CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 3 **CX/FO 13/23/3-Add.2**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FATS AND OILS

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PROPOSED DRAFT STANDARD FOR FISH OILS

Comments at Step 3

(Comments of Egypt, European Union, India, Indonesia, Kenya, Mali and Thailand)

EGYPT

Firstly, Egypt expresses its appreciation for the great efforts done by the eWG chaired by Switzerland for development of the current proposed draft Codex standard for fish Oils.

1. Scope:

- Egypt suggests to add both crude fish liver oils described in section 2.6.1 and extra low oxidized fish oils described in section 2.6.3 to the text found in square brackets, because they need further processing to become valid for human consumption.

2- Description:

- For more clarification, Egypt suggests to change the expressions of fish oils (unnamed) and fish liver oil (unnamed) to unnamed fish oils and unnamed fish liver oil (section 2.2 and 2.4).

- " Composed of fatty acids" stated in the first line of section 2.3, it is better to be written as" composed of glycerides of fatty acids"

- Egypt also suggests replacing triacylglycerides stated in section 2.5.1 and 2.5.2 with triacylglecerols or triglycerides.

- Section 2.4.1 Egypt asks about the level at which not can be considered as devitaminised fish liver oil.

3- Essential Composition and Quality Factors

3.1 Table (1) shows only fatty acid composition of both named fish oil and named fish liver oil categories (section 2.1 and 2.3) – Egypt finds that unnamed fish oils and unnamed fish liver oils (section 2.2 and 2.4) as well as all fish oil types from 2.4.1 to 2.6.3 can be also specified in table (1) for their fatty acid composition.

- Unnamed fish oils (2.2) and unnamed fish liver oils (2.4) can be deleted from the proposed draft codex standard for fish oils, because their specifications in the present draft proposal are not mentioned.

- It is also observed that there is no data in table (1) concerning the occurance of trans, branched-, and cyclic fatty acids in different fish oil types.

3.2 It was found that there are no specifications regarding quality parameters such as :

- Quality characteristics (color, odor and taste, volatile matter at 105 ºc, insoluble impurities, iron(Fe), cupper (cu) … etc.

Chemical and physical characteristics.

- Level of desmethyl sterols.
- Level of tocopherols and tocotrienols.
- Level of high phospholipids concentration.

EUROPEAN UNION

The European Union and its Member States (EUMS) would like to express its gratitude to Switzerland for preparing the Proposed Draft Standard for Fish Oils.

The EUMS would like to submit the following comments on the proposed Draft Standard:

1 Scope

This Standard applies in its entirety to the fish oils described in Section 2 that are presented in a state for human consumption. **~~[It applies partially to crude fish oils described in Section 2.6.1 that require further processing before they are placed on the market for the final consumer]~~**. 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)4. **This standard only applies to fish oils used in food and in food supplements where those are regulated as foods**

EUMS comments

The EUMS consider that a reference to crude oil in the Scope of the Standard is not appropriate. Crude oil should be regarded as a semi-processed raw material. See EUMS comments on point 2.6.1.

The EUMS suggest that the last sentence of Section 2 "Description" is moved to Section 1 "Scope" for the sake of clarity.

2 Description

Fish oils **mean oils intended for human consumption derived from the processing of fish and shellfish fit for human consumption as defined in Section 2 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)[4]~~are produced from a variety of fish and shellfish species. Whole fish are the main source, but by-products such as trimmings from fish processing may also be used. Traditionally fish oil production consists of two stages: oil extraction from raw material and refining of that oil.~~ Crude fish oils ~~and crude fish liver oils~~ are ~~oils~~ intended for human consumption only after they have undergone further processing, refining and purification as applicable.** Fish oils are primarily composed of glycerides of fatty acids whereas concentrated fish oils are either primarily composed of glycerides of fatty acids or of their ethylesters. Fish oils may contain other lipids and unsaponifiable constituents naturally present. **~~This standard only applies to fish oils used in food and in food supplements where those are regulated as foods~~**.

EUMS comments

Fish oils are covered by the "Codex Standard for edible fats and oils currently not covered by individual standards (CODEX STAN 19-1981)". Point 2.1 of this standard states that products of animal origin must be produced from animals in good health at the time of slaughter and be fit for human consumption. This view is also supported by Point 10.2.2 of FAO Fisheries Technical Paper, 142 on the production of fish meal and oil: The condition of the fish at the time of processing affects the oil physically, chemically and nutritionally. In order to manufacture oil of desirable properties the fish should be as fresh as possible.

The EUMS suggest an amendment to the text under description for consistency with the Scope of the Standard. The EUMS do not support any reference to "by products" as this term is often used for products which are not fit for human consumption. It is also proposed to move the last sentence to the scope for the sake of clarity.

The definition of 'crude fish oil' has been moved from point 2.6.1 under the subsection other definitions with some amendments as it is not necessary to make a distinction between crude fish oil and crude fish liver oils.

2.1 **Named fish oils** may be derived from specific source materials; such fish oils **could be ~~are then~~** 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.** For named fish oils, the fatty acid profiles (Table 1) shall apply. The following named fish oils are described in this Standard:

EUMS comments

The EUMS suggest an amendment to the description of named fish oils to avoid confusing consumers. For example, as stated in Codex Standard 3-1981, the use of the term "salmon" is restricted to a short list of fish; trout belongs to the family Salmonidae but the term "salmon" should not be used to name them.

2.1.1 **Anchovy oil** is derived from the family Engraulidae.

2.1.2 **Sardine oil** is derived from the family Clupeidae (genera Sardina, Sardinops or Sardinella).

2.1.3 **Wild salmon oil** or **farmed salmon oil** are derived from wild or farmed fish respectively **only from the species list in Codex Standard 3-1981** ~~**of the family Salmonidae**~~; **salmon oil** is a mixture of oils derived from wild and farmed fish.

EUMS comments

See EUMS comment on point 2.1

2.1.4 **Jack makerel oil** also known as **horse makerel oil** is derived from the family Carangidae (genus Trachurus).

2.1.5 **Menhaden oil** is derived from the family Clupeidae (genus Brevoo**rt**ia).

EUMS comments

Editorial comment.

2.1.6 **Tuna oil** is derived from the family Scombridae (genera Thunnus, Sarda, Katsuwonus and Auxis).

2.1.7 **Krill oil** is derived from the family Euphausiidae (mainly Antarctic).

2.1.8 **Squid oil** is derived from the order Teuthida.

2.1.9 **Pollock oil** is derived from the family Gadidae (genus Pollachius)

2.1.10 **Herring oil** is derived from the family Clupeidae (genus Clupea).

2.1.11 **Capelin oil** is derived from the family Osmeridae (genus Mallotus).

2.1.12 **Sandeel oil** is derived from the family Ammodytidae.

2.1.13 **Calanus oil** is derived from the family Calanidae (genus Calanus).

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 family Gadidae (genus Gadus).

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** are derived from fish oils described in Section 2.1 to 2.4 which have been subjected to processes such as 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 50 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 50 w/w % of fatty acids are in the form of triacylglycerides.

2.5.3 **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

2.5.4 **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

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

~~2.6.1 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.~~

EUMS comments

Traditionally fish oil production consists of two stages: crude oil extraction from raw material and refining of that crude oil. Crude oils are raw materials for fish oil that must undergo further processing, refining and purification, as applicable, before it can be used as food. The properties and characteristics of crude oils vary a lot and are strongly influenced by the process and the raw material. Including a definition of the term 'crude oil' creates confusion. The composition and oxidative status of crude fish oil shall still be under control as fish oil shall be prepared from wholesome fish or parts of fish being fit for human consumption. Therefore, the EUMS would like to suggest crude oil is referred to elsewhere, in the introductory part of the section 2 "description", in the section on processing and/or in the new section 3.1: Raw materials suggested by the EUMS.

[2.6.2 **Virgin fish oils** have been treated by heating not exceeding [70°C], washing with water, settling, filtering and centrifugation only. They may contain antioxidants and pigments naturally present in the raw material. **]**

EUMS comments

The EUMS would appreciate it if further clarification in relation to the use of this term for fish oil is provided.

[2.6.3 **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**.** 7**]**

EUMS comments

The EUMS consider that further discussion and clarification on the quality parameters is needed.

Proposed New Section: 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

Proposed New section 3.1 Raw materials

The raw materials used in the production of fish oils should be as fresh as possible and handled in accordance with the Code of Practice for fish and fishery products, in particular Section 4 - General Considerations for the Handling of Fresh Fish, Shellfish and other Aquatic Invertebrates (CAC/RCP 52-2003).

EUMS comments

The composition and oxidative status of fish oil presented in a state for human consumption depends on the composition and the oxidative status of the raw material including the semi-processed crude oil. Fish oil shall be prepared from sound and wholesome fish or parts of fish in a condition fit to be sold fresh for human consumption. Fish oils are today covered by the “Codex Standard for edible

fats and oils currently not covered by individual standards (CODEX STAN 19-1981)". Point 2.1 of this standard states that products of animal origin must be produced from animals in good health at the time of slaughter and be fit for human consumption. This view is also supported by Point 10.2.2 of FAO Fisheries Technical Paper, 142 on the production of fish meal and oil: The condition of the fish at the time of processing affects the oil physically, chemically and nutritionally. In order to manufacture oil of desirable properties the fish should be as fresh as possible.

3.~~1~~ 2 **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~~ 3 **Quality parameters**

Note: this section does not apply to ~~**oils described in Section 2.6.1 and**~~ flavoured fish oils where the added flavourings will interfere with the analytical determination of oxidation parameters.

EUMS comments:

See EUMS comments on 2.6.1. Crude oil is a raw material and not an oil directly used for food.

3.~~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)[5] ≤ ~~**26**~~ **30**

EUMS comments:

Is the upper value for ToTox correct?

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

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

Acid value ≤ 20 mg KOH/g

Peroxide value ≤ 5 meq/kg

3.~~3~~4 **[Vitamins**

Fish liver oils (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: no food additives are permitted in this section does not apply to fish oils described in Section 2.6.1**~~

Antioxidants, ~~**antioxidant synergists, colours, chelating agents**~~, and antifoaming agents used in accordance with Tables 1 and 2 of the Codex General Standard for Food Additives in food category *02.1.3 Lard, tallow, fish oil, and other animal fats.* Additives may not be added to virgin oils as defined in Section 2.6.2.

Flavourings may be used in fish oils in accordance with the Guidelines for the Use of Flavourings (CAC/GL 66-2008).

EUMS comments

See EUMS comments on 2.6.1, crude oil is a raw material and not an oil directly used for food.

The EUMS oppose the use of colours in fish oil as they are not technologically justified. Moreover, the EUMS are of the view that the use of colours in fish oils might mislead consumers; therefore the reference should be deleted. As for antioxidant synergists the EUMS would like to point out that antioxidant synergists fall under the functional class of antioxidants, therefore the reference to antioxidant synergists is not needed. Chelating agents are not recognised as a functional class; therefore, the reference to chelating agents should be deleted as well.

5 Contaminants

~~Note: this section does not apply to fish oils described in Section 2.6.1.~~

EUMS comments:

See EUMS comments on 2.6.1, crude oil is a raw material and not an oil directly used for food

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).

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 Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969), the Code of Practice for Fish and Fishery Products (CAC/RCP 53-2003) and the Recommended International 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 fish oils described in Section 2.6.1.~~

EUMS comments:

See EUMS comments on 2.6.1, crude oil is a raw material and not an oil directly used for food

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 **omega-3-fatty acids shall be given as the sum of** DHA and EPA **acids** **~~shall be given~~**.

Fish oils (unnamed) shall be presented as generic crude fish oil, refined fish oil, specific products as omega-3 concentrates, products such as "virgin" fish oils or extra low oxidised fish oils including

information on which species they originate from.

EUMS comments

The content of omega-3 fatty acids should be presented as the sum of EPA and DHA acids.

The EUMS suggest inserting additional provisions for fish oils (unnamed) including information on the species they originate from.

8 Methods of Analysis and Sampling

8.1 Determination of fatty acid composition

According to applicable ISO methods including ISO:5508:1990 (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), AOAC 2000 Cd 3a-63 (Acid Value), 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:

EUMS comments

The EUMS would like to propose a footnote to Table 1: "For reference taxons that can be used in each category, see section 2.1"

Specific comments on the fatty acid composition of named fish oils will be provided at a later stage. The EUMS suggest to put Table 1 into square brackets.

INDIA

We support the Development of a Codex Standard for Fish Oils.

INDONESIA

1 Scope

This Standard applies in its entirety to the fish oils described in section 2 that are presented in a state for human consumption. It applies partially to crude fish oils described in Section 2.6.1 that require further processing before they are placed on the market for the final consumer. 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].

Comment

Indonesia proposes to open the square brackets and agreed that this draft standard applies partially to crude fish oils described in Section 2.6.1.

Description

Fish oils are produced from a variety of fish and shellfish species. Whole fish are the main source, but trimmings from fish processing may also be used. Fish oils and concentrated fish oils are primarily composed of glycerides of fatty acids and ethyl esters, unless otherwise indicated. The oil may contain other lipids and unsaponifiable constituents naturally present. The oil may be used as an ingredient in food or food supplements.

Comment

Indonesia proposes that by product of fish processing should be included, because oil from by-product of canning processing is different to oil derived from trimming process. Fish oil derived from canning processing is produced during pre-cooking (trimming is not involved) in the form of stick water that further processed by sedimentation to obtain fish oil. This standard also applies to crude fish oil and oil from by product of fish processing is categorized as crude fish oil that needs further processing before consumption.

Indonesia proposes the description as followed:

Fish oils are produced from a variety of fish and shellfish species. Whole fish are the main source, but trimmings and by-product from fish processing may also be used. Fish oils and concentrated fish oils are primarily composed of glycerides of fatty acids and ethyl esters, unless otherwise indicated. The oil may contain other lipids and unsaponifiable constituents naturally present. The oil may be used as an ingredient in food or food supplements.

1.1 **Named fish oils** may be derived from specific source materials (e.g. fish species,); such fish oils are then identified by a specific name that is representative of the major species from which the oil is extracted. The following named fish oils are described in this Standard:

Question to Switzerland

Indonesia would like to seek clarification regarding the basis criteria include certain fish species in the standard?

1.1.1 **Anchovy oil** is derived from the family Engraulidae.

1.1.2 **Sardine oil** is derived from the family Clupeidae (genera Sardina, Sardinops or Sardinella).

1.1.3 **Wild salmon oil** is derived from wild fish of the family Salmonidae.

1.1.4 **Farmed salmon oil** is derived from farmed fish of the family Salmonidae.

1.1.5 **Jack makerel oil** also known as **horse makerel oil** is derived from the family Carangidae (genus Trachurus).

1.1.6 **Menhaden oil** is derived from the family Clupeidae (genus Brevootia).

[1] ***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.

1.1.7 **Tuna oil** is derived from the family Scombridae (genera Thunnus and Sarda).

1.1.8 **Krill oil** is derived from the family Euphausiidae (mainly Antarctic).

1.1.9 **Squid oil** is derived from the order Teuthida.

1.1.10 **Pollock oil** is derived from the family Gadidae (genus Pollachius)

1.1.11 **Herring oil** is derived from the family Clupeidae (genus Clupea).

1.1.12 **Capelin oil** is derived from the family Osmeridae (genus Mallotus).

1.1.13 **Sandeel oil** is derived from the family Ammodytidae.

1.2 **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.

1.3 **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.

1.3.1 **Cod liver oil** is derived from the family Gadidae (genus Gadus).

1.4 **Fish liver oils** (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.

1.5 **Concentrated fish oils** are derived from fish oils described in Section 2.1 to 2.4. Their glycerides have been subject to hydrolysis, fractionation and/or re-esterification.

1.5.1 **Concentrated fish oils** contain 40 to 60 w/w % fatty acids as sum of EPA and DHA, at least 50 w/w % of fatty acids are in the form of triacylglycerides.

1.5.2 **Highly concentrated fish oils** contain greater than 60 w/w % fatty acids as sum of EPA and DHA, at least 50 w/w % of fatty acids are in the form of triacylglycerides.

1.5.3 **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

1.5.4 **Highly concentrated fish oil ethyl esters** contains fatty acids as esters of ethanol of which greater than 60 w/w % are as sum of EPA and DHA

1.6 Other definitions applicable to fish oils (2.1 and 2.2.) and fish liver oil (2.3 and 2.4)

1.6.1 **Crude fish oils** and **crude fish liver oils** are raw materials not yet fit for human consumption that due to their composition and intended end use have to undergo, where applicable, further processing, refining and purification before they are placed on the market for the final consumer. The following parts of the standard are not applicable for crude fish oils: Section 3.2.Oxidation parameters; Section 4 Food Additives; Section 5 Contaminants; Section 6.2 Hygiene microbiological criteria; Section 7.1 Name of the Food.

1.6.2 **Virgin fish oils** have been treated by heating, washing with water, settling, filtering and centrifugation only. They may contain antioxidants and pigments found naturally in the fish.

Comment

Indonesia *proposes* to reword section 2.6.2 *as follow:*

***Virgin fish oils** have been treated by heating not exceeded 70^{o}C , washing with water, settling, filtering and centrifugation only. They may contain antioxidants and pigments found naturally in the fish.*

1.6.3 **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. They are suitable for direct use as ingredients in food and beverages.

2 Essential Composition and Quality Factors

2.1 **GLC ranges of fatty acid composition** (expressed as percentages)

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.

Comment

Indonesia agreed that the supplementary criteria applies to the standard, therefore Indonesia proposes to open the square brackets.

2.2 **Oxidation Parameters**

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

Comment

Indonesia proposes that the oxidation parameters should also apply to flavoured fish oil due to health risk of oxidized fish oil or high level of oxidation products in fish oil

2.2.1 All fish oils, fish liver oils and concentrated fish oil (Section 2.1. to 2.5) with the exception of krill oil (Section 2.1.8) 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)

Comment

-Indonesia would like to seek clarification regarding the basic principle in determining the value of each quality factors?

Indonesia *proposes* that acid value *should not be* included into the oxidation parameters because free fatty acid is not directly related to oxidation but to hydrolysis. This parameter is *also* not suitable to section 2.5 which fish oil might be subject to hydrolysis that produced free fatty acids.

2.2.2 Krill oil (Section 2.1.8) shall comply with the following:

Acid value	≤ 20 mg KOH/g
Peroxide value	≤ 5 meq/kg

2.2.3 Extra low oxidized fish oils (Section 2.6.3) shall comply with the following:

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

2.3 **Vitamins**

Fish liver oils (Sections 2.3 and 2.4) shall comply with following:

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

3 Food Additives

Antioxidants, antioxidant synergists, colours, antifoaming, and chelating agents used in accordance with Tables 1 and 2 of the Codex General Standard of Food Additives 192-1995, Rev. 7-2006 in food category *02.1.3 Lard, tallow, fish oil, and other animal fats* or listed in Table 3 of the General Standard for Food Additives are acceptable for use in foods conforming to this Standard.

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

Flavourings may be used in fish oil in accordance with the Guidelines for the Use of Flavourings (CAC/GL 66-2008).

Comments

a. Indonesia proposes that the level use of antioxidants and antioxidant synergists should be mentioned explicitly in the standard because these food additives are intensively used in fish oils. This is in accordance with the Codex standard for named vegetable oil 210-1999 for Food Additives section 4.1. Antioxidant

b. Indonesia agreed that colours applies to the standard and proposes to open the square brackets are opened.

c. Indonesia proposes to include chelating agents in this section.

4 Contaminants

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).

5 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 Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969), the Code of Practice for Fish and Fishery Products (CAC/RCP 53-2003), and Recommended International Code of Hygienic Practice for the Storage and Transport of Edible Oils and Fats in Bulk (CAC/RCP 36-1987).

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).

6 Labelling

6.1 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.

6.2 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.

6.3 Other labelling requirements

For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D shall be given.

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

Comments

Indonesia proposes that the standard should refer to :

a. General Standard for The Labeling of and Claims for Prepackaged Foods for Special Dietary Uses (Codex Stan 146-1985)

b. CAC/GL 2-1985 Guidelines on Nutrition Labelling

c. CAC/GL 1-1979 rev 1991 General Guideline on Claims

d. CAC/GL 23-1997 Guideline for Use of Nutrition Claims

7 Methods of Analysis and Sampling

7.1 Determination of GLC ranges of fatty acid composition

According to ISO:5508:1999 or any other applicable ISO method for determination of fatty acid composition.

7.2 Determination of arsenic

According to AOAC 952.13; AOAC 942.17; or AOAC 986.15.

7.3 Determination of lead

According to; AOAC 994.02; or ISO 12193: 2004; or AOCS Ca 18c-91 (03).

7.4 Determination of acid value

According to AOAC 2000 Cd 3a-63

7.5 Determination of peroxide value

According to AOCS Official Method Cd 8b-90 (03) or ISO 3960: 2001

7.6 Determination of anisidine value

According to IUPAC 1987 method II.D.26

7.7 Determination of oligomers

Information missing

7.8 Determination of vitamin A

Information missing

7.9 Determination of vitamin D

Information missing

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	Sardine	Wild Salmon	Farmed Salmon	Jack Mackerel	Menhaden	Tuna
C14:0 myristic acid	5.0-10.0	4.0-21.5	2.0-4.5	2.5-5.0	4.5-8.0	7.0-12.5	2.0-5.0
C15:0 pentadecanoic acid	ND-1.0	ND-1.0	ND-1.0	ND-0.5	0.5-1.0	ND-1.5	ND-2.0
C16:0 palmitic acid	14.0-22.0	9.0-23.5	12.0-13.5	7.0-16.5	16.5-22.0	14.0-23.0	14.0-24.0
C16:1 (n-7) palmitoleic acid	5.0-12.0	5.5-17.5	4.5-5.0	3.0-7.0	5.5-8.0	7.5-15.0	1.0-12.5
C17:0 heptadecanoic acid	ND-1.0	ND-1.0	ND-1.0	ND-0.5	ND-1.0	ND-2.5	1.0-3.0
C18:0 stearic acid	1.0-5.0	2.0-9.0	2.5-5.0	2.0-5.0	3.0-5.5	2.5-4.5	1.0-7.5
C18:1 (n-7) vaccenic acid	na	na	na	na	na	na	2.0 – 7.0
C18:1 (n-9) oleic acid	5.0-13.0	4.0-17.0	16.0-17.5	17.5-40.0	12.0-21.0	3.5-12.0	10.0-25.0
C18:2 (n-6) linoleic acid	ND-2.0	0.2-4.5	1.5-2.0	2.5-11.0	0.5-1.5	0.5-2.0	ND-3.0
C18:3 (n-3) linolenic acid	ND-7.0	ND-3.0	11.5-14.0	0.5-6.0	ND-1.0	ND-2.0	ND-2.0
C18:3 (n-6) γ-linolenic acid	ND-5.0	ND-1.0	5.0-5.5	ND-0.5	1.0-2.5	ND-1.0	ND-4.0
C18:4 (n-3) stearidonic acid	ND-5.0	ND-3.5	2.0-2.5	0.5-1.5	1.0-2.5	1.5-5.0	ND-2.0
C20:0 arachidic acid	na	0.2-1.5	na	na	na	na	ND-2.5
C20:1 (n-9) eicosenoic acid	ND-4.0	ND-2.5	4.5-6.0	1.5-7.0	2.0-2.5	0.5-2.0	ND-2.5
C20:1 (n-11) eicosenoic acid	ND-4.0	3.0-4.0		0.5-7.0		0.5-2.0	ND-3.0
C20:4 (n-6) arachidonic acid	ND-2.0	ND-3.0	5.0-5.5	ND-1.0	0.5-1.5	0.5-4.0	ND-3.0
C20:4 (n-3) eicosatetraenoic acid	ND-2.0	ND-1.0	14.0-16.5	0.5-2.0	0.5-1.0	0.5-2.5	ND-1.0
C20:5 (n-3) eicosapentaenoic acid	5.0-25.0	8.0-25.0	8.5-9.5	6.0-9.0	5.0-24.0	11.0-18.5	2.5-9.0

C21:5 (n-3) heneicosapentaenoic acid	ND-4.0	ND-1.0	ND-1.0	ND-0.5	ND-0.5	0.5-1.0	ND-0.5
C22:0	na	0.44	na	na	na	na	na
C22:1 (n-9) erucic acid	ND-5.0	ND-4.5	4.0-6.0	ND-4.0	ND-1.0	ND-0.5	ND-1.0
C22:1 (n-11) cetoleic acid	ND-5.0	ND-4.1		0.5-7.0		ND-0.5	ND-1.0
C22:5 (n-3) docosapentaenoic acid	ND-4.0	1.0-4.0	2.5-3.0	1.5-5.0	2.0-3.5	1.5-4.0	ND-3.0
C22:6 (n-3) docosahexaenoic acid	4.0-23.0	2.5-14.0	10.5-11.0	3.0-14.5	8.0-23.0	4.0-14.5	21.0-42.5
Phospholipid fraction	na	na	na	na	na	na	na

na = not available
ND = non-detect

(Table 1 continued)

Fatty acids	**Krill**	**Squid**	**Pollock**	**Herring**	**Capelin**	**Sand Eel**	**Cod Liver**
C14:0 myristic acid	ND-9.5	1.0-6.0	4.0-5.5	3.0-10.0	5.0-8.0	5.5-8.5	2.0-6.0
C15:0 pentadecanoic acid	ND-0.3	ND-1.0	ND-0.5	ND-0.5	ND-0.5	ND-0.5	ND-0.5
C16:0 palmitic acid	6.0-18.5	10.0-20.0	8.0-11.0	8.0-25.0	8.0-13.0	10.5-13.5	4.0-14.0
C16:1 (n-7) palmitoleic acid	ND-5.5	1.0-8.0	9.0-12.0	3.5-12.0	5.0-10.0	5.0-7.0	4.5-11.5
C17:0 heptadecanoic acid	ND-2.0	ND-1.0	ND-1.0	ND-0.5	na	ND-0.5	na
C18:0 stearic acid	0.5-2.0	1.0-6.0	1.0-2.0	0.5-4.0	0.5-2.0	0.5-2.0	1.0-4.0
C18:1 (n-7) vaccenic acid	na	na	na	na	na	na	2.0 – 7.0
C18:1 (n-9) oleic acid	2.5-11.0	6.0-25.0	7.0-13.5	4.0-16.0	13.0-18.0	6.5-9.0	12.0-21.0
C18:2 (n-6) linoleic acid	ND-2.0	ND-2.0	0.5-1.5	ND-2.0	1.0-2.0	0.5-1.5	0.5-3.0
C18:3 (n-3) linolenic acid	ND-1.5	ND-2.0	ND-0.5	ND-2.0	0.5-1.0	0.5-1.5	ND-2.0
C18:3 (n-6) γ-linolenic acid	ND-0.5	ND-1.0	ND-0.5	ND-2.0	na	na	na
C18:4 (n-3) stearidonic acid	ND-3.5	ND-3.0	1.0-2.0	1.0-5.0	2.0-4.5	2.5-5.5	0.5-4.5
C20:0 arachidic acid	na	na	na	na	na	na	na
C20:1 (n-9) eicosenoic acid	ND-3.5	ND-7.0	4.0-5.5	8.5-14.0	15.0-20.0	10.0-14.5	1.0-17.0
C20:1 (n-11) eicosenoic acid	ND	ND-13.0	10.0-16.0	na	na	na	1.0-5.5
C20:4 (n-6) arachidonic acid	ND-1.5	ND-3.0	na	ND-0.5	ND-0.5	ND-0.5	ND-1.5
C20:4 (n-3) eicosatetraenoic acid	ND-1.0	ND-2.0	0.3-0.5	ND-1.5	ND-1.0	ND-1.0	ND-2.0
C20:5 (n-3) eicosapentaenoic acid	> 9.0	7.0-15.0	9.5-11.0	4.0-15.0	4.0-9.0	7.0-9.5	7.0-16.0
C21:5 (n-3) heneicosapentaenoic acid	ND-2.0	ND-1.0	na	ND-1.0	ND-1.0	ND-1.0	ND-1.5
C22:1 (n-9) erucic acid	ND-2.0	ND-3.0	0.5-1.5	na	na	na	ND-1.5
C22:1 (n-11) cetoleic acid	ND-2.0	2.0-10.0	11.5-15.5	11.0-21.0	13.0-20.0	14.5-18.0	5.0-12.0
C22:5 (n-3) docosapentaenoic acid	ND-2.5	0.5-3.0	0.5-1.0	ND-1.5	ND-1.0	ND-1.0	0.5-3.0
C22:6 (n-3) docosahexaenoic acid	> 4.0	12.5-34.5	4.5-5.5	2.0-12.0	2.5-8.0	7.0-10.0	5.0-18.0
Phospholipid fraction	> 30.0	na	na	na	na	na	na

na = not available
ND = non-detect

KENYA

Kenya would like to thank the Electronic working group for the work done to facilitate codex work and ease commenting on the document.

We would like to submit the following comments and request the chair to consider our comments while conducting the plenary discussion for there will be no Kenyan delegate in this Codex Fats and Oil meeting due to unavailabilty of funds.

Comment: 2.4.1

We accept as is accept the caluse as is and propose the opening of the opening and closing brackets .Nationally we have no problem meeting these targets from clause 2.4.1-7.3

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]

Comment on 2.5.1

We accept as is accept the caluse as is and propose the opening of the opening and closing brackets.

2.5.1 Concentrated fish oil contains ~~[~~40 to 60 w/w % ~~]~~ fatty acids as sum of EPA and DHA, at least 50 w/w % of fatty acids are in the form of triacylglycerides.

Comment 2.5.2

We accept as is accept the caluse as is and propose the opening of the opening and closing brackets.

Comment 2.5.2

We accept as is accept the caluse as is and propose the opening of the opening and closing brackets

2.5.2 Highly concentrated fish oil contains greater than ~~[~~ 60 w/w % ~~]~~ fatty acids as sum of EPA and DHA, at least 50 w/w % of fatty acids are in the form of triacylglycerides.

Comment2.5.3

We accept as is accept the caluse as is and propose the opening of the opening and closing brackets

2.5.3 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

Comment on 2.5.4

We accept as is accept the caluse as is and propose the opening of the opening and closing brackets

2.5.4 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

Comment 2.6.2

We accept the temperature mentioned herein .if the oil is heated above this then it will not be called virgin oil it will lose its properties.

2.6.2 Virgin fish oils have been treated by heating not exceeding ~~[~~70°C~~]~~, ~~–~~washing with water, settling, filtering and centrifugation only. They may contain antioxidants and pigments naturally present in the raw material.

Comment 2.6.3:

We accept as is accept the caluse as is and propose the opening of the opening and closing brackets

2.6.3 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.

3.2 Quality parameters

Note: this section does not apply to oils described in Section 2.6.1 and flavoured fish oils where the added flavourings will interfere with the analytical determination of oxidation parameters.

Comment on 3.2.1

Kenya propose to remove the square bracket and accept it the way it is.

Justification:

there is correlationship between the total oxidation value and peroxide value and anisidine value which are related to food safety and quality.

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)5 ≤ 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 ≤ 20 mg KOH/g

Peroxide value ≤ 5 meq/kg

Comment 3.3

Kenya accepts the vitamins the way they are if sold as a final product. We propose the brackets to be opened.

3.3[Vitamins

Fish liver oils (Sections 2.3 and 2.4) shall comply with following:

Vitamin A ≥ 40 µg of retinol equivalents/ml

Vitamin D ≥ 1.0 µg/ml]

Comment on 7.3

We propose the value to be declared on the label so we propse the word'shall' to replace 'may' in the text mentioned below. In other words it will be mandatory to declare the labelling.

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]~~ shall be given.

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

MALI

Le Mali adresse ses remerciements à la Suisse pour la préparation de l'Avant-projet de norme pour les huiles de poisson. Il n'a pas d'observations particulières sur le document de travail et est favorable à sa progression à la prochaine étape de la procédure.

THAILAND

Thailand would like to express our appreciation for good work of the electronic working group led by Switzerland in the preparation of the Proposed Draft Standard for Fish Oils for the Committee's consideration. We recognized the need for the elaboration of the Codex Standard for Fish Oil and support the initiation of this work. However, we would like to take this opportunity to give some comments on this document as follows:

Specific Comments

We acknowledge the importance of the Proposed Draft Standard for Fish Oils to provide a reference to the government to ensure fair practices and consumer's protection. However, we are of the opinion that EPA and DHA content should be given on the labeling not only in concentrated fish oils but also for all types of fish oil products. Therefore, Section 7.3 Other labelling requirements should be read as follows;

7.3 Other labelling requirements

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