

REPORT OF THE TWENTY-THIRD SESSION OF THE CODEX COMMITTEE ON FATS AND OILS
Langkawi, Malaysia
25 February – 1 March 2013

PROPOSED DRAFT STANDARD FOR FISH OILS (AGENDA ITEM 3)⁴

35. The Committee recalled that the 34th session of the Codex Alimentarius Commission had approved the development of a Codex Standard for Fish Oils as new work as proposed by the 22nd session of the Codex Committee for Fats and Oils (CCFO) and that an electronic Working Group (eWG) chaired by Switzerland, had prepared a Proposed Draft Standard for Fish Oils based on the project document⁵, the comments received at the 22nd session of the CCFO and the discussions held within the eWG. The Proposed Draft Standard had been circulated for comments at Step 3 for consideration at the present session.

36. The delegation of Switzerland explained that it had not been possible to reach agreement on all issues. For the time being all named fish oils and their fatty acid profiles that had been submitted by members of eWG had been included in section 2.1 and Table 1, respectively.

GENERAL COMMENTS

37. The Committee supported the development of the standard.

Section 1: SCOPE

38. The Committee agreed on several amendments in accordance with the Procedural Manual. This section should only make reference to the food described in the standard and thus the reference to crude fish oils should be moved to Section 2. The words “in its entirety” were agreed to be deleted. The Committee also agreed to move the sentence concerning applicability of the standard to food and food supplements from section 2 to this section.

39. The amended scope reads as follows: “This Standard applies to the fish oils described in Section 2 that are presented in a state for human consumption. For the purpose of this Codex Standard, the term fish oils refers to oils derived from fish and shellfish as defined in Section 2 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)*. This standard only applies to fish oils used in food and in food supplements where those are regulated as foods.

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

Section 2: DESCRIPTION

40. The section was revised to have a clear distinction between crude and refined fish oils and to give an indication of the processes to obtain fish oil, which are not limited to extraction of crude oil and refining it. It was decided rather than referring to “by-products such as trimmings” to make reference to raw material as defined in the Code of Practice for Fish and Fishery Products.

41. After some discussions the Committee decided to include crude fish oil in the draft standard and noted the need to clarify which sections of the standard applies to crude fish oil.

42. After an extensive discussion on “concentrated fish oils” and “concentrated fish oils ethyl esters”, it was clarified that these esters were of importance as fish oils were commonly modified in that way.

43. Some delegations were of the opinion only if a product **was primarily composed** of fatty acids ethyl esters it should be referred to as a concentrated fish oils ethyl ester. Other delegations were of the view that if the product **contained** fatty acids ethyl ester it should be referred to as a concentrated fish oils ethyl ester. The Committee maintained both options in the text in square brackets and to be further discussed in Section 2.5.

4 CX/FO 13/23/3, CX/FO 13/23/3-Add.1 (Brazil, Chile, Iceland, Japan, Norway, Vietnam, CRN, ELC, IADSA, ISDI); -Add.2 (Egypt, European Union, India, Indonesia, Kenya, Mali and Thailand); -Add.3 (United States of America); CRD13 (Malaysia)

5 REP 11/FO Appendix VII REP13/FO 6

44. The amended description reads as follows: "*Fish oils* mean oils intended for human consumption derived from the raw material as defined in Section 2 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003). Processes to obtain fish oil for human consumption may involve, but are not limited to, extraction of *crude oil** from raw material and refining of that crude oil. *Fish oils* and *concentrated fish oils* are primarily composed of glycerides of fatty acids whereas *concentrated fish oils ethyl esters* [are primarily composed of][contain] fatty acids ethyl esters. Fish oils may contain other lipids and unsaponifiable constituents naturally present."

*as described in Section 2.6.1

Sections 2.1-2.6.3: Definitions

45. The Committee discussed the section in detail and the following comments/suggestions were made by one or several delegations:

General

- There was concern about the large number of named fish oils. Only those fish oils in compliance with the general criteria for new work in the Procedural Manual should be included.
- The description of the oils should be rephrased: naming the species or genera first and then the family.
- To refer to CCFFP to ensure alignment of terminology and consistency as well as to CCNFSDU in relation to the high vitamin content of some oils.
- Farmed fish oil has a different fatty acid profile and this was important information for the consumer which could be taken care of in the labeling section.
- It should be mentioned which sections of the standard that crude fish oils have to comply with in the standard.

Section 2.1

- It was proposed to amend Section 2.1 as follows: "**Named fish oils** may be derived from specific source materials; such fish oils ~~could be~~ **are then** identified by a specific name that is representative of the major fish or shellfish taxon from which the oil is extracted, **except when that can be confusing for the consumer.** "
- There was concern on how to determine which was the "major" fish or shellfish taxon.
- For sardines, the description should make reference to several specific types of sardine to avoid misleading the consumer.
- Only two species of krill are used for oil extraction and they should be listed.

Section 2.1.3: Mixtures of wild salmon oils and farmed salmon oils are unnamed fish oils.

Section 2.3: One delegation pointed out that there are no other components than fatty acid and vitamins that are representative of fish liver oil

Section 2.4.1: The process used to de-vitaminise fish liver oil should be indicated.

Section 2.5: The 50 w/w % fatty acids should be increased to 70% and the language should be aligned with the description.

Section 2.6.1: Proposed to add a new sentence added to this Section: Crude fish oils and crude fish liver oils have to comply with Sections 3.1, 6.1 and 7.

Section 2.6.2: There was a concern on virgin fish oil and proposals were made to delete it as it was not in line with the definition of other virgin oils in other Codex standards. Concern was also expressed regarding on the sentence on antioxidants and pigments naturally present.

Section 2.6.3: There was concern with extra low oxidized fish oil for which further clarification on quality parameters were needed. REP13/FO 7

46. A new section on processing was proposed as follows: “Fish oils are produced from (i) catches for the single purpose of fishmeal/oil production, (ii) by-catches from another fishery or (iii) fish off cuts and offal from the processing industry. Gadoids, clupeids, scombroids and salmonoids are within the most used species. Traditional processes to obtain fish oil involve two stages: oil extraction from raw material and refining of that crude oil. The refined fish oil production process typically includes several steps such as repeated heating at high temperatures (at 90-95°C and even to 180°C) as well as alkali/acid treatments and repeated removal of the water phase. Fish oils may also be subjected to processing steps (e.g. solvent extraction, saponification, re-esterification, trans-esterification).”

47. There were different opinions about the inclusion of this section. Some delegation felt it was useful while others were of the opinion that the relevant information had already been included in the description. The Committee retained the proposed new section on processing in square brackets.

48. A section on “Permitted ingredients” was also proposed to be added to include flavourings and restored vitamins. It was pointed out that flavourings and other food additives should be included in the food additives section.

49. The Committee agreed that sections 2.1-2.6.3 needed substantive further work and should be maintained in square brackets. Input from members and observers should be sought concerning trade data on individual named fish oils and fatty acid composition profiles.

SECTION 3: Essential Composition and Quality Factors

General comment

50. It should be clear which sections apply to crude fish oils.

Section 3.1

51. Many delegations raised concerns regarding the robustness and validity of the data presented in table 1 which should accommodate regional and varietal differences. Some delegations suggested that the table should be verified otherwise it should only be advisory.

52. It was mentioned that the sentence on “Supplementary criteria, for example national geographical ...” would leave the standard too open for national interpretation and should be deleted or rephrased to read “Table 1 is advisory and geographical and climate variations may be considered to confirm that the product is compliant with the standard.”

53. It was proposed to add a new section on raw materials including a reference to the Code of Practice for Fish and Fishery Products as follows: “The raw materials used in the production of fish oils should be as fresh as possible and handled in accordance with the *Code of Practice for fish and*

fishery products, in particular Section 4 - General Considerations for the Handling of Fresh Fish, Shellfish and other Aquatic Invertebrates (CAC/RCP 52-2003).”

54. There were different opinions on whether a section on raw materials would be useful in the standard and whether it should be placed in section 3 or 6 on hygiene. It was mentioned that the expression “as fresh as possible” was difficult to interpret.

Section 3.2: The parameters should be those that actually reflect quality and safety of the products.

Section 3.2.1: The database used should be clarified. Peroxide values alone is not sufficient for quality determination – needs to be considered together with anisidine value. The necessity for a parameter or a value for oligomers should be further discussed.

Section 3.2.2: It was recommended that the acid value for krill oil should be raised from 20 to 30 mg KOH /g.

Section 3.2.3: A new section 3.2.3 with quality parameters for extra low oxidized fish oils was proposed.

Section 3.3: Vitamins need to be maintained in the section while it was pointed out that deep sea shark liver oil should be excluded from this Section

55. The Committee agreed that section 3 needed substantive further work and should be maintained in square brackets. REP13/FO 8

SECTION 4: FOOD ADDITIVES

56. One delegation recommended that the food additive section apply to crude oils and refined oils. Another delegation mentioned that it was not essential if the section applied to crude oils as most additives would not be present with the refinement process of crude oils. The Committee maintained the sentence on crude oils in square brackets.

57. The Committee agreed to the following:

- To include the general statement on flavorings from the Procedural Manual in this section
- To delete antioxidant synergists and amend the term “chelating agent” to “sequestrants” which was the term for the functional class used in the GSFA.
- To put sequestrants and antifoaming agents in square brackets.
- Not to allow colours in the standard.
- There was a need for antioxidants in the standard due to the characteristics of the product

58. The Committee noted that the following new food additives were proposed for use in the standard as antioxidants: rosemary extract, astaxanthin, lecithin, citric acid, tocopherol and ascorbyl palmitate.

59. The Committee noted that rosemary extract (INS 392) and astaxanthin were not included in the GSFA and had not been evaluated by JECFA.

60. Several delegations did not agree with the inclusion of astaxanthin as in their view, insufficient information was provided to substantiate its inclusion as antioxidant and it might be used also as a colour. The Committee agreed to maintain astaxanthin in square brackets.

61. The Committee noted further that lecithin, citric acid and tocopherols were currently at step 7 of the procedure for inclusion in the GSFA for food category 02.1.3 and that Ascorbyl palmitate was covered under Ascorbyl Esters (adopted in the GSFA in 2006).

62. The Committee decided to refer to the CCFA its intention to include “rosemary extract” as an antioxidant in the standard for fish oils noting that it had not yet been included in the GSFA and not been evaluated by JECFA.

SECTION 5: CONTAMINANTS

63. The Committee decided to maintain the sentence on crude oils in square brackets. One delegation noted that most contaminants would not be present after refinement. Another delegation stated that refining does not remove all the contaminants and that maximum levels are still required for refined oils.

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

65. The Committee also noted the requests to have maximum levels in fish oils for: Cadmium, Mercury, Polychlorinated biphenyls (PCB), Dioxins and Furans. However they were maintained in square brackets for further discussion and justifications.

66. The Committee noted that pesticide residues could be present in farmed fish due to run-offs from farms but that the CCPR had not established any MRLs for pesticides in fish and fishery products. The Committee also noted that veterinary drugs and pesticides were used on farmed fish.

67. The Committee agreed to include the general text on pesticide and veterinary drugs residues as in the Procedural Manual in this section but maintained it in square brackets: [“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.”]

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SECTION 6: HYGIENE

68. The Committee maintained this section except for the note on crude oil which was placed in square brackets.

SECTION 7: LABELLING

69. The Committee agreed to maintain this section in square brackets as it relates to section 2 which has yet to be finalized. The Committee noted a comment that oils from farmed fish should be labeled as such and content of vitamins A and D should also be labeled.

SECTION 8: METHODS OF ANALYSIS AND SAMPLING

70. The Committee noted that for oligomers the method ISO 16931 or AOCS Cd 22-91 could be used and that the method for arsenic could be addressed. The Committee maintained the other parts of this section in square brackets as it relates to section 2 which has yet to be finalized. 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.

CONCLUSION

71. In view of the comments made and the need for further data and information, the Committee agreed to return the Proposed Draft Standard to Step 2 for re-drafting.

72. The Committee established an electronic working group chaired by Switzerland open to all members and observers and working in English only with the terms of reference to revise the proposed draft standard on the basis of the discussion at the session. The Committee agreed that items already agreed in this Session should not be re-opened for debate by the eWG. However, further comments may be discussed at the next session of the Committee.

73. In preparation for the eWG, the Codex Secretariat will send a Circular Letter, requesting information on volume and patterns of trade for different fish oils and information on quality and composition, including fatty acid profile for named oils.

74. The Committee noted that to justify establishing specific named fish oils in the Proposed Draft Standard, the proposals should be supported by adequate information including volume of production and consumption in individual countries and volume and pattern of trade between countries, international or regional market potential, and other information together with details of the proposed essential composition and quality factors. In addition, data on the fatty acid composition of the types of named fish oils should be robust and take into consideration main contributing factors such as climatic conditions and seasonality, geographical location etc.

75. The eWG will also identify specific questions to be referred to the CCFFP and the CCNFSDU.

76. The report of the eWG containing the revised proposed draft standard will be circulated to all members and observers for comments at step 3.

77. The Committee also agreed to convene a physical working group, chaired by Switzerland, immediately prior to its next Session and working in English only, to consider the report of the electronic working group and comments submitted to the working document in order to facilitate the discussion in the plenary at the next Session.

78. The Committee noted the referrals to CCFA and CCCF made under the relevant sections above relating to rosemary extract as food additive and Lead and Arsenic as contaminants.

Status of the Proposed Draft Codex Standard for Fish Oils

79. The Committee agreed to return the Proposed Draft Standard for Fish Oils to Step 2 of the procedure for redrafting by the above-mentioned electronic working group, circulation for comments at Step 3, discussion by the above-mentioned physical working group and discussion at Step 4 at the next session of the Committee.