

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 4

CRD17

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FATS AND OILS

25<sup>th</sup> Session

Kuala Lumpur, Malaysia, 27 February - 3 March 2017

#### DRAFT CODEX STANDARD FOR FISH OILS - Comments included

(at Step 6 of the Procedure)

(Prepared by Switzerland)

<u>Text Draft Codex Standard for Fish Oils</u>	<u>Comments</u>
<p><b>1. <u>Scope</u></b></p> <p>This Standard applies to the fish oils described in section 2 that are presented in a state for human consumption. For the purpose of this Standard, the term fish oils refers to oils derived from fish and shellfish as defined in section 2 of the <i>Code of Practice for Fish and Fishery Products</i> (CAC/RCP 52-2003)<sup>1</sup>. This standard only applies to fish oils used in food and in food supplements where those are regulated as foods.</p>	<p><b><u>Section 1 Scope</u></b></p> <p>Proposed change: The Standard applies to <del>the</del> <u>both crude and refined</u> fish oils described in Section 2 that are <u>intended</u> <del>presented in a state for</del> human consumption.</p> <p>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.</p>
<p><b>2. <u>Description</u></b></p> <p><i>Fish oils</i> means oils intended for human consumption derived from the raw material as defined in Section 2 of the <i>Code of Practice for Fish and Fishery Products</i> (CAC/RCP 52-2003). Processes to obtain fish oil for human consumption may involve, but are not limited to, extraction of crude oil from raw material and refining of that crude oil. <i>Fish oils</i> and <i>concentrated fish oils</i> are primarily composed of glycerides of fatty acids whereas <i>concentrated fish oils ethyl esters</i> are primarily composed of fatty acids ethyl esters. Fish oils may contain other lipids and unsaponifiable constituents naturally present.</p> <p>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.</p> <p>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</p>	<p><b><u>2. Description</u></b></p> <p>Crude fish oils and crude fish liver oils <del>are oils</del> intended for human consumption <u>after may</u> they have undergone further processing, refining and purification and <del>have</del> <u>should</u> to comply with section 3.1, <b><u>3.2 and 3.3</u></b>, as applicable, as well as with sections 4, 6.1 and 7.</p> <p><b>Justification:</b></p> <p>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.</p>

<sup>1</sup> [Fish: 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](#)

<p>may also be subjected to processing steps (e.g. solvent extraction, saponification, re-esterification, trans-esterification).</p>	
	<p>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. <i>refining</i>, solvent extraction, saponification, re-esterification, transesterification). Justification:</p> <p>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.</p> <p>If he you want to incorporate a definition, this ought to consider all the processes involved.</p> <p>In documents issued by FAO, defined in Chapter 5, processing and refining of edible oils (<a href="http://www.fao.org/docrep/v4700e/v4700e0a.htm">http://www.fao.org/docrep/v4700e/v4700e0a.htm</a>) 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.</p> <p>The processes involved (refining and purification), <u>does not</u> 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.</p>
	<p><b><u>2. Description</u></b></p> <p>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 <del>la Sección</del> <b>Sections</b> 3.1, <del>según sea aplicable, así como con las Secciones</del> 4, 6.1 and 7, <b><u>as applicable.</u></b></p> <p><b><u>Justification:</u></b></p> <p>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.</p>
	<p><b><u>Section 2 Description</u></b></p> <p>Proposed change to Paragraph 2: <del>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.</del></p>

	<p>Rationale: We propose to delete the second paragraph completely from this section. Please see rationale provided for item 1 above.</p> <p>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.</p>
<p>2.1 <b>Named fish oils</b> are derived from specific raw materials which are characteristic of the major fish or shellfish taxon from which the oil is extracted.</p>	<p><b>2.1 Named Fish Oils</b></p> <p>Proposed change: <del>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.</del></p> <p>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).</p>
<p>2.1.1 <b>Anchovy oil</b> is derived from species of the genus <i>Engraulis</i> (<i>Engraulidae</i>).</p>	<p><b>2.1.1 Anchovy oil</b> is obtained from the species <i>Engraulis</i> (<i>Engraulidae</i>). <b><u>In the case of the species <i>Engraulis ringens</i> (anchoveta), the sum of the content of EPA and DHA has to be at least 27%.</u></b></p> <p><b><u>Justification:</u></b></p> <p>According the Department of Fisheries and Aquaculture of FAO, the common name of the species <i>Engraulis ringens</i> corresponds to anchoveta (peruvian anchovy).</p> <p>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 <i>Engraulis ringens</i> since:</p> <p>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 <i>Engraulis ringens</i> has represented up to 70% of the world's supply.</p> <p>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.</p>
<p>2.1.2 <b>Tuna oil</b> is derived from the species of the genus <i>Thunnus</i> and from the species <i>Katsuwonus pelamis</i> (<i>Scombridae</i>).</p>	<p><b>2.1.2 Tuna oil</b></p> <p>Proposed change: Tuna oil is derived from the species of the genera <i>Euthynnus</i>, <i>Allothunnus</i> and <i>Thunnus</i> and from the species <i>Katsuwonus pelamis</i> (<i>Scombridae</i>).</p> <p>Rationale: Additional tuna genus used for the production of fish oil is provided.</p>
<p>2.1.3 <b>Krill oil</b> is derived from <i>Euphausia superba</i>. The major components are triglycerides and phospholipids. The content of phospholipids</p>	<p><b>2.3.1 Krill oil</b> - Canada notes that there are two species of krill that are commercially used for extraction of krill oil, i.e. <i>Euphausia superba</i> and</p>

<p>should be at least 30 w/w %.</p>	<p><i>Euphausia pacifica</i>. We recommend including both species in the standard under item 2.1.3.</p> <p>“2.1.3 Krill oil is derived from <i>Euphausia superba</i> <b>and <i>Euphausia pacifica</i></b>.”</p>
	<p>2.1.3 <b>Krill oil</b> is derived from the species <i>Euphausia superba</i>. The principal components are triglycerides and phospholipids. The phospholipid content has to be at least 30 <del>w/w</del> <b>m/m</b> %.</p>
	<p><b>SECTION 2.1.3 KRILL OIL</b></p> <p>Please see the additional information on krill oil attached (<b>see appendix</b>). In the attachment, the first sheet gives the fatty acid composition of 16 new batches of krill oil from 2015/2016. The second sheet gives the quality parameters in these 16 batches. In the third sheet we have listed max/min values for the 16 batches, the draft Codex values for krill oil, the United States Pharmacopeia – National Formulary (USP-NF) values for comparison, and our proposal for revised Codex values, with a rationale. The changes we propose are marked with bold numbers in sheet number three in the attachment.</p>
<p>2.1.4 <b>Menhaden oil</b> is derived from the genus <i>Brevortia</i> (<i>Clupeidae</i>).</p>	<p><b><u>2.1.4 Menhaden oil</u></b></p> <p>Proposed change: Menhaden oil is derived from the genera <i>Brevortia</i> (<i>Clupeidae</i>) <b>and <i>Ethmidium</i></b>.</p> <p>Rationale: Additional menhaden genus used for the production of fish oil is provided.</p>
<p>2.1.5 <b>Salmon oil</b> is derived from the family <i>Salmonidae</i>.</p>	<p><b>Fatty Acid Data for Wild Salmon Oil</b></p> <p>GOED has received additional fatty acid data for wild salmon oil that it would like considered for inclusion in the draft standard. Based on this data, GOED proposes (as detailed in the following table) to adjust the wild salmon oil ranges for some of the fatty acids.</p> <p>The below represents the range of fatty acid data from the 2013-2016 Alaskan Wild Salmon runs (May – August). The catch area is FAO 67, more specifically Prince William Sound, Valdez, and southeast Alaska which would be the area around Wrangell and Ketchikan, Alaska.</p>
<p>2.2 <b>Fish oils (unnamed)</b> are derived from a single 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.</p>	<p><b><u>2.2 Fish oils (unnamed)</u></b></p> <p>Proposed change: Fish oils (unnamed) <del>are</del> <b>may be</b> derived from <del>a single one or more</del> species of fish <del>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.</del></p> <p>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.</p>
<p>2.3.1 <b>Named fish liver oils</b> are derived from the livers of fish and are composed of fatty acids, vitamins or other components that are</p>	<p><del>2.3.1</del> <b>2.3 Named fish liver oils</b> are derived from the livers of fish and are composed of fatty acids, vitamins or other components that are representative of the</p>

<p>representative of the livers from the species from which the oil is extracted.</p>	<p>livers from the species from which the oil is extracted.</p> <p><u>2.3.1 and 2.3.2</u> - 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.</p> <p><del>2.3.1</del> <b>2.3</b> Named fish liver oils are derived...</p>
	<p><del>2.3.1</del> <b>2.3</b> <b>Named fish liver oils</b> 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.</p>
<p>2.3.2 <b>Cod liver oil</b> is derived from the liver of wild cod, <i>Gadus morhua</i> L and other species of <i>Gadidae</i>.</p>	<p><del>2.3.2</del> <b>2.3.1</b> Cod liver oil is derived from the liver of wild cod, <i>Gadus morhua</i> L and other species of <i>Gadidae</i>.</p> <p><del>2.3.2</del> <b>2.3.1</b> Cod liver oil is derived...</p> <p><del>2.3.2</del> <b>2.3.1</b> <b>Cod liver oil</b> is derived from the liver of wild cod, <i>Gadus morhua</i> L and from other species of <i>Gadidae</i>.</p>
<p>2.4 <b>Fish liver oil (unnamed)</b> 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.</p>	<p><b>2.4 Fish liver oil (unnamed)</b></p> <p>Proposed change: Fish liver oil (unnamed) may be derived from the livers of <u>one or more species of fish</u>. <del>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.</del></p> <p>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. <u>9. Section 2.5 Concentrated fish oils</u></p>
<p>2.5 <b>Concentrated fish oils</b> 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 specific fatty acids.</p>	<p><b>2.5 Concentrated fish oils</b></p> <p>Proposed change: Concentrated <u>EPA/DHA</u> 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 <u>EPA and DHA specific fatty acids</u>.</p> <p>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.</p>
<p>2.5.1 <b>Concentrated fish oil</b> 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.</p>	<p><b>2.5.1 and 2.5.2</b> - 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:</p> <p><b>2.5.1 and 2.5.2</b> “...at least 50 w/w % of fatty acids are in the form of triglycerides <u>and/or phospholipids</u>”.</p>
	<p><b>2.5.1 Concentrated fish oil</b></p> <p>Proposed change: Concentrated <u>EPA/DHA</u> 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)</p>

	<p>docosahexaenoic acid (DHA), at least 50 w/w % of fatty acids are in the form of triglycerides.</p> <p>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.</p>
	<p><b><u>2.5.1 Concentrated fish oil</u></b></p> <p>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.</p>
<p>2.5.2 <b>Highly concentrated fish oil</b> 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.</p>	<p><b><u>2.5.1 and 2.5.2</u></b> - 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:</p> <p><b><u>2.5.1 and 2.5.2</u></b> “...at least 50 w/w % of fatty acids are in the form of triglycerides <i>and/or phospholipids</i>”.</p>
	<p><b><u>2.5.2 Highly concentrated fish oil</u></b> contains more than 50 m/m % of the fatty acids EPA and DHA and at least 50 m/m % of the fatty acids are in the form of triacylglycerides.</p>
	<p><b><u>2.5.2 Highly concentrated fish oil</u></b></p> <p>Proposed change: Highly concentrated <u>EPA/DHA</u> 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.</p> <p>Rationale: See rationale provided for 2.5.1</p>
	<p><b><u>2.5.2 Highly concentrated fish oil</u></b></p> <p>Comment: same as above for 2.5.1: 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.</p>
<p>2.6 <b>Concentrated fish oils ethyl esters</b> are derived from fish oils described in Section 2.1 to 2.4 and are primarily composed of fatty acids ethyl esters.</p>	<p><b>2.6 Concentrated fish oils ethyl esters</b></p> <p>GOED recommends the addition of 2.7 Concentrated fish oil re-esterified triglycerides in order to differentiate from 2.6 Concentrated fish oil ethyl esters. For 2015, the volume, growth and value for EEs and rTGs were as follows:</p> <ul style="list-style-type: none"> <li>• EEs (2015)             <ul style="list-style-type: none"> <li>○ Volume: 12,152 metric tons (What is total volume?)</li> <li>○ Growth: about 4.5% per year</li> <li>○ Value: 368 million US\$</li> </ul> </li> <li>CX/FO 17/25/4 Add.1 5</li> <li>• rTGs (2015)             <ul style="list-style-type: none"> <li>○ Volume: 4640 metric tons (What is total volume?)</li> <li>○ Growth: about 16.0% per year</li> </ul> </li> </ul>

	o Value: 701 million US\$
2.6.1 <b>Concentrated fish oil ethyl esters</b> contains fatty acids as esters of ethanol of which 40 to 60 w/w % are as sum of EPA and DHA.	
2.6.2 <b>Highly concentrated fish oil ethyl esters</b> contain fatty acids as esters of ethanol of which greater than 60 w/w % are as sum of EPA and DHA.	
<p><b>3. Essential composition and quality factors</b></p> <p><b><u>3.1 GLC ranges of fatty acid composition (expressed as percentages of total fatty acids)</u></b></p> <p>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.</p>	<p><b><u>3.1 GLC ranges of fatty acid composition (expressed as percentages of total fatty acids)</u></b></p> <p>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.</p> <p>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.</p> <p>Canada recognizes the importance of having a robust standard for fish oil which takes into consideration data from various sources to reflect variations due to species, climate, geographical location, etc. and, at the same time, provide a means to safeguard against fraudulent practices. In support of this principle, Canada is pleased to submit analytical data on krill oil, contained in a document attached to this submission, for consideration in the setting of quality parameters for krill oil in the Draft Codex Standard for Fish Oils. This includes analytical data on fatty acid composition and other quality parameters of krill oil. Information has been submitted by a Canadian industry stakeholder based on analytical test results of 119 batches from commercial trade between 2010 and 2016. Additional information on krill species, geographic location as well as the harvest season is also included.</p>
	<p><b><u>3. Essential composition and quality factors</u></b></p> <p><del>3.1 GLC ranges of fatty acid composition (expressed as percentages of total fatty acids)</del> 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</p>

	<p><del>be considered, as necessary, to confirm that a sample is in compliance with the Standard.</del></p> <p><b><u>3.1 Accreditation referential origin and composition of fatty acids</u></b></p> <p><u>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.</u></p> <p><u>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.</u></p> <p><b>Justification:</b></p> <p>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.</p> <p>It attached report and executive report with detailed justification.</p>
	<p>Chile proposes that the Committee assesses the incorporation of additional tools to the profiles of fatty acids as verification criterion of the species of origin, based on criteria adjusted to the current reality of the international commerce of fish oil.</p> <p>Chile considers that the official certification of origin based on the official traceability inspection of production systems should be incorporated as part of the species verification criterion. Currently, international commerce of fish oil widely uses the support of traceability to prove origin and composition of the raw material.</p> <p>Also, it is important to take into account the existence of <i>Codex</i> standards that provide general guidelines and principles necessary to establish these criteria and to which reference should be made in the Standard for Fish Oil. The Committee should consider the existence of general guidelines and standards already established by the Codex for such purposes. In this regard, the following are quoted:</p> <ul style="list-style-type: none"> <li>▪ CAC/GL 60-2006 Principles for traceability/product tracing as a tool within a food inspection and certification system [with the aim of supporting the oil commerce. ]</li> <li>▪ CAC/GL 26-1997 Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems.</li> <li>▪ CAC/GL 38-2001 Guidelines for design, production, issuance and use of generic official certificates.</li> <li>▪ CAC/GL 47-2003 Guidelines for food import control systems</li> <li>▪ CAC/GL 89-2016 Principles and guidelines for the exchange of information between importing and exporting countries to support the trade in food.</li> </ul> <p>Taking this into account, Chile proposes that paragraph of section 3.1 of the standard to be amended as follows:</p>



	<p><b><i>“Compliance of sections 2.1 y 2.3 shall be verified through certification of origin by the relevant authority based on the traceability systems. Table 1 is to be used as a reference for fatty acid ranges of fish oils and fish liver oils specified in sections 2.1 and 2.3 of this standard. These ranges experience variations due to national climatic or geographical as well as to other biological factors.”</i></b></p> <p>Regarding quotations of standards and guidelines of the CCFICS, these may be discussed and analysed in the physical work group at the next CCFO meeting</p>
	<p><b>3.1 Composition ranges of fatty acids determined by GLC</b> (expressed as percentages of total fatty acids)</p> <p>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, <b><u>or its origin (wild or farmed)</u></b>, could be considered, as may be necessary case by case, to confirm that a sample meets the Standard.</p> <p><b><u>Justification:</u></b></p> <p><b>The intention is to consider another criterium as per species classification indicated in Table 1.</b></p>
	<p><b><u>3.1 GLC ranges of fatty acid composition (expressed as percentages of total fatty acids)</u></b></p> <p>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, <b><u>or its origin (wild or farmed)</u></b>, could be considered, as may be necessary case by case, to confirm that a sample meets the Standard.</p> <p><b><u>Justification:</u></b></p> <p><b>The intention is to consider another criterium as per species classification indicated in Table 1.</b></p>
	<p><b><u>3. Essential composition and quality factors</u></b></p> <p>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.</p> <p>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</p>

	<p>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 (<a href="http://www.omegaveritas.com/">http://www.omegaveritas.com/</a>) 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.</p> <p>We propose the following changes:</p> <p>1) The text in section 3.1 which states that “<i>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.</i>” 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.</p> <p><b>Section 3.1.1 GLC ranges of fatty acid composition</b> (expressed as percentages of total fatty acids)</p> <p>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:</p> <p>[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.]</p> <p>2) Add the following additional section:</p> <p>[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.]</p> <p>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 <b>sum of EPA and DHA</b> and the <b>total content of omega-3 fatty acids</b>, which would provide an additional measure to characterise and identify the type of oil.</p>
<p>.J.</p>	<p><b>Section on Permitted Ingredients:</b></p> <p>The Codex Alimentarius Procedural Manual, 25th edition, Format for Codex Commodity Standards indicates that the Essential Composition and Quality</p>

	<p>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.</p> <p>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:</p> <p><b><u>“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”.</u></b></p>
<p><b><u>3.2 Quality parameters</u></b></p> <p>Note: this section does not apply to flavoured fish oils where the added flavourings may interfere with the analytical determination of oxidation parameters.</p>	<p><b><u>3.2 Quality parameters</u></b></p> <p>Canada suggests the addition of astaxanthin in the quality parameters for krill oil in section 3.2.2. <b><u>Krill oil: Astaxanthin content &gt; 0.01% (&gt; 100 ppm)</u></b></p> <p><b>Rationale:</b></p> <p>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.</p> <p>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).</p>
	<p><b><u>3.2 Quality parameters</u></b></p> <p>Total oxidation value (ToTox) ≤ <del>26</del> <b><u>30</u></b></p> <p><b>Justification:</b></p> <p>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.</p> <p>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)</p>

	<table border="1"> <tr> <td data-bbox="805 143 911 241">Fatty acids</td> <td data-bbox="911 143 1098 241">Menhaden (Section 2.1.4)</td> <td colspan="2" data-bbox="1098 143 1457 241">Salmon oil (Section 2.1.5)</td> </tr> <tr> <td colspan="2" data-bbox="805 241 1098 315"></td> <td data-bbox="1098 241 1252 315">Wild</td> <td data-bbox="1252 241 1457 315"><del>Wild</del> <b>Farm</b></td> </tr> </table>	Fatty acids	Menhaden (Section 2.1.4)	Salmon oil (Section 2.1.5)				Wild	<del>Wild</del> <b>Farm</b>
Fatty acids	Menhaden (Section 2.1.4)	Salmon oil (Section 2.1.5)							
		Wild	<del>Wild</del> <b>Farm</b>						
<p><b>3.2.1 Fish oils, fish liver oils, concentrated fish oils, and concentrated fish oils ethyl esters (Section 2.1. to 2.6) with the exception of oils dealt with in Section 3.2.2 shall comply with the following:</b></p> <p>Acid value ≤ 3 mg KOH/g  Peroxide value ≤ 5 milliequivalent of active oxygen/kg oil  Anisidine value ≤ 20  Total oxidation value (ToTox)<sup>1</sup> ≤ 26</p>	<p><b>Section 3.2.1 Peroxide value</b></p> <p>Proposed change: Peroxide value &lt; 5 milliequivalent of active oxygen/kg oil</p> <p>Rationale: Correct misspelled word (i.e., oxygen).</p>								
<p><b>3.2.2 Fish oils with a high phospholipid concentration of 30% or more such as krill oil (Section 2.1.3) shall comply with the following:</b></p> <p>Acid value ≤ 30 mg KOH/g  Peroxide value ≤ 5 milliequivalent of active oxygen/kg oil</p>	<p>In relation to 3.2.2 the Acid value of krill oil</p> <p>According to the EFSA's Journal 2009 "scientific opinion on Safety of 'Lipid extract from <i>Euphausia superba</i>' as a novel food ingredient", it says "Edible oils are normally characterized by low contents of free fatty acids, expressed by the acid value (typical specification for fish oil: 0-5 mg KOH/g). The acid value given for NKO™ is much higher (25.7-32.4 mg KOH/g) owing to the inherent content of free fatty acids. Therefore, this parameter is less appropriate as stability indicator."</p> <p>Our opinion is the same as above, and here is the link of EFSA's scientific opinion</p> <p><a href="http://www.bfr.bund.de/cm/343/efsa_opinion_on_the_safety_of_lipid_extract_from_euphausia_superba.pdf">http://www.bfr.bund.de/cm/343/efsa_opinion_on_the_safety_of_lipid_extract_from_euphausia_superba.pdf</a></p> <p>In addition, the Korean company (BIOLSYSTEMS CO., LTD), which manufactures krill oil and also suggested to us to change the range of acid value of krill oil, is now testing the acid value from 10 major krill oil products imported and produced domestically. The results may come out by the end of next week. We are going to share with you and would like to discuss on this matter after reviewing the data.</p> <p>Regarding fatty acid composition of krill oil, we attached below (<b>see Appendix</b>). We considered that the attached data analyzed by the company is the only thing to consider among those materials you mentioned in the list.</p>								
<p><b>3.3 Vitamins</b></p> <p>Fish liver oils except of deep sea shark liver oil (Sections 2.3 and 2.4) shall comply with following:</p> <p>Vitamin A ≥ 40 µg of retinol equivalents/ml of oil</p>	<p><b>3.3 Vitamins:</b></p> <p>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</p>								

<sup>1</sup> [Total oxidation value \(ToTox\) = 2 x Peroxide value + Anisidine value](#)

<p>Vitamin D <math>\geq 1.0 \mu\text{g/ml}</math></p>	<p>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:</p> <p>a) 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).</p> <p>b) Should there be consideration of devitaminization if used as food oils?</p> <p>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.</p> <p><i>Section on Permitted Ingredients:</i></p> <p>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.</p> <p>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:</p> <p style="padding-left: 40px;">“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”.</p>
	<p><b><u>3.3 Vitamins</u></b></p> <p><b><u>Vitamin A <math>\geq 40 \mu\text{g}</math> of equivalents to retinol/ml</u></b></p>
<p><b><u>4. Food Additives</u></b></p> <p>Antioxidants, sequestrants, antifoaming agents, and emulsifiers used in accordance with Tables 1 and 2 of the <i>General Standard of Food Additives</i> (CODEX STAN 192-1995), in food category 02.1.3 Lard, tallow, fish oil, and other animal fats.</p>	<p><b><u>4. Food Additives</u></b></p> <p>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.</p> <p>The following editorial change is suggested to better</p>

	align with the Procedural Manual (25 <sup>th</sup> edition): "Antioxidants, sequestrants, antifoaming agents, and emulsifiers used in accordance with Tables 1 and 2 of the General Standard <del>of</del> <b>for</b> Food Additives (CODEX STAN 192-1995), in food category 02.1.3 Lard, tallow, fish oil, and other animal fats <b>are acceptable for use in foods conforming to this standard.</b> "																								
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	<b><u>4. Food Additives</u></b> Proposed change: Antioxidants, sequestrants, antifoaming agents, and emulsifiers used in accordance with Tables 1 and 2 of the <u>Codex</u> General Standard <del>of</del> <b>for</b> Food Additives (GSFA) (CODEX STAN 192-1995), in food category 02.1.3 Lard, tallow, fish oil, and other animal fats <b>are acceptable for use in foods conforming to this standard.</b> Rationale: Changes indicated reflect standard language used in referring to the GSFA.																								
The following additives may be used in addition: <table border="1"> <thead> <tr> <th>INS level</th> <th>Additive name</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td colspan="3"><b><u>Antioxidant</u></b></td> </tr> <tr> <td>300</td> <td>Ascorbic acid, L-</td> <td>GMP</td> </tr> <tr> <td>304, 305</td> <td>Ascorbyl esters</td> <td>2500 mg/kg, as ascorbyl stearate</td> </tr> <tr> <td>307a, b, c</td> <td>Tocopherols</td> <td>6000 mg/kg, singly or in combination</td> </tr> <tr> <td colspan="3"><b><u>Emulsifier</u></b></td> </tr> <tr> <td>322 (i)</td> <td>Lecithin</td> <td>GMP</td> </tr> <tr> <td>471</td> <td>Mono- and di-glycerides of fatty acids</td> <td>GMP</td> </tr> </tbody> </table>	INS level	Additive name	Maximum	<b><u>Antioxidant</u></b>			300	Ascorbic acid, L-	GMP	304, 305	Ascorbyl esters	2500 mg/kg, as ascorbyl stearate	307a, b, c	Tocopherols	6000 mg/kg, singly or in combination	<b><u>Emulsifier</u></b>			322 (i)	Lecithin	GMP	471	Mono- and di-glycerides of fatty acids	GMP	
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The flavourings used in products covered by this standard should comply with the <i>Guidelines for the Use of Flavourings</i> (CAC/GL 66-2008).	On the use of flavourings, the text reflects the Procedural Manual (25 <sup>th</sup> edition) which is not accurate, hence a minor editorial is suggested as follows: "The <b>use of</b> flavourings <del>used</del> in products covered by this standard should comply with the <i>Guidelines for the Use of Flavourings</i> (CAC/GL 66-2008)".																								
<b><u>5. Contaminants</u></b> The products covered by this Standard shall comply with the Maximum Levels of the <i>General Standard for Contaminants and Toxins in Food and Feed</i> (CODEX STAN 193-1995).	<b><u>5. Contaminants</u></b> 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																								

<p>The products covered by this Standard shall comply with the maximum residue limits for pesticides and/or veterinary drugs established by the Codex Alimentarius Commission.</p>	<p>fish oils.</p> <p><b>Rationale:</b></p> <p>Presently, the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF, Codex Stan 1931995) 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.</p> <p>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.</p>
	<p><b><u>5. Contaminants</u></b></p> <p>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.</p>
	<p><b><u>5. Contaminants</u></b></p> <p>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).</p>
	<p><b><u>5. Contaminants</u></b></p> <p>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).</p> <p>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</p>

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.

23<sup>rd</sup> 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 reevaluating 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.” 24<sup>th</sup> 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 foodstuffs<sup>1</sup>. In Canada, Health Canada addressed an arsenic limit issue by providing limits for total arsenic, inorganic arsenic and organic arsenic<sup>2</sup>. 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

<sup>1</sup> [https://members.wto.org/crnattachments/2016/SPS/EEC/16\\_1773\\_00\\_e.pdf](https://members.wto.org/crnattachments/2016/SPS/EEC/16_1773_00_e.pdf)

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



	<p>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.</p> <p>Given the above, GOED suggests that the limit for inorganic arsenic in the standard be defined as 0.1 mg/kg.</p>
<p><b>6. Hygiene</b></p> <p><b>6.1 General hygiene</b></p> <p>It is recommended that the products covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969), the <i>Code of Practice for Fish and Fishery Products</i> (CAC/RCP 52-2003), and <i>Code of Hygienic Practice for the Storage and Transport of Edible Oils and Fats in Bulk</i> (CAC/RCP 36-1987).</p>	
<p><b>6.2 Microbiological criteria</b></p> <p>The products should comply with any microbiological criteria established in accordance with the <i>Principles for the Establishment and Application of Microbiological Criteria for Foods</i> (CAC/GL 21-1997).</p>	
<p><b>7. Labelling</b></p> <p>7.1 Name of the food</p> <p>The product shall be labelled in accordance with the <i>General Standard for the Labelling of Pre-packaged Foods</i> (CODEX STAN 1-1985). The name of the fish oil shall conform to the descriptions given in Section 2 of this Standard. For salmon oil the label shall specify the source of the raw material (wild, farmed).</p>	<p><b>Sections 7.1 and 7.2 appear</b> to be consistent with the presentation of other Codex standards.</p> <p>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.</p> <p>“Where a fish oil has had flavouring added to it, the name of the oil shall be prefaced with “flavoured” or “naming the flavour”.</p>
<p><b>7.2 Labelling on non-retail containers</b></p> <p>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.</p> <p>However, lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark, provided that such a mark is clearly identifiable with the accompanying documents.</p> <p>For crude fish oils and crude fish liver oils the label shall indicate that these oils are intended for human consumption only after they have undergone further processing.</p>	
<p><b>7.3 Other labelling requirements</b></p> <p>[For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D shall be given.</p>	<p><b>7.3 Other labelling requirements</b></p> <p><del>[For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D shall be given.</del></p>

<p>or</p> <p>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.]</p> <p>The content of EPA and DHA [ shall/may ] be given for all fish oils covered by this Standard.</p>	<p><del>or</del></p> <p><u>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.]</u></p> <p>The content of EPA and DHA [ <del>shall</del>/<b>may</b> ] be given for all fish oils covered by this Standard.</p> <p><b>or</b></p> <p>The content of EPA and DHA [ <b>shall</b>/<del>may</del> ] be given for all fish oils covered by this Standard, <b><u>if required by country of retail sale.</u></b></p>
	<p><b><u>7.3 Other labelling requirements</u></b></p> <p>With respect to the two options in square brackets that are presented in the draft standard for declaring vitamin nutrients in fish oils and fish liver oils, Canada supports retaining the second option for mandatory labelling of vitamin A and D in fish liver oil, naturally present or restored, where this is required by country of retail sale. Canada also supports using the term “may” when providing the content of EPA/DHA for fish oils covered by this standard.</p> <p><del>[For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D shall be given.</del></p> <p><del>or</del></p> <p>For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D, naturally present or restored, shall</p> <p>be given if required by country of retail sale.]</p> <p>The content of EPA and DHA [<del>shall</del>/ may] be given for all fish oils covered by this Standard.</p>
	<p><b><u>7.3 Other labelling requirements</u></b></p> <p>This section contains two options for the specific labelling of vitamin A and vitamin D. <b>The second option is preferred</b> because it offers flexibility as to the different requirements for retail sale.</p> <p>This section contains two options for the labelling of the content of EPA a DHA (obligatory/optional). <b>The first option (obligatory) is preferred.</b> 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.</p>
	<p><b><u>7.3 Other labelling requirement Proposed text:</u></b></p> <p>For fish liver oils (Section 2.3 and 2.4) <b><u>except shark liver oils</u></b> the content in vitamin A and vitamin D shall be given.</p> <p>The content of EPA and DHA [<del>shall</del>/<del>may</del>] be given for all fish oils covered by this Standard <b><u>except shark liver oils.</u></b></p>

	<p><b><u>Rationale:</u></b></p> <p>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.</p>
	<p><b><u>7.3 Other labelling requirements</u></b></p> <p><u>In the case of fish liver oils (Sections 2.3 and 2.4) the content of vitamin A and vitamin D must be shown. e</u></p> <p><del>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.]</del></p> <p>In the case of all the fish oils regulated by this Standard, the content of EPA, DHA and <b>linoleic acid must be shown.</b></p> <p><b><u>Justification:</u></b></p> <p>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.</p>
	<p><b><u>Section 7.3 Other labeling requirements</u></b></p> <p>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. <del>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.</del> The content of EPA and DHA shall/<del>may</del> be stated on the label for all fish oils covered by this Standard.</p> <p><i>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 is information should be provided on the label.</i></p>
	<p><b>SECTION 7.3 OTHER LABELLING REQUIREMENT</b></p> <p>In response to proposals for alternative texts in Section 7.3 “Other Labelling Requirements”, Thailand is of the view that the text in options two appear in square</p>

	<p>brackets provide more flexibility to the different requirements of countries for retail sale. We also agree to use the term “shall” for declaring the content of EPA/DHA for fish oils under this proposed draft standard. The amended texts should be read:</p> <p><del>[For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D shall be given.</del></p> <p>or</p> <p>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.]</p> <p>The content of EPA and DHA [shall/may] be given for all fish oils covered by this Standard.</p>
	<p><b>SECTION 7.3 OTHER LABELLING REQUIREMENTS</b></p> <p><del>{For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D shall be given.</del></p> <p>or</p> <p><del>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.]</del></p> <p>The content of EPA and DHA {shall/may] be given for all fish oils covered by this Standard.</p> <p><i>Rationale: Cod liver oil is the most traditional fish oil that has been on the marked for more than hundred years</i></p> <p><i>and the natural content of vitamins is the main characteristic for liver oils distinguishing them from other fish oils.</i></p> <p><i>In addition, Norway do prefer that the content of EPA and DHA shall be given.</i></p>
	<p><b>Section 7.3- Other Labelling requirements</b></p> <p>India accepts the following text with regard to vitamin A and Vitamin D:</p> <p><i>For Fish liver oils (Section 2.3 and 2.4) the content of vitamin A and vitamin D should be given</i></p> <p><b>Rationale:</b></p> <p>Since Vitamin A and Vitamin D are nutrients their content should be given on the labels for the health benefits of the public so that wiser choices can be made as mostly fish liver oils are consumed as health supplements.</p> <p><i>India feels that the content of EPA and DHA should be given for all fish oils covered by this standard.</i></p> <p><b>Rationale:</b></p> <p>As fish oils are consumed by the public to achieve the maximum health benefits in regards to Omega-3 fatty acids, the content of EPA and DHA should be given on the label so that the consumer can differentiate between the various products on the shelf. Thus it should not be optional but be made mandatory.</p>
	<p><b>7.3 Other labelling requirements</b></p> <p>- This section contains two options for the specific labelling of vitamin A and vitamin D. <b>The second</b></p>

	<p><b>option is preferred</b> because it offers flexibility as to the different requirements for retail sale. CX/FO 17/25/4 7</p> <p>- This section contains two options for the labelling of the content of EPA a DHA (obligatory/optional). <b>The first option (obligatory) is preferred.</b> 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.</p> <p>- Egypt supports Norway 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</p>
	<p><b>7.3 Other labelling requirements</b></p> <p>[For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D shall be given.</p> <p>or</p> <p>For fish liver oils (Sections 2.3 and 2.4) the content in vitamin A and vitamin D, naturally present or restored, shall</p> <p>be given if required by country of retail sale.]</p> <p>GOED recommends vitamins A and D be labelled with the units of micrograms RE and micrograms, respectively.</p> <p>The content of EPA and DHA [shall/may ] be given for all fish oils covered by this Standard.</p> <p>In addition, GOED recommends that concentrated fish oils state the chemical form (e.g. ethyl ester, TG).</p>
	<p><b><u>Section 7.3: Other labelling requirements:</u></b></p> <p>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.</p> <p><b>Proposed text:</b></p> <p><i>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]</i></p>
<p><b><u>8. Methods of Analysis and Sampling</u></b></p>	<p><b><u>8. Methods of Analysis and Sampling</u></b></p> <p>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.</p> <p>Also, as discussed in item 5 above, Canada suggests</p>

	<p>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.</p> <p>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.</p>
	<p><b><u>In Section 8 Methods of Analysis and Sampling,</u></b> 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:</p> <p style="text-align: center;"><b>[8.11 Determination of uncertain fish oil identity</b></p> <p>According to PhEur 01/2009:2398 Cod Liver Oil, farmed <sup>13</sup>C 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.]</p>
<p><b>8.1 Sampling</b></p> <p>ISO 5555: Animal and vegetable fats and oils -- Sampling</p>	
<p><b><u>8.2 Determination of fatty acid composition</u></b></p> <p>According to applicable ISO methods including: ISO 5508 and ISO 12966-2 (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 1i-07 (Determination of saturated cis-, monounsaturated, and cis-polyunsaturated fatty acids in Marine 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)</p>	<p><b>8.2 Determination of fatty acid composition</b></p> <p>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:</p> <p>"According to applicable ISO methods including: <del>ISO 5508 and ISO 12966-2,</del> <b>ISO 12966</b> (Animal and vegetable fats and oils - Analysis by gas chromatography of methyl esters of fatty acids)..."</p>
	<p><b><u>Section 8.2 Determination of fatty acid composition</u></b></p> <p>Proposed change: According to applicable ISO methods including: ISO 5508 (<u>Animal and vegetable fats and oils -- Analysis by gas chromatography of methyl esters of fatty acids</u>) and ISO 12966-2 (<del>Animal and vegetable fats and oils -- Analysis by gas chromatography of methyl esters of fatty acids</del>) (<u>Animal and vegetable fats and oils -- Gas chromatography of fatty acid methyl esters -- Part 2: Preparation of methyl esters of fatty acids</u>); or AOCS</p>

	<p>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), <del>Ce 1a-13 (Determination of Fatty Acids in edible oils and fats by capillary GLC)</del> and Ce 2-66 (Preparation of Methyl Esters of Fatty Acids)</p> <p>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.</p>
<p><b>8.3 Determination of arsenic</b></p> <p>According to AOAC 952.13 (Silver Diethyldithiocarbamate Method); AOAC 942.17 (Molybdenum Blue); or AOAC 986.15 (Spectroscopy/Atomic Absorption Spectroscopy).</p>	<p><b>Section 8.3 Determination of arsenic</b></p> <p>Proposed change: According to AOAC 952.13 (Silver Diethyldithiocarbamate Method); AOAC 942.17 (Molybdenum Blue <u>Method</u>); or AOAC 986.15 (<del>Spectroscopy/Atomic Absorption Spectroscopy</del> <u>Multielement Method</u>).</p> <p>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."</p>
	<p><b>SECTION 8.3 DETERMINATION OF ARSENIC</b></p> <p>According to AOAC 952.13 (Silver Diehyldithiocarbamate Method); AOAC 942.17 (Molybdenum Blue); AOAC 986.15 (Spectroscopy/Atomic Absorption Spectroscopy); <b>CEN-EN 16802:2016.</b></p> <p><i>Rationale: Because inorganic arsenic is the most toxic arsenic compound, and because inorganic arsenic usually constitutes a small share of the total amount of arsenic in sea food, it is important that we have good methods to measure inorganic arsenic. We would propose adding the method CEN-EN 16802:2016 to the list of methods for determination of arsenic. This is a new and updated method suitable for this purpose.</i></p>
<p><b>8.4 Determination of lead</b></p> <p>According to AOAC 994.02 (Atomic Absorption Spectroscopy); 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).</p>	<p><b>Section 8.4 Determination of lead</b></p> <p>Proposed change: According to AOAC 994.02 (Atomic Absorption <del>Spectroscopy</del> <u>Spectrophotometric Method</u>); <del>or</del> 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).</p> <p>Rationale: This is an editorial change.</p>
<p><b>8.5 Determination of acid value</b></p> <p>According to AOCS Ca 5a-40 (Free Fatty Acids), AOCS Cd 3d-63 (Acid Value); ISO 660 (Animal and vegetable fats and oils -- Determination of acid value and acidity); European Pharmacopoeia 2.5.1</p>	

(Acid value).	
<p><b>8.6 Determination of peroxide value</b></p> <p>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); European Pharmacopoeia 2.5.5 (Peroxide value).</p>	<p><b><u>Section 8.6 Determination of peroxide value</u></b></p> <p>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); <u>or</u> European Pharmacopoeia 2.5.5 (Peroxide value).</p> <p>Rationale: This is an editorial change.</p>
<p><b>8.7 Determination of p-anisidine value</b></p> <p>According to AOCS Cd 18-90</p>	<p><b><u>Section 8.7 Determination of p-anisidine value</u></b></p> <p>Proposed change: According to AOCS Cd 18-90 <u>or</u> European Pharmacopoeia 2.5.36 (Anisidine value).</p> <p>Rationale: The protocol recommended in European Pharmacopoeia 2.5.36 is the same as that of AOCS Cd 1890.</p>
	<p><b><u>8.7 Determination of p-anisidine value</u></b></p> <p>According to AOCS Cd 18-90 <u>or</u> <b>PhEur 2.5.36</b></p>
<p><b>8.8 Determination of vitamin A</b></p> <p>According to PhEur 2.2.29 liquid chromatography, monograph Cod liver oil (type A).</p>	<p><b><u>Section 8.8 Determination of Vitamin A</u></b></p> <p>Proposed change: According to <del>PhEur 2.2.29 liquid chromatography, European Pharmacopoeia monograph Cod-Liver Oil (Type A).</del></p> <p>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.</p>
<p><b>8.9 Determination of vitamin D</b></p> <p>According to PhEur 2.2.29 liquid chromatography, monograph Cod liver oil (type A).</p>	<p><b><u>Section 8.9 Determination of Vitamin D</u></b></p> <p>Proposed change: According to <del>PhEur 2.2.29 liquid chromatography, European Pharmacopoeia monograph Cod-Liver Oil (Type A).</del></p> <p>Rationale: See rationale provided for 8.8.</p>
	<p><b><u>Section 8.x. Determination of triglycerides</u></b></p> <p>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 [for 2.5.1 and 2.5.2]</p>
<p><b>8.10 Determination of phospholipids</b></p> <p>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).</p>	<p><b><u>SECTION 8.10 DETERMINATION OF PHOSPHOLIPIDS</u></b></p> <p>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 7<sup>th</sup> 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.</p>
	<p><b><u>Section 8.10 Determination of phospholipids</u></b></p> <p>Proposed change: According to AOCS Ca 12b-92 (Phosphorus by <del>D</del>irect <del>G</del>raphite <del>F</del>urnace <del>A</del>atomic <del>A</del>bsorption <del>S</del>pectrometry); AOCS Ca 12a-02 (Colorimetric <del>D</del>etermination of <del>P</del>hosphorus <del>C</del>ontent</p>



	<p>in <u>F</u>ats and <u>O</u>ils); or AOCS Ca 20-99 (Analysis for <u>P</u>hosphorus in <u>O</u>il by <u>I</u>nductively <u>C</u>oupled <u>P</u>lasma <u>O</u>ptical <u>E</u>mission <u>S</u>pectroscopy).</p> <p>Rationale: AOCS methods capitalize their method titles.</p>
	<p><b><u>Determination of phospholipids</u></b></p> <p>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).</p> <p>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.</p>

**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)**

**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	Farm
C14:0 myristic acid	5.0-11.5	2.0-6.0	ND-5.0	6.4-13.0	8.0-11.0	2.0-4.5	1.5-5.5
C15:0 pentadecanoic acid	ND-1.5	ND-0.5	ND-2.0	NA	ND-1.0	ND-1.0	ND-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	ND-12.5	2.1-8.9	9.0-13.0	4.5-6.0	2.0-5.0
C17:0 heptadecanoic acid	ND-2.0	na	ND-3.0	NA	ND-1.0	ND-1.0	ND-0.5
C18:0 stearic acid	1.0-7.0	1.0-4.0	ND-7.5	NA	2.5-4.0	2.0-5.0	2.0-5.0
C18:1 (n-7) vaccenic acid	na	2.0-7.0	ND-7.0	8.4-21.7	2.5-3.5	na	na
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	ND-3.5	0.5-3.0	ND-3.0	0.7-2.1	2.0-3.5	1.5-2.0	8.0-15.0
C18:3 (n-3) linolenic acid	ND-7.0	ND-2.0	ND-2.0	0.1-4.7	ND-2.0	ND-1.0	3.0-6.0
C18:3 (n-6) γ-linolenic acid	ND-5.0	na	ND-4.0	NA	ND-2.5	ND-1.0	ND-0.5
C18:4 (n-3) stearidonic acid	ND-5.0	0.5-4.5	ND-2.0	1.0-8.1	1.5-3.0	1.0-2.5	0.5-1.5
C20:0 arachidic acid	na	na	ND-2.5	NA	0.1-0.5	ND-0.5	0.1-0.5
C20:1 (n-9) eicosenoic acid	ND-4.0	5.0-17.0	ND-2.5	NA	ND-0.5	4.5-6.0	1.5-7.0
C20:1 (n-11) eicosenoic acid	ND-4.0	1.0-5.5	ND-3.0	NA	0.5-2.0	na	na

**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	<del>8.4-21.7</del> <b>6.3-8.1</b>
C18:1 (n-9) oleic acid	NA	8.64-12.53	<del>NA</del> <b>8.6 – 12.5</b>
C20:5 (n-3) eicosapentaenoic acid	14.3-24.3	17.65-27.58	14.3- <del>24.3</del> <b>27.6</b>

ND = non-detect, defined as ≤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”.

C20:4 (n-6) arachidonic acid	ND-2.0	ND-1.5	ND-3.0	NA	ND-2.0	0.5-1.0	ND-1.2
C20:4 (n-3) eicosatetraenoic acid	ND-2.0	ND-2.0	ND-1.0	NA	na	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	ND-4.0	ND-1.5	ND-1.0	NA	0.5-1.0	ND-1.0	na
C22:1 (n-9) erucic acid	ND-5.0	ND-1.5	ND-2.0	NA	0.1-0.5	1.0-1.5	3.0-7.0
C22:1 (n-11) cetoleic acid	ND-5.0	5.0-12.0	ND-1.0	NA	ND-0.1	1.0-1.5	na
C22:5 (n-3) docosapentaenoic acid	ND-4.0	0.5-3.0	ND-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

ND = non-detect, defined as  $\leq 0.05\%$  na = not available

**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)	Salmon Oil (Section 2.1.5)	
		Wild	<b>Silvestre Farmed</b>
C14:0 miristic acid	5,0-11,5	2,0-4,5	1,5-5,5
C15:0 pentadecanoic acid	IN-1,5	IN-1,0	IN-0,5
C16:0 palmitic acid	13,0-22,0	12,0-16,0	6,5-12,0
C16:1 (n-7) palmitoleic acid	5,0-12,0	4,5-6,0	2,0-5,0
C17:0 heptadecanoic acid	IN-2,0	IN-1,0	IN-0,5
C18:0 stearic acid	1,0-7,0	2,0-5,0	2,0-5,0
C18:1 (n-7) vaccenic acid	n. d.	n. d.	n. d.
C18:1 (n-9) oleic acid	5,0-17,0	16,0-18,0	30,0-47,0
C18:2 (n-6) linoleic acid	IN-3,5	1,5-2,0	8,0-15,0
C18:3 (n-3) linolenic acid	IN-7,0	IN-1,0	3,0-6,0
C18:3 (n-6) $\gamma$ -linolenic acid	IN-5,0	IN-1,0	IN-0,5
C18:4 (n-3) estearidonic acid	IN-5,0	1,0-2,5	0,5-1,5
C20:0 araquidic acid	n. d.	IN-0,5	0,1-0,5
C20:1 (n-9) eicosenoic acid	IN-4,0	4,5-6,0	1,5-7,0
C20:1 (n-11) eicosenoic acid	IN-4,0	n. d.	n. d.
C20:4 (n-6) araquidónico acid	IN-2,0	0,5-1,0	IN-1,2
C20:4 (n-3) eicosatetraenoic acid	IN-2,0	1,0-2,0	0,5-1,0

C20:5 (n-3) eicosapentaenoic acid	5,0-26,0	6,5-9,5	2,0-6,0
C21:5 (n-3) heneicosapentaenoic acid	IN-4,0	IN-1,0	n. d.
C22:1 (n-9) erucic acid	<b>IN-5,0</b>	1,0-1,5	3,0-7,0
C22:1 (n-11) cetoleic acid	IN-5,0	1,0-1,5	n. d.
C22:5 (n-3) docosapentaenoic acid	IN-4,0	1,5-3,0	1,0-2,5
C22:6 (n-3) docosahexaenoic acid	4,0-23,0	6,0-8,5	3,0-10,0
<b>SUM OF EPA + DHA</b>	<b>Mín. 27</b>		

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.

	<p>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.</p>								
	<p><b>Table 1</b></p> <p>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.</p>								
	<p><b>Table 1</b></p> <p>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)</p> <p>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.</p>								
	<p><b><i>Information regarding the fatty acid profile in Peruvian anchovy (anchoveta) <i>Engraulis ringens</i>, determined by gas liquid chromatography from authentic samples (expressed as a percentage of total fatty acids)</i></b></p> <table border="0"> <thead> <tr> <th style="text-align: left;"><b>Fatty acids</b></th> <th style="text-align: left;"><b>Peruvian Anchovy (Anchoveta) (<i>Engraulis ringens</i>)</b></th> </tr> </thead> <tbody> <tr> <td>C14:0 miristic acid</td> <td><b>2.7 – 9.0</b></td> </tr> <tr> <td>C15:0 pentadecanoic acid</td> <td><b>N.D.</b></td> </tr> <tr> <td>C16:0 palmitic acid</td> <td><b>13.0-22.0</b></td> </tr> </tbody> </table>	<b>Fatty acids</b>	<b>Peruvian Anchovy (Anchoveta) (<i>Engraulis ringens</i>)</b>	C14:0 miristic acid	<b>2.7 – 9.0</b>	C15:0 pentadecanoic acid	<b>N.D.</b>	C16:0 palmitic acid	<b>13.0-22.0</b>
<b>Fatty acids</b>	<b>Peruvian Anchovy (Anchoveta) (<i>Engraulis ringens</i>)</b>								
C14:0 miristic acid	<b>2.7 – 9.0</b>								
C15:0 pentadecanoic acid	<b>N.D.</b>								
C16:0 palmitic acid	<b>13.0-22.0</b>								

C16:1 (n-7) palmitoleic acid	<b>4.0 – 11.0</b>
C17:0 heptadecanoic acid	<b>N.D.</b>
C18:0 estearic acid	<b>1.5 – 6.0</b>
C18:1 (n-7) vaccenic acid	<b>1.7 – 3.7</b>
C18:1 (n-9) oleic acid	<b>5.3 - 17.0</b>
C18:2 (n-6) linoleic acid	<b>0.7 – 2.3</b>
C18:3 (n-3) linolenic acid	<b>0.1 – 2.0</b>
C18:3 (n-6) γ-linolenic acid	<b>N. D.</b>
C18:4 (n-3) estearidonic acid	<b>IN-5.0</b>
C20:0 araquidic acid	<b>IN – 1.0</b>
C20:1 (n-9) eicosenoic acid	<b>IN-3.0</b>
C20:1 (n-11) eicosenoic acid	<b>N.D.</b>
C20:4 (n-6) araquidonic acid	<b>IN – 2.5</b>
C20:4 (n-3) eicosatetraenoic acid	<b>0.4 – 1.4</b>
C20:5 (n-3) eicosapentaenoic acid	<b>5.0-26.0</b>
C21:5 (n-3) heneicosapentaenoic acid	<b>N – 1.1</b>
C22:1 (n-9) erucic acid	<b>IN – 0.5</b>
C22:1 (n-11) cetoleic acid	<b>IN- 5.6</b>
C22:5 (n-3) docosapentaenoic acid	<b>1.0 – 3.1</b>
C22:6 (n-3) docosahexaenoic acid	<b>5.2 – 26.5</b>
<b>SUM OF EPA + DHA</b>	<b>Min. 27</b>
IN = Non detectable, defined as ≤ 0,05 %	
N.D. = not available	
N.A. = not applicable	
Source: Organismo Nacional de Sanidad Pesquera del Perú (SANIPES)	
Method used: AOCS Ce-1b-89 Fatty Acid Composition of Marine Oils by GLC	
Number of samples: 1141	

Canada is pleased to submit the following fatty acid analytical data on krill oil from a Canadian industry member.

Data includes test results from 119 lots from 2010-2016

Additional information on krill species, geographic location, harvest season and method of analysis are provided below.

		Year:	2010												
		Lot:	1	2	3	4	5	6	7	8	9	10	11	12	13
Parameter		Units													
Fatty acid profile	C14:0	% total fatty acids	11.17	12.75	11.40	11.24	10.97	10.98	10.83	10.65	10.39	10.46	10.59	10.05	9.77
	C16:0		22.04	22.50	22.22	22.01	22.36	22.47	22.36	22.59	22.32	22.11	21.96	21.32	20.95
	C16:1 n-7cis		7.04	6.82	6.86	6.28	5.88	5.92	5.79	6.02	5.93	6.08	5.91	5.37	4.75
	C18:1 n-9		12.05	11.93	12.11	12.12	12.02	12.22	12.25	12.53	12.35	12.13	12.11	9.73	9.63
	C18:1 n-7		7.17	7.69	7.17	7.09	7.14	7.07	7.03	7.02	6.98	6.99	7.06	6.88	6.89
	C18:2 n-6		1.71	1.83	1.73	1.87	1.94	1.90	1.90	1.82	1.85	1.87	1.83	1.57	1.55
	C18:3 n-3		1.12	0.87	1.13	1.13	1.19	1.19	1.23	1.14	1.21	1.23	1.20	1.49	1.73
	C18:4 n-3		3.66	3.09	3.80	3.63	3.57	3.68	3.76	3.60	3.72	3.81	3.81	5.16	5.78
	C20:1 n-9		0.74	0.81	0.75	0.82	0.79	0.80	0.77	0.75	0.74	0.73	0.76	0.66	0.65
	C20:5 n-3 EPA		18.27	17.65	18.13	18.20	18.15	18.01	18.22	18.07	18.38	18.45	18.67	20.45	20.53
	C22:1 n-9		0.07	0.05	0.06	0.10	0.09	0.09	0.09	0.10	0.11	0.11	0.09	0.05	0.06
	C22:5 n-3 DPA		0.41	0.40	0.39	0.43	0.43	0.42	0.42	0.40	0.41	0.41	0.56	0.42	0.45
C22:6 n-3 DHA	9.61	8.79	9.39	9.78	10.07	9.82	10.07	10.15	10.48	10.48	10.28	12.06	12.73		
Other compositional parameters	Total lipids as FA	g/100g oil	73.8	74.5	73.5	72.5	70.2	72.1	71.7	71.7	71.3	70.8	72.2	74.2	74.3
	Omega-3	g/100g oil	25.6	23.8	25.4	24.4	23.9	24.2	24.4	24	24.4	24.2	24.8	30	30.4
	Omega-6	g/100g oil	1.5	1.6	1.5	1.6	1.6	1.6	1.6	1.5	1.6	1.6	1.5	1.4	1.4
	Omega-9	g/100g oil	8.9	9.1	8.9	8.9	8.6	9	8.9	9.1	8.9	8.7	8.9	7.5	7.2
	Saturated FA	g/100g oil	25.3	27.2	25.4	25.8	25.1	25.9	25.5	25.6	25.2	18.4	25.5	24	24.4
	Monounsaturated FA	g/100g oil	20.3	20.9	20.1	19.6	18.7	19.4	19.2	19.5	19.2	19.1	19.3	17.5	16.8
	Polyunsaturated FA	g/100g oil	28.2	26.5	28	27.0	26.5	26.9	27.7	26.6	27	26.8	27.4	32.7	33
	Carotenoids	mg/100g oil	76.5	66.9	72	68.1	76.6	74.2	84.8	87.6	90.6	81.8	88.1	81	62.1
	Astaxanthin (esterified)	mg/100g oil	135.6	116	128.1	124.2	138.9	155.7	154	147.8	164.2	148	159.4	141.3	108.2
	Total phospholipids	g/100g oil	41.7	43.8	39	38.7	41.7	40.7	40.6	39.5	39.4	39.5	40.3	45.3	43.8
Stability indexes	Peroxide value	mEq peroxide/kg	0	0.2	0	0.0	0.0	0	0	0	0	0	0	0	
	p-Anisidine value	-	1.1	2.5	1.1	1.3	1.2	2	1.8	1.8	2	1.6	1.2	0.9	1.2
	Acid value	mg KOH/g oil	20.5	7.2	19.1	15.5	13.6	13.2	15.9	15.7	17.2	15.9	17	26.3	21.2
	Saponification value	mg KOH/g oil	178.6	182.3	178.6	178.4	182.0	173.8	176.5	182	174.3	171	172.5	173.6	175.2

		Year:	Overall				
		Lot:	Min	Max	Average	Std. dev.	
		Parameter	Units				
Fatty acid profile		C14:0	7.23	12.75	9.40	0.80	
		C16:0	18.58	22.59	20.65	0.88	
		C16:1 n-7cis	3.93	7.04	5.25	0.63	
		C18:1 n-9	8.64	12.53	9.85	0.87	
		C18:1 n-7	6.26	8.05	6.82	0.37	
		C18:2 n-6	1.51	2.20	1.80	0.17	
		C18:3 n-3	0.87	2.69	1.66	0.48	
		C18:4 n-3	2.47	7.06	4.92	1.20	
		C20:1 n-9	0.00	0.82	0.54	0.11	
		C20:5 n-3 EPA	17.65	27.58	21.69	1.82	
		C22:1 n-9	0.00	0.20	0.06	0.04	
		C22:5 n-3 DPA	0.38	0.63	0.47	0.04	
		C22:6 n-3 DHA	8.79	15.54	12.47	1.05	
	Other compositional parameters		Total lipids as FA	g/100g oil	61.00	75.80	69.29
		Omega-3	g/100g oil	23.80	34.93	29.09	2.35
		Omega-6	g/100g oil	1.10	1.90	1.48	0.17
		Omega-9	g/100g oil	5.60	9.51	7.10	0.88
		Saturated FA	g/100g oil	17.47	27.20	21.94	2.20
		Monounsaturated FA	g/100g oil	12.80	20.90	16.15	1.87
		Polyunsaturated FA	g/100g oil	26.50	36.47	31.16	2.14
		Carotenoids	mg/100g oil	38.60	90.60	57.33	13.65
		Astaxanthin (esterified)	mg/100g oil	69.71	164.20	101.92	24.38
Stability indexes		Total phospholipids	g/100g oil	35.80	48.60	41.64	2.83
		Peroxide value	mEq peroxide/kg	0.00	1.40	0.07	0.21
		p-Anisidine value	-	0.00	3.20	1.12	0.50
		Acid value	mg KOH/g oil	7.20	42.50	31.50	7.01
		Saponification value	mg KOH/g oil	161.00	182.30	172.20	4.26



**Krill Oil****Fatty Acids**

Fatty acids (Area %)	Draft Codex values	G037/001/A15	G138/002/A15	G243/001/A15	G307/001/A15	G334/001/A15	G009/001/A16	G036/001/A16	G036/004/A16
C14:0	6,4-13,0	10.6	10.6	9.6	9.7	9.8	7.7	6.5	7.1
C15:0	NA								
C16:0	17,0-24,6	20.4	21.1	21.7	20.6	20.3	18	18.7	18.6
C16:1, n-7	2,1-8,9	5.5	7.9	4.2	4.7	5.4	3.7	3.3	3.4
C17:0	NA								
C18:0	NA								
C18:1, n-7	8,4-21,7	6.1	6.4	6.5	6.1	6.1	5.5	5.9	6.1
C18:1, n-9	NA								
C18:2 n-6	0,7-2,1	1.6	1.3	1.5	1.6	1.5	1.4	1.5	1.6
C18:3, n-3	0,1-4,7	2.1	0.5	1.9	2.7	2	2.5	2.3	2.5
C18:3, n-6	NA								
C18:4, n-3	1,0-8,1	5.6	2.5	5.4	6	4.9	5.4	5.1	5.7
C20:0	NA								
C20:1, n-9	NA								
C20:1, n-11	NA								
C20:4, n-6	NA								
C20:4, n-3	NA								
C20:5, n-3	14,3-24,3	16.4	18.1	19.6	16.6	15.8	17.1	23.6	21.8
C21:5 n-3	NA								
C22:1, n-9	NA								
C22:1, n-11	NA								
C22:5, n-3	0-0,07	0.4	0.4	0.4	0.4	0.3	0.4	0.6	0.5
C22:6, n-3	7,2-25,7	8.2	7.3	10.7	9.4	8.2	9.9	13.6	13.1

Fatty acids (Area %)	G036/006/A16	G046/001/A16	G047/001/A16	G049/002/A16	G106/001/A16	G106/002/A16	G106/003/A16	G243/002/A16	min	max
C14:0	8.5	5.3	5.1	5.2	6.50	6.60	6.50	6.60	5.1	10.6
C15:0										
C16:0	20	18.4	18.2	18.4	20.20	20.30	20.20	20.30	18	21.7
C16:1, n-7	3.7	2.6	2.6	2.6	4.60	4.60	4.50	3.40	2.6	7.9
C17:0										
C18:0										
C18:1, n-7	6.7	5.8	5.8	5.8	5.9	5.8	5.8	5.7	5.5	6.7
C18:1, n-9										
C18:2 n-6	1.8	1.5	1.5	1.5	1.7	1.6	1.6	1.4	1.3	1.8
C18:3, n-3	2.8	2.5	2.6	2.5	1.2	1.2	1.2	2.3	0.5	2.8
C18:3, n-6										
C18:4, n-3	6.7	5.1	5.3	5.1	2.9	2.8	2.8	4.3	2.5	6.7
C20:0										
C20:1, n-9										
C20:1, n-11										
C20:4, n-6										
C20:4, n-3										
C20:5, n-3	21.1	26	26.2	26.5	26.8	26.6	27.1	23.5	15.8	27.1
C21:5 n-3										
C22:1, n-9										
C22:1, n-11										
C22:5, n-3	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.5	0.3	0.6
C22:6, n-3	12.9	15.2	15.5	15.6	13.4	13.7	13.8	12.8	7.3	15.6

### Quality Parameter

	G037/001/A15	G138/002/A15	G243/001/A15	G307/001/A15	G334/001/A15	G60/001/A16	G82/001/A16	G167/008/A16	G036/001/A16	G036/004/A16	G036/006/A16	G046/001/A16	G047/001/A16	G049/002/A16	G106/001/A16	G106/002/A16
Acid value (mg KOH/g)	11.3	12	11.68	13.79	12.39	11.64	13.7	13	19.97	18.5	15.43	18.38	19.3	17.99	n.d	n.d
Peroxide value (mEq/kg)	<2,0	<2,0	<0,10	<0,10	<0,10	<0,10	<0,10	<0,10	<0,10	<0,10	<0,10	<0,10	<0,10	<0,10	<0,10	<0,10
Phospholipids (g/100g)	45.5	n.d	44.5	40.1	41.1	45.3	44.6	45	50.4	45.6	40.8	56.4	56.6	57	58.2	58

**Proposal**

Fatty acids (Area %)	Draft Codex values	Current USP-NF (United States Pharmacopeia - National Formulary)	max/min value analyzed	Proposal for revised Codex values	Comments
C14:0	6,4-13,0	6,4-13,0	5,1-10,6	5,0-13,0	The Draft Codex corresponds to USP-NF, but we have analyzed some batches below the lower limit and would like to decrease it to 5,0
C15:0	NA	NA	NA	NA	
C16:0	17,0-24,6	17,0-24,6	18,0-21,7	17,0-24,6	Ok
C16:1, n-7	2,1-8,9	2,5-9,0	2,6-7,9	2,5-9,0	We suggest to update the limit in the Draft Codex standard according to the current USP-NF
C17:0	NA			NA	
C18:0	NA			NA	
C18:1, n-7	8,4-21,7	4,7-8,0	5,5-6,7	4,7-8,0	We suggest to update the limit in the Draft Codex standard according to the current USP-NF
C18:1, n-9	NA	7,0-14,5		NA	
C18:2 n-6	0,7-2,1	0-3,0	1,3-1,8	0-3,0	We suggest to update the limit in the Draft Codex standard according to the current USP-NF
C18:3, n-3	0,1-4,7		0,5-2,8	0,1-4,7	Ok
C18:3, n-6	NA			NA	
C18:4, n-3	1,0-8,1		2,5-6,7	1,0-8,1	OK
C20:0	NA			NA	
C20:1, n-9	NA	0,0-2,0		NA	
C20:1, n-11	NA			NA	
C20:4, n-6	NA			NA	
C20:4, n-3	NA			NA	
C20:5, n-3	14,3-24,3	14,0-24,3	15,8-27,1	14,3-28,0	The Draft Codex standard corresponds to USP-NF, but we have analyzed some batches above the upper limit and would like to increase it to 28,0
C21:5 n-3	NA			NA	
C22:1, n-9	NA	0,0-1,5		NA	
C22:1, n-11	NA			NA	
C22:5, n-3	0-0,7	0-0,7	0,3-0,6	0-0,7	
C22:6, n-3	7,2-25,7	7,1-15,7	7,3-15,6	7,1-15,7	We suggest to update the limit in the Draft Codex standard according to the current USP-NF

## Comparison of fatty acid composition of krill oil by manufacturer

No	Compound	LIAOYU	Fully	BKO	USP Krill Oil	Enymotec	Neptuen	USP STANDARD*
1	Butyric acid C4:0	-	-	-	-	-	-	
2	Caproic acid C6:0	-	-	-	-	-	-	
3	Caprylic acid C8:0	-	-	-	-	-	-	
4	Capric acid C10:0	-	-	-	-	-	-	
5	Undecanoic acid C11:0	-	-	-	-	-	-	
6	Lauric acid C12:0	0.2	0.1	0.2	0.2	0.2	0.2	
7	Tridecanoic acid C13:0	0.1	0.0	0.1	0.0	0.0	0.1	
8	Myristic acid C14:0	8.2	5.6	9.6	7.9	8.7	9.8	
9	Myristoleic acid C14:1	0.1	0.1	0.2	0.1	0.2	0.1	
10	Pentadecanoic acid C15:0	0.4	0.3	0.3	0.3	0.3	0.4	
11	cis-10-Heptadecenoic acid C15:1	0.0	0.0	0.1	0.0	0.0	0.1	
12	Palmitic acid C16:0	19.0	16.8	21.2	18.8	19.5	19.0	2.5-6.9
13	Palmitoleic acid C16:1	5.5	4.6	5.2	4.5	4.0	6.0	
14	Heptadecanoic acid C17:0	0.9	0.7	1.4	1.1	1.3	2.3	
15	cis-10-Heptadecenoic acid C17:1	0.2	0.3	0.2	0.2	0.3	0.3	
16	Stearic acid C18:0	1.4	1.9	1.0	1.0	0.9	1.1	
17	Elaidic acid C18:1n9t	0.1	0.1	0.1	0.1	0.1	0.1	
18	Oleic acid C18:1n9c	8.7	10.0	9.8	8.9	8.8	10.2	7.0-14.5
19	cis-vaccenic acid C18:1	5.4	4.8	6.3	6.0	6.1	6.4	4.7-7.0
20	Linolelaidic acid C18:2n6t	0.2	0.2	0.2	0.1	0.2	0.2	
21	Linoleic acid C18:2n6c	1.5	2.2	1.6	1.4	1.8	1.6	1.4-3.0
22	γ-Linolenic acid C18:3n6	0.2	0.3	0.2	0.2	0.2	0.2	
23	α-Linolenic acid C18:3n3	1.3	1.7	1.4	1.2	2.1	1.3	0.5-3.5
24	Stearidonic acid C18:4n3	3.6	3.5	3.9	4.1	5.2	3.1	1.8-7.2
25	Arachidic acid C20:0	0.2	0.1	0.1	0.1	0.1	0.1	
26	cis-11-Eicosenoic acid C20:1	0.8	0.7	0.6	0.6	0.5	0.6	0.1-1.2
27	cis-11,14-Eicosadienoic acid C20:2	0.2	0.2	0.1	0.1	0.1	0.1	
28	Heneicosanoic acid C21:0	-	-	-	-	-	-	
29	cis-8,11,14-Eicosatrienoic acid C20:3n6	0.1	0.1	0.1	0.1	0.1	0.1	
30	Methyl cis-5,8,11,14-eicosatetraenoic acid C20:4n6	0.6	0.8	0.4	0.5	0.3	0.4	
31	cis-11,14,17-Eicosatrienoic acid C20:3n3	0.2	0.2	0.2	0.2	0.3	0.2	
32	cis-5,8,11,14,17-Eicosapentaenoic acid C20:5n3	18.3	19.1	17.0	20.3	18.6	16.3	14.0-22.1
33	Behenic acid C22:0	0.1	0.1	0.1	0.1	0.2	0.1	
34	Erucic acid C22:1n9	0.5	0.3	0.7	0.6	0.5	0.5	0.0-0.9
35	cis-13,16-Docosadienoic acid C22:2	-	-	-	-	-	-	
36	Tricosanoic acid C23:0	0.6	0.6	0.5	0.6	0.6	0.4	
37	Lignoceric acid (C24:0)	-	-	-	-	-	-	
38	Docosapentaenoic acid C22:5n3	0.8	1.1	0.4	0.4	0.4	0.4	0.0-0.7

39	cis-4,7,10,13,16,19-Docosahexaenoic acid C22:6n3	11.1	13.5	9.3	12.2	10.2	9.6	7.5~13.2
40	Nervonic acid C24:1	0.2	0.2	0.2	0.1	0.1	0.1	

**Test method** : USP38 chemical tests - Fats and fixed oils - "fatty acid composition"

**Analytical condition**

Mode: GC (Gas Chromatography)

Detector : Flame Ionization

Column : 0.25-mm(ID)x 30-m x 0.25 um film, DB-23 (Agilent technologies)

**Temperatures**

- Injection port : 250°C

- Detector : 270 °C

- Column oven temperature program(split injection)

Carrier gas : Helium

Flow rate : 0.85mL/min

Split flowrate : 50:1

Injection size : 1 µL

Initial Temp. (°C)	Hold Time at 200°C (min)	Temp. Ramp (°C/ min)	Final Temp. (°C)	Hold Time at Final Temp. (min)
100	5	4	240	10

**Result** : Result = 100 x (A/B)

GOED Wild Salmon Oil:

Fatty Acids	As written in CL 2015/23-FO July 2015	Proposed Revision
C14:0 myristic acid	2.0-4.5	2.0-5.0
C15:0 pentadecanoic acid	ND-1.0	No change
C16:0 palmitic acid	12.0-16.0	10.0-16.0
C16:1 (n-7) palmitoleic acid	4.5-6.0	4.0-6.0
C17:0 heptadecanoic acid	ND-1.0	No change
C18:0 stearic acid	2.0-5.0	No change

C18:1 (n-7) vaccenic acid	n/a	1.5-2.5
C18:1 (n-9) oleic acid	16.0-18.0	8.0-16.0
C18:2 (n-6) linoleic acid	1.5-2.0	1.5-2.5
C18:3 (n-3) linolenic acid	ND-1.0	ND-2.0
C18:3 (n-6) $\gamma$ -linolenic acid	ND-1.0	ND-2.0
C18:4 (n-3) stearidonic acid	1.0-2.5	1.0-4.0
C20:0 arachidic acid	ND-0.5	No change
C20:1 (n-9) eicosenoic acid	4.5-6.0	2.0-10.0
C20:1 (n-11) eicosenoic acid	n/a	No change
C20:4 (n-6) arachidonic acid	0.5-1.0	0.5-2.5
C20:4 (n-3) eicosatetraenoic acid	1.0-2.0	1.0-3.0
C20:5 (n-3) Eicosapentaenoic acid	6.5-9.5	6.5-11.5
C21:5 (n-3) heneicosapentaenoic acid	ND-1.0	ND-4.0
C22:1 (n-9) erucic acid	1.0-1.5	ND-1.5
C22:1 (n-11) cetoleic acid	1.0-1.5	No change
C22:5 (n-3) docosapentaenoic acid	1.5-3.0	No change
C22:6 (n-3) docosahexaenoic acid	6.0-8.5	6.0-14.0

<p><u>General Comments</u></p>	<p><u>General Comments</u></p> <p>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.</p> <p>Regarding Table 1, Brazil does not have additional information regarding fatty acids composition of anchovy and krill oils.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p><b>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”.</b></p> <p>Regarding the methods for phospholipids on section 8 (8.10), Brazil would like to <b>ask for clarification</b> about the <b>conversion factor</b> 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.</p>
	<p><u>General Comments</u></p> <p>Canada supports the scope and description as</p>

	<p>written.</p>
	<p><b><u>General Comments</u></b></p> <p>The Subcommittee on Fats and Oils presents its comments at the draft standard fish oil. The following general comments are detailed.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
	<p><b><u>General Comments</u></b></p> <p>We support the document and the joint effort to develop a common standard on this subject.</p>
	<p><b><u>General Comments</u></b></p> <p>The Technical National Commission on Fats and Oils presents its comments to the draft standard for fish oils. We now detail the general remarks.</p> <p>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.</p> <p>There are differences in the composition of the oils (fatty acids profile) of marine origin, between wild and</p>



	<p>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.</p> <p>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.</p> <p>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.</p> <p>In response to the request from CCFO, Perú submits information on the profile of fatty acids present in the oil from Peruvian anchovy (anchoveta). The ranges submitted are based on information from official sources on the results of analyses of fish oil from catches of the Peruvian species <i>Engraulis ringens</i> between the years 2013 to 2015 in several areas of the Peruvian coast.</p> <p>It is important for the draft CODEX Standard for Fish Oils to include the minimum sum of EPA + DHA (both omega 3) and the contents of linoleic acid (omega 6), that characterize and identify each species and that can contribute to guaranteeing the authenticity of the fish oil, as well as its declaration on the product label.</p> <p>It is necessary to take into account and debate the fact that it is important to adequately distinguish oil from wild fish species compared with 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.</p>
	<p><b><u>General Comments</u></b></p> <p>The United States supports development of the Proposed Draft Standard for Fish Oils in the Codex Committee on Fats and Oils.</p>
	<p><b><u>General Comments</u></b></p> <p>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</p>

	<p>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.</p>
	<p><b>General Comments</b></p> <p>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.</p> <p>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.</p>
	<p><b>ISDI supports the adoption of the Codex draft Standard for Fish Oils at Step 8 during the 25<sup>th</sup> CCFO.</b></p> <p>Background:</p> <p>Fish oil for human consumption is an important product that is produced and traded internationally. It is sold to consumers directly and used as a key nutritional ingredient in foods.</p> <p>In nutrition products it is used to provide important fatty acids such as DHA (docosahexaenoic acid). In particular in infant formula and foods for young children the use of fish oil as a source of DHA is common.</p> <p>A clear Codex Standard will help ensure consumer protection and facilitate international trade when countries recognize the CODEX Standard.</p> <p><b>Position:</b></p> <p><b>ISDI supports the adoption of the Codex draft Standard for Fish Oils at Step 8 during CCFO25.</b></p> <ul style="list-style-type: none"> <li>• <b>ISDI supports the work previously done regarding Codex draft Standard for Fish Oils and in particular to keep the scope, descriptions and definitions of named and unnamed Fish Oils as agreed previously during CCFO24<sup>1</sup>.</b></li> <li>• <b>ISDI is open to proposals of introductions of defined species, providing that criteria regarding volumes and fatty acids data are met.</b></li> </ul>
	<p>Egypt supports the document and the joint effort to develop a common standard on the following subject:</p>

<sup>1</sup> See REP15/FO