CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 3

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#### JOINT FAO/WHO FOOD STANDARDS PROGRAMME

#### CODEX COMMITTEE ON FATS AND OILS

#### **Twenty-forth Session**

#### Melaka, Malaysia, 9 – 13 February 2015

#### COMMENTS ON PROPOSED DRAFT STANDARD FOR FISH OILS

#### (Comments of Brazil, Chile, Costa Rica, Iceland, India, Japan, Kenya, Malaysia, Norway, Thailand, Unites States of America, IADSA, IFFO and ISDI)

#### BRAZIL

#### **General Comments**

First of all, Brazil would like to thanks Switzerland for the work developed and for the opportunity to present its comments. Secondly, we support the approach used by Switzerland to categorize and to establish the named fish oils that are more relevant in international market and therefore should be included in the proposed draft standard. On the other hand, we would like to express our concern about the fatty acids profiles of these named fish oils especially regarding the way they are expressed. We think that before the ranges are established it is important to assure that the data presented in the electronic working group (eWG) can be considered equivalent in terms of expression units and methodology.

Regarding the recommendations in the report of the electronic working group we would like to present the following comments:

- a. Brazil agrees that the minimum content of the sum of EPA and DHA for unnamed / not specified fish oils (section 2.2) should be established in the standard since fish oils are used as an important source of these fatty acids. As a proposal, Brazil suggests that the minimum amount should be defined according to the minimum sum of EPA and DHA result considering all datasets of fatty acids composition provided in the eWG.
- b. Brazil agrees that only sections 3.1, 6.1 and 7.2 are applicable to crude oils.
- c. Regarding the proposed ranges of fatty acids for anchovy oil, cod liver oil, and tuna oil (Table 1),Brazil would like to ask for clarification if the datasets are comparable, because in the tables with the datasets each result is expressed in a different manner (% fatty acids, % area). It is not clear how these data were obtained. It seems that the minimum and maximum of each specie was considered to establish the ranges but it is necessary to clarify the methodology used to establish the proposed ranges.
- d. Considering the rationale used to build this proposed draft standard, Brazil understands that for coherence it is not appropriate to include the definition of devitaminised fish liver oil in the proposed draft standard since there were not trade or vitamin levels data presented to justify its inclusion. In this sense, the processes applied to devitaminise should not be included as well.
- e. Brazil agrees with the proposal of an own subsection 2.6 for the ethyl esters at an equal level to the concentrated fish oils, since they are distinct products.
- f. Considering the rationale used to build this proposed draft standard, Brazil understands that for coherence the definition of Extra low oxidised fish oils (Section 2.7.2) should not be included in the proposed draft standard since there were not trade or other parameters data presented to justify its inclusion.

#### Specific Comments

#### 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.

<u>Comments</u>: Brazil considers that the expression "are primarily composed of" is more appropriate because fish oils ethyl esters are basically fatty acids ethyl esters.

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. For named fish oils the fatty acid profiles (Table 1) shall apply.

**<u>Comments</u>**: Brazil asks for clarification about the need to include the phrase "except when that can be confusing for the consumer" since this is useless and raises opportunity for interpretation if no parameter to define what is "representative of major fish or shellfish taxon" is included. To be in line with item 2.3, Brazil suggests including the following phrase: "For named fish oils the fatty acid profiles (Table 1) shall apply" to this item.

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]

**Comments**: Considering the rationale used to build this proposed draft standard, Brazil understands that for coherence it is not appropriate to include the definition of devitaminised fish liver oil in the proposed draft standard since there were not trade or vitamin levels data presented to justify its inclusion. Moreover, it is not clear what is the purpose of this product since fish liver oils are used because their contents of vitamins A and D.

**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.

**Comments**: Brazil agrees with the range proposed for the sum of EPA and DHA for concentrated fish oils.

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

<u>Comments</u>: Brazil agrees with the minimum value proposed for the sum of EPA and DHA for highly concentrated fish oils.

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

<u>Comments</u>: Brazil considers that the expression "are primarily composed of" is more appropriate because fish oils ethyl esters are basically 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

<u>Comments</u>: Brazil agrees with the levels as sum of EAP and DHA proposed for concentrated fish oil ethyl ester and highly concentrated fish oil ethyl ester.

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.]

<u>Comments</u>: Considering the rationale used to build this proposed draft standard, Brazil understands that for coherence the definition of Extra low oxidised fish oils (Section 2.7.2) should not be included in the proposed draft standard since there were not trade or other parameters data presented to justify its inclusion.

#### 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 <u>alkali/acid treatments and repeated removal of the water phase.</u> Fish oils may also be subjected to processing steps (e.g. solvent extraction, saponification, re-esterification, trans-esterification).]

<u>Comments</u>: Brazil proposes to delete this item because this information narrows the possibilities of new processing development and does not necessarily contribute to the quality and safety of fish oils. Moreover, other Codex Standards do not specify processing stages with such details as these.

#### 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) <sup>1</sup>	≤ 26	
[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)]	

3.2.2 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  $\leq 5 \text{ meq/kg}$ 

<u>Comments</u>: Brazil would like to highlight that the flavoured fish oils were not defined before in the standard as well as the oils with a high phospholipid concentration. So it is necessary to evaluate if these definitions should be included on section 2 or if these exceptions really need to be included in this section.

Additionally, Brazil would like to ask for clarification about the data used to define the oxidation parameters proposed on item 3.2.1. Considering the peroxide value specifically, the Codex Stan 19/1981, which includes at the present moment fish oils, defines the maximum of 10meq/kg as peroxide value and the proposed value (≤5meq/kg) is much lower than that. So it is necessary to check if there are analytical data that support the proposed levels.

Regarding anisidine parameter, Brazil understands and agrees with the importance of this parameter to evaluate the oxidation process. On the other hand, it is necessary to consider that this analysis is very difficult to perform and the risk of some reagents involved in this analysis.

About the oligomers, Brazil asks for clarification about its necessity since oligomers formation significantly changes physical and sensory aspects of the oil.

Finally, Brazil asks for clarification about the acid value proposed for fish oils with a high phospholipid concentration and asks if this is for crude oil, since this value (30mg KOH/g) is too high for a refined oil.

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

<sup>&</sup>lt;sup>1</sup>Total oxidation value (ToTox) = 2 x Peroxide value + Anisidine value

Total oxidation value  $(ToTox)^2 \le 5$ 

[Oligomers: ≤ 0.5 %]

**Comments**: In line with the suggestion included on item 2.7.2, Brazil suggests to delete this item.

#### 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  $\geq$  40 µg of retinol equivalents/ml
- Vitamin D ≥ 1.0 µg/ml]

<u>Comments</u>: Brazil would like to ask for clarification about the data used to establish the minimum levels for vitamins A and D in fish liver oils.

#### 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 in food category 02.1.3 Lard, tallow, fish oil, and other animal fats.

[The flavourings used in products covered by this standard should comply with the Guidelines for the use of flavourings (CAC/GL 66-2008).]

<u>Comments</u>: Brazil does not agree with the inclusion of astaxanthin in this section since this substance is not included in the GSFA, and therefore it is not considered a food additive. Moreover, astaxanthin is the name of a substance and in this section only the technological function of the additives should be included.

Brazil does not agree to keep the note between brackets in this section because item 2.7.1 already defines which sections are applicable to crude fish oils.

#### 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."]

**<u>Comments</u>**: Brazil agrees with the proposed section, but does not agree to keep the note in this section because item 2.7.1 already defines which sections are applicable to crude fish oils.

Brazil would like to ask for clarification if limits of veterinary drugs are applicable to fish oils.

#### 7 [Labelling

#### 7.1 Name of the food

The product shall be labelled in accordance with the Codex General Standard for the Labelling of Prepackaged 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 may be given.]

**<u>Comments</u>**: Brazil agrees with the proposed section with the following comments.

Regarding item 7.3, Brazil agrees with the use of the expression "may" because like this, the declaration of vitamin A and D will be optional. In the same way, Brazil thinks that the declaration of DHA and EPA content is also optional for concentrated fish oils, and the expression "may" should be also used in the last sentence. Like this, this section will be in coherence with the Guidelines on Nutrition Labeling (CAC/GL 2-1985).

Nutrient declaration is defined as a standardized statement or listing of the nutrient content of a food and it is considered a component of nutrition labeling. This tool is applied with public health purposes. It provides consumers with a profile of public health relevant nutrients contained in the food so that a wise choice can be made.

The list of nutrients that is always declared when nutrition labeling is required does not include EPA, DHA, vitamin A or vitamin D. These nutrients were not considered of public health relevance in the recent review conducted by CCFL. Additionally, it should be noted that the Guidelines on Nutrition Labeling requires the declaration of the amount of any nutrient for which a nutrition or health claim is made.

#### **COSTA RICA**

Costa Rica agradece la solicitud efectuada, sin embargo en este momento no emite comentarios.

#### **CHILE**

PROPOSED DRAFT CODEX STANDARD FOR FISH OILS	
<b>1 Scope</b> 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 <i>Code of Practice for Fish and Fishery Products</i> (CAC/RCP 52-2002). This standard applicate fish side used and	
2003)1. This standard only applies to fish oils used in food and in food supplements where those are regulated as foods.	
1 <i>Fish:</i> Any of the cold-blooded (ecothermic) aquatic vertebrates. Amphibians and aquatic reptiles are not included. <i>Shellfish:</i> Those species of aquatic molluscs and crustaceans that are commonly used for food.	
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.	
<ul> <li>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.</li> <li>2.1.1 Anchovy oil is derived from species of the genus <i>Engraulis</i> (<i>Engraulidae</i>).</li> <li>2.1.2 Tuna oil is derived from the species of the genus <i>Thunnus</i> and from the species <i>Katsuwonus pelamis</i> (<i>Scombridae</i>).</li> <li>2.2 Fish oils (unnamed) may be derived from a single species</li> </ul>	
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 <b>Named fish liver oils</b> 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 <b>Cod liver oil</b> is derived from the species <i>Gadus morhua</i> ( <i>Gadidae</i> ).	

Although a detailed description of the process in section 2.7.2 is not necessary, the definition of this type of product could be appropriate depending on its importance (e.g. quantities traded). In this point , it is worthwhile noting that it would be
necessary to change the structure of the document in order to give most coherence at the classification of the different types of fish oils, according to their raw matherials or further processing. Thus, Chile proposes to change the structure of the section 2, as follows 2. Description 2.1. General description-definition of fish oil in general 2.2. Unnamed fish oils 2.3. Named Fish oil 2.3.1. According to species or specific part of fish used as raw material 2.3.2. According to processing (named- unnamed by spp) 2.3.2.1. Crude fish oil 2.3.2.3. Concentrated Oil 2.3.2.4. Fish oil undergone to further processing Should improve the definition of refined oil making it more general. This class definition should indicate that the refined fish oil is the product obtained crude

	processes, maintaining its original structure of triglycerides. This may involve degumming, neutralization, washing, drying, bleaching and eventually winterizing. These processes allow removal non triglycerides substances like phospholipids from crude oil, resins, proteinaceous components, free fatty acids, pigments, unsaponifiables, soaps, trace metals, free water, oxidation products, sulfur compounds and substances non triglycerides (International Fishmeal & Oil Manufacturers Association "IFOMA" GUIDELINES FOR CHARACTERISING FOOD- GRADE FISH OIL; International Association of Fish Meal Manufacturers "IAFMM" FISH OIL BULLETIN NO.17).
3 [Essential composition and quality factors	It is necessary to remove all ranges of fatty acid
3.1 <b>GLC ranges of fatty acid composition</b> (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.	content related to certain species. Fatty acids profiles it seems not to be a property given by the species used as raw material, However, taking into account the importance of differentiate some species or certain organs of fish used as raw materials and the difficulties to use a chemical criteria to ensure this condition, Chile considers that this condition must be ensured through official certification, based on catching and/or processing control. This should be the current method used by the exporters to guarantee the nature of raw materials for fish oils and should be maintained, at least, until a more effective method based on the properties of final product is developed. Additionally, given that that fish oil from wild-catch composed 100% by a single species is rare, some criterion based on minimum proportion of certain species as raw material must be considered.
3.2 Quality parameters	New definitions in terms of processes, which should
<ul> <li>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.</li> <li>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</li> </ul>	specify quality parameter is feasible to use crude, refined or other oils by category or processing received view comments.
concentration shall comply with the following:	
Acid value ≤ 3 mg KOH/g Peroxide value ≤ 5 meg/kg	
Anisidine value $\leq 20$	
Total oxidation value (ToTox)2≤ 26	
2 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)]	
3.2.2 Fish oils with a high phospholipid concentration such as krill oil or squid oil, shall comply with the following: Acid value ≤ 30 mg KOH/g	
Peroxide value $\leq 5 \text{ meq/kg}$	
3.2.3 Extra low oxidised fish oils Section 2.7.2 shall comply with the following:	
Total oxidation value $(ToTox)2 \le 5$	
[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: V termin $A > 10$ up of ratio loguitudente (m)	
Vitamin A $\ge$ 40 µg of retinol equivalents/ml	

Vitamin D ≥ 1.0 µg/ml]

4 Food Additives	As well justified why should not these apply to section
[Note: this section does not apply to oils described in Section 2.7.1]	2.7.1 .
Antioxidants, [sequestrants, antifoaming agents and astaxanthin] used in accordance with Tables 1 and 2 of the <i>Codex General Standard of Food Additives</i> (CODEX STAN 192- 1995), in food category 02.1.3 Lard, tallow, fish oil, and other animal fats. CX/FO 15/24/3 10	
[The flavourings used in products covered by this standard should comply with the <i>Guidelines for the use of flavourings</i> (CAC/GL 66-2008).]	
5 Contaminants	As well justified why should not these apply to section
[Note: this section does not apply to oils described in Section 2.7.1]	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 <i>General Principles of Food</i> <i>Hygiene</i> (CAC/RCP 1-1969), the <i>Code of Practice for Fish and</i> <i>Fishery Products</i> (CAC/RCP 53-2003), and <i>Code of Hygienic</i> <i>Practice for the Storage and Transport of Edible Oils and Fats in</i> <i>Bulk</i> (CAC/RCP 36-1987).	
6.2 Microbiological criteria	As well justified why should not these apply to section
[Note: this section does not apply to oils described in Section 2.7.1]	2.7.1 .
The products should comply with any microbiological criteria established in accordance with the <i>Principles for the Establishment and Application of Microbiological Criteria for Foods</i> (CAC/GL 21-1997).	
7 Labelling	
7.1 Name of the food	
The product shall be labelled in accordance with the <i>Codex</i> <i>General Standard for the Labelling of Pre-packaged Foods</i> (Ref. CODEX STAN 1-1985). The name of the fish oil shall conform to the descriptions given in Section 2 of this Standard. <b>7.2 Labelling on non-retail containers</b>	
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 [ <i>may</i> ] 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).CX/FO 15/24/3 11	
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)]	

#### ICELAND

Iceland would like to comment on the following topics:

- 2.31 Definition of cod liver oil.
- 8.1 Determination of fatty acid composition.
- 8.3 Determination of Arsenic.
- Table 1 Fatty acid profile.

#### Definition of cod liver oil

Iceland supports that cod liver oil should be one of the named fish oils, based on tradition and volume traded. However the current wording of article 2.3.1 is not in line with existing standards that have defined cod liver oil (e.g. European Pharmacopoeia). The current description is:

2.3.1 Cod liver oil derived from the species Gadus morhua (Gadidae).

Iceland would like to suggest a broader description of cod liver oil and proposes the following description:

2.3.1 Cod liver oil is derived from the fresh liver of wild cod, *Gadus morhua* L and other species of *Gadidae*.

This would make the description in line with the European Pharmacopoeia (Ph. Eur) and the US Pharmacopeia (USP). This is also in line with other named fish oils in the Codex standard for fish oils, i.e. referring to genus instead of species.

The definition of cod liver oil in the Ph.Eur is as follows:

Purified fatty oil obtained from the fresh liver of wild cod, Gadus morhua L and other species of Gadidae.<sup>2</sup>

The definition of cod liver oil in the USP is as follows:

Cod liver oil is the partially destearinated fixed oil obtained from fresh liver of *Gadus morhua* Linné and other species of Fam. Gadidae.<sup>3</sup>

The latter definition is supported by existing standards and tradition. One important factor is that a broader definition as suggested will support the better utilization of fish liver since otherwise oils from the liver of other cod fishes (such as Pollock, haddock and Pacific cod) would not be utilized for human consumption.

#### Determination of fatty acid composition

Iceland would like to suggest that a reference to other comparable methods would also be included in article 8.1.

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). Other analytical methods can also be used if they have been shown to produce comparable results as the methods above.

#### **Determination of Arsenic**

The methods suggested for the determination of arsenic refer to total arsenic while the limits in CODEX-STAN 193-1995 are based on risk assessment of inorganic arsenic. The levels of total arsenic in oils of for example whole herring, capelin and blue whiting will exceed the maximum limit of CODEX-STAN 193-1995 (0,1 mg/kg: Edible fats and oils not covered by individual standards) if no specific measures are taken to remove their natural content of total arsenic. Arsenic in marine oils as in seafood in general is mostly bound in the naturally occurring and nontoxic compound arsenobetaine. However, the content of these oils of inorganic arsenic will most likely not exceed this limit. It is therefore suggested that a method on inorganic arsenic will be accommodated in the standard or a limit will be stipulated specifically for total arsenic in marine oils.

#### Fatty acid profile

Iceland would like to propose that the fatty acid profile for the cod liver oil should be in harmony with existing standards (Ph.Eur and USP). The fatty acid profiles from these standards have widely been used in trade for decades. The changes proposed are to the limits for C16:0, C20:1 (n-9) and C22:6 (n-3) which thus become those of Ph.Eur and USP.

**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	7.0-14.0	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

<sup>&</sup>lt;sup>2</sup> European Pharmacopoeia 8.0. page 1950

<sup>&</sup>lt;sup>3</sup> US Pharmacopeia 34 page 2424

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	5.0-17.0	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	6.0-18.0	21.0-42.5

na = not available

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

#### **INDIA**

#### **General Comment:**

India appreciates the opportunity to comment on the proposed draft Standard for Fish Oil. The draft Standard will enable local manufacturers/marketers to upgrade skills and capabilities and lead to purer and better quality products to be produced locally.

The Working Group has developed several questions for the consideration of the Committee which have been included in paragraph 33. Replies to these are provided below:

33a. 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?

### It is necessary to have EPA/DHA limit for unnamed fish oil. The combined EPA plus DHA limit can be put as 18-35% of total fatty acids.

33b. 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?

### For crude fish oils other sections are not required as it is difficult to establish any quality parameters or contaminant level for this category.

33.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 submitted. 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.

### The Fatty acid composition range as provided in the standard is in order and there is no need for modification, removal or addition as the Fatty Acid ranges are based on the data submitted.

33.d Is it appropriate to mention processes applied to devitaminize fish oils described in Section 2.4.1?

#### Not necessary.

33. 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.

#### Agreed.

33.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?

#### To justify the claim of extra-low oxidised fish oil, separate quality criteria must be provided.

#### Taking into account the above, our specific comments are provided below:

#### **Specific Comments:**

#### Section 2: Description

**Para 2.2:** Fish oil (unnamed) may be derived from a single species of fish other than the ones listed in Section 2.1 or to be a mixture of fish oils derived from specified and or/ unspecified source materials.

### India would request the committee to clarify on the term "unspecified" source materials in the Fish Oil Definition.

#### Para 2.8 (iii) Fish off cuts and offal from the processing industry.

India expects that this category has to be clearly demarcated when it comes for human consumption as food. If this has to be allowed, then it has to be allowed only after the safety is proven.

#### **Section 3.2 Quality Parameters**

#### Para 3.2.1: Acid Value ≤ 3mg KOH/g

India feels that such low value as Acid Value is not possible so request the Committee to clarify the value proposed.

#### Para 3.2.1: Oligomers: ≤1.5% for fish oils and liver oils

India feels that Oligomers are not formed at the temperature ranges (90-95 °C and even to 180 °C) at which fish oils are currently processed.

#### Section 3.3 Vitamins

India requests the Committee to mention the value of Vitamin E also along with the other Vitamins.

#### **Section 7 Labelling**

Para 7.2:- Labelling on Non-Retail Containers: 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.

India seeks clarification on the term used "an identification mark".

#### Para 7.3:- Other labelling requirements

India feels that declaring the content of Vitamin A or D should be made mandatory along with DHA and EPA. However, it should also be declared for Raw fish oils.

The label should also declare that the product has its own odour and a neutral taste.

#### Section 8 Methods of Analysis and Sampling

#### Para 8.7:- Determination of Oligomers

India seeks clarification for the text used "Information missing" under Determination of Oligomers

#### <u>JAPAN</u>

Comments are generally presented below in **bold font** (addition) and strike through font (deletion).

#### Specific Comments

#### 1 Scope

#### Proposed text:

This standard only applies to fish oils used in food and in food supplements where those which are regulated as foods in accordance with laws and regulations of the country where the product is sold.

#### Rationale:

In order to clarify that some of food supplements, in which fish oils are used, might be regulated as foods, while others be regulated as drugs or medicines even within a country.

#### 2.2 Fish oils (unnamed)

#### Comments:

Japan considers fish oils which are categorized under this section should be simply labeled as "Fish oil" because "(unnamed)" may cause confusion of consumers or retailers

#### 2.5 Concentrated fish oil

#### Proposed text:

Concentrated fish oils means oils intended for human consumption, are 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.

#### Rationale:

It is clearly stated in the Scope that this Standard applies only to the fish oils intended for human consumption.

#### 2.5.1 Concentrated fish oil

#### Proposed text:

Concentrated fish oil contains [4035 to 6050 w/w %] fatty acids as sum of EPA and DHA, at least 70 w/w % of fatty acids are in the form of triacylglycerides.

#### Rationale:

It should be noted that the figures indicated in the text are not fatty acid compositions but weight/weight percent (w/w %). As glycerin is contained in fish oils, when a fatty acid composition is 40% as sum of EPA and DHA, its w/w % is less than 40. Thus, it is appropriate to use 35 instead of 40, and 50 instead of 60.

#### 2.5.2 Highly concentrated fish oil

#### Proposed text:

Highly concentrated fish oil contains greater than  $\frac{6050}{100}$  w/w % fatty acids as sum of EPA and DHA, at least 70 w/w % of fatty acids are in the form of triacylglycerides.

#### Rationale:

Please see comment on the section 2.5.1 above.

#### 2.6.1 Concentrated fish oils ethyl esters

#### Proposed text:

Concentrated fish oil ethyl ester contains fatty acids as esters of ethanol of which and [40 to 60 w/w %] are fatty acids as sum of EPA and DHA

#### Rationale:

It should be clarified that 40 to 60 w/w % of all fatty acids, not of fatty acids as esters of ethanol, should be EPA and DHA. This is consistent with the definition of "2.5.1 Concentrated fish oils".

#### 2.6.2 Highly concentrated fish oils ethyl esters

#### Proposed text:

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

#### Rationale:

It should be clarified that 60 w/w % or more of all fatty acids, not of fatty acids as esters of ethanol, are EPA and DHA. This is consistent with the definition of "2.5.2 Highly concentrated fish oils".

#### 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.]

#### Comments:

We are afraid that the volume of international trade of extra low oxidized fish oils is too small to be standardized. It would be really appreciated if their trade information are provided.

#### Proposed new category:

2.8 Flavoured fish oil is derived from fish oils described in Section 2.1 to 2.7, to which flavourings are added.

#### Rationale:

"Flavoured fish oil" described in Section 3.2 should be set out in Section 2 "Description".

#### 2.8 Processing

#### Proposed text:

2.89 [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, fish market or retail shops.

#### Rationale:

Fish oils are also produced from fish off cuts and offal from fish market and retail shops.

#### 3.1 GLC ranges of fatty acid composition

#### Proposed text:

Samples falling within the appropriate ranges specified in Table 1 may be referred to confirm that samples are in compliance with this Standard.

#### Rationale:

The works of Switzerland and the EWG for analyzing fatty acid composition are really appreciated. However, we are still afraid that the numbers of analytical data were not sufficient to cover all of GLC ranges of fatty acid composition of fish oils which are internationally traded. Under the current provision, even when only one of analytical data is only 0.1% out of the range in Table 1, the fish oil can no longer be categorized as "Named fish oils". In order to avoid any potential or unnecessary disputes in the international trade of "Named fish oils", the Table should be used just as a reference until more analytical data are collected.

Alternatively, if such a table is used to confirm compliance with the Standard, the fatty acids included in the table should be limited to major fatty acids (e.g. Fatty acids that could be contained more than 5%).

### <u>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:</u>

#### Proposed text:

[Oligomers:  $\leq 1.5$  % 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)]

#### Rationale:

Oligomers are produced during long-term high temperature treatment. Fish oils do not go through such treatment since they are easily oxidized. Peroxide value and Anisidine value are more suitable parameters since their values increase before those of oligomers start increasing. Actually, the analysis of Oligomers is not common in our country; there is no laboratory that is regularly performing its analysis. As a result, requiring the analysis of Oligomers will put much economic burden on fish oil industries as they have to order its analysis overseas frequently.

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

#### (1) Comments:

"Fish oils with a high phospholipid concentration such as krill or squid oil" are not defined in the Section 2. If different quality parameters are set for those fish oils, they should be clearly defined in the Section 2.

#### (2) Proposed text:

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

#### Anisidine value

#### ≤ X

#### Total oxidation value (ToTox) $\leq X$

#### Rationale:

If different quality parameters are set for "Fish oils with a high phospholipid concentration such as krill or squid oil", the parameters of Anisidine value and ToTox should also be included.

#### 4 Food Additives

#### Proposed text:

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

#### Antioxidant

INS	Additive Name	Maximum level
300	Ascorbic acid, L-	GMP
304	Ascorbyl palmitate	2500 mg/kg
307a, b, c	Tocopherols	15000 mg/kg, singly or in combination
310	Propyl gallate	200 mg/kg
322 (i)	Lecithin	GMP

#### Emulsifier

INS	Additive Name	Maximum level
322 (i)	Lecithin	GMP
471	Mono- and di-glycerides of fatty acids	GMP

In addition, Antioxidants, [sequestrants, [and antifoaming agents and astaxanthin] can be 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.

[The flavourings used in products covered by this standard should comply with the Guidelines for the use of flavourings (CAC/GL 66-2008).]

#### Rationale:

(1) Deletion of square brackets of the first sentence

Food additives are not used for crude fish oils.

(2) Addition of the list of antioxidant

Since fish oils, which contain more unsaturated fatty acids, are more easily oxidized than other food products in food category No. 02.1.3, the maximum levels of antioxidants should be separately set. Also, antioxidants that are not included in Tables 1 and 2 for food category No. 02.1.3 are currently used by industries.

(3) Addition of the list of emulsifier

Emulsifiers are indispensable to keep antioxidants emulsified with in fish oils.

(4) Deletion of astaxanthin

Astaxanthin has not been evaluated by JECFA and thus should not be included in the Standard.

#### Comment:

For antifoaming agents, technical justifications for their use should be provided.

#### 5 Contaminants

#### Proposed text:

[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).-]

#### Rationale:

The levels of contaminants may change during refinement process of crude oils and thus, the Section should

be applied to final products.

The general reference to GSCTFF should be included.

#### 6.2 Microbiological criteria

#### Proposed text:

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

#### Rationale:

The levels of microorganisms may change during refinement process of crude oils and thus, the Section should be applied to final products.

#### 7.3 Other labelling requirements

#### Proposed text:

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.

#### Rationale for deletion:

Since Vitamin A and vitamin D are not main compounds of deep sea shark liver oils, the labeling of their content should not be mandatory.

#### **KENYA**

#### 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.

#### Comment:

We propose the word 'contain' to be deleted.

#### Justification:

'The primarily compost of' means that is the main higher percentage of components.

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-2.4.1:

We accept it the way it is and proposed to remove the opening and closing the brackets. Justification: Once the vitamins are devitaminised, the limits will not meet the declared requirements.

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.

#### Comment:

The concentration fish oil depends on the type of fish so the committee needs to collect data on these types of fish so the range can be determined and implemented appropriately.

[The flavourings used in products covered by this standard should comply with the *Guidelines for the use of flavourings* (CAC/GL 66-2008).]

### <u>Comment</u>: we propose that it is in order to use the Guidelines for the use of flavourings (CAC/GL66-2008 where necessary so we propose to remove the open and closed square brackets

#### **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."]

#### COMMENT: we have no objection to the above statements under 'Contaminants"

#### 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).

#### <u>COMMENT</u>: we have no objection to the above statements under General hygiene.

#### 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 Prepackaged 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)-

### <u>COMMENT</u>: we have no objection to the above statements so we propose to remove the open and closed square brackets

#### 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).

### <u>COMMENT</u>: we have no objection to the above statements so we propose to remove the open and closed square brackets

#### 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)

### <u>COMMENT</u>: we have no objection to the above statements so we propose to remove the open and closed square brackets

#### 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).

<u>COMMENT</u>: we have no objection to the above statements so we propose to remove the open and closed square brackets

#### 8.6 Determination of p-anisidine value

AOCS Cd 18 - 90 (11)]

<u>COMMENT</u>: we have no objection to the above statements so we propose to remove the open and closed square brackets

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)]

### <u>COMMENT</u>: we have no objection to the above statements so we propose to remove the open and closed square brackets

#### MALAYSIA

Firstly, Malaysia would like to commend Switzerland as the Chair of the electronic working group on the Proposed Draft Standard for Fish Oils for the good effort in preparing the improved version of the Proposed Draft Standard for Fish Oils. In general, Malaysia supports the development of this standard in view of the increasing trade of fish oils. Hence, there's a need to ensure consumer protection as well as transparency and fair trade practices.

Malaysia appreciates the opportunity to offer specific comments on the draft standard as outlined below:

#### Section 2 Description

Malaysia notes that for Section 2.1, Named fish oil is described as '... may be derived from ..', while in its subsection it is written as '..is derived..", for example in 2.1.1; *Anchovy oil is derived from species of the genus Engraulis (Engraulidae)*.

We proposed the word "may be" in Section 2.1 to be replaced with the word "is" to correctly address that named fish oil must come from respective specific source. This change is consistent with 2.1 subsections. The proposed amendment is as follows:

2.1 Named fish oils may be is derived from specific source materials;...

Similarly, the word "may be" in Section 2.2, 2.3 and 2.4 shall be replaced with the word "is".

#### Section 2.4.1 Fish liver oil devitaminised and Section 2.7.2 Extra low oxidised fish oils

Malaysia is strongly of the view that only fish oils that are traded internationally in substantial volume should be included in this proposed draft standard. Data provided in Annex I of CX/FO 15/24/3 do not specify the classification of the fish oils. As such, the introduction of specific classification of fish oils to differentiate specific quality characteristic is still premature at this juncture.

If the Committee agrees to include these classifications, maximum or range of Vitamin A and Vitamin D for fish<u>liver</u> oils devitaminised must be included in Section 3.3 Vitamins, to characterise the product. Similarly, the characteristic for Extra low oxidised fish oils shall be established. These characteristics shall be based on substantial scientific data and are important for identification and to avoid misleading consumers.

#### Sections 2.5 Concentrated Fish Oils to 2.5.2

#### Sections 2.6 Concentrated Fish Oils Ethyl Esters to 2.6.2

Malaysia feels that the introduction of specific categories of fish oils is still premature at this juncture. If the Committee agrees to include such categories, we are of the view that the composition of DHA and EPA for fish oils in Section 2.5.1, 2.5.2, 2.6.1 and 2.6.2 should be set based on scientific data and be provided to the Committee.

Once agreed, the composition should be specified clearly in Section 3 of this draft standard for consistency with other Codex standards developed by this Committee such as the Codex Standard for Named Vegetable Oils.

#### Section 3.1 GLC Ranges of Fatty Acid Composition (expressed as percentages of total fatty acids)

As mentioned in our comments on Sections 2.5 and 2.6, the proposed draft standard should specify the EPA and DHA compositions of these types of oils in this Section. This is for consistency with other Codex standards such as Codex Standard for Named Vegetable Oils.

#### **Section 5 Contaminants**

Contaminant is one of the most important requirements that should be specified in this standard. Referring to Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF), Malaysia note that there is no specific provision pertaining to fish oil. Nevertheless, there are two (2) parameters which referred to CS 19-1981 *Edible fats and oils not covered by individual standards* which may be applicable to fish oil. i.e. Arsenic at 0.1mg/kg and Lead at 0.1mg/kg. Malaysia would like to seek confirmation on this matter.

We are of the view that the main contaminants associated with fish oils are arsenic, lead, cadmium, mercury, dioxins, furans and polychlorinated biphenyls. As such, Malaysia proposes to include cadmium, mercury, dioxins, furans and polychlorinated biphenyls in Section 5 Contaminants and the maximum levels for these contaminants be established by the Committee.

#### Section 7.3 Other labelling requirements

#### Vitamin A and D

Malaysia is of the view that even though deep sea shark liver oil is proposed to be excluded from the minimum requirement for Vitamin A and D in Section 3.3, the content for both Vitamin A and D must be declared on the label if it is present. This is particularly important to give information to consumer that is susceptible to other supplements such as pregnant woman, in order to avoid excessive intake. Therefore, Malaysia proposes amendment as follows:

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.

#### DHA and EPA

It is important for consumers' information and safety to know the DHA and EPA content in all types of fish oil. Therefore, Malaysia proposes to amend as follows:

For concentrated fish oils (Section 2.5) For fish oils (Section 2) the content of DHA and EPA shall be given.

#### Source of Fish Oil

Malaysia proposes the origin i.e. the common name of the fish/es where the oil is derived be declared on the principal display panel of the product. Where common name might differ between countries, scientific name shall be provided. This requirement is to be inserted under Section 7.3 Other labelling requirements as follows:

For fish oil (unnamed), the common name of fish where the oil is derived shall be declared on the principal display panel. Where common name might differ, scientific name shall be provided.

All together, Section 7.3 is proposed to be amended as follows:

#### 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) For fish oils (Section 2) the content of DHA and EPA shall be given.]

# For fish oil (unnamed), the common name of fish where the oil is derived shall be declared on the principal display panel. Where common name might differ, scientific name shall be provided.

#### NORWAY

(See Annex I for data submitted by Norway)

Norway did participate in the electronic working group (eWG). Due to time constraint it was not possible to discuss and include all the eWG member's latest comments to the draft, and therefore Switzerland asked us to resubmit our comments and additional data as comments to the 24<sup>th</sup> CCFO. We would have preferred that these issues had been discussed in the eWG.

Please accept Norway's comments to proposed draft standard for fish oil, CX/FO 15/24/3. Because of the above mentioned reason, we have quite a few specific comments.

#### (i) General Comments

Norway mainly supports the document and the joint effort to develop a common standard on this subject.

Based on the time constraint explained above, we would like to suggest using track changes when presenting the deleted parts of the proposed draft Codex Standard for fish oils. This will make it easier for the delegates not part of the eWG to follow our discussions.

The entire section 2 Description in the proposed draft Codex Standard for fish oils, from section 2.1 and through the whole section as it was shown in the 23<sup>rd</sup> CCFO in 2013, should probably be in square brackets. This is stated in paragraph 49 in REP13/FO.

#### (ii) Specific Comments

NEW SECTION 2.1.3 FARMED SALMON OIL

#### 2.1.3 Farmed salmon oil is derived from the family Salmonidae

Rationale: This oil should be kept as a named fish oil.

3 000 tons farmed salmon oil are produced and traded internationally through Norway, as shown in "Data collection for named fish oils – Norway – Sept2014.docx" resubmitted with this response. The trade data are quality assured to ensure that this is human consumption only.

We have also resubmitted "6 datasets for farmed salmon oil – fatty acid profile – Sept2014.xlsx".

In addition, salmon oil is a highly valuable oil, and there have been several occasions of fraud regarding this oil. Mixtures of other oils are added the right color, and sold as farmed salmon oil. Including farmed salmon oil as a named oil in the standard will serve to limit the amount of forgeries. The same applies to krill oil, as described below.

#### NEW SECTION 2.1.4 KRILL OIL

#### 2.1.4 Krill oil is derived from Euphasia superba

Rationale: This oil should be kept as a named fish oil.

Approximately 1 000 tons of krill oil are produced and traded internationally, as shown in "Data collection for named fish oils – Norway – Sept2014.docx" resubmitted with this response. The trade data are quality assured to ensure that this is human consumption only.

We have also resubmitted "12 datasets for krill oil – fatty acid profile – Sept2014.xlsx".

As we have pointed out earlier, the marine raw material that forms the basis for fish oil production is a limited resource. Nevertheless, the trade and consumption of these products are increasing. Krill is yet a resource with much untapped potential and the krill oil production are experiencing a massive growth. In fact, krill oil has had a 30 % yearly increase in sale since 2010. International or regional market potential is one of the criteria stated in the Codex Alimentarius Commission Procedural manual, regarding criteria applicable to commodities.

The total value of krill oil sold in 2013 was 119 mills USD, and in comparison the total value of for instance tuna oil sold were 109 mills USD. Krill oil is thus a highly valuable oil. This has resulted in several occasions of fraud regarding krill oil. Mixtures of other oils are added the right color, and sold as krill oil. Including krill oil as a named oil in the standard will serve to limit the amount of forgeries. The same applies to farmed salmon oil, as described above.

#### SECTION 2.3 NAMED FISH LIVER OILS

Named fish liver oils may be derived from the livers of fish and are composed of fatty acids, <u>and</u> vitamins <del>or other components</del> 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.

Rationale: Cod liver oils is the most traditional marine oil, and has been on the marked for more than hundred years. The natural content of vitamins is the main characteristic for liver oils distinguishing them from other marine oils. Vitamins are an essential characteristic. To our knowledge other components are not an essential characteristic, if so, they should be identified.

This is also stated in paragraph 45 in REP13/FO.

[SECTION 2.7.2 EXTRA LOW OXIDISED FISH OILS]

Rationale: Norway does recommend keeping this section on extra low oxidized fish oils as it is, without square brackets. Extra low oxidized fish oils should be in a separate category, in the same way that the concentrated and highly concentrated oils are.

**NEW SECTION 2.9 RAW MATERIALS** 

#### 2.9 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).

Rationale: To include a new section on raw materials is stated in paragraph 53 in REP13/FO.

According to the Codex Alimentarius Commission Procedural manual the section regarding description should contain a definition of the product or products with an indication, where appropriate, of the raw materials from which it is derived and any necessary references to processes of manufacture. This makes section 2 appropriate for the text regarding raw materials.

[SECTION 3 ESSENTIAL COMPOSITION AND QUALITY FACTORS]

Rationale: Norway does recommend keeping this section on essential composition and quality factors as it is, without square brackets. These parameters are necessary to ensure trading with good quality oil, and to prevent fraud.

SECTION 4 FOOD ADDITIVES, SECTION 5 CONTAMINANTS, SECTION 6.2 MICROBIOLOGICAL CRITERIA

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

(...)

Rationale: Norway does recommend keeping this note at the beginning of Section 4, 5 and 6.2 as it is, without square brackets.

Crude fish oils and crude fish liver oils are oils intended for human consumption only after they have undergone further processing, refining and purification. This makes regulating additives, contaminants and microbiological criteria excessive, as it is what's left after this rough treatment that matter.

Keeping the notes will make the text easier to understand.

#### SECTION 7.3 OTHER LABELLING REQUIREMENTS

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

Rationale: The standard has separate groups for cod liver oil, fish liver oil and fish liver oil devitaminised. For Section 2.3.1 and 2.4 (with the exemption of 2.4.1) it is essential to keep requirements for vitamin A and D as an essential composition factor. Liver oils have been on the market for more than hundred years, and the natural content of vitamins is the main characteristic for liver oils distinguishing them from other marine oils. Therefor the labeling of vitamin A and D should be mandatory.

TABLE 1: FATTY ACID (FA) COMPOSITION OF NAMED FISH OIL AND FISH LIVER OIL CATEGORIES

Fatty acids	Anchovy	Cod Liver	Tuna
()			
C20:1 (n-9) eicosenoic acid	ND-4.0	<del>1.0</del>	ND-2.5

(...)

Rationale: The level of the fatty acid C20:1 (n-9) eicosenoic acid is high in cod liver oil, and low in fish oils.

The electronic working group has collected a total of 6 data sets giving fatty acid profiles for cod liver oil, in addition to the European Pharmacopoeia. All of these 6 have a level of C20:1 (n-9) higher than 10.

We therefore suggest following the European Pharmacopoeia by raising the minimum level of this fatty acid to 5.0.

#### 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. 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 provide some specific comments on draft Standard as follows:

#### **Specific Comments**

Section 2 Description

2.8 Processing

Thailand considers that the text refer to temperature during repeated heating should be deleted for consistency with the subsequent process on alkali/acid treatment which also use high temperature.

#### We recommend rewording as follows:

"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)."

Section 3 [Essential composition and quality factors]

#### 3.1 GLC ranges of fatty acid composition

Thailand take note that the specifications for fatty acid profile for fully refined fish oil currently outlined in Section 3.1 of the Proposed Draft Standard. We could generally agree with the opinion of the eWG for the adoption of the proposed specifications for fatty acid composition for Anchovy, Cod liver and Tuna. In our view the current values of these three fish oil in table 1 are so broad and could limited in determining the authenticity of tuna oil.

For these reason, the fatty acid composition in crude and semi refined tuna oil were studied in Thailand in the year of 2013-2014. Recent analysis of 182 samples of crude tuna oil show different fatty acid profiles from refined tuna oil. Considering that refining process may change the fatty acid composition of crude tuna oil, it is suggested not to combine the data of crude tuna oil with refined tuna oil. In our opinion, it is therefore crucial for CCFO to consider incorporate the table 2 for GLC ranges of fatty acid composition of crude tuna oil in section 3.1 as the proposed profile does not reflect crude tuna oil.

The proposed values for crude tuna oil are as follows:

#### Table 2 Fatty acid composition of crude tuna oil (expressed as percentage of total fatty acids)

Fatty acids (% area) (n=182 )	Min	Max	Mean	Proposed range
C14:0 Myristic acid	0.03	3.89	3.35	0.03-3.89
C15:0 Pentadecanoic acid	0.00	1.26	1.09	0.00-1.26
C16:0 Palmitic acid	0.05	23.60	20.55	0.05-23.60
C16:1n7 Palmitoleic acid	0.11	6.18	4.72	0.11-6.18
C17:0 Margaric acid	0.00	1.77	1.23	0-1.77
C18:0 Stearic acid	0.00	6.57	6.04	0-6.57
C18:1n9 Oleic acid	2.16	15.30	11.93	2.16-15.30

C18:1n7 cis-11 Octadecenoic acid	0.00	4.42	1.67	0-4.42
C18:2n6 Linoleic acid	0.53	1.81	1.27	0.53-1.81
C18:3n3 Linolenic acid	0.45	0.88	0.53	0.45-0.88
C18:4n3 cis-6,9,12,15-Octadecatetraenoic acid	0.39	1.12	0.87	0.39-1.12
C20:0 Arachidic acid	0.00	0.64	0.41	0.00-0.64
C20:1n9 cis-11-Eicosanoic acid	0.10	1.99	1.16	0.10-1.99
C20:2n6 cis-11,14-Eicosadienoic acid	0.00	1.94	0.25	0.00-1.94
C20:4n6 Arachidonic acid ,AA	1.01	2.04	1.81	1.01-2.04
C20:4n3 cis-8,11,14,17-Eicosatetraenoic acid	0.34	0.52	0.42	0.34-0.52
C20:5n3 cis-5,8,11,14,17-Eicosapentaenoic acid, EPA	4.50	6.30	5.35	>4.0
C22:5n6 cis-4,7,10,13,16-Docosapentaenoic acid	1.51	2.64	1.92	1.51-2.64
C22:5n3 cis-7,10,13,16,19-Docosapentaenoic acid	0.82	1.32	1.06	0.82-1.32
C24:0 Lignoceric acid	0.00	0.42	0.07	0.00-0.42
C22:6n3 cis-4,7,10,13,16,19-Docosahexaenoic acid, DHA	23.34	27.20	25.49	> 23.0

### Note : Method of analysis: AOCS (2001) CE-1B-89 for 177 samples and In-house method based on AOAC (2010) 963.22 for 5 samples

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

### We would like to seek clarification on the criteria for classification of high phospholipid which we cannot find this term elsewhere of the proposed draft standard.

4. Food Additive and 5. Contaminants

We support removing square bracket of the first sentence of this section. This sentence would be read as follows:

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

#### 7.3 Other labelling requirements

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;

For <u>all concentrated fish oils (Section 2.5.)</u> the content of DHA and EPA shall be given.

#### UNITED STATES OF AMERICA

#### **GENERAL COMMENTS**

The United States (U.S.) supports the development of the proposed Draft Standard for Fish Oil. The U.S. supports including anchovy and cod liver oil as named fish oils based on available trade data; the U.S. would also support including other named fish oils (e.g., tuna, salmon) if adequate trade data is available. Furthermore, the U.S. supports including a category named "unspecified fish oils and fats" based on available trade data. The U.S. recommends additional discussion on fatty composition for named fish oils to determine limits that take into account variability that may occur due to climatic conditions and seasonality, geographical location, etc.

#### SPECIFIC COMMENTS

**Section 2.5.1 Concentrated Fish Oil:** The U.S. recommends that for concentrated fish oils, the minimum % fatty acids in the form of triglycerides be changed from 70% to 50%. This was the value originally included in the draft Standard and more accurately represents what is traded internationally.

Section 2.5.2 Highly Concentrated Fish Oil: The U.S. recommends that for highly concentrated fish oils,

the minimum % fatty acids in the form of triglycerides be changed from 70% to 50%. This was the value originally included in the draft Standard and more accurately represents what is traded.

**Section 8 Method of Analysis and Sampling:** The U.S. recommends that CCMAS review the listed methods to confirm that they are appropriate.

**Table 1 Fatty Acid Composition:** U.S. recommends additional discussion on fatty composition for named fish oils to determine limits that take into account variability that may occur due to climatic conditions and seasonality, geographical location, etc.

#### INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS (IADSA)

#### Section 2.1 Named fish oils

Referring to paragraph 18 of the discussion paper CX/FO 15/24/3, IADSA supports that salmon oil is included in the standard for fish oils as a named fish oil as the trade of salmon oil has gained significant importance in recent years as it is currently traded in considerable quantities. In addition, as IADSA considers that Codex standards are very instrumental for the development of high quality standards and regulations at regional and national level, IADSA believes that the inclusion of salmon oil in the standard for fish oils would contribute to ensure that genuine salmon oil is present on the market and avoid the commercialization of adulterated and misbranded salmon oils currently also present in some markets.

In this regard, IADSA proposes the inclusion of a new section:

"2.1.3 Wild salmon oil or farmed salmon oil are derived from wild or farmed fish respectively of the family Salmonidae; Salmon oil is a mixture of oils derived from wild and farmed fish."

IADSA would also like to take this opportunity to provide additional data on salmon oil for consideration by the Committee. The following table provides data from two lots of wild salmon oil (i.e. Sockeye Salmon) from catch zone 67:

Named Fish Oil		Wild Sockeye Salmon	Wild Sockeye Salmon
Catch Date		July 2011	July 2012
Analysis Date		December 2012	January 2013
Catch Zone		67	67
Fatty Acids		%	%
C14:0	Myristic acid	3.80	3.96
C15:0	Pentadecanoic acid	0.53	0.50
C16:0	Palmitic acid	16.07	13.69
C16:1 (n-7)	Palmitoleic acid	4.51	5.67
C17:0	Heptadecanoic acid	not analyzed	not analyzed
C18:0	Stearic acid	2.68	2.42
C18:1 (n-7)	Vaccenic acid	not analyzed	not analyzed
C18:1 (n-9)	Oleic acid	17.65	17.17
C18:2 (n-6)	Linoleic acid	1.87	1.60
C18:3 (n-3)	Linolenic acid	0.93	0.79
C18:3 (n-6)	γ-Linolenic acid	0.10	<0.1
C18:4 (n-3)	Stearidonic acid	2.11	1.35
C20:0	Arachidic acid	0.19	<0.1
C20:1 (n-9)	Eicosenoic acid	not analyzed	not analyzed
C20:1 (n:11)	Eicosenoic acid	not analyzed	not analyzed
C20:4 (n-6)	Arachidonic acid	0.28	<0.1
C20:4 (n-3)	Eicosatetraenoic aicd	1.41	1.04
C20:5 (n-3)	Eicosapentaenic acid	8.19	6.92
C21:5 (n-3)	Heneicosapentaenoic acid	not analyzed	not analyzed
C22:0	Docosanoic acid	not analyzed	not analyzed
C22:1 (n-9)	Erucic acid	1.14	1.40
C22:1(n-11)	Cetoleid acid	not analyzed	not analyzed

C22:5 (n-3)	Docosapentaenoic acid	1.77	1.55
C22:5 (n-6)	Docosapentaenoic acid	not analyzed	not analyzed
C22:6 (n-3)	Docosahexaenoic acid	7.24	6.17

Furthermore, as indicated in paragraph 19 of the discussion paper CX/FO 15/24/3, krill oil is widely used in food supplements, and as the standard applies to food supplements, IADSA supports the inclusion of krill oil in the standard for fish oils under a new section:

"2.1.4 Krill oil is derived from the family Euphausiidae (mainly Antarctic)."

#### Section 2.2 & Paragraph 33.a: Minimum content of EPA/DHA

Other than concentrated and highly concentrated fish oils, IADSA considers that a minimum content of EPA+DHA is not necessary for unnamed fish oils. IADSA recommends stipulating that the labelling clearly indicates the content of EPA+DHA for concentrated and highly concentrated fish oils.

#### Section 2.3.1 Cod liver oil

It has been brought to our attention that, whilst the draft standard defines cod liver oil as being derived from the species *Gadus morhua*, it has been common commercial practice for a number of years to include liver oils from other species in the Gadidae family (for example, *Pollachius pollachius and Pollachius virens*). Inclusion of only *Gadus morhua* may not represent the breadth of globally marketed cod liver oil.

Many countries specify which fish genus and species can be called cod and many countries specify which genus and species can be used in a product marketed as cod liver oil. For example, in the United States, the Food and Drug Administration's Seafood List<sup>4</sup> is a searchable guide to acceptable market names for seafood sold in interstate commerce.

In Canada, cod liver oil sold as a Natural Health Product can include any of the following: Liver of Atlantic cod, *Gadus morhua* L. (Gadidae), Liver of Greenland cod, *Gadus ogac* Richardson (Gadidae), Liver of Pacific cod, *Gadus macrocephalus* Tilesius (Gadidae), Liver from Arctic cod, *Arctogadus glacialis* Peters (1872) (Gadidae), and Liver from all species of Gadidae (Cod family).

Liver oil for *Pollachius pollachius* (Pollock) and *Pollachius virens* (Saithe) apparently can commonly occur in oils being traded as cod liver oil. As P. pollachius and P. virens are a common by-catch with Gadus morhua, liver oils from these two species in particular, form a significant proportion of oil traded as cod liver oil in Europe. This issue is further compounded by the monograph for cod liver oil in the European Pharmacopeia (EurPh), which defines cod liver oil as:

"Purified fatty oil obtained from the fresh livers of *Gadus morhua* L. and other species of Gadidae, solid substances being removed by cooling and filtering. A suitable antioxidant may be added."

In the absence of a current international food standard, Pharmacopeial monographs have been considered by the fish oil industry to be international authoritative references.

Experience over many years has shown that it is almost impossible to differentiate between the fatty acid profiles for pure cod liver oil and those for cod liver oil containing liver oils from other Gadidae species.

In this regard, IADSA proposes that the section is amended as follows:

"2.3.1 Cod liver oil is derived from the species-Gadus morhua (Gadidae) of the family Gadidae."

#### Section 2.5.1 (Concentrated fish oil) & Section 2.5.2 (Highly concentrated fish oil)

IADSA proposes to keep as follows the original amount of concentrated fish oils at least 50 w/w % of fatty acids in the form of triacylglycerides, which is more representative of the concentrated fish oils present on the market. In this regard, IADSA proposes the following amendments:

"2.5.1 **Concentrated fish** oil contains [40 to 60 w/w %] fatty acids as sum of EPA and DHA, at least  $\frac{70}{50}$  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  $\frac{70}{50}$  w/w % of fatty acids are in the form of triacylglycerides."

#### Section 2.6 and Paragraph 33.e: Concentrated fish oils ethyl esters

IADSA agrees with the inclusion of Section 2.6 as suggested in paragraph 33.e of the discussion paper.

<sup>&</sup>lt;sup>4</sup><u>http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=seafoodlist&sort=SLMNMM&order=ASC&startrow=251&type</u> <u>=basic&search</u>

#### Section 2.7.1 Crude fish oils and crude fish liver oils

IADSA proposes the following editorial amendments for better clarity of the sentence:

"<u>Named</u> crude fish oils and <u>named</u> crude fish liver oils have to comply with Section 3.1. <u>All</u> crude fish oils and crude fish liver oils have to comply with sections 6.1 and 7."

The reason for this is that section 3.1 relates only to named fish oils specified in Table 1.

In addition, IADSA supports that crude fish oils and crude fish liver oils should also comply with Section 4, thus:

"<u>Named</u> crude fish oils and <u>named</u> crude fish liver oils have to comply with Section 3.1. <u>All</u> crude fish oils and crude fish liver oils have to comply with sections <u>4</u>, 6.1 and 7."

#### Section 3.2 Quality Parameters

IADSA proposes the following amendments in the introductory Note:

"...added flavourings will may interfere with the analytical determination of oxidation parameters..."

The reason is that not all flavourings interfere with the measurement of oxidation.

#### Section 3.3 Vitamins

IADSA recommends that the levels of **vitamins A and D** are expressed as a range of minimum-maximum levels that most resemble the levels naturally present in fish liver oil (i.e., prior to processing). These vitamins are commonly added back into the final liver oil product to account for loss during processing and should be subject to maximum limits, similar to the restoration principles per CAC/GL 09-1987 for the addition of essential nutrients to food.

#### Section 4 Food Additives

IADSA would like to take this opportunity to comment on the level of tocopherols (INS 307) as an antioxidant in fish oils.

The Codex General Standard of Food Additive (GSFA) currently has the provision for tocopherols (INS 307) in category 02.1.3 Lard, tallow, fish oil and other animal fats at a level of 300mg/kg that is currently being held at Step 7 and will be discussed at the 47th session of the Codex Committee on Food Additives (CCFA) in March 2015.

IADSA believes a much higher level of tocopherols should be required for fish oil. Unlike some vegetable oils, fish oils do not naturally contain anti-oxidants such as tocopherols, and fish oils are less stable due to their polyunsaturated nature. The stability of fish oil depends on the degree of unsaturation / omega-3 concentration, which varies according to the type of fish oil considered. Therefore setting a low level at 300mg/kg to control the stability of various fish oils is not technologically possible. IADSA is currently evaluating the necessary levels to maintain the stability of fish oil. Further data will be shared once available.

Current regulations of Tocopherols around the world include the European Union for example, where *Commission Regulation No 1129/2011* on food additives stipulates that Tocopherols can be added to non-emulsified oils and fats (including fish oils) at Quantum Satis levels.

IADSA strongly suggests CCFO and CCFA consider more data and technical justifications on the level of tocopherols for fish oils.

#### Section 8 Methods of Analysis and Sampling

#### General Comment:

IADSA proposes that alternative equivalent methods should be also accepted. This allows for future improvements in methodology. Feedback from industry has highlighted that there may already be more appropriate methods of analysis that should be considered. In view of the complexity of the issue, IADSA proposes that Codex Committee on Methods of Analysis and Sampling (CCMAS) is consulted for recommendation of appropriate methods.

#### Section 8.2 Determination of Arsenic

Section 8.2 of the draft currently provides three analytical methods for the determination of <u>arsenic</u>. It has been observed that, for the determination of arsenic in fish oils, the three proposed methods cannot be considered to be directly equivalent. As such, they cannot necessarily be used for a proposed upper limit value, as experience has shown that they may give markedly different results with very different analytical tolerances.

#### Section 8.6 Determination of p-anisidine value

The draft standard only includes one method (AOCS Cd 18 - 90 (11)). While this method may be appropriate, we question the limitations and whether it is the only appropriate method.

#### Section 8.7 Determination of oligomers

Care must be taken with the specification of methodology to be used, as many techniques may be outside the available resources of the control laboratories in a number of the Codex member countries.

#### Table 1 & Paragraph 33.c: Fatty Acid (FA) composition of named fish oils and fish liver oil categories

IADSA considers that some fatty acids have very narrow ranges, e.g. C21:5 (n-3) for tuna oil, ND-0.5. A range of only 0.5% seems too tight. IADSA proposes at least a 2 percentage point range for each fatty acid to take into account variations by seasons, diet, and regions, among other aspects.

However, IADSA is of the concern that the usefulness or adequacy of Table 1 could be questioned. Adulteration of products is always possible by just by adding EPA, DHA or other fatty acids to meet the specified ranges. Further discussion is necessary in order to identify which fatty acids are necessary for each of the named fish oils. This will require more work, but will result in a more robust and equitable standard.

Other methods such as using traceability data, isolation of DNA from fish oil and Nuclear Magnetic Resonance (NMR) exist, and these could be considered once they become validated, more widely available, and within the resources of all Codex participating countries.

#### THE MARINE INGREDIENTS ORGANISATION (IFFO)

#### (See Annex II for data submitted by IFFO)

IFFO represents fishmeal and fish oil producers and related industries. IFFO's members account for over 50% of world production and 75% of the fishmeal and fish oil traded worldwide. IFFO appreciates the opportunity to put forward comments from the fish oil industry with regards to the proposed draft report of the eWG and the proposed draft Codex Standard for fish oils.

IFFO appreciate the work that has been done in drafting the Codex standard for fish oil. IFFO did participate in the eWG but unfortunately our comments could not be included into the draft due to time constraints and we are therefore re-submitting our comments and additional data to the 24<sup>th</sup> CCFO. Although we generally agree with the proposed draft standard we would like to submit additional information that we have received.

#### Trade data and named fish oils:

- i. Menhaden oil is produced in the USA in significant volumes of 60,000 80,000 tons per year. The majority (up to 75%) is exported and a significant volume up to 2,000 tons is used for direct human consumption. It is foreseen that the volume used for direct human consumption will increase markedly in the next few years. Fatty acid profile data of menhaden oil is submitted in an attachment. (paragraph 12 Draft report of the eWG)(See Annex II)
- ii. Although Krill oil is not one of the fish oils traded in high volume of ≥10,000, the unique properties and its market presence oil along with increasing awareness of krill oil warrants its inclusion in the standard as a named fish oil if sufficient fatty acid profile data sets have been obtained. (paragraph 16 Draft report of the eWG to include krill oil)

#### Other:

- i. 2. Description: IFFO suggests that the raw material should include by-products from fish processing.
- ii. 2.7.2 Extra low oxidized fish oils: IFFO does not feel that this category should be included as it is not represented in significant volumes in the industry. The Quality parameters for this category as listed in section 3.2.3 should also be deleted.
- iii. 3.2.2 Fish oils with a high phospholipid concentration such as krill oil or squid oil, shall comply with the following:
  - ≤ 30 mg KOH/g ≤ 5 meq/kg

**IFFO comment:** The Acid Value method and level is not relevant for Fish Oils with high Phospholipid concentration like Krill oil, as the carotenoids interfere with the end point titration. This is also the reason that Acid value has been removed by the new USP/FCC krill oil monograph.

#### INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

#### **Background**

Fish oil is produced and trade internationally. This oil is mainly used to provide DHA in food such as formula for infants and young children.

A clear CODEX standard will help insuring consumer protection and facilitate international trade by avoiding that different countries develop their own regulations (e.g. China, Indonesia...).

The new work was accepted by the CAC in 2011.

The proposal was thoroughly discussed during the CCFO meeting in 2013 in Langkawi, Malaysia, without achieving any real progress.

The matter will be on the agenda of the upcoming 24th CCFO session, which will take place in Melaka, Malaysia, from the 9th until the 13th February 2015.

Switzerland is chairing an e-WG working on the draft that will be further discussed in a physical WG in Melaka before the meeting.

#### ISDI strongly support the development of this standard

#### E-wg report

Switzerland, which leads the eWG, has compiled data and comments further to the last CCFO session in 2013, and has presented them in a report to be discussed in Meleka.

The International Special Dietary Foods Industries (ISDI), representing the associations of manufacturers of special dietary foods at CODEX Alimentarius, thanks the Swiss delegation of for their work and welcomes the progress made to clarify the draft standard.

It is crucial for our industry that significant progress is made in 2015 in order to get a standard as soon as possible.

ISDI would like to draw your attention on the following comments on the recommendations:

#### 1. Paragraph 32 of the e-WG report

Comments on the proposed draft Codex Standard for Fish Oils (Annex II) shall be provided taking into account the previous deliberations of the 23rd CCFO (REP13/FO) and the discussion of the eWG summarized above. Codex members shall 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.

#### ISDI strongly supports removal of square brackets for the following sections:

- 2.8 Processing
- 3 Essential composition and Quality factors
- 7 Labelling

#### 2. Paragraph 33

33. The eWG proposes that following issues shall be discussed specifically by the physical working group 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 an minimum content in EPA/DHA. If needed, what level would be appropriate?

**b**. For crude oils (Section 2.7.1) only some parts of the standard shall be applicable. These are: Sections3.1 (GLC ranges of fatty acid composition), 6.1 (General hygiene) and 7 (Labelling). Shall 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) specific quality criteria that separate this category from other fish oils have been proposed by one member. Are these suitable parameters to distinguish it from other fish oils? Should this category be include in the standard?

ISDI fully supports sections a. b. c.

ISDI doesn't support the inclusion of category 'Extra Low oxidized Fish Oils' in section f

#### ANNEX I

 Table 1 6 datasets for farmed salmon oil - fatty acid profile - Sept2014

		Codex draft (if available)	Species for all 6 datasets	Farmed Salmon Oil	Farmed Salmon Oil	Farmed Salmon Oil	Farmed Salmon Oil	Farmed Salmon Oil	Farmed Salmon Oil
		salmon	farmed salmonids	Norway	Norway	Norway	Norway	Norway	Norway
		-	mainly Atlantic salmon ( <i>Salmo</i> <i>salar</i> ) but also Rainbow trout ( <i>Oncorhychis</i> <i>mykiss</i> )	May 2014	Dec. 2013	Sep-14	Feb-14	May 2014	2014
		-	as raw materials are not separated	May 2014	Dec. 2013	Sep-14	Feb-14	May 2014	2014
		-		farmed	farmed	farmed	farmed	farmed	farmed
	Method of analysis:	-		GC-FID	GC-FID	GC-FID	GC-FID	GC-FID	GC-FID
	Source of data:	CX/FO 13/23/3	Internal Testing	Internal Testing	Internal Testing	Internal Testing	Internal Testing	Internal Testing	Internal Testing
	Units:	%	all analysis are performed at a accredited laboratory	% of total FA	in g FA og 100g oil	in g FA og 100g oil			
	ID Code			1	2	3	4	5	6
Fatty acids									
C14:0	Myristic acid	2.5-5.5		2.0	2.0	2.0	2.0	1.9	1.9
C15:0	Pentadecanoic acid	ND-0.5		0.1	0.1	0.2	0.1	0.1	0.09
C16:0	Palmitic acid	7.0-16.5		7.9	7.9	7.7	7.4	7.4	6.9
C16:1 (n-7)	Palmitoleic acid	3.0-8.0		2.8	2.4	2.6	2.4	2.6	2.2
C17:0	Heptadecanoic acid	ND-0.5		0.3	0.3	0.1	0.2	0.1	0.19
C18:0	Stearic acid	2.0-5.0		2.2	2.3	2.2	2.2	2.1	2.1
C18:1 (n-7)	Vaccenic acid	na		not analyzed	not analyzed	not analyzed	not analyzed	not analyzed	not analyzed
C18:1 (n-9)	Oleic acid	16.0-40.0		44.8	44.4	44.3	44.8	42	42
C18:2 (n-6)	Linoleic acid	2.5-11.0		13.8	13.7	13.9	14.1	13	13
C18:3 (n-3)	Linolenic acid	0.5-6.0		4.9	5.0	5.2	5.0	4.6	4.7
C18:3 (n-6)	γ-Linolenic acid	ND-0.5		0.1	0.1	0.1	0.1	0.1	0.09
C18:4 (n-3)	Stearidonic acid	0.5-1.5		0.7	0.6	0.7	0.6	0.66	0.56
C20:0	Arachidic acid	na		0.3	0.3	0.3	0.3	0.28	0.28
C20:1 (n-9)	Gadoleic acid	1.5-7.0		4.6	4.6	4.0	4.7	4.3	4.4
C20:1 (n:11)	Eicosenoic acid	0.5-7.0		not analyzed	not analyzed	not analyzed	not analyzed	not analyzed	not analyzed
C20:4 (n-6)	Arachidonic acid	ND-1.0		0.2	0.2	0.2	0.2	0.2	0.2
C20:4 (n-3)	Eicosatetraenoic aicd	0.5-2.0		0.8	0.8	0.8	0.8	0.75	0.75
C20:5 (n-3)	Eicosapentaenic acid	6.0-9.0		2.4	2.1	2.4	2.5	2.3	2.3

#### CX/FO 15/24/3 Add.1

		Codex draft (if available)	Species for all 6 datasets	Farmed Salmon Oil	Farmed Salmon Oil	Farmed Salmon Oil	Farmed Salmon Oil	Farmed Salmon Oil	Farmed Salmon Oil
C21:5 (n-3)	Heneicosapentaenoic acid	ND-1.0		not analyzed	not analyzed	not analyzed	not analyzed	not analyzed	not analyzed
C22:0	Docosanoic acid	na		0.1	0.5	0.2	0.1	0.1	0.09
C22:1 (n-9)	Erucic acid	ND-4.0	analyzed C22:1	3.4	3.2	3.1	3.4	3.2	3.2
C22:1(n-11)	Cetoleid acid	0.5-7.0		not analyzed	not analyzed	not analyzed	not analyzed	not analyzed	not analyzed
C22:5 (n-3)	Docosapentaenoic acid	1.5-5.0		1.3	1.4	1.2	1.3	1.2	1.2
C22:5 (n-6)	Docosapentaenoic acid			<0,1	<0,1	0.1	<0,1	<0,1	0.09
C22:6 (n-3)	Docosahexaenoic acid	3.0-14.5		3.5	3.4	3.6	3.3	3.3	3.1

### Table 2 12 datasets for krill oil - fatty acid profile - Sept2014

	Source of data:	CX/FO 13/23/3	Internal Testing		
	Units:	%	in g FA/100 g of oil		
	ID Code		KRI1		
Fatty acids			Average	Min	Max
C14:0	Myristic acid	ND-9.5	6.3	4.9	7.8
C15:0	Pentadecanoic acid	ND-0.3	0.2	0.1	0.3
C16:0	Palmitic acid	6.0-18.5	13.3	13.0	13.5
C16:1 (n-7)	Palmitoleic acid	ND-5.5	2.6	1.8	4.2
C17:0	Heptadecanoic acid	ND-2.0	na		
C18:0	Stearic acid	0.5-2.0	0.8	0.7	1.1
C18:1 (n-7)	Vaccenic acid	na	8.5	5.9	10.2
C18:1 (n-9)	Oleic acid	2.5-11.0	na		
C18:2 (n-6)	Linoleic acid	ND-2.0	1.2	1.0	1.4
C18:3 (n-3)	Linolenic acid	ND-1.5	1.8	0.7	2.6
C18:3 (n-6)	γ-Linolenic acid	ND-0.5	0.3	0.1	2.1
C18:4 (n-3)	Stearidonic acid	ND-3.5	4.3	2.0	5.4
C20:0	Arachidic acid	na	na		
C20:1 (n-9)	Eicosenoic acid	ND-3.5	0.3	0.2	0.4
C20:1 (n:11)	Eicosenoic acid	ND	na		
C20:4 (n-6)	Arachidonic acid	ND-1.5	0.6	0.5	0.7
C20:4 (n-3)	Eicosatetraenoic aicd	ND-1.0	0.4	0.3	0.5
C20:5 (n-3)	Eicosapentaenic acid	> 9.0	12.8	12.2	13.6
C21:5 (n-3)	Heneicosapentaenoic acid	ND-2.0	0.5	0.3	0.5
C22:0	Docosanoic acid	na	na		
C22:1 (n-9)	Erucic acid	ND-2.0	na		

	Source of data:	CX/FO 13/23/3	Internal Testing		
C22:1(n-11)	Cetoleid acid	ND-2.0	na		
C22:5 (n-3)	Docosapentaenoic acid	ND-2.5	0.3	0.3	0.4
C22:5 (n-6)	Docosapentaenoic acid		na		
C22:6 (n-3)	Docosahexaenoic acid	> 4.0	7.3	6.7	7.8

### 24.9.2014 -- All production numbers are confirmed to only include fish oil for human consumption Data collection for named fish oils

Data collected from (Country name): NORWAY

Please indicate in the table the catch area according to the major fishing areas as defined by FAO (http://www.fao.org/fishery/area/search/en) for each of the named fish oils. In order to designate a fish oil with a specific name, how much oil from the species representative for the named oil is required?

Please keep in mind that the data provided should refer to crude or refined fish oil for human consumption only!

Named fish oil	Common name and the scientific name (genus and species) of fish used to	Catch area Major fishing area as	Production		Internal consumption		Export		Main country exported to	Crude oil	OR Refined oil
	produce the specific named fish oil		Volume in t	Value in USD	Volume in t	Value in USD	Volume in t	Value in USD			
Salmon/ Trout Oil	Atlantic salmon, Salmo salar Rainbow Trout, Oncorhynchus mykiss	farmed	262		260		2		EU		×
Salmon oil	Atlantic salmon Salmo salar, Rainbow Trout, Oncorhynchus mykiss	farmed	3000 This concerns only HC *	5,4 mill	0		3000	5,4	EU	X	
Krill oil Export via Spain after extraction	Euphausia superba	48,1	6-700 Estimated 2014: 800		0		6-700		USA		X
Krill oil Export via USA or New Zealand after extraction	Euphausia superba	48,1	350 Estimated capacity at end of 2014: 1 800		0		250-300		USA/EU		X

\* = Total Norwegian production of salmon oil is approximately 55 000 tons annually.

Fish oil for human consumption Import and export Norway 2012 and 2013 trade statistics according to customs declaration – all values in tons

		2012	2013	2014	Main species
		tons	tons	Total Jan- July	
Import	Total	30 300	23 220	9 304	
Customs tariff 150402031	Fish oil for human consumption				
Major countries	Peru	22 300	15 280		Anchovetas
	Chile	1 800	2 250		Anchovetas
	Morocco	1700	955		Sardine
	USA	200			Menhaden
	Thailand	940	640		Most likely Tuna
	Denmark	920			Most likely transit of anchovetas oil
	Netherlands		865		Most likely transit of anchovetas oil
Export		2012	2013	2014	
				Total Jan- July	
Customs tariff 150402031	Fish oil -total	62 300	59 280	24 082 tons	
Fish oil for human consumption					
Cod liver oil	Cod liver oil for human	Export	Export		
Customs tariff 150401091	consumption	2012: 1 240 t	2013: 1 756 t		

		Та	able Menhader	Fatty Acid Pro	ofiles Data_2014	and 2007-2014	4		
2014 FATTY	ACID PROFILES - FISH OIL								
	Named fish oil:	Menhaden							
	Submitted by:	IFFO							
	Analyses dating from:								
	Catch date:	21/4-26/4	30/4-3/5	5/5-10/5	12/5-17/5	19/5-24/5	26/5-31/5	2/6-7/6	9/6-14/6
	Catch area:	USA Gulf of M	exico and Atlantic			L	I.	1	
	Method of analysis:	AOCS Ce 1b-8	9						
	Source of data:								
	Units:	% area							
	ID Code								
C 8:0	Caprylic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 6:0	Caproic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 10:0	Capric acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 12:0	Lauric acid	0.10	0.12	0.12	0.15	0.14	0.14	0.15	0.13
C 13:0	Tridecanoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 14:0	Myristic acid	9.87	9.56	8.60	9.70	9.70	9.55	10.13	9.32
c 14:1	Myristoleic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 15:0	Pentadecanoic acid	0.47	0.47	0.68	0.50	0.52	0.55	0.52	0.60
C 15:1	Pentadecenoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 16:0	Palmitic acid	18.61	19.07	19.43	19.08	18.94	18.84	18.73	19.36
C 16:1	Palmitoleic acid	11.68	11.64	9.84	12.40	12.20	12.04	12.25	11.62
C 16:2	Hexadecadienoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 16:3	Hexadecatrienoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 16:4	Hexadecatetraenoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 17:0	Margaric acid	0.28	0.28	0.53	0.31	0.32	0.35	0.33	0.42
C 17:1	Margaroleic acid	0.11	0.11	0.16	0.10	0.10	0.11	0.10	0.12
C 18:0	Stearic acid	2.88	2.94	3.57	2.98	2.96	3.00	2.97	3.16
C 18:1n7	Vaccenic acid	2.99	3.02	3.10	3.11	3.09	3.06	3.06	3.06
C 18:1n9	Oleic acid	7.47	7.88	8.21	7.21	6.98	6.52	6.70	6.09
C 18:2n6	Linoleic acid	3.04	2.88	2.37	2.60	2.60	2.54	2.38	2.33
C 18:3n3	alpha-Linolenic	0.62	0.59	0.80	0.69	0.75	1.02	0.80	1.32
C 18:3n6	gamma-Linolenic acid	0.31	0.28	0.26	0.27	0.27	0.28	0.27	0.28
C 18:4n3	Stearidonic acid	2.07	2.07	1.79	2.02	2.17	2.45	2.02	2.60
C 20:0	Arachidic acid	0.20	0.19	0.32	0.27	0.28	0.24	0.27	0.24
C 20:1	Eicosenoic acid	1.47	1.59	1.22	1.55	1.52	1.41	1.50	1.35
C 20:1n9	Gadoleic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10

Annex II

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2014 FATTY A	CID PROFILES - FISH OIL								
C 20:2n6	Eicosadienoic acid	0.61	0.60	0.11	0.58	0.36	0.55	0.55	0.31
C 20:3n3	Eicosatrienoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	0.11	<0.10	0.17
C 20:3n6	homo-gamma-Liolenic acid	0.23	0.22	0.23	0.21	0.22	0.22	0.22	0.22
C 20:4	Arachidonic acid	0.85	0.81	1.22	0.84	0.84	0.85	0.85	0.89
C 20:4n3	Eicosatetaenoic acid	1.07	1.06	0.87	1.09	1.14	1.23	1.13	1.31
C 20:4n5	Eicosatetraenoic	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 20:5n3	Eicosapentaenoic acid	18.26	17.68	14.64	17.24	17.13	16.53	17.25	15.50
C 21:0	Heneicosanoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 21:5n3	Heneicosapentaenoic acid	0.77	0.76	0.62	0.72	0.74	0.74	0.71	0.70
C 22:0	Behenic acid	0.11	0.11	0.17	0.12	0.12	0.13	0.13	0.14
C 22:1n11	Cetoleic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 22:1n9	Erucic acid	0.26	0.25	0.23	0.24	0.24	0.23	0.23	0.23
C 22:2n6	Docosadienoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 22:4n3	Eicosatetraenoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 22:4n6	Docosatetraenoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 22:5n3	Docosapentaenoic acid	2.45	2.39	2.30	2.47	2.49	2.48	2.64	2.52
C 22:5n6	Docosapentaenoic acid	0.21	0.20	0.54	0.21	0.22	0.25	0.23	0.10
C 22:6n3	Docosahexaenoic acid	5.44	5.41	9.54	5.69	5.85	6.69	6.08	7.91
C 23:0	Tricosanoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
C 24:0	Lignoceric acid	<0.10	<0.10	0.13	<0.10	<0.10	<0.10	<0.10	<0.10
C 24:1	Nervonic acid	0.21	0.21	0.33	0.21	0.21	0.21	0.21	0.23
Unknown Com	ponents	7.16	7.45	7.92	7.24	7.50	7.54	7.37	7.65
Total Omega 3	Fatty Acids	30.70	30.00	30.60	30.00	30.30	31.20	30.70	32.00
Total Omega 6	Fatty Acids	5.30	5.10	4.80	4.80	4.80	4.80	4.60	4.20

2014 FAT	TY ACID PROFILES - FIS	SH OIL												
		6/16-6/21	6/23-6/28	6/30-7/5	7/7-7/12	7/14-7/19	7/21-7/26	7/28-8/2	8/4-8/9	8/11-8/16	8/18-8/23	8/25-8/30	9/2-9/6	Averages
C 8:0	Caprylic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 6:0	Caproic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 10:0	Capric acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 12:0	Lauric acid	0.12	0.12	0.13	0.11	0.11	0.11	0.11	0.11	0.11	0.10	0.11	0.10	
C 13:0	Tridecanoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 14:0	Myristic acid	8.50	8.68	8.52	8.21	8.94	8.18	8.77	9.57	9.57	8.55	9.33	9.19	9.12
c 14:1	Myristoleic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 15:0	Pentadecanoic acid	0.64	0.63	0.62	0.68	0.65	0.71	0.67	0.65	0.68	0.74	0.69	0.72	0.62
C 15:1	Pentadecenoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	

2014 FAT	TY ACID PROFILES - FISH	H OIL												
C 16:0	Palmitic acid	20.14	19.87	19.96	20.35	19.81	20.21	19.85	19.62	19.79	20.20	19.47	20.43	19.59
C 16:1	Palmitoleic acid	11.16	11.14	10.90	10.73	11.29	10.76	11.16	11.88	11.73	10.95	11.71	11.27	11.42
C 16:2	Hexadecadienoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 16:3	Hexadecatrienoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 16:4	Hexadecatetraenoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 17:0	Margaric acid	0.47	0.45	0.45	0.53	0.48	0.55	0.51	0.48	0.52	0.59	0.52	0.55	0.45
C 17:1	Margaroleic acid	0.13	0.12	0.12	0.13	0.12	0.13	0.12	0.11	0.11	0.14	0.12	0.13	0.12
C 18:0	Stearic acid	3.29	3.23	3.17	3.37	3.27	3.37	3.32	3.35	3.45	3.54	3.39	3.62	3.24
C 18:1n7	Vaccenic acid	3.02	2.99	2.94	2.96	3.00	2.97	2.98	3.05	3.04	3.02	3.06	3.01	3.03
C 18:1n9	Oleic acid	6.01	5.99	6.10	5.76	6.06	5.52	5.85	6.13	6.11	5.65	5.83	6.05	6.41
C 18:2n6	Linoleic acid	2.21	2.17	2.18	2.12	2.17	2.06	2.08	2.03	1.99	1.93	1.01	1.05	2.19
C 18:3n3	alpha-Linolenic	1.56	1.46	1.48	1.54	1.33	1.62	1.42	1.19	1.22	1.56	1.33	1.43	1.19
C 18:3n6	gamma-Linolenic acid	0.28	0.28	0.31	0.33	0.34	0.32	0.34	0.29	0.29	0.28	0.29	0.29	0.29
C 18:4n3	Stearidonic acid	2.98	2.81	2.92	2.88	2.42	2.89	2.48	2.00	1.96	2.51	2.05	2.17	2.36
C 20:0	Arachidic acid	0.23	0.22	0.22	0.23	0.25	0.23	0.25	0.25	0.28	0.26	0.27	0.30	0.25
C 20:1	Eicosenoic acid	1.36	1.39	1.42	1.31	1.37	1.28	1.34	1.37	1.36	1.29	1.33	1.35	1.39
C 20:1n9	Gadoleic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 20:2n6	Eicosadienoic acid	0.16	0.53	0.53	0.53	0.53	0.50	0.51	0.46	0.46	0.44	0.46	0.42	0.46
C 20:3n3	Eicosatrienoic acid	0.20	0.27	0.25	0.28	0.24	0.29	0.26	0.24	0.22	0.29	0.24	0.26	0.24
C 20:3n6	homo-gamma-Liolenic acid	0.22	0.22	0.21	0.22	0.23	0.22	0.23	0.25	0.24	0.23	0.24	0.24	0.23
C 20:4	Arachidonic acid	0.87	0.87	0.85	0.90	0.96	0.98	1.03	1.10	1.14	1.12	1.08	1.20	0.96
C 20:4n3	Eicosatetaenoic acid	1.45	1.41	1.43	1.47	1.33	1.48	1.34	1.18	1.16	1.37	1.21	1.24	1.25
C 20:4n5	Eicosatetraenoic	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 20:5n3	Eicosapentaenoic acid	13.87	14.02	13.93	13.09	14.16	12.85	13.72	14.49	14.17	12.90	13.87	13.20	14.93
C 21:0	Heneicosanoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 21:5n3	Heneicosapentaenoic acid	0.69	0.70	0.71	0.66	0.67	0.68	0.67	0.66	0.64	0.37	0.64	0.64	0.67
C 22:0	Behenic acid	0.15	0.13	0.13	0.15	0.15	0.16	0.16	0.17	0.17	0.18	0.18	0.19	0.15
C 22:1n11	Cetoleic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 22:1n9	Erucic acid	0.24	0.24	0.25	0.24	0.24	0.24	0.24	0.24	0.23	0.23	0.22	0.23	0.24
C 22:2n6	Docosadienoic acid	<0.10	<0.10	<0.10	<0.10	0.11	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 22:4n3	Eicosatetraenoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	

2014 FAT	TY ACID PROFILES - FISH	I OIL												
C 22:4n6	Docosatetraenoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 22:5n3	Docosapentaenoic acid	2.42	2.51	2.55	2.56	2.68	2.58	2.68	2.77	2.77	2.68	2.77	2.67	2.57
C 22:5n6	Docosapentaenoic acid	0.12	0.32	0.32	0.39	0.37	0.44	0.41	0.41	0.44	0.50	0.45	0.48	0.33
C 22:6n3	Docosahexaenoic acid	8.92	8.63	8.52	9.63	8.55	9.77	8.88	7.85	8.12	9.51	8.37	8.77	7.91
C 23:0	Tricosanoic acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	
C 24:0	Lignoceric acid	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10	0.10	<0.10	<0.10	0.12
C 24:1	Nervonic acid	0.24	0.25	0.23	0.25	0.26	0.25	0.26	0.27	0.26	0.26	0.27	0.26	0.24
Unknown (	Components	8.31	8.20	8.50	8.24	7.84	8.49	8.19	7.63	7.58	8.16	8.96	8.53	7.92
Total Omega 3 Fatty Acids		32.10	31.80	31.80	32.10	31.40	32.10	31.40	30.40	30.20	31.50	30.80	30.30	31.07
Total Omega 6 Fatty Acids		3.90	4.40	4.50	4.50	4.70	4.60	4.70	4.60	4.60	4.50	3.60	3.70	4.54

2007-201	4 Fish Oil Fatty Acid Profile											
	Named fish oil:	Menhaden	Menhaden	en Menhaden Menl	Menhaden	Menhaden	Menhaden	Menhaden	Menhaden		Atlantic Menhaden (Brevoortia Tyrannus)	Gulf Menhaden (Brevoortia patronus)
	Submitted by:	IFFO	IFFO	IFFO	IFFO	IFFO	IFFO	IFFO	IFFO		IFFO	IFFO
	Analyses dating from:											
	Catch date:	14/6-1/11 2007	2/6-17/10 2008	20/4-19/9 2009	17/5-1/10 2010	18/4-1/11 2011	19/4- 1/11 2012	15/4-3/10 2013	21/4-6/9 2014		21/03/2013	21/03/2013
	Catch area:	USA Gulf of	Mexico and A	tlantic		Atlantic, Western- Central; (major fishing area 31); Northwest Atlantic (major fishing area 21)	Atlantic, Western- Central (major fishing area 31)					
	Method of analysis:	AOCS Ce 1	AOCS Ce 1b-89									AOCS Ce 1i- 07
	Source of data:											
	Units:	% area	% area	% area	% area		% area	% area				
	ID Code											
		2007	2008	2009	2010	2011	2012	2013	2014	Average		
C 12:0	Lauric acid	0.14	0.10	0.11	0.13	0.20	0.12	0.10	0.12	0.13		
C 14:0	Myristic acid	9.85	9.65	9.83	9.25	10.29	10.73	9.38	9.12	9.76	9.32	11.40
C 15:0	Pentadecanoic acid	0.71	0.59	0.65	0.63	0.83	0.78	0.63	0.62	0.68	0.88	0.74

#### CX/FO 15/24/3 Add.1

2007-2014	Fish Oil Fatty Acid Profile											
C 16:0	Palmitic acid	19.06	19.92	19.47	19.97	19.15	19.52	19.49	19.59	19.52	17.97	19.53
C 16:1	Palmitoleic acid	11.91	11.92	12.11	11.36	12.32	12.58	12.36	11.42	12.00	11.54	12.14
C 17:0	Margaric acid	0.53	0.36	0.48	0.51	0.60	0.53	0.45	0.45	0.49	0.63	0.47
C 17:1	Margaroleic acid	0.13	0.12	1.00	1.62	1.38	1.19	0.12	0.12	0.71		
C 18:0	Stearic acid	3.28	3.25	3.29	3.51	3.25	3.31	3.26	3.24	3.30	3.27	3.18
C 18:1n7	Vaccenic acid	3.15	3.10	3.17	3.01	3.38	2.96	3.15	3.03	3.12		
C 18:1n9	Oleic acid	8.90	9.47	8.18	8.54	5.77	7.06	6.84	6.41	7.65	6.29	7.28
C 18:2n6	Linoleic acid	1.92	1.60	1.27	1.25	1.28	1.29	1.77	2.19	1.57	1.98	1.39
C 18:3n3	alpha-Linolenic	1.05	0.87	0.99	1.01	1.35	1.10	1.03	1.19	1.07	1.39	0.78
C 18:3n6	gamma-Linolenic acid	2.42	0.39	0.36	0.36	0.39	0.48	0.29	0.29	0.62	0.31	0.35
C 18:4n3	Stearidonic acid	2.24	2.12	2.46	2.26	2.64	2.24	2.17	2.36	2.31	2.67	1.75
C 20:0	Arachidic acid	0.25	0.30	0.28	0.33	0.32	0.33	0.21	0.25	0.28	0.23	0.29
C 20:1	Eicosenoic acid	1.14	1.48	0.90		0.59	0.69	1.69	1.39	1.13	1.02	1.20
C 20:2n6	Eicosadienoic acid	0.17	0.33	0.24	0.26	0.24	0.69	0.29	0.46	0.34		
C 20:3n3	Eicosatrienoic acid	0.19	0.14	0.19	0.16	0.17	0.16	0.15	0.24	0.18		
C 20:3n6	homo-gamma-Liolenic acid	0.25	0.36	0.31	0.20	0.26	0.34	0.29	0.23	0.28		
C 20:4n6	Arachidonic acid	1.59	1.28	1.17	1.09	1.26	0.91	1.36	0.96	1.20	1.09	1.58
C 20:4n3	Eicosatetraenoic acid	1.2	1.24	1.3	1.25	1.27	1.06	1.15	1.25	1.22	1.42	1.03
C 20:5n3	Eicosapentaenoic acid	13.55	13.11	13.6	13.04	13.42	12.92	13.91	14.93	13.56	13.42	14.29
C 21:5n3	Heneicosapentaenoic acid	0.67	0.72	0.69	0.66	0.61	0.67	0.69	0.67	0.67	0.6	0.66
C 22:0	Behenic acid	0.17	0.17	0.17	0.20	0.20	0.21	0.16	0.15	0.18	0.11	0.15
C 22:1n9	Erucic acid	0.17	0.17	0.19	0.28	0.16	0.15	0.17	0.24	0.19	0.21	0.21
C 22:5n3	Docosapentaenoic acid	2.71	2.51	2.51	2.57	2.48	2.30	2.33	2.57	2.50	2.34	2.76
C 22:5n6	Docosapentaenoic acid	0.4	0.36	0.39	0.45	0.55	0.48	0.35	0.33	0.41	0.51	0.48
C 22:6n3	Docosahexaenoic acid	8.45	6.49	7.53	8.3	8.87	7.79	7.43	7.91	7.85	11.29	7.14
C 24:0	Lignoceric acid	0.11	0.14	0.16	0.15	0.17	0.18	0.12	0.12	0.14		
Unknown C	components	2.59	5.02	6.85	6.63	6.18	6.57	8.81	7.92	6.32	5.01	4.55
Total Omeg	a 3 Fatty Acids	29.64	27.24	29.23	29.16	30.79	28.24	28.64	31.07	29.25		
Total Omeg	a 6 Fatty Acids	4.38	4.33	3.61	3.30	3.88	4.57	4.38	4.54	4.12		