CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 3 **CX/FO 13/23/3-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FATS AND OILS

Twenty-third Session

Langkawi, Malaysia, 25 February – 1 March 2013

PROPOSED DRAFT STANDARD FOR FISH OILS

Comments at Step 3

(Comments of Brazil, Chile, Iceland, Japan, Norway, Seychelles, Vietnam, CRN, ELC, IADSA, ISDI)

BRAZIL

General Comments

Brazil would like to thanks Switzerland for the work developed in the eWG and thanks the opportunity to present comments regarding this document.

Brazil agrees with keeping the minimum values for A and D vitamin for fish liver oil in the standard since it is expected that these oils provide this type of nutrients.

As already questioned in the eWG, Brazil would like to clarify the data used to support the proposed peroxide value for fish oils. The Codex Stan 19/1981 defines the maximum of 15 meq/kg for peroxide value and it the proposed value (≤5meq/kg) is much lower than this.

Regarding the additives section, Brazil suggests that the expressions "antioxidants synergist" and "chelating agent" shall be in accordance with functional classes defined in CAC/GL 36-1989, that means that they are referred in the document as antioxidants" and "sequestrants". Besides that, Brazil does not agree with the use of colours in fish oils because it is usually used as food ingredient or food supplement in capsules for which colours are not technologically justified.

Brazil does not support section 7.3 on labeling and suggests its exclusion. We understand that these provisions are not coherent with the Guidelines on Nutrition Labelling (CAC/GL 2-1985) because nutrient declaration is not intended to inform consumers about the standardized essential composition of the food.

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 labelling. 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 labelling 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 Labelling requires the declaration of the amount of any nutrient for which a nutrition or health claim is made.

Brazil asks for clarification on how the ranges of fatty acids were defined and the data used to establish these ranges.

Specific Comments

1) Brazil suggests to remove brackets and maintain item 3.3 of the Essential Composition and Quality Factors session:

[3.3 Vitamins

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

Vitamin A ≥ 40 µg of retinol equivalents/ml

Vitamin D ≥ 1.0 µg/ml~~]~~

Rationale: Brazil agrees with keeping the minimum values for A and D vitamins for fish liver oil in the standard since it is expected that these oils provide this type of nutrients.

2) Brazil suggest the following changes in section 4 Food Additives:

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

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

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

Rationale: Brazil suggests that the expressions "antioxidants synergist" and "chelating agent" shall be in accordance with functional classes defined in CAC/GL 36-1989, that means that they are referred in the document as antioxidants" and "sequestrants". Besides that, Brazil does not agree with the use of colours in fish oils because it is usually used as food ingredient or food supplement in capsules for which colours are not technologically justified.

3) Brazil suggests excluding item 7.3 of the labelling session:

~~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.~~

Rationale: Brazil understands that these provisions are not coherent with the Guidelines on Nutrition Labelling (CAC/GL 2-1985) as explained in the general comments.

CHILE

PROPOSED DRAFT CODEX STANDARD FOR FISH OILS (At Step 3) CX/FO 13/23/3	Comments by Chile
Scope This Standard applies in its entirety to the fish oils described in Section 2 that are presented in a state for human consumption. ~~[~~It applies partially to crude fish oils described in Section 2.6.1 that require further processing before they are placed on the market for the final consumer~~]~~. For the purpose of this Codex Standard, the term fish oils refers to oils derived from fish and shellfish as defined in Section 2 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)[1]. **Description** Fish oils are produced from a variety of fish and shellfish species. Whole fish are the main source, but by-products such as trimmings from fish processing may also be used. Fish oils are primarily composed of glycerides of fatty acids whereas concentrated fish oils are either primarily composed of glycerides of fatty acids or of their ethylesters. Fish oils may contain other lipids and unsaponifiable constituents naturally present. This standard only applies to fish oils used in food and in food supplements where those are regulated as	2.1 We insist, the fatty acid profile is not a good maner

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

foods. **Named fish oils** may be derived from specific source materials; such fish oils are then identified by a specific name that is representative of the major fish or shellfish taxon from which the oil is extracted. For named fish oils, the fatty acid profiles (Table 1) shall apply. The following named fish oils are described in this Standard: **Anchovy oil** is derived from the family Engraulidae. **Sardine oil** is derived from the family Clupeidae (genera Sardina, Sardinops or Sardinella). **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. **Jack makerel oil** also known as **horse makerel oil** is derived from the family Carangidae (genus Trachurus). **Menhaden oil** is derived from the family Clupeidae (genus Brevootia). **Tuna oil** is derived from the family Scombridae (genera Thunnus, Sarda, Katsuwonus and Auxis). **Krill oil** is derived from the family Euphausiidae (mainly Antarctic). **Squid oil** is derived from the order Teuthida. **Pollock oil** is derived from the family Gadidae (genus Pollachius) 0 **Herring oil** is derived from the family Clupeidae (genus Clupea). 1 **Capelin oil** is derived from the family Osmeridae (genus Mallotus). 2 **Sandeel oil** is derived from the family Ammodytidae. 3 **Calanus oil** is derived from the family Calanidae (genus Calanus). **Fish oils** (unnamed) may be derived from a single species of fish other than the ones listed in Section 2.1 or be a mixture of fish oils derived from specified and/or unspecified source materials. This includes also mixtures with fish liver oils. **Named fish liver oils** may be derived from the livers of fish and are composed of fatty acids, vitamins or other components that are representative of the livers from the species from which the oil is extracted. For named fish liver oils the fatty acid profiles (Table 1) shall apply. **Cod liver oil** is derived from the family Gadidae (genus Gadus). **Fish liver oil** (unnamed) may be derived from the livers of fish other than those used for named fish liver oils or are a mixture of named fish liver oils and/or single species fish liver oils. **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] **Concentrated fish oils** are derived from fish oils described in Section 2.1 to 2.4 which have been subjected to processes such as hydrolysis, fractionation, winterization and/or re-esterification to increase the concentration of specific fatty acids. **Concentrated fish oil** contains [40 to 60 w/w %]fatty acids as sum of EPA and DHA, at least 50 w/w % of fatty acids are in the form of triacylglycerides. **Highly concentrated fish oil** contains greater than [60 w/w %] fatty acids as	to identify the fish because can to change dramatically around the year (is possible to obtain a profile from sardine or abchovy similar to profile of jack mackerel). We propose to use the trasability that is certify by the authority 2.5.1 We believe that as least 70% of fatty acids in form of triacylglyceride must be present in the concentrated fish oil. And if it was re-esterified must be indicated

sum of EPA and DHA, at least 50 w/w % of fatty acids are in the form of triacylglycerides. **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 **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 Other definitions applicable to fish oils (2.1 and 2.2.) and fish liver oils (2.3 and 2.4) **Crude fish oils** and **crude fish liver oils** are oils intended for human consumption after they have undergone further processing, refining and purification as applicable. **Virgin fish oils** have been treated by heating not exceeding [70°C], washing with water, settling, filtering and centrifugation only. They may contain antioxidants and pigments naturally present in the raw material. **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**.** **Essential Composition and Quality Factors** **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. **Quality parameters** Note: this section does not apply to oils described in Section 2.6.1 and flavoured fish oils where the added flavourings will interfere with the analytical determination of oxidation parameters. 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: ≤ 3 mg KOH/g ≤ 5 meq/kg ≤ 20 ≤ 26 ≤ 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)] Fish oils with a high phospholipid concentration such as krill oil or squid oil, shall comply with the following: ≤ 20 mg KOH/g	2.5.2 We believe that as least 70% of fatty acids in form of triacylglyceride must be present in the highly concentrated fish oil. And if it was re-esterified must be indicated. 3.2.1 Anisidine Value must be incorporated in the quality parameters

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

≤ 5 meq/kg **[Vitamins** Fish liver oils (Sections 2.3 and 2.4) shall comply with following: ≥ 40 µg of retinol equivalents/ml ≥ 1.0 µg/ml] **Food Additives** Note: this section does not apply to fish oils described in Section 2.6.1 Antioxidants, antioxidant synergists, colours, chelating agents, and antifoaming agents used in accordance with Tables 1 and 2 of the Codex General Standard for Food Additives in food category *02.1.3 Lard, tallow, fish oil, and other animal fats.* Additives may not be added to virgin oils as defined in Section 2.6.2. Flavourings may be used in fish oils in accordance with the Guidelines for the Use of Flavourings (CAC/GL 66-2008). **Contaminants** Note: this section does not apply to fish oils described in Section 2.6.1. 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). **Hygiene** **General hygiene** It is recommended that the products covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969), the Code of Practice for Fish and Fishery Products (CAC/RCP 53-2003) and the Recommended International Code of Hygienic Practice for the Storage and Transport of Edible Oils and Fats in Bulk (CAC/RCP 36-1987). **Microbiological criteria** Note: this section does not apply to fish oils described in Section 2.6.1. 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). **Labelling** **Name of the food** The product shall be labelled in accordance with the Codex General Standard for the Labelling of Pre-packaged Foods (Ref. CODEX STAN 1-1985). The name of the fish oil shall conform to the descriptions given in Section 2 of this Standard. **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	7.3 Is necessary indicating the fatty acids profiles and the quantity of saturated, monounsaturated and polyunsaturated fatty acids. **Specialy if** this profile contain erusic acid or other fatty acids questioned.

clearly identifiable with the accompanying documents. **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. **Methods of Analysis and Sampling** **Determination of fatty acid composition** According to applicable ISO methods including ISO:5508:1990 (Animal and vegetable fats and oils -- Analysis by gas chromatography of methyl esters of fatty acids) or AOCS methods including Ce 1b-89 (Fatty acid composition of Marine Oils by GLC), Ce 1j-07 (Determination of cis-, trans-, Saturated, Monounsaturated, and Polyunsaturated Fatty Acids in Extracted Fats by Capillary GLC), Ce 2b-11 (Direct Methylation of Lipids in Foods by Alkali Hydrolysis), Ce 1-62 (Fatty Acid Composition by Packed Column Gas Chromatography) and Ce 2-66 (Preparation of Methyl Esters of Fatty Acids). **Determination of arsenic** According to AOAC 952.13 (Silver Diethyldithiocarbamate Method**)**; AOAC 942.17 (Molybdenum Blue); or AOAC 986.15 (Spectroscopy/Atomic Absorption Spectroscopy). **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). **Determination of acid value** According to AOCS Ca 5a-40 (Free Fatty Acids), AOAC 2000 Cd 3a-63 (Acid Value), AOCS Cd 3d-63 (Acid Value); ISO 660:2009 (Animal and vegetable fats and oils -- Determination of acid value and acidity); European Pharmacopoeia 2.5.1 (Acid value) **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). **[Determination of p-anisidine value** AOCS Cd 18 - 90 (11) **Determination of oligomers** Information missing] **Determination of vitamin A** PhEur 2.2.29 liquid chromatography, monograph Cod liver oil (type A) **Determination of vitamin D** PhEur 2.2.29 liquid chromatography, monograph Cod liver oil (type A)	8.6 Could be used the Gas chromatographic method too

ICELAND

1. Under points 2.1 and 2.3 there is a reference to the fatty acid profiles in Table 1. In these points it also states that the fish oil shall fulfil the criteria in the table. This is in our opinion too strong a wording, especially if the wording under point 3.1. is considered:

> *"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."*

We would like to suggest deleting the sentences stating that the fish oil fatty acid profile in Table 1 **shall** apply or use different statement, more in line with point 3.1.

It should also be pointed out that in order to be able to use this kind of data as presented in table 1, the scientific background would have to be very strong to take into account the biological variations of the fatty acid composition.

2. Under point 2.1.3 we would suggest to split this point so that:

> *2.1.3 (a) Wild salmon oil is derived from wild fish of the family Salmonidae*
> *2.1.3 (b) Farmed salmon oil is derived from farmed fish of the family Salmonidae*

We also would like to suggest that the sentence: "*salmon oil is a mixture of oils derived from wild and farmed fish"* to be deleted. This kind of mixture is defined under point 2.2 fish oils (unnamed).

3. We would suggest changing point 2.3.1 to *"Cod liver oil is derived from the wild fish of the family Gadidae (genus Gadus)"*. This is relevant because of the increasing production of farmed cod.

4. Under point 2.3 named fish liver oils we would like to add point 2.3.2 "Shark liver oil from the family *Squalidae, Centrophoridae, Etmopteridae, Somniosidae and Cetorhinidae."*

5. **Both 2.6.2 Virgin fish oils** and **2.6.3 Extra low oxidised fish oils** should be omitted in our view. Both categories are based on arbitrary process parameters (max. 70 °C; min. 97°C for max 20 min.). The oils are not fundamentally different from other fish oils. Besides, there is no general consensus on the meaning of the name **Virgin fish oil**. It seems to be taken from the olive industry where the word "virgin" describes a product which is processed in a completely different manner to oil that does not bear the name.

Extra low oxidised fish oils are defined as oils that "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". There is no need for this category. What is meant by the phrase "extra low" is not clear, but disregarding this there is no guarantee oils treated in this manner are extra low in oxidation parameters. Furthermore further purification will make it impossible to verify that "extra low oxidised fish oil" has been produced as such.

6. In Chapter 8 Methods of Analysis and Sampling we would suggest to delete those methods that are not referred to in Chapter 3, Essential Composition and Quality Factors. The methods that should be deleted are:

8.2 Determination of arsenic

8.3 Determination of lead

8.6 Determination of vitamin A

8.7 Determination of vitamin D

For those methods that remain, 8.1 determination of fatty acid composition, 8.4 determination of acid value and 8.5 determination of peroxide value the named methods should in our opinion not be included. It would be far too limiting to determine once and for all which methods should be used in this regard since the analytical methods are constantly evolving. Therefore, it would be better to refer to e.g. validated methods.

Iceland has viewed the opinion that it would be preferable to use quantitative determination of fatty acids. If, however if it would be decided to use area percentages then it should be made clear in the text.

> *3.1. GLC ranges of fatty acid composition (expressed as **area** percentage of total fatty acids).*

This also applies to Table 1.

JAPAN

SPECIFIC COMMENTS:

1.Proposal: Delete Section 2.1.13

Proposed text:

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

Rationale:

Calanidae is outside the scope of this standard, because they are not included in the definition of "Shellfish" in Section 2 of the "Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)". Calanidae is not commonly used for food.

2.Proposals: Add a sentence at the end of Section 2.5.1 and 2.5.2 and modified Section 2.5.3 and 2.5.4 as follows.

Proposed text:

2.5.1 Concentrated fish oil contains [40 to 60 w/w %] fatty acids as sum of EPA and DHA, at least 50 w/w % of fatty acids are in the form of triacylglycerides. **Ethyl esters residue should be less than[1] w/w % when re-esterification is used as a concentration methods.**

2.5.2 Highly concentrated fish oil contains greater than [60 w/w %] fatty acids as sum of EPA and DHA, at least 50 w/w % of fatty acids are in the form of triacylglycerides. **Ethyl esters residue should be less than[1] w/w % when re-esterification is used as a concentration methods.**

2.5.3 Concentrated fish oil ethyl ester contains **[1]w/w% and more of** fatty acids as **in the form of** esters of ethanol **and contains** ~~of which~~ [40 to 60 w/w %] ~~are~~ **fatty acids** as sum of EPA and DHA

2.5.4 Highly concentrated fish oil ethyl ester contain **[1]w/w% and more of** fatty acids as **in the form of** esters of ethanol **and contains** ~~of which~~ greater than [60 w/w %] ~~are~~ **fatty acids** as sum of EPA and DHA

Rationale:

Fish oils (2.5.1 and 2.5.2) and fish oil ethyl ester (2.5.3 and 2.5.4) should be clearly differentiated because they have different characteristics. Ethyl esters are chemically synthesized materials, not existed naturally in fish oils. Because of this, some consumers prefer fish oil to fish oil ethyl ester.

Some industries produce fish oil through re-esterification from ethyl ester to triacylglycerid. In this case, there may be a residue of ethyl ester in the fish oil. To differentiate fish oil and fish oil ethyl ester, criteria is necessary in terms of concentration of ethyl ester.

3.Proposal: Delete "Oligomers" from oxidation parameters.

Proposed text:

3.2.1

~~Oligomers: ≤ 1.5 % for fish oils and liver oils (Sections 2.1 – 2.4)~~

~~≤ 3 % for concentrated and highly concentrated fish oils (Section 2.5.1 and 2.5.2)~~

Rationale:

Oligomers are produced during long term high temperature treatment. Fish oil seldom goes through such high temperature treatment since fish oil is easily oxidized. Peroxide value and Anisidine value are more suitable parameters since they increase before the oligomers start increasing.

4.Proposal: Add words in Section 3.3.

Proposed text:

3.3 Vitamins

Fish liver oils (Sections 2.3 and 2.4 **except shark liver oil**) **should** ~~shall~~ comply with following:

Vitamin A ≥40 µg of retinol equivalents/ml

Vitamin D ≥1.0 µg/ml

Rationale:

Vitamin A and vitamin D are not necessarily main compounds of shark liver oils. Shark liver oil contains squalene rather than vitamin A and vitamin D.

5.Proposal: Add a sentence at the end of Section 7.3.

Proposed text:

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 **and form of fatty acids (i.e. fish oil or fish oil ethyl esters)** ~~shall~~ **should** be given.

Rationale:

The form of fatty acids should be clearly indicated (Please see the proposal 2).

NORWAY

Norway appreciates this opportunity to comment upon the proposed draft codex standard for fish oils.

(i) General Comments

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

(ii) Specific Comments

SECTION 2 DESCRIPTION

Fish oils are produced from a variety of fish and shellfish species. Whole fish are the main source, but ~~by-products such as~~ trimmings from fish processing may also be used. Fish oils are primarily composed of glycerides of fatty acids whereas concentrated fish oils are either primarily composed of glycerides of fatty acids or of their ethylesters. Fish oils may contain other lipids and unsaponifiable constituents naturally present. This standard only applies to fish oils used in food and in food supplements where those are regulated as foods.

Rationale: The word by-products should be removed throughout from this standard for food for human consumption as by-products in some regions, as i.e. within the EEC, are not allowed as raw materials for foodstuffs.

SECTION: 2.1.3 WILD SALMON OIL OR FARMED SALMON OIL

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~~.

Rationale: Farmed salmon oil and wild salmon oil are separate categories with separate distinct fatty acid profile. As salmon oil is not a separate group with a distinct fatty acid profile, it is not a named fish oil but falls in the category 2.2 fish oils.

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~~,~~ **and** 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.

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

SECTION: 2.5.1 CONCENTRATED FISH OIL

Concentrated fish oil contains ~~[~~40 to 60 w/w % ~~]~~fatty acids as sum of EPA and DHA, at least 50 w/w % of

fatty acids are in the form of triacylglycerides.

Rationale: As all concentrates by definition are characterized by the increase of specific acids, mainly EPA and DHA, they have to be easily distinguishable from other unnamed fish oils by the definition of the level of EPA and DHA contained, and labeling requirements, or at least one of these options. Square brackets should therefor be removed.

SECTION: HIGHLY CONCENTRATED FISH OIL

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

Rationale: See rationale for section 2.5.1.

SECTION: CONCENTRATED FISH OIL ETHYL ESTER

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.

Rationale: See rationale for section 2.5.1.

SECTION: HIGHLY CONCENTRATED FISH OIL ETHYL ESTER

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.

Rationale: See rationale for section 2.5.1.

SECTION: 3.1 GLC RANGES OF FATTY ACID COMPOSITION (EXPRESSED AS **WEIGHT** 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.

Rationale: The title should be changed to reflect on how the percentage is expressed, by inserting the word area or weight before percentage. It may be that table 1 has to be revised to ensure that all data are reported identical.

SECTION: 3.2.1 ALL FISH OILS, FISH LIVER OILS AND CONCENTRATED FISH OIL

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)	≤ 26
Oligomers:	≤ 1.5 % for fish oils and liver oils (Sections 2.1 – 2.4)

≤ 3 % for concentrated and highly concentrated fish oils (Section 2.5.1 and 2.5.2)~~]~~

Rationale: Peroxide value only is not sufficient as the only parameter for quality determination. It is well known that crude fish oils are subject to several processing steps and it is easy to control/lower oxidation levels of PV results in the process without reflecting the true quality and the oxidation status of the fish oil. It is important to also specify minimum quality requirements with regard to secondary oxidation products. Oxidation levels are of concern and focused on both by scientist and risk managers and existing private standards are referenced by EFSA when discussing oxidation levels in fish oil. Quality parameters are much more correctly defined by analyzing both Peroxide value (PV) and anisidine value (ANV), and preferably by using the well-established combination of the PV and ANV results = TOTOX, and this should be a general quality requirement. It is also known that some types of oils, for example those with added flavors, may cause false ANV results, as some flavors have similar wavelength to the one used in ANV detection spectra. These types of oils can be excluded from quality parameter of ANV. Tertiary oxidation parameters should also be considered.

SECTION: 3.2.2 FISH OILS WITH A HIGH PHOSPHOLIPID CONCENTRATION

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

Acid value ≤ ~~20~~ **30** mg KOH/g

Peroxide value ≤ 5 meq/kg

Rationale: We have received new information from the industry that for fish oil with a high content of phospholipids, that an acid value ≤ 30 mg KOH/g better reflects the actual value of good quality krill oil.

SECTION: **3.2.3 EXTRA LOW OXIDIZED FISH OILS (Section 2.6.3) shall comply with the following:**

Total oxidation value (ToTox)[5] ≤ 5

Oligomers ≤ 0,5 %

Rationale: Quality parameters for extra low oxidized fish oils have to be in place as this is an essential characteristic of such oils in section 2.6.3.

SECTION 3.3 ~~[~~VITAMINS

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

Vitamin A ≥ 40 µg of retinol equivalents/ml

Vitamin D ≥ 1.0 µg/ml~~]~~

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 are the fish oils that have been on the marked for more than hundred years and the natural content of vitamins is the main characteristic for liver oils distinguishing them from other fish oils.

SECTION 4 FOOD ADDITIVES

Note this section does not apply to **crude** fish oils **and crude fish liver oils** described in Section 2.6.

Rationale: This edit will make the text easier to understand.

In addition, while the Codex General Standard for Food Additives (GSFA) includes fish oils in category 02.1.3 Lard, tallow, fish oil, and other animal fats, some widely used antioxidants in fish oils are not listed. Norway would like CCFO to suggest the inclusion of these antioxidants in the GSFA to the Codex Committee on Food Additives (CCFA). Fish oils are more susceptible to oxidation than other oils, and the following antioxidants are necessary to stabilize the fish oils sufficiently:

- *Ascorbyl palmitate (INS 304) - Ascorbyl palmitate is included in the Codex General Standard for Food Additives (Codex Stan 192-1995), but not for use in 02.1.3 Lard, tallow, fish oil, and other animal fats.*
- *Tocopherols (INS 307 a, b, & c) – Tocopherols are included in the Codex General Food Additives (Codex Stan 192-1995), but not for use in 02.1.3 Lard, tallow, fish oil, and other animal fats.*
- *Rosemary extract (E 392) is not currently included in the Codex General Standard for Food Additives (Codex Stan 192-1995)) .*

SECTION 5 CONTAMINANTS

Note this section does not apply to **crude** fish oils **and crude fish liver oils** described in Section 2.6.

Rationale: This edit will make the text easier to understand.

SECTION 6.2 MICROBIOLOGICAL CRITERIA

Note this section does not apply to **crude** fish oils **and crude fish liver oils** described in Section 2.6.

Rationale: This edit will make the text easier to understand.

SECTION 7.3 OTHER LABELLING REQUIREMENTS

For fish liver oils (Sections 2.3 and 2.4 **except Section 2.4.1**, only applicable if naturally present or restored) the content in vitamin A and vitamin D ~~[may]~~ **shall** be given.

Rationale: With reference to our previous comments to section 3.3, and the definition of fish liver oils in 2.3, the square brackets should be removed and the labeling of vitamin A and D should be mandatory.

SECTION 8 METHODS OF ANALYSIS AND SAMPLING

Where specific methods are indicated, Norway recommend either 1) providing more than one method as an option or 2) indicating "scientifically valid methods must be used" or "or equivalent".

SECTION 8.4 DETERMINATION OF ACID VALUE

According to AOCS Ca 5a-40 (Free Fatty Acids), ~~AOAC 2000 Cd 3a-63 (Acid Value),~~ AOCS Cd 3d-63 (Acid Value); ISO 660:2009 (Animal and vegetable fats and oils -- Determination of acid value and acidity); European Pharmacopoeia 2.5.1 (Acid value)

Rationale: AOAC 2000 Cd 3a-63 (Acid Value) should be deleted because it has been replaced by AOCS Cd 3d-63 (Acid Value).

SECTION TABLE 1: Fatty acid (FA) composition of named fish oil**s** and fish liver oil**s (triglyceride)** ~~categories~~ as determined by gas liquid chromatography **(GLC)** from authentic samples (expressed as **weight** percentage of total fatty acids) (see Section 3.1 of the Standard)

Fatty acids	**Farmed Salmon**	**Krill~~*~~**	**Squid**
C14:0 myristic acid	2.5-5.5	~~ND-9.5~~ **4.0-14.0**	1.0-6.0
C15:0 pentadecanoic acid	ND-0.5	ND-~~0.3~~ **1.0**	ND-1.0
C16:0 palmitic acid	7.0-16.5	~~6.0-18.5~~ **10.0-26.0**	10.0-20.0
C16:1 (n-7) palmitoleic acid	3.0-8.0	~~ND-5.5~~ **2.0-8.0**	1.0-8.0
C17:0 heptadecanoic acid	ND-0.5	ND-2.0	ND-1.0
C18:0 stearic acid	2.0-5.0	0.5-2.0	1.0-6.0
C18:1 (n-7) vaccenic acid	na	~~na~~ **2.0-9.0**	na
C18:1 (n-9) oleic acid	16.0-40.0	~~2.5-11.0~~ **5.0-14.0**	6.0-25.0
C18:2 (n-6) linoleic acid	2.5-11.0	ND-~~2.0~~ **3.0**	ND-2.0
C18:3 (n-3) linolenic acid	0.5-6.0	ND-~~1.5~~ **3.0**	ND-2.0
C18:3 (n-6) γ-linolenic acid	ND-0.5	ND-0.5	ND-1.0
C18:4 (n-3) stearidonic acid	0.5-1.5	~~ND-3.5~~ **2.0-8.0**	ND-3.0
C20:0 arachidic acid	na	~~na~~ **ND-1.0**	na
C20:1 (n-9) eicosenoic acid	1.5-7.0	ND-3.5	ND-~~7.~~0 **13.0**
C20:1 (n-11) eicosenoic acid	0.5-7.0	ND-**2.0**	ND-~~13.~~0 **7.0**
C20:4 (n-6) arachidonic acid	ND-1.0	ND-1.5	ND-3.0
C20:4 (n-3) eicosatetraenoic acid	0.5-2.0	ND-1.0	ND-2.0
C20:5 (n-3) eicosapentaenoic acid	~~6.~~0 **2.0**-9.0	> ~~9.0~~ **10.0**	7.0-15.0
C21:5 (n-3) heneicosapentaenoic acid	ND-1.0	ND-2.0	ND-1.0
C22:0 docosanoic acid	na	~~na~~ **ND-2.0**	na
C22:1 (n-9) erucic acid	ND-4.0	ND-2.0	ND-3.0
C22:1 (n-11) cetoleic acid	0.5-7.0	ND-2.0	2.0-10.0
C22:5 (n-3) docosapentaenoic acid	1.5-5.0	ND-2.5	0.5-3.0
C22:6 (n-3) docosahexaenoic acid	3.0-14.5	> ~~4.0~~ **5.0**	12.5-34.5
Phospholipid fraction	na	> 30.0	na

na = not ~~available~~ **applicable**

ND = non-detect, defined as ≤0.05%

~~*~~ = phospholipid and triglyceride oil

Rationale:

- *The change in the title will make the text easier to understand. In addition, the title should be changed to reflect on how the percentage is expressed, by inserting the word area or weight before percentage. It may be that all data in the table has to be revised to ensure that all data are reported identical.*

- *For farmed salmon oil the limits for C20:5 (n-3) EPA are proposed to be changed to 2.0 - 9.0, to reflect the latest developments in the industry due to continuous decrease of the fish oil content in fish feed.*

- *For krill oil almost all data have to be changed to reflect that, unlike other oils which mainly consists of triglyceride oils, in krill oil the triglyceride part and the phospholipid part are equally important. So the table for krill oil has to be totally revised, and in addition a footnote for krill "* = phospholipid and triglyceride oil" has to be added for explanation.*

- *For squid oil, it seems that data for C20:1 (n-9) and C20:1 (n-11) have been switched.*

- *The footnote explaining "na" should be changed from "na = not available" to "na = not applicable", as this is more correct.*

SEYCHELLES

The Seychelles would like to thank the Switzerland delegation for the work achieved on the Draft Standard for Fish Oils to be presented during the 23rd session of the CCFO in Malaysia, 25th February to 1st March 2013.

The Seychelles is very supportive for a Codex Standard on fish oil and expect that significant progress will be achieved during the 23rd session of CCFO. However, the Seychelles has the following comments that it would like to put forward on the draft prepared by the eWG.

1. Virgin/Extra Low oxidized Fish Oils

Seychelles does not support the classification proposed by the eWG. Virgin/Extra Low Oxidized Fish Oils trade is not significant enough to be categorized separately.

Virgin/Extra Low Oxidized Fish Oils need to be refined before being delivered to the consumers. The only difference in this type of oil is in the manufacturing process.

2. Named Fish Oil

Seychelles does not support the introduction under named fish oils of very specific species that are sold in small volume. Small volume trade is generally not in the scope of the Codex discussion.

3. Quality Parameters

Seychelles support in general quality parameters, but some of them are not well scientifically substantiated and it is the reason why Seychelles is not in favour to introduce new parameters such as Anisidine value, Totox and Oligomers to Acid and Peroxide values as for all oils and fats.

VIETNAM

First of all, Vietnam highly appreciates the efforts made by the Working Group in preparing the Proposed Draft Codex Standard for Fish Oils.

Vietnam fully support the Draft Codex Standard for Fish Oils at Step 3 in particular on Hygiene and Essential Composition and Quality Factors.

CRN

The Council for Responsible Nutrition (CRN)[3] submits this letter on behalf of its members to provide comments on the Proposed Draft Standard for Fish Oils. CRN is an international non-governmental organization (NGO) officially recognized by the Codex Alimentarius for more than a decade. CRN has participated as a Codex Observer on the eWG responsible for the development of the Proposed Draft Standard for Fish Oils.

CRN represents the interests of U.S. and international companies involved in the dietary/food supplement industry. CRN staff and representatives commonly participate in several Codex meetings each year, with emphasis on the CAC, CCNFSDU, CCGP, and CCFL. CRN frequently submits written comments on scientific and technical issues, including nutrient risk assessment, nutrient reference values, health claims, and proper uses of precaution.

Summary of recommendations:

- We recommend that the process steps for concentrated oils be removed from section 2.5.
- We request a more in-depth review of the data used to develop Table 1 to ensure scientific validity.
- We recommend incorporating realistic oxidation parameters for flavored fish oils.
- We recommend that the issue of additives used in fish oils be deferred to the Codex Committee on Food Additives.
- We recommend that the issue of contaminants in fish oils be deferred to the Codex Committee on Contaminants in Foods.
- We recommend that the issue of analytical methods be deferred to the Codex Committee on Methods of Analysis and Sampling.

Further details on these recommendations are outlined below.

Section 2.5, Concentrated fish oils

The process definitions should be removed because they are too restrictive and limit future innovations in fish oil processing. There is no need to list steps used to concentrate oils for it could be misconstrued that these are the only steps allowed. The art and science of concentrating oils is always evolving and innovation is an important part of fish oil refining. CRN is concerned that a list of specific steps that can be used to concentrate oil may not cover all methods currently in use, and may hamper future innovation.

We recommend that the process steps be removed from section 2.5.

Section 3.1, GLC Ranges of fatty acid composition

CRN is significantly concerned with Table 1 on fatty acid profiles for named fish oils. Table 1 was designed to provide a tool to identify named fish oils as per their fatty acid profiles. However, CRN questions the validity and/or reproducibility of the data provided. We are concerned that the source of data for named fish oils cannot be traced to specific fishing zones and years. We question whether the data listed for each named fish oil in Table 1 are representative of all the major global fisheries. Furthermore, CRN is aware that the data in Table 1 have not been confirmed by a qualified entity or third party.

CRN's concerns stem from the fact that fatty acid profiles are prone to significant fluctuations. Factors that impact fatty acid profiles include geographical waters, food sources, environmental conditions and variations of seasonal fisheries. The International Alliance of Dietary/Food Supplement Associations (IADSA) has submitted comments on the Codex Proposed Draft Standard for Fish Oils that include Annex I, *Scientific Implications of Reliance on Fatty Acid Profiling for Fish Identification*. As a member of IADSA, CRN agrees that Annex I provides additional scientific justification for the concern that data in Table 1 may not be representative of global fisheries.

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[3] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 100 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

We request a more in-depth review of the data used to develop Table 1 to ensure scientific validity.

Section 3.2, Oxidation parameters

CRN is concerned with the oxidation exemptions for flavored fish oils. Crude fish oils are exempt, which we feel is acceptable. However, flavored oils should not be exempt. CRN is aware that added flavors can skew acid and peroxide values and lead to false positive test results for oxidation. Therefore, for flavored fish oil, standard testing methodology and limits are not fit-for-purpose. However, the Proposed Draft Standard for Fish Oils, as currently written, creates a quality loophole that will allow low-quality fish oils the privilege of not having to meet the standard acid and peroxide values simply by adding flavors.

We recommend incorporating realistic oxidation parameters for flavored fish oils.

Section 4, Food Additives

The Proposed Draft Standard for Fish Oils references the Codex Genearl Standard for Food Additives (Codex Stan 192-1995). Specifically, antioxidants used must be in accordance with *Category 02.1.3 Lard, tallow, fish oil and other animal fats*. CRN feels this is inappropriate due to the fact that there are critical antioxidants commonly used in fish oils that are absent from *Category 02.1.3.*

- Ascorbyl palmitate (INS 304) - Ascorbyl palmitate is included in the Codex General Standard for Food Additives (Codex Stan 192-1995), but not for use in *02.1.3 Lard, tallow, fish oil, and other animal fats*.
- Citric acid (INS 330) – Citric Acid is included in the Codex General Standard for Food Additives (Codex Stan 192-1995), but not for use in *02.1.3 Lard, tallow, fish oil, and other animal fats*.
- Tocopherols (INS 307 a, b, & c) – Tocopherols are included in the Codex General Standard for Food Additives (Codex Stan 192-1995), but not for use in *02.1.3 Lard, tallow, fish oil, and other animal fats*.
- Rosemary extract (E 392); not currently included in the Codex General Standard for Food Additives (Codex Stan 192-1995).

We recommend that this issue be deferred to the Codex Committee on Food Additives. Codex Standard 192-1995 needs to be revised to address this critical omission.

Section 5, Contaminants

As stated in the Proposed Draft Standard for Fish Oils, contaminants shall comply with the maximum levels stated in the Codex General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995). There is no mention of contaminants such as PCBs, dioxin and furans that are commonly included in fish oil monographs.

We recommend that this issue be deferred to the Codex Committee on Contaminants in Foods.

Section 8, Methods of Analysis and Sampling

CRN disagrees that only selected test methods are defined as acceptable. There needs to be an acceptance of alternative validated methods such as USP, PhEur, and EPA.

We recommend that this issue be deferred to the Codex Committee on Methods of Analysis and Sampling

ELC

The following comments related to Agenda Item 3 - Proposed Draft Standard for Fish Oils are being submitted for and on behalf of the ELC.

First and foremost, we propose an inter-session meeting in Malaysia to consider what will likely be a substantial number of written comments.

2 Description

The word ‘by-products’ has been introduced, which may cause confusion in some

regions due to legislation related to by-products that is not applicable to fish oil production. Furthermore, we see no added value in the inclusion of the second sentence. We would propose to remove the second sentence, and change the first sentence to read ‘*Fish oils are derived from a variety of fish and shellfish*’.

2.1.3

Since mixtures of named oils are included already in the definition of fish oils (unnamed), the

recommendation is to delete the following, '*; salmon oil is a mixture of oils derived from wild and farmed fish.*'

2.1.5

In order to correct a spelling mistake, '*Brevootia*' should be changed to '*Brevoortia*'.

2.1.7

In order to provide greater clarity, and correct a spelling mistake; the description

should be changed to read '*Krill oil is derived from Antarctic Krill from the family Euphausia.*'

2.5

A process description has been incorporated. There are a number of methods utilized

for the preparation of concentrated oils that are not covered by this process description. We propose that the process description be removed and replaced to read '*…have been processed to increase the concentration of specific fatty acids.*'

3.2 Quality Parameters

- We do not believe it is possible to differentiate '*2.6.2 virgin fish oils*' and '*2.6.3 extra low oxidised fish oils*' unless they are linked to defined quality parameters. The processing parameters in and of themselves do not sufficiently provide differentiation from other categories of fish oils. Furthermore, relevant oxidation parameters in general may require further consideration.

- While we recognize that certain flavouring agents can invalidate oxidation testing (i.e. P-Anisidine) results, we are concerned that flavoured fish oils are not required to comply with some quality parameters. As such, these fish oils may not be of the same standard of quality as all other fish oils. We recommend that this issue be referred to the Codex Committee on Methods of Analysis and Sampling (CCMAS).

3.2.2

In order to accurately reflect the higher acid value associated with fish oils with a high phospholipid concentration, we recommend changing '*≤ 20 mg KOH/g*' to '*≤ 30 mg KOH/g*'.

4 Food Additives

While the Codex General Standard for Food Additives (GSFA) includes fish oils in category *02.1.3 Lard, tallow, fish oil, and other animal fats*, some widely used antioxidants in fish oils are not listed. We would like to request that the following antioxidants be referred to the Codex Committee on Food Additives (CCFA) for consideration for inclusion.

- ascorbyl palmitate (INS 304) - Ascorbyl palmitate is included in the Codex General Standard for Food Additives (Codex Stan 192-1995), but not for use in *02.1.3 Lard, tallow, fish oil, and other animal fats*.

- citric acid (INS 330) – Citric Acid is included in the Codex General Standard for Food Additives (Codex Stan 192-1995), but not for use in *02.1.3 Lard, tallow, fish oil, and other animal fats*.

- tocopherols (INS 307 a, b, & c) – Tocopherols are included in the Codex General Standard for Food Additives (Codex Stan 192-1995), but not for use in *02.1.3 Lard, tallow, fish oil, and other animal fats*.

- rosemary extract (E 392; not currently included in the Codex General Standard for Food Additives (Codex Stan 192-1995))

In addition, other food additives like lecithin (INS 322(i)), which is an "additive permitted for use in food in general, unless otherwise specified, in accordance with GMP", should be permitted for use in category *02.1.3 Lard, tallow, fish oil, and other animal fats*.

5 Contaminants

- We recommend that '*Note: this section does not apply to fish oils described in Section 2.6.1*' be changed to '*Note: this section does not apply to crude fish oils and crude fish liver oils described in Section 2.6.1*'.

- Given the high content of organic arsenic (considered non-toxic and not associated with a PTWI) in phospholipid oils, the more appropriate contaminant to apply the ML would be inorganic arsenic (considered

toxic and associated with a PTWI of 0.015 mg/kg bw). Given that the residue definition ('*Definition of the contaminant in the form of which the ML applies or which may or should be analyzed in commodities*') is for total arsenic, we recommend that this issue be referred to the Codex Committee on Contaminants in Food (CCCF) for review.

- Referral to the Codex Committee on Contaminants in Food (CCCF) is requested to ensure that contaminants relevant to fish oils are fully considered.

7.3 Other Labelling Requirements

- Fish liver oils (Sections 2.3 & 2.4) are traded partly on the basis of their vitamin content. Vitamin content should be a mandatory requirement, except in the case of devitaminised oils.

- The Proposed Draft Standard for Fish Oils stipulates that '*For concentrated fish oils (Section 2.5.) the content of DHA and EPA shall be given*.' This requirement should apply to all fish oils.

8 Methods of Analysis and Sampling

- Where specific methods are indicated, we recommend either 1) providing more than one method as an option or 2) indicating '*scientifically valid methods must be used*' or '*or equivalent*'. For further discussion, we recommend this issue be referred to the Codex Committee on Methods of Analysis and Sampling (CCMAS).

8.4 Determination of acid value

'*AOAC 2000 Cd 3a-63 (Acid Value)*' should be deleted because it has been replaced by '*AOCS Cd 3d-63 (Acid Value)*'.

Table 1:

We request that table 1 be modified to reflect stakeholder feedback. A revised table with proposed changes indicated by strikethroughs and red font is being provided.

Fatty Acid Composition of Named Triglyceride Oils (min-max)

Fatty acids	**Wild Salmon**	**Farmed Salmon**	**Menhaden**	**Krill**	**Squid**
C14:0 myristic acid	2.0-4.5	2.5-5.5	6.5-12.5	ND-20.5~~9.5~~	1.0-6.0
C15:0 pentadecanoic acid	ND-1.0	ND-0.5	ND-1.5	ND-1.0 ~~0.3~~	ND-1.0
C16:0 palmitic acid	12.0-13.5	7.0-16.5	14.0-23.0	6.0 -26.0~~18.5~~	10.0-20.0
C16:1 (n-7) palmitoleic acid	4.5-5.0	3.0-8.0	7.5-15.5	ND-8.0 ~~5.5~~	1.0-8.0
C17:0 heptadecanoic acid	ND-1.0	ND-0.5	ND-2.5	ND-4.0 ~~2.0~~	ND-1.0
C18:0 stearic acid	2.5-5.0	2.0-5.0	2.5-4.5	0.5-2.0	1.0-6.0
C18:1 (n-7) vaccenic acid	na	na	na	na	na
C18:1 (n-9) oleic acid	16.0-17.5	16.0-40.0	3.5-16.0	2.5-14.0~~11.0~~	6.0-25.0
C18:2 (n-6) linoleic acid	1.5-2.0	2.5-11.0	0.5-2.0	ND-3.0 ~~2.0~~	ND-2.0
C18:3 (n-3) linolenic acid	1.0-1.5	0.5-6.0	ND-2.0	ND-3.0 ~~1.5~~	ND-2.0
C18:3 (n-6) γ-linolenic acid	ND-0.5	ND-0.5	ND-1.0	ND-3.0 ~~0.5~~	ND-1.0
C18:4 (n-3) stearidonic acid	2.0-2.5	0.5-1.5	1.5-5.0	ND-8.0 ~~3.5~~	ND-3.0
C20:0 arachidic acid	na	na	na	na	na
C20:1 (n-9) eicosenoic acid	4.5-6.0	1.5-7.0	0.5-2.0	ND-3.5	ND-13~~7.0~~
C20:1 (n-11) eicosenoic acid		0.5-7.0	0.5-2.0	ND-3.5	ND-7~~13.0~~

C20:4 (n-6) arachidonic acid	5.0-5.5	ND-1.0	0.5-4.0	ND-1.5	ND-3.0
C20:4 (n-3) eicosatetraenoic acid	14.0-16.5	0.5-2.0	0.5-2.5	ND-1.0	ND-2.0
C20:5 (n-3) eicosapentaenoic acid	8.5-9.5	2~~6~~.0-9.0	5.0 ~~11.0-18.5~~ 19.0	> ~~9.0~~ 8.5-17.5	7.0-15.0
C21:5 (n-3) heneicosapentaenoic acid	ND-1.0	ND-1.0	0.5-1.0	ND-2.0	ND-1.0
C22:0 docosanoic acid	na	na	na	na	na
C22:1 (n-9) erucic acid	4.0-6.0	ND-4.0	ND-0.5	ND-2.0	ND-3.0
C22:1 (n-11) cetoleic acid		0.5-7.0	ND-0.5	ND-2.0	2.0-10.0
C22:5 (n-3) docosapentaenoic acid	2.5-3.0	1.5-5.0	1.5- 5.0~~-4.0~~	ND-2.5	0.5-3.0
C22:6 (n-3) docosahexaenoic acid	10.5-11.0	3.0-14.5	4.0-20.0~~14.5~~	> 4.0-13.5	12.5-34.5
Phospholipid fraction	na	na	na	> 30.0	na

na = not available applicable
ND = non-detect
*phospholipid & triglyceride oil

IASDA

The International Alliance of Dietary/Food Supplement Associations (IADSA) welcomes the opportunity to comment on the Report of the electronic Working Group on the Development of a Codex Standard for Fish Oils (CX/FO 13/23/3). IADSA wishes to thank Switzerland for its work in chairing the discussions of the eWG on the development of a draft standard for fish oils and on drafting the Report.

IADSA general comments are specific to the fatty acid profiles in Table 1 of the proposed draft standard. We have concerns on the appropriateness and scientific validity of using such a table as an identifier for named fish oils. Our concerns are outlined in the below 4 points and Annex I (attached):

1. IADSA is concerned about the provenance and scientific validity of the revised Table 1 of fatty acid profiles (pages 10-12 of the Report). IADSA has noted that there have been a large number of suggested changes to the values and ranges of these profiles since the circulation of the draft dated 5th April 2012. None of these changes appear to have been supported by any scientific provenance, and in almost every case the ranges have been considerably expanded.

2. There is a concern that some of the profiles assessed from the scientific literature were either based on very few data or from a limited fishing area/season. Furthermore, it would appear that some of the data may go back to the 1980s or earlier. If this is verified, then this data should be excluded, as both the composition of the fish oil for most fish and the methodology for assaying fatty acid composition have changed considerably over the last thirty years.

3. IADSA has commissioned a scientific paper - see **Annex I** below - that considers the natural variability in the oil composition, depending upon the age of the fish, period of harvesting, variation in fish diet, habitat, climatic conditions etc. This indicates that very wide ranges would be necessary to accommodate the variations in fatty acid composition that could be expected for any particular species or group of species of marine animals. This creates a lack of confidence in identification and the distinct possibility of adulteration with other oils.

4. IADSA recommends that the values and ranges of the profiles in Table 1 for all fifteen named fish should be independently and scientifically validated to fixed criteria before the table is presented for adoption.

ANNEX I (IASDA)

Scientific Implications of Reliance on Fatty Acid Profiling for Fish Identification

In the Codex Alimentarius draft Standard for Fish Oils (CX/FO 13/23/3), Table 1 contains fatty acid composition data (fatty acid profiles) for 15 named fish.

The fish are defined in the table by their common names (e.g. Anchovy, Sardine and Cod). From section 2.1 of the draft it is stated that some oils are defined only by family (for example, Anchovy oil is derived from the family *Engraulidae*), whilst others, such as tuna oil, are specified by genera. This inconsistency is significant, as the family *Engraulidae* relates to small salt-water forage fish and encompasses 144 species in 17 genera. Members of this family are found in most of the major oceans and seas. Of these 144 species, only six belonging to the genus *Engraulis*, are considered to be commercially significant.

These six commercial species of Anchovy are spread across the globe with each species inhabiting a different habitat (for example: North East Pacific, South East Pacific, South East Atlantic, South West Atlantic, China Seas, Mediterranean and Black Seas). Each habitat has a number of different environmental conditions affecting the growth characteristics and oil composition of the fish.

A large number of studies have been reported which investigate the influence of a range of factors on the oil composition of different species of fish of commercial interest.

Some of the main factors identified are:

i) Age and maturity of the fish in the harvested population

ii) Seasonality, with significant differences between catches between the beginning and end of the season

iii) Composition of food source, which can be affected by both climatic conditions and season

iv) Changes in climatic conditions (for example; the effects of 'El Niño- Southern Oscillation on the Pacific Ocean)

v) Geographical location of fishing grounds

The above list is not exhaustive.

The effects of these factors can be illustrated with Cod Liver Oil (CLO). There are a number of advantages in using CLO. It appears to be the oldest oil prepared commercially for human consumption, with evidence of sales going back to the early part of the twentieth century. It also appears to have the longest period of scientific research on oil composition, covering at least eight decades.

CLO is derived from the livers of two species of cod *Gadus morhua* (Atlantic cod) and *Gadus macrocephalus* (Pacific cod). Adult cod are active hunters of a range of marine animals including whiting, mackerel, haddock, herring, sprat, squid, molluscs, crustacea (lobsters and crabs) and worms. In some habitats (for example, the Baltic Sea) herring and sprat comprise the main food source, (Köster et al 2001), whilst in others it is more varied.

This very varied diet of fish, crustacean and molluscs can have a marked effect on the fatty acid composition of the liver oil depending on the proportions consumed. There is a considerable amount of published data which indicate highly significant relationships between the composition of the fatty acids in the feed and the fatty acids in the CLO. This work has been used to manipulate the quantities of selected fatty acids, particularly omega-3 fatty acids in farmed cod, (Jobling et al 2008, Jobling and Leknes 2010, Kirsch et all 1998). The fatty acid composition of CLO has been found to be significantly affected by the seasons, (Jangaard et al 1997, Pedersen and Jobling 1989). The greatest changes were reported to be in female fish with C20:1 ranging from 4.5 to 14.9% and C22:1 from 1.8 to 12.3%. Significant differences in levels were also reported between the seasonal effects on medium and very large cod, (Karalazos et al 2007, Standal et al 2008).

Temperature has been demonstrated to have a marked effect on the growth and development of the fish and also on the composition of the liver lipids (Levesque et al 2005, Brander 1995). It must be appreciated that the factors influencing the composition of the cod liver lipids discussed briefly above are not occurring in isolation and that the fish are likely to be influenced by a combination of two or more of these factors, (Lambertsen and Braekkan 1965). This results in very wide ranges for the fatty acids when these effects are compounded. It also makes it very difficult to develop 'typical' levels and ranges of fatty acids for the genus, unless a number of criteria and caveats are specified.

The need to have a wide range for each fatty acid in order to accommodate the reported profiles of fish from widely separated fishing grounds, for example Atlantic cod and Pacific cod, greatly reduces the usefulness of the profiles for identification purposes.

This can be illustrated by a commercial project undertaken between 1996 and 1998 with the aim of preventing

adulteration of cod liver oil with oils of less value, a major commercial risk at the time. A considerable amount of effort was expended during the first year of the project in trying to obtain a reliable set of fatty acid values and ranges for commercial cod liver oil. This work had to be abandoned when it was found that the liver oil could be adulterated with up to 10% w/w of lower value vegetable oil (canola / rapeseed oil) before the adulteration could be routinely detected from a comparison of fatty acid profiles. It was also not possible to confidently differentiate Pollock liver oil from Cod liver oil using fatty acid profiles. It is noted that Table 1 of CX/FO 13/23/3 refers to Pollock oil. Supplies of Pollock liver oil are also commercially available.

There is further evidence that the lipid composition of CLO appears to have been changing over time. Accumulated data from a major European supplier of CLO covering over a quarter of a century shows major changes in the fatty acid composition of the oil. This is illustrated in **Appendix 1** (see further below) which compares data from the production period 1984 – 1990 with the period 2003 – 2010. For interest, the values from Table 1 of the proposed draft Codex Standard for Fish Oils have been included in Appendix 1.

It is considered that the reason for the differences in the fatty acid values over time is multi-factorial. One factor is likely to be related to the changes in the methods of analysis, both in methodology and precision, which are known to have occurred during the 26 years covered by the data. Other factors include a reduction in the size and maturity of the cod in the catches over the years, (Mayo et al 2002, Hansen 1987, Rogers et al 2010).

A survey of the literature shows that the issues highlighted for Cod liver oil can be repeated for most of the fatty acid profiles for other fish listed in Table 1 of CX/FO. 13/23/3. A major hindrance in the assessment of the values in Table 1 is that there is no indication of provenance for any of the values. It is noted that between the draft Table 1 released on the 3rd April 2012 and Table 1 in CX/FO. 13/23/3, 28% of the fatty acid ranges for Anchovy oil have been increased as have 16% of those for Sardine. In none of the cases has an explanation or reference been given. No criteria appear to have been set on, for example, the number of samples analysed, the fishing grounds and seasons or, more fundamentally, the species of fish. A serious concern is that the time periods of the analysis of the profiles are not given. To be scientifically credible, only data from the last 15 years or less should be included. From the data reviewed it is considered that, for the table to have any validity as a means of identifying fish oils, a full and critical analysis of the data should be undertaken.

This could result in it being found necessary to increase the number of profiles for each generic group of oils to allow for the variation between species. The current table based on families and genera (and in some cases on families alone) is not specific enough to provide a tool for the confident use of the values for the identification of the oil sources. As discussed above, doubt is expressed as to whether the tables alone in their present form can identify significant adulteration of the fish oils with other oils, including vegetable oils.

Before Table 1 is submitted for adoption by the Codex Committee on Fats and Oils, a comprehensive independent review of the data sources should be undertaken to ensure scientific credibility.

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Appendix 1 (IASDA)

Cod liver oil data 1984 - 2010

The following data relate to cod liver oil from Norwegian or Icelandic fish (*Gadus morhua)*, but it could also represent a blend from both sources. The data are from two distinct time periods: 1984-1990 and 2003-2010.

Factors affecting differences in the data between the two time periods include the fact that the methods of analysis for fatty acids (FA) in fish oil changed in the early 1990s. In addition, along with climatic changes, the size of the fish that are caught has reduced considerably over the past decades.

	Based on production of CLO from 1984-1990		***Data for 2003 - 2010***		***Codex Draft Table 1***	
Fatty Acids	**Max**	**Min**	**Max**	**Min**	**Max**	**Min**
C14:0	5.50	3.55	4.80	3.90	6.00	2.00
C15:0	0.41	0.24	0.45	0.30	0.50	ND
C16:0	12.50	9.96	13.10	11.30	14.00	4.00
C16:1n7	10.10	5.02	7.10	6.20	11.50	4.50
C18:0	2.85	1.67	2.40	2.10	4.00	1.00
C18:1n7	5.70	2.31	3.90	3.00	7.0	2.0
C18:1n9	19.30	12.90	16.70	13.60	21.00	12.00
C18:2n6	1.93	1.04	3.00	2.00	3.00	0.50
C18:3n3	1.67	0.48	1.30	0.80	2.00	ND
C18:4n3	4.06	1.52	2.50	2.00	4.50	0.50
C20:1n9	11.90	7.50	9.40	7.10	17.00	1.00
C20:1n11	5.29	1.30	1.90	1.20	5.50	1.00
C20:4n6	0.38	0.18	0.90	0.50	1.50	ND
C20:4n3	0.87	0.45	1.30	0.80	2.00	ND
C20:5n3	10.40	7.29	9.10	7.80	16.00	7.00
C21:5n3	0.46	0.27	0.90	0.40	1.50	ND
C22:1n9	1.30	0.51	1.40	1.00	1.50	ND
C22:1n11 **	11.70	5.89	9.50	8.50	12.00	5.00
C22:5n3	1.29	0.79	2.20	1.50	3.00	0.50
C22:6n3	13.30	7.64	10.90	9.80	18.00	5.00

** This FA also usually contains a peak for C22:1n13, which is normally inseparable from the C22:1n11 except by mass spectrometry.

ISDI

The International Special Dietary Foods Industries (ISDI), representing the associations of manufacturers of special dietary foods at Codex Alimentarius, thanks the delegation of Switzerland for their work and makes the following comments:

1. Virgin/Extra Low oxidised Fish Oils

ISDI does not support the classification proposed by the E-WG. Virgin/Extra Low oxidised Fish Oils trade is not significant enough to go in this segmentation.

Virgin/Extra Low oxidised Fish Oils as other Fish Oils need to be refined before being delivered to the consumer.

The only distinction for this type of oils is only on manufacturing process.

2. Named fish Oils

ISDI proposed to avoid starting any debate for the name of very specific species that are sold in small volume. Small volume trade is generally not in the scope of the Codex discussion.

3. Quality parameters

ISDI supports the inclusion of quality parameters and looks forward to additional discussions to determine which parameters are the most appropriate to include.

ISDI welcomes the opportunity to participate in the discussion at Codex Alimentarius and will continue to offer its scientific and technical expertise to further advance the discussions.