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CODEX COMMITTEE ON FATS AND OILS

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PROPOSED DRAFT STANDARD FOR FISH OILS

REPLIES TO CL 2015/23-FO

(At Step 6)

BRAZIL

General Comments

On section 2 (description) Brazil noticed that there is a mistake in the number of the definition of “Named fish liver oils” and “Cod liver oil”. The correct numbering is pointed in the specific comments below.

Regarding Table 1, Brazil does not have additional information regarding fatty acids composition of anchovy and krill oils.

In relation to section 7.3 (other labeling requirements), Brazil recognizes that EPA and DHA are nutrients that naturally occur in fish oils, as well as vitamin A and vitamin D occur in fish liver oils. Then, it is appropriate to establish minimal contents of these nutrients for specific products. The reference values for these nutrients are already defined in the sections “Description” and “Essential composition and quality factors” of the Draft Codex Standard for Fish oil presented in the CL 2015/23-FO.

However, the obligation to declare the EPA, DHA, vitamin A and vitamin D content in the labelling of fish oils or fish liver oils is not coherent with the Guidelines on Nutrition Labeling (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 wiser choices can be made.

The list of nutrients that is always declared when nutritional 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 Labelling requires the declaration of the amount of any nutrient for which a nutrition or health claim is made.

In this way, Brazil understands that the declaration of vitamin A and D for fish liver oils and EPA and DHA for fish oils should be optional and not mandatory. Therefore, our understanding is that both the phrases on section 7.3 should have the same meaning: **“shall be given if required by country of retail sale”** or **“may”**.

Regarding the methods for phospholipids on section 8 (8.10), Brazil would like to ask for clarification about the conversion factor to be considered to convert phosphorus to phospholipids, since the three methods included in this section quantify phosphorus in fats and oils and none of them establishes a conversion factor to phospholipids.

Specific Comments

~~2.3.1~~ **2.3** Named fish liver oils are 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.

~~2.3.2~~ **2.3.1** Cod liver oil is derived from the liver of wild cod, *Gadus morhua* L and other species of *Gadidae*.

7.3 Other labelling requirements

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

or

For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D, naturally present or restored, shall be given if required by country of retail sale.

The content of EPA and DHA [~~shall~~**may**] be given for all fish oils covered by this Standard.

or

The content of EPA and DHA [**shall**/~~may~~] be given for all fish oils covered by this Standard, **if required by country of retail sale.**

CANADA

Canada supports the scope and description as written.

2.3.1 - Canada notes that there are two species of krill that are commercially used for extraction of krill oil, i.e. *Euphausia superba* and *Euphausia pacifica*. We recommend including both species in the standard under item 2.1.3.

“2.1.3 Krill oil is derived from *Euphausia superba* **and *Euphausia pacifica*.**”

2.3.1 and 2.3.2 - The numbers for these sections should be changed to 2.3 and 2.3.1 respectively to match the numbering in the standard, i.e. named fish liver oil is a main category and cod liver oil is a sub-category under this.

~~2.3.4~~ **2.3** Named fish liver oils are derived...

~~2.3.2~~ **2.3.1** Cod liver oil is derived...

2.5.1 and 2.5.2 - Canada notes that the form of EPA and DHA in krill oils may be present as triglycerides and phospholipids. As such, we suggest that the form of EPA and DHA in sections 2.5.1 and 2.5.2 be changed as shown below:

2.5.1 and 2.5.2 “...at least 50 w/w % of fatty acids are in the form of triglycerides **and/or phospholipids**”.

3 Essential composition and quality factors

3.1 GLC ranges of fatty acid composition (expressed as percentages of total fatty acids)

Canada appreciates the opportunity to review and comment on the fatty acid profile of krill oil. As part of our comments to Circular Letter CL 2015/5-FO Part B, Point 4, Canada has submitted analytical data on krill oils for consideration in this current standard, to assist in the development of a robust standard that is evidence-based and takes into account various factors. The data includes fatty acids which are present in significant amounts and does not include those which are present in minute amounts, and which does not contribute to the identification of the oil.

While the contents of the various fatty acids fall mostly within the current limits for these fatty acids in the draft standard for krill oil, we note that three fatty acids had limits that are significantly different than what is presented in the current draft, as follows: C18:1 (n-7) vaccenic acid, C18:1 (n-9) oleic acid and C20:5 (n-3) eicosapentaenoic acid. We propose that the analytical data for these fatty acids be reviewed, taking into consideration the new data submitted by Canada, and considering the changes proposed in the last column of the table below.

Table 1 - fatty acid range for krill oil

Fatty acids	Current Draft Standard Krill Oil (Section 2.1.3)	Canadian Industry Data (n=119)	Proposed changes to Draft Standard Krill Oil (Section 2.1.3)
C18:1 (n-7) vaccenic acid	8.4-21.7	6.26-8.05	8.4-21.7 6.3 -8.1
C18:1 (n-9) oleic acid	NA	8.64-12.53	NA 8.6 – 12.5
C20:5 (n-3) eicosapentaenoic acid	14.3-24.3	17.65-27.58	14.3- 24.3 27.6

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

~~na~~ **NA**= not available

Other editorial comments on Table 1:

Canada suggests including the term “oil” in the headings of each column with the specific named oils, e.g. anchovy oil, tuna oil, krill oil etc.

Canada also suggests rearranging the columns for the named fish oils and fish liver oils according to the order in which they are numbered in the proposed standard. Information for cod liver oil should be placed at the right most column after farmed salmon oil.

The second column under salmon oil should be “Farmed” (add “ed”).

We suggest to have consistency in the abbreviation used for “not available” - either all capitalized “NA” or all small letters “na”.

3.2 Quality parameters:

Canada suggests the addition of astaxanthin in the quality parameters for krill oil in section 3.2.2. **Krill oil: Astaxanthin content > 0.01% (> 100 ppm)**

Rationale:

Krill biomass contains high levels of astaxanthin, a strong anti-oxidant carotenoid that provides krill with its notable reddish colour. Along with krill oil’s phospholipid content, its astaxanthin content is another parameter that makes krill oil distinct from other named fish oils. Accordingly, the United States Pharmacopoeia (USP) Krill Oil monograph has included astaxanthin as a defined specification. This is an important parameter that could be used to assess purity of the oils.

We suggest to use the current specification for astaxanthin in the USP monograph for krill oil, which recommends astaxanthin content of not less than 0.01% (equivalent to 100 parts per million).

3.3 Vitamins:

Canada recalls that the issue related to Vitamin A and Vitamin D seeking maximum concentrations as well as minimums would be referred to the Codex Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU) and that the electronic working group working at that time would identify specific questions to be referred. Canada would like to offer the following questions for consideration by CCNFSDU:

- Considering the minimum levels of vitamin A and D in the proposed draft standard for fish oils, should there be a maximum identified? For example, in cod liver oil, the concentration of Vitamin D can be 232 IU per ml or more, which would be about 3500 IU in a tablespoon, where the UL for adults is 4000 (1000 for infants 0-6 months - other age groups in between).
- Should there be consideration of devitaminization if used as food oils?

As indicated earlier, there may need to be maximum levels of vitamins established for this product to ensure that it does not contribute to excessive intake of the vitamins.

Section on Permitted Ingredients:

The Codex Alimentarius Procedural Manual, 25th edition, Format for Codex Commodity Standards indicates that the Essential Composition and Quality Factors should include compulsory and optional ingredients. Canada notes that, while this section is not included in the standard, there are indications that other ingredients may be added. For example, Section 4, Food Additives, indicates that flavourings may be used in fish oils. Section 7.3 appears to provide for vitamin A and D fortification of fish liver oils to restore.

It is suggested that, if flavours and fortificants are included in this standard that, similar to other Codex commodity standards, a subsection be added to Section 3 to identify permitted ingredients that are not food additives, and permitted nutrients. An example of this can be found in Codex Standard for Whey Cheese, Codex Stan 7, Rev 2-2006. As well, as indicated in this standard, Section 3.3, for permitted nutrients:

“Where allowed in accordance with the Codex General Principles for the Addition of Essential Nutrients for Food (CAC/GL 9-1987), maximum and minimum levels for minerals and other nutrients, where appropriate, should be laid down by national legislation in accordance with the needs of individual country including, where appropriate, the prohibition of the use of particular nutrients”.

4. Food Additives

Canada suggests that the food additives section of the draft standard be forwarded to CCFA for consideration and endorsement, together with the justification for the five additives proposed for inclusion in the commodity standard outside of the general reference to the GSFA.

The following editorial change is suggested to better align with the Procedural Manual (25th edition):

“Antioxidants, sequestrants, antifoaming agents, and emulsifiers used in accordance with Tables 1 and 2 of the General Standard ~~of~~ **for** Food Additives (CODEX STAN 192-1995), in food category 02.1.3 Lard, tallow, fish oil, and other animal fats are acceptable for use in foods conforming to this standard.”

On the use of flavourings, the text reflects the Procedural Manual (25th edition) which is not accurate, hence a minor editorial is suggested as follows:

“The use of flavourings ~~used~~ in products covered by this standard should comply with the Guidelines for the Use of Flavourings (CAC/GL 66-2008)”.

5. Contaminants – Arsenic speciation

Consideration for maximum levels for arsenic in food products should be referred to the Codex Committee on Contaminants in Food (CCCF). Canada recommends that the CCFO refer to the CCCF to consider maximum levels (ML) for inorganic arsenic in fish oils.

Rationale:

Presently, the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF, Codex Stan 193-1995) includes an ML of 0.1 mg/kg for total arsenic in edible fats and oils, which includes edible fats and oils of marine origin (CODEX STAN 19-1981). Data from monitoring programs on fish and seafood products indicate that the inorganic arsenic contributes minimally to the total arsenic content in these products. It is also generally accepted that of the organic forms of arsenic, arsenobetaine, which is the major form in fish and seafood, is of very low toxicological concern to human health. Arsenobetaine is the major arsenic species in Antarctic krill.

Canada considers it reasonable to refer this matter to the CCCF. The CCCF may consider revising the existing ML for total arsenic for edible fats and oils of marine origin such that it would apply to inorganic arsenic, or establishing a separate ML for total or inorganic arsenic in edible krill oil specifically.

7. Labelling

Sections 7.1 and 7.2 appear to be consistent with the presentation of other Codex standards.

As indicated earlier, the draft standard includes text that indicates flavouring as an optional ingredient. Canada therefore recommends that naming for flavoured oils be included in the labelling section.

“Where a fish oil has had flavouring added to it, the name of the oil shall be prefaced with “flavoured” or “naming the flavour”.

7.3 Other Labelling Requirements

As indicated in our submission to CL 2015/05-FO, Canada supports the second option in the statement below:

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

Or

For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D, naturally present or restored, shall be given if required by country of retail sale.]

Canada also supports using the word “may” in the statement: “The content of EPA and DHA [shall/may] be given for all fish oils covered by this Standard.”

8. Methods of Analysis and Sampling

All the methods identified in the standard will need to be collaboratively studied using the matrix identified in the standard. Canada suggests that CCFO refer all the methods to CCMAS for consideration.

Also, as discussed in item 5 above, Canada suggests that CCFO refer the matter to CCCF to consider maximum levels of inorganic arsenic in fish oils. If inorganic arsenic is considered to be appropriate in this standard, the method for such test would need to be elaborated.

Canada suggests reviewing the need to keep the Acid Value as a test for fish oils with high phospholipid content, such as krill oils. Currently, the limit set for this parameter is less than or equal to 30 mg KOH/g. The current version of the USP monograph on krill oil has removed acid value as a test for this type of oil, as it provides minimum added value to the monograph. We would suggest reviewing the usefulness of this quality parameter for fish oils with high phospholipid content.

CHILE

GENERAL REMARKS

The Subcommittee on Fats and Oils presents its comments at the draft standard fish oil. The following general comments are detailed.

There is no scientific evidence to demonstrate and guarantee unequivocally the species of origin of an oil sample based on the fatty acid profiles specified in Table 1, as they may be cases where oil samples made from the species listed in section 2.1, not from obtaining results within specified ranges. Also, it is possible to obtain results of samples from mixtures of oils from more than one species found within the specified ranges.

Therefore, if the rule provides that compliance with sections 2.1 and 2.3 will be verified only based on the profiles specified in Table 1, this could induce error and seriously affect trade because they could be rejected items oil fish specified, that despite be elaborated of raw material described in sections 2.1 and 2.3 may not meet the ranges specified in Table 1. Also, it could consider oil samples made from raw materials unspecified in sections 2.1 and 2.3 to this standard, it comply with the fatty acids rank indicated in Table 1.

Since the fatty acid profiles ranges indicated, does not seem to be a tool reliable enough for verification of raw materials, it should be considered more realistic alternatives for international trade.

In addition, the draft standard mentions that there are (geographic, food, etc.) factors that could affect the fatty acid profiles for specified oils but does not indicate which or how compliance with this standard will be confirmed.

In the experience of Chile, the most effective way, corresponds to verification of traceability through systems quality companies inspection activities of competent bodies in origin which in turn can issue the appropriate certification if it is required by a third party.

SPECIFIC COMMENTS

2. Description

Crude fish oils and crude fish liver oils ~~are oils~~ intended for human consumption ~~after~~ may they have undergone further processing, refining and purification and ~~have~~ should to comply with section 3.1, 3.2 and 3.3, as applicable, as well as with sections 4, 6-4 and 7.

Justification:

It include the obligation to comply with Sections 3.1, 3.2 and 3.3. Likewise, all must comply with section 6 and not just 6.1.

~~The refined fish oil production process typically includes several steps such as repeated heating at high temperatures as well as alkali/ acid treatments and repeated removal of the water phase. Fish oils may also be subjected to processing steps (e.g. refining, solvent extraction, saponification, re-esterification, trans-esterification).~~

Justification:

The description given for the refining process should be removed, due to the lack of specification. The definition of this process is irrelevant to this norm.

If he you want to incorporate a definition, this ought to consider all the processes involved.

In documents issued by FAO, defined in Chapter 5, processing and refining of edible oils (<http://www.fao.org/docrep/v4700e/v4700e0a.htm>) that: Refining oil. Oil Refining. Refining produces an edible oil with characteristics that consumers desire such as bland flavour and odour, clear appearance, light colour, stability to oxidation and suitability for frying. Two main refining routes are alkaline refining and physical refining (steam stripping, distillative neutralisation) which are used for removing the free fatty acids.

The processes involved (refining and purification), does not generate denaturing or structural change in triglycerides, alone segregation and purification. Understanding the definition as impurities described in bulletin No. 17 of IFFO, which states "Impurities": The impurities which are found in crude oils can be grouped according to their effect. a) Hydrolytic: eg: moisture, insoluble matter, free fatty acids, mono and di glycerides, enzymes, soap.

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 sections 2.1 and 2.3 of 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.~~

3.1 Accreditation referential origin and composition of fatty acids

Compliance with sections 2.1 and 2.3 shall be verified by accreditation at source by the competent authority on the basis of traceability systems.

Table 1 reference ranges fatty acids from fish oils and liver oils fish specified in sections 2.1 and 2.3 of this standard is. These ranges experience variations due to weather or national geographic differences as well as due to other biological factors.

Justification:

You cannot prove, by using the fatty acid profiles of fish oil (Table 1), the species with which he elaborated the oil, taking into account the overlap between ranges.

It attached report and executive report with detailed justification.

3.2 Quality parameters

Total oxidation value (ToTox) \leq ~~26~~ 30

Justification:

Error in the calculation for total oxidation value (ToTox) = 2 x Peroxide value + Anisidine value. The result according to the values of Peroxide = 5 meq active / kg oil oxygen, and anisidine value = 20, would give a total value of 30 and not 26.

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 (Section 2.1.1)	Cod Liver (Section 2.3.1)	Tuna (Section 2.1.2)	Krill (Section 2.1.3)	Menhaden (Section 2.1.4)	Salmon oil (Section 2.1.5)
						Wild <u>Wild Farm</u>

Justification:

Error in Table 1, is repeated 2 times the word wild in translation in Spanish.

EUROPEAN UNION

7.3 Other labelling requirements

This section contains two options for the specific labelling of vitamin A and vitamin D. **The second option is preferred** because it offers flexibility as to the different requirements for retail sale.

This section contains two options for the labelling of the content of EPA and DHA (obligatory/optional). **The first option (obligatory) is preferred.** EPA and DHA are the most valuable constituents of fish oils. According to Table 1 of the draft standard the EPA and DHA contents may vary over a rather broad range. This is valuable and essential information for the consumer about the real content of EPA and DHA in the different fish oils. It should therefore be safeguarded in order to ensure that consumers can make informed choices.

8.2 Determination of fatty acid composition

The standard ISO 5508 has been recently replaced by ISO 12966-1 and 12966-4. At present gas chromatography of fatty acid methyl esters in animal and vegetable fats and oils is covered by 4 parts of ISO 12966. This section should therefore be amended as follows:

"According to applicable ISO methods including: ~~ISO 5508 and ISO 12966-2~~, **ISO 12966** (Animal and vegetable fats and oils - Analysis by gas chromatography of methyl esters of fatty acids)..."

JAPAN

7.3 Other labelling requirement

Proposed text:

For fish liver oils (Section 2.3 and 2.4) **except shark liver oils** the content in vitamin A and vitamin D shall be given.

The content of EPA and DHA [~~shall/may~~] be given for all fish oils covered by this Standard **except shark liver oils**.

Rationale:

It is not necessary to give content in vitamin A, vitamin E, EPA and DHA for shark liver oils because shark liver oils generally do not contain these substances. If it is indicated as "0", it will give a negative image of the product and mislead consumers.

NORWAY

(i) General Comments

We support the document and the joint effort to develop a common standard on this subject.

(ii) Specific Comments

SECTION 5 CONTAMINANTS

We would like to emphasize that we consider it important that CCCF, as soon as the fish oil standard is finalized, consider whether it is appropriate that the ML for arsenic in fish oils apply to total arsenic or to only inorganic arsenic. The inorganic arsenic is considered far more toxic than the organic arsenic, and it is the organic arsenic which is mainly found in seafood.

SECTION 8.10 DETERMINATION OF PHOSPHOLIPIDS

Norway would like to inform the CCFO of the progress for the validation of the USP-NF method for the determination of phospholipids. The work is ongoing, and this method may be included in the forthcoming 7th edition of AOCS methods due for release in May 2017.

Norway would like to ask CCFO to refer to this method in section 8.10 in the fish oil standard, as soon as the method is adapted by AOCS.

PERU

GENERAL REMARKS

The Technical National Commission on Fats and Oils presents its comments to the draft standard for fish oils. We now detail the general remarks.

The draft standard must guarantee the right of access to the information on fish oil products for human consumption available in the market. Consumers have a right of access to sufficient information that is truthful and easily accessible, relevant to make a decision or making a consumption choice in accordance with their interests, as well as to determine an adequate use or consumption of the products for the purposes of enhancing and preserving their health.

There are differences in the composition of the oils (fatty acids profile) of marine origin, between wild and farmed species. The importance of the fish oils resides principally in their content of the EPA and DHA fatty acids, which are not present in those oils of vegetable origin. These fatty acids contribute to improving anti-inflammatory processes and to avoid the appearance of cardiovascular disorders.

It is important for the draft CODEX Standard for Fish Oils to include the minimum content of EPA + DHA (both omega 3) and the content of linoleic acid (omega 6), that characterize and identifies each species and that can contribute to guaranteeing fish oil authenticity, as well as such declaration in the labelling of this product.

It is necessary to consider and debate the fact that it is important to adequately distinguish fish oil from wild fish in comparison with the oil from farmed fish. To ignore this could affect the health benefits inherent in fish oil due to the relationship between the content of omega 3 and omega 6.

SPECIFIC REMARKS

Perú does not agree with the following paragraphs:

2. Description:

Raw fish oils and raw fish liver oils are oils destined for human consumption after being subjected to additional processes, refining and purifying and have to meet the provisions in ~~la Sección~~ **Sections** 3.1, ~~según sea aplicable, así como con las Secciones~~ 4, 6.1 and 7, **as applicable**.

Justification:

It is necessary to state that the specifications and requirements indicated in the foregoing sections are only applicable to oils suitable for human consumption, in accordance with the definition appearing in Section 2 and not raw oils originating in the primary extraction processes.

2.1.1 **Anchovy oil** is obtained from the species *Engraulis (Engraulidae)*. **In the case of the species *Engraulis ringens* (anchoveta), the sum of the content of EPA and DHA has to be at least 27%.**

Justification:

According the Department of Fisheries and Aquaculture of FAO, the common name of the species *Engraulis ringens* corresponds to anchoveta (peruvian anchovy).

As specified in Section 2.1.3 for krill oil, it is necessary to specify the sum of the content of EPA and DHA for the specific case of the species *Engraulis ringens* since:

This resource has been and continue to be the most important source of fish oil for human consumption in the world. Only in the omega 3 industry sector, the oil from *Engraulis ringens* has represented up to 70% of the world's supply.

As can be seen in the official statistics, the sum of both fatty acids shows consistently values equal to or greater than 27%, in any geographic, oceanographic or climatic circumstances.

2.1.3 **Krill oil** is derived from the species *Euphausia superba*. The principal components are triglycerides and phospholipids. The phospholipid content has to be at least 30 ~~w/w~~ **m/m**%.

2.3.1 **2.3 Named fish liver oils** are derived from from fish livers and are composed of fatty acids, vitamins or other components that represent the livers of those species from which the oil is extracted.

2.3.2 **2.3.1 Cod liver oil** is derived from the liver of wild cod, *Gadus morhua* L and from other species of *Gadidae*.

2.5.2 **Highly concentrated fish oil** contains more than 50 m/m % of the fatty acids EPA and DHA and at least 50 m/m % ~~of~~ of the fatty acids are in the form of triacylglycerides.

3.1 **Composition ranges of fatty acids determined by GLC** (expressed as percentages of total fatty acids)

The samples which meet the corresponding ranges indicated in Table 1 meet the requirements of Sections 2.1 and 2.3 of that Standard. Complementary criteria such as national geographic or climatic, **or its origin (wild or farmed)**, could be considered, as may be necessary case by case, to confirm that a sample meets the Standard.

Justification:

The intention is to consider another criterium as per species classification indicated in Table 1.

3.3 Vitamins

Vitamin A $\geq 40 \mu\text{g}$ of ~~of~~ equivalents to retinol/ml

4. Food Additives

Antioxidants, sequestrants, antifoaming agents, and emulsifiers used in accordance with con las **the** Tables 1 and 2 of the *General Standard for Food Additives* (CODEX STAN 192-1995), in the category of foodstuffs 02.1.3 *Pork Lard, tallow, fish oil, and other fats of animal origin.*

7.3 Other labelling requirements

In the case of fish liver oils (Sections 2.3 and 2.4) the content of vitamin A and vitamin D must be shown.

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En el caso de aceites de hígado de pescado (Secciones 2.3 y 2.4) deberá indicarse el contenido de vitamina A y vitamina D, si las vitaminas están presentes o han sido restauradas de forma natural, si así lo solicitase el país de venta minorista.]

In the case of all the fish oils regulated by this Standard, the content of EPA, DHA and **linoleic acid must be shown.**

Justification:

Being aware of the present importance of the equilibrium in the consumption of the fatty acids Omega 3 (EPA and DHA) and Omega 6 (linoleic acid) and their impact on consumer health, it becomes necessary as a matter of transparency, that in addition to highlighting the content of the Omega 3 fatty acids, the user or consumer should also find listed in the label the content of linoleic acid, the object being that the user can evaluate the equilibrium mentioned above in addition to distinguishing if the fish oil is from a wild resource (which would normally have a low linoleic acid content) or if it is from farmed fish or from a mixture of the two.

Table 1: Content of fatty acids in the categories of fish oil and named fish liver oils, determined by gas liquid chromatography using authentic samples (expressed as percentage of total fatty acids) (see Section 3.1 of the Standard)

Fatty Acids	Anchovy or anchoveta (Section 2.1.1)	Cod liver (Section 2.3.1)	Tuna (Sección 2.1.2)	Krill (Section 2.1.3)	Atlantic Tarpon (Section 2.1.4)	almon Oil (Section 2.1.5)	
						Wild	Silvestre Farmed
C14:0 miristic acid	5,0-11,5	2,0-6,0	IN-5,0	6,4-13,0	8,0-11,0	2,0-4,5	1,5-5,5
C15:0 pentadecanoic acid	IN-1,5	IN-0,5	IN-2,0	NA	IN-1,0	IN-1,0	IN-0,5
C16:0 palmitic acid	13,0-22,0	7,0-14,0	14,0-24,0	17,0-24,6	18,0-20,0	12,0-16,0	6,5-12,0
C16:1 (n-7) palmitoleic acid	5,0-12,0	4,5-11,5	IN-12,5	2,1-8,9	9,0-13,0	4,5-6,0	2,0-5,0
C17:0 heptadecanoic acid	IN-2,0	n. d.	IN-3,0	NA	IN-1,0	IN-1,0	IN-0,5
C18:0 estearic acid	1,0-7,0	1,0-4,0	IN-7,5	NA	2,5-4,0	2,0-5,0	2,0-5,0
C18:1 (n-7) vaccenic acid	n. d.	2,0-7,0	IN- 7,0	8,4-21,7	2,5-3,5	n. d.	n. d.
C18:1 (n-9) oleic acid	5,0-17,0	12,0-21,0	10,0-25,0	NA	5,5-8,5	16,0-18,0	30,0-47,0
C18:2 (n-6) linoleic acid	IN-3,5	0,5-3,0	IN-3,0	0,7-2,1	2,0-3,5	1,5-2,0	8,0-15,0
C18:3 (n-3) linolenic acid	IN-7,0	IN-2,0	IN-2,0	0,1-4,7	IN-2,0	IN-1,0	3,0-6,0
C18:3 (n-6) γ -linolenic acid	IN-5,0	n. d.	IN-4,0	NA	IN-2,5	IN-1,0	IN-0,5
C18:4 (n-3) estearidonic acid	IN-5,0	0,5-4,5	IN-2,0	1,0-8,1	1,5-3,0	1,0-2,5	0,5-1,5
C20:0 araquidic acid	n. d.	n. d.	IN-2,5	NA	0,1-0,5	IN-0,5	0,1-0,5
C20:1 (n-9) eicosenoic acid	IN-4,0	5,0-17,0	IN-2,5	NA	IN-0,5	4,5-6,0	1,5-7,0
C20:1 (n-11) eicosenoic acid	IN-4,0	1,0-5,5	IN-3,0	NA	0,5-2,0	n. d.	n. d.

C20:4 (n-6) araquidónico acid	IN-2,0	IN-1,5	IN-3,0	NA	IN-2,0	0,5-1,0	IN-1,2
C20:4 (n-3) eicosatetraenoic acid	IN-2,0	IN-2,0	IN-1,0	NA	n. d.	1,0-2,0	0,5-1,0
C20:5 (n-3) eicosapentaenoic acid	5,0-26,0	7,0-16,0	2,5-9,0	14:3-24,3	12,5-19,0	6,5-9,5	2,0-6,0
C21:5 (n-3) heneicosapentaenoic acid	IN-4,0	IN-1,5	IN-1,0	NA	0,5-1,0	IN-1,0	n. d.
C22:1 (n-9) erucic acid	IN-5,0	IN-1,5	IN-2,0	NA	0,1-0,5	1,0-1,5	3,0-7,0
C22:1 (n-11) cetoleic acid	IN-5,0	5,0-12,0	IN-1,0	NA	IN-0,1	1,0-1,5	n. d.
C22:5 (n-3) docosapentaenoic acid	IN-4,0	0,5-3,0	IN-3,0	0-0,07	2,0-3,0	1,5-3,0	1,0-2,5
C22:6 (n-3) docosahexaenoic acid	4,0-23,0	6,0-18,0	21,0-42,5	7,2-25,7	5,0-11,5	6,0-8,5	3,0-10,0
SUM OF EPA + DHA	<u>Min. 27</u>						

IN = non-detectable, defined as $\leq 0.05\%$

n. d. = not available NA = not applicable

Justification:

The wild type of salmon oil is repeated twice, one should be farmed.

Justification for erucic acid:

Data available in Perú indicates the higher range is not representative, in December 2016 we will present data and proposed range.

Justification for the sum of EPA + DHA:

The high content of EPA and DHA is the principal characteristic of the marine fish oils from wild species. Their marketing and sale from the raw oil is based on this content. The species *Engraulis ringens* is the principal species that supplies the world market for oil in the Omega 3 industrial sector (up to 70% in 2013). In its technical guide GOED establishes a typical profile for the peruvian anchovy (anchoveta) as well as a minimum of EPA + DHA of 27%. In general terms oils from wild fish also have the characteristic of a low linoleic acid content (LA).

Likewise, institutions such as FAO Experts Consultation: FAO Study on Food and Nutrition N° 91 and EUFIC mention the importance of EPA and DHA as contributors to the prevention of cardiovascular disorders (CHD) and possibly of other degenerative disorders linked to ageing. Also the importance for pregnant women, and for the development of the foetus and new born.

This is why it is important to include the content of Omega 6 (linoleic acid) in the label, as its low content is one of the characteristics inherent in wild fish oils as opposed other types of oils from farmed species.

UNITED STATES OF AMERICA

General Comments

The United States supports development of the Proposed Draft Standard for Fish Oils in the Codex Committee on Fats and Oils. Specific comments on the various sections are as follows (additions underlined, deletions in strikethrough).

Specific Comments

1) Section 1 Scope

Proposed change: The Standard applies to ~~the~~ both crude and refined fish oils described in Section 2 that are intended presented in a state for human consumption.

Rationale: Crude fish oils may be consumed directly or with minimal processing. This standard should apply to both crude fish oils and refined fish oils intended for human consumption.

2) Section 2 Description

Proposed change to Paragraph 2: ~~Crude fish oils and crude fish liver oils are oils intended for human consumption after they have undergone further processing, refining and purification and have to comply with section 3.1, as applicable, as well as with sections 4, 6.1 and 7.~~

Rationale: We propose to delete the second paragraph completely from this section. Please see rationale provided for item 1 above.

Proposed change to Paragraph 3: Fish oils and concentrated fish oils are primarily composed of glycerides of fatty acid whereas concentrated fish oils ethyl esters are primarily composed of fatty acids ethyl esters.

Rationale: We propose to remove the “s” as fish oil and fatty acid are non-plural descriptors for ethyl esters.

4) Section 2.1 Named Fish Oils

Proposed change: Named fish oils are derived from ~~specific raw materials which are characteristic of the major a single fish or shellfish taxon from which the oil is extracted~~ as indicated in Sections 2.1.1 through 2.1.5. Other fish or shellfish taxa that cannot be practically removed from the named fish oil raw material prior to processing must be less than [5%] by raw weight.

Rationale: Proposed changes provide assurance that named fish oils are obtained from the named fish in the appropriate taxon, and not from other fish with similar characteristics (e.g., fatty acid profile) or from mixtures of fish where the named fish is in the majority (i.e., the highest percentage, but with no minimum percentage).

5. Section 2.1.2 Tuna oil

Proposed change: Tuna oil is derived from the species of the genera *Euthynnus*, *Allothunnus* and *Thunnus* and from the species *Katsuwonus pelamis* (Scombridae).

Rationale: Additional tuna genus used for the production of fish oil is provided.

6. Section 2.1.4 Menhaden oil

Proposed change: Menhaden oil is derived from the genera *Brevortia* (Clupeidae) and *Ethmidium*.

Rationale: Additional menhaden genus used for the production of fish oil is provided.

7. Section 2.2 Fish oils (unnamed)

Proposed change: Fish oils (unnamed) ~~are~~ may be derived from ~~a single one or more species of fish other than the ones listed in Section 2.1 or are a mixture of fish oils derived from specified and/or unspecified raw materials. This includes also mixtures with fish liver oils.~~

Rationale: It is not required to name a fish oil made from a fish oil listed in Section 2.1. Conversely, a fish oil may be named using a name not listed in Section 2.1 as long as it is made from the correct fish and the name is not misleading.

8. Section 2.4 Fish liver oil (unnamed)

Proposed change: Fish liver oil (unnamed) may be derived from the livers of one or more species 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.~~

Rationale: It is not required to name a fish liver oil made from a fish liver oil listed in Section 2.3.1. Conversely, a fish liver oil may be named using a name not listed in Section 2.3.1 as long as it is made from the correct fish and the name is not misleading.

9. Section 2.5 Concentrated fish oils

Proposed change: Concentrated EPA/DHA fish oils are derived from fish oils described in Sections 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 EPA and DHA ~~specific fatty acids.~~

Rationale: The term “concentrated fish oils” is misleading because fish oils are not concentrated; EPA and DHA are concentrated, while other constituents of fish oil are removed. Proposed changes provide clarity.

10. Section 2.5.1 Concentrated fish oil

Proposed change: Concentrated EPA/DHA fish oil contains 35 to 50 w/w % fatty acids as sum of C20:5 (n-3) eicosapentaenoic acid (EPA) and C22:6 (n-3) docosahexaenoic acid (DHA), at least 50 w/w % of fatty acids are in the form of triglycerides.

Rationale: The term “concentrated fish oil” is misleading because fish oil is not concentrated; EPA and DHA are concentrated, while other constituents of fish oil are removed. Proposed changes provide clarity.

11. Section 2.5.2 Highly concentrated fish oil

Proposed change: Highly concentrated EPA/DHA fish oil contains greater than 50 w/w % fatty acids as sum of EPA and DHA, at least 50 w/w % of fatty acids are in the form of triglycerides.

Rationale: See rationale provided for Item 10.

12. Section 3.2.1 Peroxide value

Proposed change: Peroxide value < 5 milliequivalent of active oxygen/kg oil

Rationale: Correct misspelled word (i.e., oxygen).

13. Section 4 Food Additives

Proposed change: Antioxidants, sequestrants, antifoaming agents, and emulsifiers used in accordance with Tables 1 and 2 of the Codex General Standard for Food Additives (GSFA) (CODEX STAN 192-1995), in food category 02.1.3 Lard, tallow, fish oil, and other animal fats are acceptable for use in foods conforming to this standard.

Rationale: Changes indicated reflect standard language used in referring to the GSFA.

14. Section 5 Contaminants

Comment: CCCF should be notified that CCFO is working to establish a Standard for Fish Oils. Depending on source, there could be a need to establish maximum levels for certain contaminants found in fish oil (e.g., PCBs, dioxin).

15. Section 7.3 Other labeling requirements

Proposed change: For fish liver oils (Sections 2.3 and 2.4) the content of Vitamin A and D shall be stated on the label. ~~For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D, naturally present or restored, shall be given if required by country of retail sale.~~ The content of EPA and DHA shall/may be stated on the label for all fish oils covered by this Standard.

Rationale: Fish oils are generally consumed for their EPA/DHA content. Fish liver oils are generally consumed for their Vitamin A and D content. Therefore, this information should be provided on the label.

16. Section 8.2 Determination of fatty acid composition

Proposed change: According to applicable ISO methods including: ISO 5508 (~~Animal and vegetable fats and oils -- Analysis by gas chromatography of methyl esters of fatty acids~~) and ISO 12966-2 (~~Animal and vegetable fats and oils -- Analysis by gas chromatography of methyl esters of fatty acids~~) (Animal and vegetable fats and oils -- Gas chromatography of fatty acid methyl esters -- Part 2: Preparation of methyl esters of fatty acids); or AOCS methods including: Ce 1b-89 (Fatty Acid Composition of Marine Oils by GLC), Ce 1i-07 (Determination of Saturated, cis-, Monounsaturated, and cis-Polyunsaturated Fatty Acids in Marine and Other Oils Containing Long Chain Polyunsaturated Fatty Acids (PUFAs) by Capillary GLC), Ce 2b-11 (Direct Methylation of Lipids in Foods by Alkali Hydrolysis), ~~Ce 1a-13 (Determination of Fatty Acids in edible oils and fats by capillary GLC)~~ and Ce 2-66 (Preparation of Methyl Esters of Fatty Acids)

Rationale: These are editorial changes-- AOCS Ce 1a-13 is not a valid method; it exists as neither a current method, nor a surplused method.

17. Section 8.3 Determination of arsenic

Proposed change: According to AOAC 952.13 (Silver Diethyldithiocarbamate Method); AOAC 942.17 (Molybdenum Blue Method); or AOAC 986.15 (~~Spectroscopy/Atomic Absorption Spectroscopy-Multielement Method~~).

Rationale: This is an editorial change--the full title of AOAC 986.15 is "Arsenic, Cadmium, Lead, Selenium, and Zinc in Human and Pet Foods. Multielement Method". For consistency with the other methods for arsenic, it is appropriate to shorten the title to just "Multielement Method."

18. Section 8.4 Determination of lead

Proposed change: According to AOAC 994.02 (Atomic Absorption ~~Spectroscopy~~Spectrophotometric Method); ~~or~~ ISO 12193 (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).

Rationale: This is an editorial change.

19. Section 8.6 Determination of peroxide value

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

Rationale: This is an editorial change.

20. Section 8.7 Determination of p-anisidine value

Proposed change: According to AOCS Cd 18-90 or European Pharmacopoeia 2.5.36 (Anisidine value).

Rationale: The protocol recommended in European Pharmacopoeia 2.5.36 is the same as that of AOCS Cd 18-90.

21. Section 8.8 Determination of Vitamin A

Proposed change: According to ~~PhEur 2.2.29 liquid chromatography, European Pharmacopoeia monograph Cod-Liver Oil (Type A).~~

Rationale: PhEur 2.2.29 provides only a generic description of liquid chromatography. Reference to “European Pharmacopoeia”, instead of “PhEur”, should be used consistently throughout the draft Standard.

22. Section 8.9 Determination of Vitamin D

Proposed change: According to ~~PhEur 2.2.29 liquid chromatography, European Pharmacopoeia monograph Cod-Liver Oil (Type A).~~

Rationale: See rationale provided for item 21.

23. Section 8.10 Determination of phospholipids

Proposed change: According to AOCS Ca 12b-92 (Phosphorus by Direct Graphite Furnace Atomistic Absorption Spectrometry); AOCS Ca 12a-02 (Colorimetric Determination of Phosphorus Content in Fats and Oils); or AOCS Ca 20-99 (Analysis for Phosphorus in Oil by Inductively Coupled Plasma Optical Emission Spectroscopy).

Rationale: AOCS methods capitalize their method titles.

24. Table 1

Comment: The wide fatty acid ranges found in Table 1 brings into question if there are statistically significant differences in fatty acid composition between the oils listed. At minimum, Table 1 should include a column that indicates how these data were obtained. Additional information, such as species, number of studies/sample number, standard deviation, would be useful. If Table 1 is retained, it should be considered for informational purposes only, and not as a requirement. Moreover, the column for farmed salmon should be removed because the fatty acid profile for farmed salmon would not necessarily differ from wild salmon but depends on components in the feed.

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S (GOED)

The Global Organization for EPA and DHA Omega-3s (GOED) is an association of processors, refiners, manufacturers, distributors, marketers, retailers and supporters of products containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 fatty acids. GOED's membership represents a broad range of businesses, from small entrepreneurs to multinational food companies. The Organization's objectives are to educate consumers about the health benefits of EPA/DHA and to collaborate with government groups, the healthcare community and the industry on issues related to omega-3s, while setting high standards for our business sector. As such, our members have a profound interest in ensuring that valuable information regarding EPA and DHA is communicated to consumers in a meaningful and timely way. Thus said, we appreciate the opportunity to provide comments at Step 6 on the Draft Standard for Fish Oils.

Specific Comments

2.5.1 Concentrated fish oil

Comment: Since it is specified that at least 50 w/w % of fatty acids are in the form of triglycerides, a method (e.g. USP method for "CONTENT OF OLIGOMERS AND PARTIAL GLYCERIDES") is needed for inclusion in Section 8 (Methods of Analysis and Sampling) to determine the percentage of triglycerides.

2.5.2 Highly concentrated fish oil

Comment: same as above for 2.5.1

5. Contaminants

The products covered by this Standard shall comply with the Maximum Levels of the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995).

Comment: GOED believes that inorganic arsenic, not total arsenic, is the more appropriate contaminant for measurement in fish oils. At past meetings of the CCFO, the appropriateness of compliance with the maximum level of arsenic (currently included in the Maximum Levels of the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995), as opposed to inorganic arsenic, in fish oils, has been discussed. It's clear from the below recaps that the intention is for the CCCF to evaluate this issue once the fish oil standard is adopted. As work on the fish oil standard progresses, the chances appear better than not that a standard will be adopted. GOED is concerned that if the CCCF waits until a fish oil standard is adopted that certain oils will be excluded, for an unspecified period of time, from being traded as Codex "compliant". In order to avoid this scenario, GOED suggests the CCFO recommend the CCCF adopt a limit for inorganic arsenic for fish oils pending the adoption of the fish oil standard. GOED understands that every committee is different, but GOED notes that the CCFA agreed for the level of tocopherols (INS 307a, b, c) in the General Standard for Food Additives (GSFA) food category 02.1.3 'Lard, tallow, fish oil, and other animal fats' to be forwarded for adoption at Step 8 at 300 mg/kg, with a new note added "Except for use in fish oils at 6,000 mg/kg, singly or in combination." Once the fish oil standard is finalized and adopted, the note in the GSFA will be amended to refer to the relevant standard number.

23rd Session of the CCFO (25 Feb – 1 March 2013):

- "The Committee agreed to ask the CCCF to include the current level for arsenic and lead in the GSCTFF under the Proposed Draft Standard of Fish Oils and at the same time to ask the CCCF to re-evaluate the level of lead and arsenic in fish oils, taking into account the notes for arsenic in the GSCTFF. When re-evaluating the level for arsenic, the CCCF should consider whether total arsenic or inorganic arsenic is more appropriate for fish oils as the form of arsenic occurring in fish oils is mainly the organic methylated form, with a low acute toxicity."
- "The Committee noted that the method for arsenic may need to be reviewed pending the reply from CCCF whether the method for arsenic should be in the form of total arsenic or inorganic arsenic."

24th Session of the CCFO (9-13 February 2015):

- "The Committee recalled that CCCF7 had agreed to consider the allocation of MLs for lead and arsenic for fish oils once the Standard for Fish Oils was finalized and whether the MLs should apply to total arsenic or inorganic arsenic as more appropriate for these products and agreed to inform CCCF when the Standard will be completed."

GOED notes that the CCCF is not unfamiliar with the topic of inorganic arsenic since it has been discussing the contaminant as it relates to setting a level for husked rice.

In addition, in recent years, the topic of inorganic arsenic has received greater attention by regulatory authorities. The European Commission has set maximum levels of inorganic arsenic in foodstuffs¹. In Canada, Health Canada addressed an arsenic limit issue by providing limits for total arsenic, inorganic arsenic and organic arsenic². If total arsenic content in the finished product exceeds the current tolerance limit of 0.14 µg/kg b.w./day (taking into account dosage and subpopulation), the license holder is required to conduct additional testing with arsenic speciation to demonstrate that the dose of inorganic arsenic does not exceed 0.03 µg/kg b.w./day and the dose of organic arsenic does not exceed 20.0 µg/kg b.w./day.

Given the above, GOED suggests that the limit for inorganic arsenic in the standard be defined as 0.1 mg/kg.

¹https://members.wto.org/crnattachments/2016/SPS/EEC/16_1773_00_e.pdf

²<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq-eng.php>

8.7 Determination of p-anisidine value

According to AOCS Cd 18-90 **or PhEur 2.5.36**

8.10 Determination of phospholipids

According to AOCS Ca 12b-92 (Phosphorus by direct graphite furnace atomic absorption spectrometry); AOCS Ca 12a-02 (Colorimetric determination of phosphorus content in fats and oils; Ca 20-99 (Analysis for phosphorus in oil by inductively coupled plasma optical emission spectroscopy).

Comment: GOED wants to make the CCFO aware that the validation of the USP-NF method for the determination of phospholipids is in progress and may be included in the forthcoming 7th edition of AOCS methods due for release as early as May 2017. Once adopted by AOCS, we would ask that the committee consider referencing this method in the fish oil standard.

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)

Comment: In farmed salmon, the content of linoleic acid, eicosapentaenoic acid and docosahexaenoic acid is dependent upon their feed. In theory, the ranges of optimally fed farmed salmon would approach that of wild salmon. GOED recommends the inclusion of a note to Table 1 to explain that, in the future, the fatty acid ranges may need to be adjusted/expanded as salmon farmers change feed composition.

THE MARINE INGREDIENTS ORGANISATION (IFFO)

IFFO represents fishmeal and fish oil producers and related industries worldwide. 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 as the standard is fundamental to the business of IFFO and its members.

IFFO appreciates the work that has been done in drafting the Codex standard for fish oil. Although we generally agree with the proposed draft standard we would like to submit additional information including some that we have received from within our membership.

Sections:

3. Essential composition and quality factors

The industry is very concerned that due to the wide range in the individual fatty acids in the fatty acid composition of fish species, there may be overlapping compositions between oils which will make it difficult to distinguish between some fish species. Relying on the fatty acid composition only to identify oils can result in unreliable identification of fish oil. It is therefore important to include additional identity parameters into the Fish Oil Standard.

There is a need to include reference to a method for instances where the identity of the fish oil is questionable and may be a contentious issue. Such a method, due to the nature of its complexity and consequently the technology required, may not be readily available to all at this stage and potentially may only be used on an occasional basis. An example of such a technique is based on Nuclear Magnetic Resonance (NMR), and we would like to suggest that the NMR authenticity analysis method should be added to the Codex Fish Oil Standard. There is a small but growing amount of scientific literature on the technique dating back to the early 2000s. As a result of the complexity of the technique, specialised equipment and the need for a substantial, reliable database of known reference samples, analyses may need to be sent to specialised, recognised laboratories that are experienced and equipped to perform the analyses. The Norwegian company OmegaVeritas (<http://www.omegaveritas.com/>) is an example of a laboratory that specialises specifically on the identification of marine oils having built a substantial database with reference samples, showing that this technique is now becoming a reality in the sector. A brief description of the method and the back ground is attached.

We propose the following changes:

- 1) The text in section 3.1 which states that “*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.*” acknowledges that geographical and seasonal variations exist but does not clarify how these variations are addressed in ensuring compliance with the Standard. It leaves the fatty acid composition open to interpretation, and is therefore ambiguous.

Section 3.1.1 **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 sections 2.1 and 2.3 of 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.] to be replaced with:

[Supplementary analyses (in 3.1.2) that will allow for national geographical and/or climatic variations, may be considered, as necessary, to confirm that a sample is in compliance with the Standard.]

- 2) Add the following additional section:

[3.1.2 Characterisation of questionable fish oil identity

Nuclear Magnetic Resonance (NMR) pattern recognition analyses may be performed in the instances where the fatty acid composition cannot provide clear identification of the fish oil species.]

- 3) Fish oil from certain species is a highly desirable source of EPA and DHA (omega-3 fatty acids), levels for which the global annual supply is a finite resource. We suggest that Table No. 1 should contain the **sum of EPA and DHA** and the **total content of omega-3 fatty acids**, which would provide an additional measure to characterise and identify the type of oil.
- 4) In the section 7.3: Other labelling requirements:

For transparency, labels that are linked to consumer rights, should incorporate information on the sum of EPA + DHA oil visible on the packaging, as well as the species from which it originates as well as whether it is from a wild or cultivated raw material source.

Proposed text:

The content of EPA and DHA, [the sum of EPA and DHA, the linoleic acid content and species from which it originates and whether it is wild or cultivated] [shall/may-] be given for all fish oils covered by this Standard. [The number of the FAO fishing area may also be given]

- 5) In Section 8 Methods of Analysis and Sampling, additional analyses should be included that will allow for the identification of fish oil that is of questionable or uncertain identity when it is based on their fatty acid composition only:

[8.11 Determination of uncertain fish oil identity

According to PhEur 01/2009:2398 Cod Liver Oil, farmed ¹³C NMR spectrometry. The raw data output from the NMR-analysis is sent electronically to companies that can provide analysis by the NMR method for identification.]