



## Agenda Item 3

CX/FO 13/23/3-Add.3  
Original Language Only

### JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FATS AND OILS

Twenty-third Session  
Langkawi, Malaysia, 25 February – 1 March 2013

### PROPOSED DRAFT STANDARD FOR FISH OILS

#### Comments at Step 3

*(Comments of the United States of America)*

#### UNITED STATES OF AMERICA

##### General Comments:

The United States continues to generally support the effort by Switzerland and the electronic Working Group to develop a new Codex Standard for fish oils and appreciates this opportunity to provide additional specific comments on the draft Standard.

While we recognize that general information showing international trade in fish oils was provided to support the new work proposal on fish oils, the subsequent expansion of the proposal to include 13 named fish oils did not undergo a similar scrutiny. The United States believes that trade information should be developed to assure that all of the proposed thirteen named fish oils have some demonstrated international trade as outlined in the Guidelines on the Application of the Criteria for the Establishment of Work Priorities Applicable to Commodities for each to be added to the draft standard. Currently, for other oils, the proposed addition of any specific individual oil to a standard has required a new work proposal together with a demonstration of international trade in that oil to justify the addition of that oil to the standard.

We are also concerned that the current proposed standard includes very broad limits of various fatty acids that may not be scientifically supportable, may not be effective for confirming authenticity and may not be enforceable, as described further below. In summary, we support the development of a fish oil standard, but we believe that care needs to be taken to make it an effective and enforceable standard.

##### Specific comments:

Section 1. Scope - The specific language, “in its entirety” and “presented in a state” are confusing and can be misunderstood. Additionally, the sentence that appears in square brackets is subject to misinterpretation. We recommend rewording as follows:

“This Standard applies ~~in its entirety~~ to the crude and refined fish oils intended for human consumption as described in Section 2 ~~that are presented in a state for human consumption~~. ~~It applies partially to crude fish oils described in Section 2.6.1 that require further processing before they are placed on the market for the final consumer~~. For the purpose of this Codex Standard, the term fish oils refers to oils derived from fish and shellfish as defined in Section 2 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)4.”

Section 2. Description – This section is confusing because it does not correspond to the naming scheme described in section 2.5. We recommend rewording as follows:

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

fish oils used in food and in food supplements where those are regulated as foods.”

Section 2.1 – We consider the information in Table 1 to be of questionable validity due to strong concerns about where the data originate and whether it accurately represents the many variations reportedly observed due to geographical source, climate in the harvest regions, available food in the harvest regions, purity of the samples used to generate the data and possible differing methodology used to identify the fatty acid profiles. Additionally, the values currently in the table are so broad as to be of limited or no value in determining the authenticity of a fish oil. For these reasons, we recommend that the table be eliminated and the text of this section revised accordingly. If the committee considers a table to be necessary and helpful, it should be clear that it is illustrative only, and we would recommend rewording this section as follows:

“Named fish oils may be derived from specific source materials; such fish oils are then identified by a specific name that is representative of the major fish or shellfish taxon from which the oil is extracted. For named fish oils, the fatty acid profiles in (Table 1) shall apply **have been reported and provide information on some quality factors that may be useful to trading partners.**”

Section 2.1.2 – We recommend that the genus *Harengula*, a genus that is commonly marketed as sardine be added to this list.

Section 2.1.3 – We question the statement that “salmon oil is a mixture of oils derived from wild and farmed fish.” The general term “salmon oil” refers to oil derived from either. Since oil from farmed salmon may contain much lower levels of the desirable omega 3 fatty acids, products containing any proportion of oils from farmed salmon should be distinguished from products containing only oils from wild salmon. We recommend that this section be reworded as follows:

“Wild salmon oil or farmed salmon oil are derived from wild or farmed fish respectively of the family Salmonidae; **farmed** salmon oil ~~is~~ **and** mixtures of oils derived from wild and farmed fish **salmon are subject to the labeling requirements of section 7.1.**”

Section 2.1.5 - We recommend that the genus *Ethmidium*, a genus that is commonly marketed as menhaden be added to this list.

Section 2.1.6 - We recommend that the genera *Euthynnus* and *Allothynnus*, genera that are commonly marketed as tuna be added to this list.

Section 2.1.9 - We recommend that the genus *Theragra*, a genus that is commonly marketed as pollock be added to this list.

Section 2.1.10 - We recommend that the genera *Ilisha*, *Etrumeus*, *Pellona*, *Harengula*, *Opisthopterus* and *Alosa*, genera that are commonly marketed as herring be added to this list.

Section 2.2 - We question why a product described as “fish oils (unnamed)” should exclude fish oils from named species identified in Section 2.1. We suggest revising this section to read as follows:

“Fish oils (unnamed) **and mixtures of fish oils with fish liver oils** may be derived from a single species of fish ~~other than the ones listed in Section 2.1~~ or be a mixture of fish oils ~~derived from specified and/or unspecified source materials. This includes also mixtures with fish liver oils.~~”

Section 2.3 - We consider the information in Table 1 to be of questionable validity due to strong concerns about where the data originate and whether it accurately represents the many variations reportedly observed due to geographical source, climate in the harvest regions, available food in the harvest regions, purity of the samples used to generate the data and possible differing methodology used to identify the fatty acid profiles. Additionally, the values currently in the table are so broad as to be of limited or no value in determining the authenticity of a fish liver oil. For these reasons, we recommend that the table be eliminated and the text of this section revised accordingly. If the committee considers a table to be necessary and helpful, it should be clear that it is illustrative only, and we would recommend rewording this section as follows:

“Named fish liver oils may be derived from the livers of fish and are composed of fatty acids, vitamins or other components that are representative of the livers from the species from which the oil is extracted. For named fish liver oils the fatty acid profiles in (Table 1) shall apply **have been reported and provide information on some quality factors that may be useful to trading partners.**”

Section 2.3.1 – We note that the genera *Boreogadus*, *Arctogadus*, *Paranotothenia*, and *Eleginus*, are genera also commonly marketed as cod and we question whether they ought to be added to this list.

Section 2.4.1 – We are concerned that this definition actually encompasses all refined fish liver oils, irrespective of actual vitamin content, since the processing reduces the vitamin content. However, no maximum vitamin content is specified in this definition. Consumers may understand the term “devitaminized” to mean that all of the vitamins have been removed. We suggest that this section be deleted in its entirety or that maximum levels of vitamins be specified.

Section 2.5 - The language in this section should be revised to incorporate the “ethyl ester” fish oils identified as subcategories in the section. We suggest the following revised language:

“Concentrated fish oils **and concentrated fish oil ethyl esters** are derived from fish oils described in Section 2.1 to 2.4 which have been subjected to processes such as hydrolysis, fractionation, winterization and/or re-esterification to increase the concentration of specific fatty acids.

Section 2.6.2 and 2.6.3 – We question the need for these sections. They define the articles “Virgin fish oils” and “Extra low oxidized fish oils” in terms of a maximum time and/or temperature process rather than by a composition or characteristic that can be readily verified. We suggest that these sections be deleted.

Section 3.1 – We question the validity of the table referenced in this section for a variety of reasons as we previously noted in our comments to Section 2.1. This view is reinforced by the language in this section. We do not believe that the values in this table can be considered “**essential** composition and quality factors” if, as the second sentence advises:

“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.”

For these reasons, we recommend that the table and section 3.1 be eliminated. If the committee considers a table to be necessary and helpful, it should be clear that it is illustrative only, and we recommend deletion of the second sentence identified above because these supplementary criteria and how they would be used, their limits, and the values that would be applied are not identified with sufficient specificity as to be included in the standard as “essential composition and quality factors”.

#### Section 4 – Food Additives

The introductory note excluding crude fish oils and crude fish liver oils as described in section 2.6.1 should be deleted. Additives used in crude fish oils and crude fish liver oils should be limited to those specifically authorized in this standard or in the GSFA. The United States has identified a technological need for antioxidants, sequestrants and antifoaming agents in fish oil. Members of the eWG did not agree on the inclusion of antioxidant synergists or colors (CX/FO 13/23/3, para 20). Therefore, the United States recommends that, as indicated in CX/FO 13/23/3, this section contain the standard language in the *Codex Procedural Manual* (20<sup>th</sup> Ed., pp. 51-52) that references the GSFA:

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

The eWG identified a technological need for flavorings in fish oil. Therefore, the United States supports the following standard language for use of flavorings:

“Flavorings may be used in fish oil in accordance with Guidelines for the Use of Flavorings (CAC/GL 66-2008).”

The United States notes that Citric acid (INS 330), Tocopherols (INS 307a, 307b, and 307c), and Lecithin (INS 322i) are required for use in fish oil as antioxidants. Citric acid (INS 330), Tocopherols (INS 307a, 307b, and 307c), and Lecithin (INS 322i) are all listed in Table 3 of the GSFA with the functional class “antioxidant,” but are not listed in Tables 1 and 2 of the GSFA under food category 02.1.3. Food category 0.2.1 and, therefore, food category 02.1.3 are excluded from Table 3. Therefore, the United States recommends that CCFO recommend to CCFA that these food additives be included in Tables 1 and 2 under food category 02.1.3.

Other ingredients used as antioxidants in fish oil are Rosemary Extract and Astaxanthin. These ingredients do not have INS numbers and have not been reviewed by JECFA. The United States tentatively proposes that these antioxidants be added to the Proposed Draft Standard for Fish Oil in section 3 (Essential Composition and Quality Factors) as “Optional Ingredients.”

## Section 5 –Contaminants

We recommend that, as indicated in CX/FO 13/23/3, this section contains the standard language contained in the Codex Procedural Manual (20th Ed., pp. 52) that references the General Standard for Contaminants and Toxins in Food and Feed:

“The products covered by this Standard should comply with the Maximum Levels of the Codex General Standard for Contaminants and Toxins in Food and Feed (Codex Stan 1993-1995).”

The Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) currently includes MLs for both arsenic (0.1 mg/kg) and lead (0.1 mg/kg) for Edible Fats and Oils Not Covered by Individual Standards (CODEX STAN 19-1981) which currently applies to fish oil because no individual standard for fish oil exists. If CCFO wants the current MLs for arsenic and lead to apply to fish oil to be covered by the proposed fish oil standard, CCFO should request that CCCF revise the GSCTFF to include these same MLs for the proposed fish oil standard. In addition, if CCFO has concern about other contaminants in fish oil (e.g., other heavy metals, dioxin, PCBs) the Committee should review current Codex documents available that address contaminants in food and feed, including fish oil (Code of Practice Concerning Source Directed Measures to Reduce Contamination of Foods with Chemicals, CAC/RCP 49-2001 and Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Foods and Feeds, CAC/RCP 62-2006). In addition, CCFO can provide data on contaminant levels in fish oil to CCCF so that CCCF can determine if additional MLs for contaminants in fish oil are warranted.

For residues of pesticides and veterinary drugs, this section should also contain a general reference which should take the following form, without reference to specific provisions on residues of pesticides and veterinary drugs:

“The products covered by this Standard should comply with the Maximum Residue Limits for pesticides and/or veterinary drugs established by the Codex Alimentarius Commission.”

We recognize that crude fish oils may contain contaminants that will be removed by further processing. However, we suggest that the introductory note excluding these products should be deleted and the text revised to indicate that after processing is complete, the products covered by the standard will conform to the contaminants requirements.

Section 7.1 – When farmed fish are a source of the fish oil, depending on what food the fish are fed, the oil derived from farmed fish may contain different levels of desirable fatty acids. Accordingly, when farmed fish are used to make the oil, consumers should be advised of that fact. We recommend adding an additional sentence to this section to provide for this issue. We suggest revising this section to read as follows:

“The product should be labeled in accordance with the Codex General Standard for the Labeling of Pre-packaged Foods (Ref. CODEX STAN 1-1985). The name of the fish oil should conform to the descriptions given in Section 2 of this Standard. **If any farmed fish are used to make the oil, the name specified in Section 2 should also include the term “farmed”, e.g. “from farmed fish”.**”

Section 7.3 - We recommend that the levels of Vitamins A & D should be declared on all fish liver oils, whether naturally present or restored. We recommend that the word “may” in square brackets in the first sentence be replaced with the word “should” and the square brackets removed. Consumers need the information on the Vitamin content to assure that they can control the levels they consume.

Table 1 – We consider the information in Table 1 to be of questionable validity due to strong concerns about where the data originated and whether it accurately represents the many variations reportedly observed due to geographical source, climate in the harvest regions, available food in the harvest regions, whether the fish is farmed or wild, purity of the samples used to generate the data and possible differing methodology used to identify the fatty acid profiles. It is not clear for example, that all of the data were generated by appropriately qualified laboratories using the methodology specified in Section 8. We further note that the working group has some obvious concern about the applicability of the values in this table since they originally proposed in Section 3.1 to consider “Supplementary criteria, for example national geographical and/or climatic variations” in lieu of the values in this table. This reference to supplementary criteria is not a specific criteria. It does not identify a specific value that can be readily ascertained and applied by countries.

However, this is consistent with our concerns that variations from the values in Table 1 may occur due to geographic and climatic conditions and suggests that variation from the values in this table may be normal and appropriate. If variations from the values in this table are normal and appropriate, the values in this table

cannot be considered to be essential composition and quality factors.

We recommend that this table be removed. If the committee considers a table to be necessary and helpful we recommend that it be designated as containing additional quality factors and that product that fails to conform to a level specified in the table may, nevertheless, conform to the standard.

We note that there are many sections in the fatty acid table that have NA (not available) in the value section and that for some fatty acids, there are so few values that we question why they are included in the table. If the table is retained, it should be clearly noted that it is incomplete and that the committee anticipates adding timely updates of any new or supplemental compositional information. To facilitate this supplementation, we recommend that the Committee consider requesting authorization from the Codex Alimentarius Commission to update the table as a ministerial/custodial matter without requiring authorization for new work each time it needs to amend or update the levels. Values considered for addition to the table should be derived using the methodology specified in the Section 8.