	ND–0.9	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	8.7–19.9	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	0.1–1.2	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	2.1–5.6	5.0–17.0
C20:1 (n-11) eicosenoic acid	ND–4.0	ND–3.0	NA	0.5–2.0	NA	NA	0.2–0.8	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–0.7	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	0.9-2.0	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	10.8–16.8	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	0.5–0.7	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–0.8	ND–1.5
C22:1 (n-11) cetoleic acid	ND–5.6	ND–1.0	NA	ND–0.1	1.0–1.5	NA	3.1–8.3	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	0.5–0.8	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	7.2–12.3	6.0–18.0

ND = non-detectable, defined as ≤0.05%

NA = not applicable or available

NOTES

[1] FAO and WHO. 2003. *Code of Practice for Fish and Fishery Products*. Codex Alimentarius Code of Practice, No. CXC 52-2003. Codex Alimentarius Commission. Rome.

[2] FAO and WHO. 1987. *General principles for the addition of essential nutrients to foods.* Codex Alimentarius Guideline, No. CXG 9-1987. Codex Alimentarius Commission. Rome.

[3] FAO and WHO. 1995. *General Standard for Food Additives.* Codex Alimentarius Standard. No. CXS 192- 1995. Codex Alimentarius Commission. Rome.

[4] FAO and WHO. 2008. *Guidelines for the Use of Flavourings.* Codex Alimentarius Guideline, No. CXG 66- 2008. Codex Alimentarius Commission. Rome.

[5] FAO and WHO. 1995. *General Standard for Contaminants and Toxins in Food and Feed*. Codex Alimentarius Standard. No. CXS 193-1995. Codex Alimentarius Commission. Rome.

[6] FAO and WHO. 1969. *General Principles of Food Hygiene*. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.

[7] FAO and WHO. 1987. *Code of Hygienic Practice for the Storage and Transport of Edible Fats and Oils in Bulk*. Codex Alimentarius Code of Practice, No. CXC 36-1987. Codex Alimentarius Commission. Rome.

[8] FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods.* Codex Alimentarius Guideline, No. CXG 21-1997. Codex Alimentarius Commission. Rome.

[9] FAO and WHO. 1985. *General Standard for the Labelling of Pre-packaged Foods*. Codex Alimentarius Standard. No. CXS 1-1985. Codex Alimentarius Commission. Rome.

[10] FAO and WHO. 1985. *Guidelines on Nutrition Labelling*. Codex Alimentarius Guideline, No. CXG 2-1985. Codex Alimentarius Commission. Rome.

[11] FAO and WHO. 1999. *Recommended Methods of Analysis and Sampling*. Codex Alimentarius Standard. No. CXS 234-1999. Codex Alimentarius Commission. Rome.