



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FATS AND OILS

Twenty-fourth Session

Melaka, Malaysia, 9 – 13 February 2015

PROPOSED DRAFT STANDARD FOR FISH OIL

(Prepared by the electronic working group led by Switzerland)

Governments and interested international organizations are invited to submit comments on the Proposed Draft Standard (**Annex II**) at Step 3 in writing, preferably by email, to the Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, e-mail codex@fao.org with copy to the Malaysian Secretariat for CCFO, Food Safety and Quality Division, Ministry of Health Malaysia, E-mail: cfo_malaysia@moh.gov.my , by **9 January 2015**.

Background

1. At the 23rd session of the CCFO the proposed draft standard for Fish Oil (CX/FO 13/23/3) was discussed. In view of the comments made and the need for further data and information the Committee agreed to return the Proposed Draft Standard to Step 2 for re-drafting. It was decided that for this purpose an electronic working group (eWG) should be established chaired by Switzerland. The Committee agreed that items already agreed at the 23rd session should not be re-opened for debate by the eWG. However, further comments may be discussed at the next session of the Committee.
2. The Committee noted that to justify the inclusion of specific named fish oils in the Proposed Draft Standard, those should be supported by adequate information including volume of production and consumption in individual countries and volume and pattern of trade between countries, international or regional market potential, and other information together with details of the proposed essential composition and quality factors. In addition, data on the fatty acid composition of the types of named fish oils should be robust and take into consideration main contributing factors such as climatic conditions and seasonality, geographical location etc.
3. The eWG was also asked by the Committee to identify specific questions to be referred to the CCFFP and the CCNFSDU.
4. CL 2013/07-FO requesting information on volumes and patterns of trade for different fish oils as well as information on their quality and composition was distributed in March 2013 to all members of Codex Alimentarius. The deadline for submission of data was September 30, 2013. Comments from the following countries and interested organizations were received: Canada, Chile, Iceland, Ireland, Japan, Norway, Seychelles, Thailand, USA, IADSA, IFFO.
5. In February 2014 the Codex Secretariat distributed an invitation to participate in the eWG to prepare the Proposed Draft Standard for Fish Oil. The following countries and interested organizations announced their interest: Argentina, Australia, Brazil, Canada, Chile, Denmark, Egypt, European Union, France, Ghana, Iran, Japan, Netherlands, Norway, Poland, Republic of Korea, Russian Federation, Seychelles, Thailand, USA, IADSA, IFFO.

Data received in response to the CL 2013/07-FO

6. The survey's objective was to identify types of fish oil which are significant items in trade (volume and value) and whether for those the fatty acid composition of several batches would allow the definition of a distinct fatty acid profile. The original data received were transferred in two spreadsheets and circulated to all members of the eWG for comments. Annex I of this document summarizes both types of information submitted by members of the eWG (trade data, analytical data).
7. Trade data: production and trade volumes and their value (in USD) were submitted by producers & exporters, importers, and organizations representing producers and users. In general, the data was inconsistent and difficult to reconcile. For anchovies e.g. several parties reported large production and

trade volumes of anchovy oil from Latin American countries which suggested that these oils are derived from one species or a major species (*E. ringens*). However, one major producer stated that anchovies forms shoals with other fish species and that these differ between areas which would suggest that the country does not export anchovy oil as such but a fish oil consisting of oils obtained from different fish species among the anchovy as a major one. Similar inconsistencies were also obvious for other types of fish oil. Since the objective was not to produce robust trade data but to assess the importance of single fish oils in trade, production, (internal) consumption, export, and import figures were added up without major corrections for double reporting. Volumes were categorized as high (> 10'000 t/a), medium (1'000 - 10'000 t/a), and low (< 1'000 t/a).

8. Crude vs refined oil: the trade and the analytical data submitted did not provide sufficient information to assess in detail the relative importance of crude vs refined oil. It was also not specified whether the trade data of crude fish oils concern fish oil for human consumption only. The trade data therefore may include also use of oils in feed or other non-food uses (pharmaceutical, cosmetic, technical). Trade data were consolidated without making a distinction for crude or refined oils.
9. Analytical data: each analytical report, reported fatty acids ranges, or existing standard (e.g. European Pharmacopoeia) was considered to constitute one dataset. The number of such datasets and members doing submissions for a fish oil was used as prime evidence for existing documentation. Robustness of analytical data received was rated as high for > 10 datasets, medium for 5 – 10 datasets, and low for < 5 datasets per type of fish oil. A considerable number of fish oils were not documented at all with respect to their fatty acid composition.
10. Some of the submissions answered the questions on seasonal and regional variability: the limited data available indicate that fatty acid spectra are not rigid and may vary based on diet which depends on the region, season etc. One member emphasized that the compositional data may vary due to the analytical methods being applied.

Trade data on specific fish oils

11. The data provided by eWG members allowed ranking of fish oils according to traded quantities. With respect to the quantities: five types of fish oil stood out as being traded in amounts well beyond or close to 10'000 tons per year and these were: anchovy oil (from *E. ringens*), unspecified fish oils and fats, cod liver oil (from *G. morhua*), salmon/trout oil (from Salmonidae) and tuna oil (from *Thunnus* spp and *Katsuwonus pelamis* (Scombridae)).
12. Other oils with trade volumes between 1'000 to 10'000 tons per year were, sardine oil, anchovy oil (from *E. encrasicolus*), boarfish oil (crude oil from *Capros aper*), sprat oil (crude oil from *Spratulus sprattus*), herring oil, blue whiting (crude oil from *Micromesistius poutassou*) and krill oil (mainly from *Euphasia superba*). Trade volumes from all other types of fish oil nominated by eWG member were below 1'000 tons per year.
13. Ranking the fish oils according to their value was not possible as no sufficient data concerning the value of the fish oils was received. However, the few data on the value received seemed to support the proposed ranking based on volumes. One Member stated that krill oil is marketed at significantly higher prices than regular fish oil.

Fatty acid composition of named fish oils

14. With respect to setting standards for certain types of fish oils using their fatty acid composition, a representative number of data sets would be needed to understand regional and seasonal variation and to define ranges for typical or for all fatty acids. The eWG members submitted analytical data for single batches, aggregated ranges of fatty acids (usually no explanation how the ranges had been derived were offered), and ranges of fatty acids from regulatory standards.
15. More than ten data sets were submitted for anchovy oil (mainly *E. ringens*) and tuna oil (several species). Between 5 and 10 data sets (including an official standard) were submitted for cod liver oil (from *G. morhua*) and Pacific saury oil (*Cololabis saira*). For all other types less than 5 data sets were available.

Proposed fish oils to be included in the standard

16. Based on the available trade and analytical data it may be possible to include into the fish oil standard at the present time the following types of named fish oil:

Fish oil	Comments
Anchovy oil from <i>Engraulis</i> spp. (Engraulidae)	Available analytical data were mainly from <i>Engraulis ringens</i> , <i>E. japonicus</i> ; no data were submitted for the European <i>E. encrasicolus</i> . Data confirm proposal of first draft (CX/FO 13/23/3) that may encompass all members of the genus <i>Engraulis</i> .
Cod liver oil from <i>G. morhua</i> (Gadidae)	Available fatty acid composition confirms proposal of first draft (CX/FO 13/23/3); available standard from Eur. Pharm. could be used as additional reference for composition.
Tuna oil from <i>Thunnus</i> spp and <i>Katsuwonus pelamis</i> (Scombridae)	At least five species were mentioned as commercially important; analytical data broken down by species supported grouping under one category. Data confirmed proposal of first draft (CX/FO 13/23/3)

Furthermore, based on the available trade data it was justified to maintain in the fish oil standard:

Fish oils and fats (unspecified)	Generic standard not based on species-specific fatty acid description
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Other named fish oils

17. Some members of the eWG supported the inclusion of salmon oil and krill oil. Both fish oils have gained importance very recently and their traded volume or value may be soon close to the four categories identified above.
18. As salmon oil may be derived from wild or farmed salmon, but may be offered also as a mixture of oils from both origins, separate fatty acid composition would be required; those were not yet available and an inclusion at this point in time is not sufficiently supported. Once sufficiently robust analytical data are submitted for wild and for farmed salmon this may be discussed further.
19. It was noted that krill oil is used in high value food supplements, but as the standard would apply rather to the oils traded as such and the corresponding robust data on the volume of traded krill oil did not allow categorizing it as "high volume", the inclusion could not be supported at this point in time. It was noted that the United States Pharmacopoeia's Food Chemical Codex (FCC) contains since 2013 a monograph for high phospholipid krill oil which includes also compositional fatty acid data and an assay for phospholipids. The fatty acid ranges were not in conformity with the data submitted to the eWG. It was noted that a request for changing the fatty acid ranges has been filed with FCC.
20. The eWG agreed to propose initially only a limited number of robustly documented named fish oil in order to progress the standard. Additional named oils may be added at a later stage as trade becomes significant and fatty acid ranges are robustly documented. Therefore the structure of section 2 of the standard remains unchanged which will allow addition of subsections under sections 2.1 and 2.3. Furthermore also generic fish oils and fish liver oils (sections 2.2 and 2.4) remain and are covered by the standard if they comply with the other requirements of the standard.

Ranges of fatty acid an integral part of the standard?

21. It was also recognized by some members that there is significant variation due to factors such as diet, climate, season and region, and that it would be more adequate to include the fatty acid ranges as references but not as part of the standard. It is understood that the reported fatty acid ranges already reflect the variability caused by these factors and that the proposed three named oils could stay as part of the standard (see Table 1 in Annex II).
22. Several comments supported the suggestion that other means than determination of ranges of fatty acid could be applied to identify and verify the source and species of named fish oils. However, there were no specific proposals made as to how the concept of traceability could be applied to identify species at the fish oil level. In that respect it was also noted that there were no other simple and easily accessible methods available to all stakeholders that allow independent verification of the claimed species.

Analytical methods

23. With respect to the analytical data submitted to the eWG it was noted that those were obtained using several different analytical methods and it was suggested by one member that CCMAS should review the eight identified methods used. As the definition of robust fatty acid ranges was the task of the eWG (and the CCFO), such assessment needs to be done by the eWG within its mandate and consultation of CCMAS on this matter was deemed not to be appropriate.

24. For the three named fish oils which were proposed for inclusion into the standard the submitted data expressed largely the content of individual fatty acids as % of total fatty acids or area %. The submitted data generally supported the ranges proposed in Table 1 of the first draft of the standard (CX/FO 13/23/3).
25. In line with other Codex standards, Table 1 should state that the ranges are expressed as percentage of total fatty acids. The analytical methods mentioned in Section 8.1 are deemed to be appropriate for such analysis.
26. CCMAS should be asked to assess whether the methods proposed in Section 8.1 are appropriate to analyse the three named fish oils with respect to their fatty acid composition and for compliance with ranges given in Table 1.
27. CCMAS should further be invited to comment on the other analytical methods proposed in section 8.

Content in nutrients

28. The CCFO may discuss whether there is a need to consult CCNFSDU whether the proposed minimum contents for vitamins A and D (Section 4.3) are consistent with those Codex texts that address nutrients.

Revised proposed draft Codex Standard for Fish Oil

29. The proposed draft Codex Standard for Fish Oil (Annex II) was prepared in line with the discussion of the 23rd session of the CCFO. The recommendations and agreements as written down in paragraphs 35 to 79 of REP13/FO were integrated with the view that those changes (unless stated otherwise) would not be discussed by the eWG but that comments would be sought at Step 3 and discussed by the physical working group (pWG) prior to the 24th session of the CCFO followed by a further review at the 24th session. The changes in the proposed draft Codex Standard for Fish Oil made due to the recommendations are underlined text. Proposed sections in square brackets were maintained and not considered.
30. The additional revisions proposed by the eWG are either based on the trade and analytical data submitted by the members of the eWG or are in response to specific requests made by the CCFO at its 23rd session.
31. Major changes proposed by the eWG are the deletion of all named fish and fish liver oils with exception of three named oils (anchovy oil, cod liver oil, tuna oil) for which international trade was reported to be significant and for which analytical data that allowed to lay down sufficiently robust reference fatty acid compositions were available.

Recommendations

32. Comments on the proposed draft Codex Standard for Fish Oils (Annex II) should be provided taking into account the deliberations of the 23rd CCFO and the discussion of the eWG summarized above. Codex members should focus specifically on those sections put in [square brackets] by the CCFO as those will be addressed with high priority with a view to seek consensus.
33. The eWG proposes that the following issues should be discussed specifically by the pWG to be held prior to the 24th session of the CCFO. This discussion will also take into account any comments received in response to the proposed draft standard for fish oil circulated at Step 3:
 - a. It was proposed to lay down for unnamed/not specified fish oils (Section 2.2) the criterion of a minimum content in EPA/DHA. If a minimum content is needed, what level would be appropriate?
 - b. For crude oils (Section 2.7.1) only some parts of the standard should be applicable. These are: Sections 3.1 (GLC ranges of fatty acid composition), 6.1 (General hygiene) and 7 (Labelling). Should other sections be mentioned as mandatory requirements?
 - c. Table 1 proposes ranges of fatty acids justified by analytical data for anchovy oil, cod liver oil, and tuna oil. They are based on the data submissions. Should any of the proposed ranges be modified, removed or are additional ones needed? In line with the approach agreed by the Committee such requests can only be considered if supported by adequate analytical data obtained from commercial products.
 - d. Is it appropriate to mention processes applied to devitaminize fish oils described in Section 2.4.1?
 - e. According to para 45 of the report of the 23rd session of CCFO (Section 2) it is stated that the definition for *Concentrated fish oils* and *concentrated fish oil ethyl esters* should be aligned with the description. This means that concentrated fish oils and concentrated fish oil ethyl esters are distinct categories. Therefore it is proposed to create for the ethyl esters an own subsection 2.6 at equal level to the concentrated fish oils.

- f. For the category *Extra low oxidised fish oils* (Section 2.7.2), one member proposed to develop specific quality criteria that separate this category from other fish oils. Are the proposed criteria suitable to distinguish Extra low oxidized fish oils from other fish oils? Should this category be include in the standard?

Trade and analytical data submitted by eWG members and their relative importance and quality

The specific fish oils are listed according to their reported trade importance

Designation	Fish species	Trade data (submissions)	Production (t) <i>Consumption (t)</i> Export (t) Import (t)	Values of amounts in left column (1000 USD)	Crude oil / Refined oil	Trade importance (high / medium / low)	Analytical data: Single datasets (submissions)	Species covered (datasets)	Quality of analytical data (high / medium / low)
Anchovis oil	Engraulis ringens	6	159'704 5'603 157'053 25'020	341'847 14'587 463'321 -	CO / RF	High (> 10'000 t/a)	41 (6)	E. japonicas (4) E. sp. (1) E. ringens (8)	High > 10 datasets
Fish fats & oils	Not specified / mixtures	5	- - 74'810 84'753	- - 79'015 50'156	CO / RF	High (> 10'000 t/a)	-	-	Not available
Cod liver oil	Gadus morhua	4	9'850 1'105 16'620 18'727	23'725 615 52'934 30'564	CO / RF	High (> 10'000 t/a)	7 (4)	Gadus morhua (5)	Medium 5 – 10 datasets
Tuna oil	Various species (min. 5)	3	12'392 25 8'072 1'705	48'327 - 22'557 -	CO / RF	High (> 10'000 t/a)	27 (9)	Thunnus spp. (5) Thunnus obesus (1) K. pelamis (1)	High > 10 datasets
Salmon (Trout) oil	Salmon salar Oncorhynchus mykiss	2	10'186 2'708 7'475 -	47'441 9'003 34'863 -	CO / RF	High (> 10'000 t/a)	1 (1)	S. salar (farmed) (1)	Low < 5 datasets
Anchovis oil	Engraulis encrasicolus plus others	1	- - 8'422 -	- - 24'657 -	CO / -	Medium (1'000 - 10'000 t/a)t/a)	-	-	Not available
Boarfish oil	Capros aper	1	- - 8'000 -	- - - -	CO / -	Medium (1'000 - 10'000 t/a)t/a)	6 (1)	Capros aper	Medium 5 – 10 datasets
Mackerel oil	Scomber scombrus	1	150 - 6'000 -	315 - - -	CO / -	Medium (1'000 - 10'000 t/a)t/a)	7 (3)	S. japonicas (3) S. scombrus (43)	High > 10 datasets
Herring oil	Clupae harengus	2	- - 4'000 -	- - - > 666	CO / RF	Medium (1'000 - 10'000 t/a)t/a)	4 (1)	Clupae harengus	Low < 5 datasets
Blue whiting	Micromesistius poutassou	1	- - 2'000 -	- - - -	CO / -	Medium (1'000 - 10'000 t/a)t/a)	2 (1)	Micromesistius poutassou	Low < 5 datasets

Designation	Fish species	Trade data (submissions)	Production (t) <i>Consumption (t)</i> Export (t) Import (t)	Values of amounts in left column (1000 USD)	Crude oil / Refined oil	Trade importance (high / medium / low)	Analytical data: Single datasets (submissions)	Species covered (datasets)	Quality of analytical data (high / medium / low)
Krill oil	Euphasia superba	1	1'000 - 925 -	- - - -	- / RF	Low ($< 1'000$ t/a)	2 (1)	Not given	Low < 5 datasets
Sardine oil	Sardine (main species)	1	- - - 1'700	- - - -	- / -	Medium (1'000 - 10'000 t/a)t/a)	3 (2)	Not given	Low < 5 datasets
Fish liver oil	-	2	- - 52 924	- - 1'341 9'420	CO / RF	Low ($< 1'000$ t/a)	-	-	Not available
Sprat oil	Spratus spratuss	1	- - 500 -	- - - -	CO / -	Low ($< 1'000$ t/a)	2 (1)	Spratus spratuss	Low < 5 datasets
Squid oil	Illex argentinus, Dosidicus gigas, Todarodes pacificus	1	> 400 - - -	> 2'000 > 500 > 2'000 -	- / RF	Low ($< 1'000$ t/a)	-	-	Not available
Herring	Not specified	1	- - 418 -	- - 666 -	CO / RF	Low ($< 1'000$ t/a)	-	-	Not available
Pollock liver oil	-	1	100 - 100 -	- - - -	CO / -	Low ($< 1'000$ t/a)	1 (1)	Theragra chalcogramma (Pollock oil or Pollock liver oil)	Low < 5 datasets
Menhaden oil	Menhaden (main species)	1	- - - 200	- - - -	- / -	Low ($< 1'000$ t/a)	1 (1)	Not given	Low < 5 datasets
Capelin oil	Mallotus villosus	1	100 - 100 -	- - - -	CO / -	Low ($< 1'000$ t/a)	-	-	Not available
Calanus oil	Calanus s.l. (mainly)	1	- - - -	> 4'000 > 500 > 3'500 -	- / RF	Low ($< 1'000$ t/a)	-	-	Not available
Pacific saury oil	Cololabis saira	-	-	-	- / -	No data provided	5 (1)	Cololabis saira (5)	Medium 5 – 10 datasets

PROPOSED DRAFT CODEX STANDARD FOR FISH OILS

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 Codex 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 (as described in Section 2.7.1) 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] [contain] fatty acids ethyl esters. Fish oils may contain other lipids and unsaponifiable constituents naturally present.

2.1 **Named fish oils** may be derived from specific source materials; such fish oils could be identified by a specific name that is representative of the major fish or shellfish taxon from which the oil is extracted, except when that can be confusing for the consumer.

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*).

2.2 **Fish oils** (unnamed) may be derived from a single species of fish other than the ones listed in Section 2.1 or be a mixture of fish oils derived from specified and/or unspecified source materials. This includes also mixtures with fish liver oils.

2.3 **Named fish liver oils** may be 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. For named fish liver oils the fatty acid profiles (Table 1) shall apply.

2.3.1 **Cod liver oil** is derived from the species *Gadus morhua* (*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.

2.4.1 **Fish liver oil devitaminised** is derived from fish liver oil that has been processed to reduce the content of vitamin A and vitamin D. [Section 3.3 does not apply]

2.5 **Concentrated fish oils** means oils intended for human consumption, derived from fish oils described in Section 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 [40 to 60 w/w %] fatty acids as sum of EPA and DHA, at least 70 w/w % of fatty acids are in the form of triacylglycerides.

2.5.2 **Highly concentrated fish oil** contains greater than [60 w/w %] fatty acids as sum of EPA and DHA, at least 70 w/w % of fatty acids are in the form of triacylglycerides.

2.6 **Concentrated fish oils ethyl esters** [are primarily composed of] [contain] fatty acids ethyl esters.

2.6.1 **Concentrated fish oil ethyl ester** 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 ester** contain fatty acids as esters of ethanol of which greater than [60 w/w %] are as sum of EPA and DHA

2.7 **Other definitions applicable to fish oils** (2.1 and 2.2.) and fish liver oils (2.3 and 2.4)

2.7.1 **Crude fish oils** and **crude fish liver oils** are oils intended for human consumption after they have undergone further processing, refining and purification as applicable. Crude fish oils and crude fish liver oils have to comply with Sections 3.1, 6.1 and 7.

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.

2.7.2 **[Extra low oxidised fish oils** are produced by mechanical maceration of the fresh raw materials at a temperature not exceeding 97 °C, and a heating time not exceeding 20 minutes, and without using solvents. After centrifugation the oil may be processed by further purification steps.]

2.8 **[Processing**

Fish oils are produced from:

- (i) catches for the single purpose of fishmeal/oil production
- (ii) by-catches from another fishery, or
- (iii) fish off cuts and offal from the processing industry.

Gadoids, clupeids, scombroids and salmonoids are within the most used species. Traditional processes to obtain fish oil involve two stages: oil extraction from raw material and refining of that crude oil. The refined fish oil production process typically includes several steps such as repeated heating at high temperatures (at 90-95 °C and even to 180 °C) 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).]

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 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 oils described in Section 2.7.1 and flavoured fish oils where the added flavourings will interfere with the analytical determination of oxidation parameters.

3.2.1 All fish oils, fish liver oils and concentrated fish oil (Section 2.1. to 2.5) with the exception of oils with a high phospholipid concentration shall comply with the following:

Acid value	≤ 3 mg KOH/g
Peroxide value	≤ 5 meq/kg
Anisidine value	≤ 20
Total oxidation value (ToTox) ²	≤ 26
[Oligomers:	≤ 1.5 % for fish oils and liver oils (Sections 2.1 – 2.4)
	≤ 3 % for concentrated and highly concentrated fish oils (Section 2.5.1 and 2.5.2)]

3.2.2 Fish oils with a high phospholipid concentration such as krill oil or squid oil, shall comply with the following:

Acid value	≤ <u>30</u> mg KOH/g
Peroxide value	≤ 5 meq/kg

3.2.3 Extra low oxidised fish oils Section 2.7.2 shall comply with the following:

Total oxidation value (ToTox) ²	≤ 5
[Oligomers:	≤ 0.5 %]

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
Vitamin D	≥ 1.0 µg/ml]

4 **Food Additives**

[Note: this section does not apply to oils described in Section 2.7.1]

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

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

[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

[Note: this section does not apply to oils described in Section 2.7.1]

[The products covered by this Standard shall comply with the Maximum Levels of the *Codex 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 53-2003), 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

[Note: this section does not apply to oils described in Section 2.7.1]

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 *Codex General Standard for the Labelling of Pre-packaged Foods* (Ref. CODEX STAN 1-1985). The name of the fish oil shall conform to the descriptions given in Section 2 of this Standard.

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.

7.3 Other labelling requirements

For fish liver oils (Sections 2.3 and 2.4, only applicable if naturally present or restored) the content in vitamin A and vitamin D [*may*] be given.

For concentrated fish oils (Section 2.5) the content of DHA and EPA shall be given.]

8 Methods of Analysis and Sampling

8.1 [Determination of fatty acid composition

According to applicable ISO methods including ISO 5508:1990 and ISO 12966-2:2011 (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 1j-07 (Determination of cis-, trans-, Saturated, Monounsaturated, and Polyunsaturated Fatty Acids in Extracted Fats by Capillary GLC), Ce 2b-11 (Direct Methylation of Lipids in Foods by Alkali Hydrolysis), Ce 1-62 (Fatty Acid Composition by Packed Column Gas Chromatography) and Ce 2-66 (Preparation of Methyl Esters of Fatty Acids).]

8.2 Determination of arsenic

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

8.3 [Determination of lead

According to AOAC 994.02 (Atomic Absorption Spectroscopy); or ISO 12193:2004 (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).

8.4 Determination of acid value

According to AOCS Ca 5a-40 (Free Fatty Acids), AOCS Cd 3d-63 (Acid Value); ISO 660:2009 (Animal and vegetable fats and oils -- Determination of acid value and acidity); European Pharmacopoeia 2.5.1 (Acid value)

8.5 Determination of peroxide value

According to AOCS CD 8b-90 (Peroxide Value Acetic Acid-Isooctane Method); ISO 3960:2007 (Animal and vegetable fats and oils -- Determination of peroxide value -- Iodometric (visual) endpoint determination); European Pharmacopoeia 2.5.5 (Peroxide value).

8.6 Determination of p-anisidine value

AOCS Cd 18 - 90 (11)]

8.7 Determination of oligomers

Information missing

8.8 [Determination of vitamin A

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

8.9 Determination of vitamin D

PhEur 2.2.29 liquid chromatography, monograph Cod liver oil (type A)]

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	Cod Liver	Tuna
C14:0 myristic acid	5.0-11.5	2.0-6.0	2.0-5.0
C15:0 pentadecanoic acid	ND-1.5	ND-0.5	ND-2.0
C16:0 palmitic acid	14.0-22.0	4.0-14.0	14.0-24.0
C16:1 (n-7) palmitoleic acid	5.0-12.0	4.5-11.5	1.0-12.5
C17:0 heptadecanoic acid	ND-2.0	na	1.0-3.0
C18:0 stearic acid	1.0-7.0	1.0-4.0	1.0-7.5
C18:1 (n-7) vaccenic acid	na	2.0 – 7.0	2.0 – 7.0
C18:1 (n-9) oleic acid	5.0-17.0	12.0-21.0	10.0-25.0
C18:2 (n-6) linoleic acid	ND-3.5	0.5-3.0	ND-3.0
C18:3 (n-3) linolenic acid	ND-7.0	ND-2.0	ND-2.0
C18:3 (n-6) γ -linolenic acid	ND-5.0	na	ND-4.0
C18:4 (n-3) stearidonic acid	ND-5.0	0.5-4.5	ND-2.0
C20:0 arachidic acid	na	na	ND-2.5
C20:1 (n-9) eicosenoic acid	ND-4.0	1.0-17.0	ND-2.5
C20:1 (n-11) eicosenoic acid	ND-4.0	1.0-5.5	ND-3.0
C20:4 (n-6) arachidonic acid	ND-2.0	ND-1.5	ND-3.0
C20:4 (n-3) eicosatetraenoic acid	ND-2.0	ND-2.0	ND-1.0
C20:5 (n-3) eicosapentaenoic acid	5.0-26.0	7.0-16.0	2.5-9.0
C21:5 (n-3) heneicosapentaenoic acid	ND-4.0	ND-1.5	ND-0.5
C22:1 (n-9) erucic acid	ND-5.0	ND-1.5	ND-1.0
C22:1 (n-11) cetoleic acid	ND-5.0	5.0-12.0	ND-1.0
C22:5 (n-3) docosapentaenoic acid	ND-4.0	0.5-3.0	ND-3.0
C22:6 (n-3) docosahexaenoic acid	4.0-23.0	5.0-18.0	21.0-42.5

na = not available

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