European Union comments

CODEX COMMITTEE ON FATS AND OILS
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Agenda Item 3:

PROPOSED DRAFT STANDARD FOR FISH OILS
(CX/FO 13/23/3)

Mixed Competence
European Union Vote

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) 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 Brevoortia).

**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.

3.3.1 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)\(^5\) \(\leq\) 26 30

**EUMS comments:**

Is the upper value for ToTox correct?

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

Oligomers: \(\leq 1.5\%\) for fish oils and liver oils (Sections 2.1 – 2.4)

\(\leq 3\%\) 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 \(\leq 20\ mg\ KOH/g\)
- Peroxide value \(\leq 5\ meq/kg\)

3. 3.4 [Vitamins

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

- Vitamin A \(\geq 40\ \mu g\ of\ retinol\ equivalents/ml\)
- Vitamin D \(\geq 1.0\ \mu g/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

Ph Eur 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.