

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

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PROPOSED DRAFT STANDARD FOR MICROBIAL OMEGA-3 OILS

(Step 3)

(Prepared by the Electronic Working Group chaired by the United States of America and co-chaired by China)

Codex Members and Observers wishing to submit comments, at Step 3, on the proposed draft *Standard for Microbial Omega-3 Oils* should do so as instructed in CL2025/80 available on the Codex webpage/Circular Letters: <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

INTRODUCTION AND TERMS OF REFERENCE

1. At the 28th Session of the Codex Committee on Fats and Oils (CCFO28), the Global Organisation for EPA and DHA omega 3s (GOED) presented the new work proposal to develop a Codex standard for microbial omega-3 oils to ensure fair practices in trade and protect consumer health as these were high value commodities with increasing production and global trade.
2. CCFO28 agreed to:
 - i. Submit for approval by CAC47 the proposal for new work on a standard for microbial omega-3 oils.
 - ii. Establish an electronic working group (EWG) chaired by the United States of America and co-chaired by China working in English, subject to the approval of new work by CAC47, to prepare the proposed draft standard for circulation for comments at Step 3 and consideration by CCFO29.
 - iii. Make the report of the EWG available to the Codex Secretariat at least three months before CCFO29.
3. The CAC47 approved the new work proposal in November 2024.

PARTICIPATION AND METHODOLOGY

4. Codex Members and Observers were invited to register their experts for the EWG in June 2024. Experts from 26 Members and 3 Observers registered to participate in the EWG¹. The work of the EWG was conducted on the Codex EWG platform.
5. The EWG worked on the standard and associated parameters during three rounds of consultations. The first draft of the proposed standard for microbial omega-3 oil was circulated to the EWG for comments in August 2024, while the third draft was circulated for comments in August 2025.

SUMMARY OF EWG DISCUSSIONS

6. The EWG discussed the safety considerations relating to microbial omega-3 oils as novel foods involving new production processes. Based on the ongoing efforts by FAO on cell-based food and precision fermentation derived food products, and current regulatory landscape requiring pre-market food safety assessment by most countries/jurisdiction, the EWG agreed that there is no need for specific scientific advice from FAO/WHO.

¹ Members and observers of the EWG included: Australia, Brazil, China, Colombia, Canada, Egypt, European Union, Food Industry Asia, France, Ghana, India, Indonesia, Iran, Japan, Kingdom of Saudi Arabia, Malaysia, New Zealand, Nigeria, Norway, Peru, Poland, Republic of Korea, Russia, Thailand, United Kingdom, United States of America, Uruguay, GOED and USP.

7. The EWG discussed the need to add information regarding use of species/strain, production process or their safety assessment at national level. There were concerns raised that any provision added should not be restrictive to innovation. A general provision was added to the standard that “Microbial omega-3 oils can be considered as novel food in some countries, and it may be necessary to consider their authorization of use as foods for human consumption by the country of retail sale.” There was general consensus that it may not be practical to list all relevant species currently used in microbial omega-3 oil production. It could result in limiting innovation and require often updating the standard to be comprehensive.
8. The EWG discussed the nomenclature and classification approach for naming different types of microbial omega-3 oils based on the microorganism used to derive omega-3 oils. Considerations were given to classify oils based on microbial source (e.g., microalgae, bacteria, fungi), taxonomic classification, and terminologies commonly used in international trade. The EWG agreed to name the omega-3 oils by microbial source without any further categorization and note any taxonomic classification that may be referred differently for trade purpose.
9. The EWG members discussed proposal to include additional microbial sources in the standard. There was general consensus to include oils from all microbial sources if they authorized for use in some countries and meet production and trade volume criteria. The EWG agreed to focus on most commonly traded microbial omega-3 oils and to not include additional oils at this time as there was scarce information on their trade or not sufficient information was available to propose their compositional and quality parameters. Additional microbial oils (e.g., oils from *Nannochloropsis spp.*, *Isochrysis galbana* and *Phaeodactylum tricornutum*) can be included in future once the standard is adopted by CAC and there is consensus for its inclusion based on trade volume, compositional and quality parameters, and associated methods.
10. The EWG discussed the fatty acid composition of microbial omega-3 oils and if all fatty acids were essential compositional parameters. The EWG agreed that EPA and DHA are essential fatty acids for the purpose of trade and are often measured by methods different than those used for fatty acid composition. However, the EWG had mixed response on the utility of complete fatty acid composition in the standard and some members noted selecting few fatty acids to be included in the standard, an approach similar to the USP-FCC monograph for certain microbial omega-3 oils. Other members noted complete fatty acid composition may be helpful to authenticate the oil and identify oil substitution/dilution with other oils. It was agreed that fatty acid composition should be included to be consistent with other CCFO standards, but it should be added as an appendix to the standard.
11. The EWG discussed the need to include the parameter of LCPUFA to the standard. Its inclusion was not favoured when fatty acid composition was provided in the standard and could be used to determine LCPUFA. Section 2, Description, was revised to specify that microbial omega-3 oils contain substantial level of LCPUFA, which includes at least 15% w/w fatty acids as sum of EPA and DHA.
12. The EWG discussed the provisions relating to Section 4 (Food Additives) and Section 5 (Contaminants), and made recommendations for CCFO to consult with CCFA and CCCF regarding amendments to *General Standard for Food Additives* (CXS 192-1995) and *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995), respectively.
13. The EWG discussed the methods of analysis for parameters proposed in the standard and made recommendations for CCFO to refer them for endorsement by CCMAS.
14. The EWG discussed the compositional and quality parameters and made appropriate revisions.
 - a. EPA and DHA values in Table 1 and Table 3: There was general consensus among the EWG members on majority of the fatty acid parameters proposed in the draft standard. Some members noted that the EPA and DHA values in both Tables 1 and 3 can be contradictory as presented, although acknowledging that different methods are used to measure their amounts in the two Tables. The concern was specifically raised between the EPA requirements in Table 1 and EPA range in Table 3 for *Schizochytrium* oils. There is an explanatory note added to Table 3 footnote to address the difference.
 - b. Quality parameters in Table 2: The EWG members had differences in the anisidine value, TOTOX and Acid value of *Cryptocodinium* oil and *Schizochytrium* oil.
 - i. For the Acid value, the EWG discussed maximum values of 3.0, 1.0 and 0.5. The proposed standard includes the maximum value of 3.0 to accommodate oils currently produced. For comparison, the CCFO fish oil standard also has maximum Acid value of 3.0, and the USP-FCC monograph has maximum Acid value of 0.5 for *Ulkenia* oil, and no acid value is provided for *Cryptocodinium* oil and *Schizochytrium* oil. The Acid value of *Ulkenia* oil is retained at maximum of 0.5 in the proposed standard.

- ii. The EWG discussed maximum values for Anisidine value (≤ 20 vs ≤ 10) and TOTOX (≤ 26 vs ≤ 20). A higher maximum value is proposed in the standard to accommodate existing oils. It also aligns with USP-FCC monographs and CCFO fish oil standard.

CONCLUSION AND RECOMMENDATION

15. The EWG requests CCFO29 to consider the proposed draft Standard for Microbial Omega-3 Oils in Annex 1 and advance it in the Codex Step Process.
16. The EWG recommends that CCFO29:
 - i. Revise scope of Codex Standard 19-1981 to include that it does not apply to any oil covered by the Standard for microbial omega-3 oils. Additionally, the proposed standard does not apply to commercial oils that are blended with other microbial oils and/or other edible oils. CCFO should consider if a clarification is needed for CXS 19-1981 that it covers blended oils made from two or more different sources of oils covered in various CCFO standards.
 - ii. Consult with CCFA on either the addition of a new food category for microbial omega-3 oils in the *General Standard for Food Additives* (CXS 192-1995) or the expansion of the name for food category 02.1.3 to include microbial omega-3 oils.
 - iii. Consult with CCFA to amend or create the following Notes in the *General Standard for Food Additives* (CXS 192-1995):
 - a. Note 526 (related to ascorbyl esters INS 304, 305) – “Except for use in products conforming to the Standards for Fish Oils (CXS 329-2017) at 2500 mg/kg” – should be extended to include standard for microbial omega-3 oils once the Standard is adopted.
 - b. Note 527 (related to tocopherols INS 307a, b, c) – “Except for use in products conforming to the Standards for Fish Oils (CXS 329-2017), singly or in combination at 6000 mg/kg” should be extended to include standard for microbial omega-3 oils once the Standard is adopted.
 - c. A new Note similar to XS329 be created to read “Excluding products conforming to the Standard for microbial omega-3 oils” once the Standard is adopted and should be cited similar to XS329.
 - iv. Consult with CCCF to amend and extend the following note/remarks to include microbial omega-3 oils: the *Notes/Remarks in General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) applicable to Arsenic in edible fats and oils, which reads as “For fish oils covered by CXS 329-2017, the ML is for fish oils (As-in). Countries or importers may decide to use their own screening when applying the ML for As-in in fish oils by analyzing total arsenic (As-tot) in fish oils. If the As-tot concentration is below the ML for As-in, no further testing is required, and the sample is determined to be compliant with the ML. If the As-tot concentration is above the ML for As-in, follow-up testing shall be conducted to determine if the As-in concentration is above the ML.”
 - v. Refer the methods of analysis to CCMAS for the microbial omega-3 oil for endorsement and appropriate inclusion to CXS 234-1999.
 - vi. Refer the labelling provisions to CCFL for endorsement.

PROPOSED DRAFT STANDARD FOR MICROBIAL OMEGA-3 OILS

(Step 3)

1. SCOPE

This Standard applies to the microbial omega-3 oils described in Section 2 that are presented in a state for human consumption. For the purpose of this Standard, the term microbial omega-3 oils refers to oils derived from microorganisms, including microalgae, and only applies to microbial oils used in food and in food supplements where those are regulated as foods². This standard does not apply to crude oils.

2. DESCRIPTION

Microbial omega-3 oils mean oils intended for human consumption derived from microorganisms, including microalgae, that contain a substantial level of long-chain omega-3 polyunsaturated fatty acids (omega-3 LCPUFA), including at least 15% w/w fatty acids as sum of C20:5 (n-3) eicosapentaenoic acid (EPA) and C22:6 (n-3) docosahexaenoic acid (DHA).

Processes to obtain microbial omega-3 oils for human consumption may involve, but are not limited to, photoautotrophic or heterotrophic growth, separation of the biomass, extraction of crude oil from raw material and refining of that crude oil. Microbial omega-3 oils may also be subjected to additional processing steps, e.g. solvent extraction, enzymatic extraction, saponification, re-esterification, and trans-esterification. High EPA and/or DHA concentrations can be achieved through strain selection and optimization of growth conditions, and/or genetic modification³. Microbial omega-3 oils may also be concentrated to adjust their LCPUFA content via physical, chemical or biological processes. All specifications in this standard apply only to unblended oils from single microbial source, however, commercial products may be a blend of microbial oils with other edible oils.

Microbial omega-3 oils can be composed of glycerides of fatty acids (primarily triglycerides, although some oils may have high levels of phospholipids and glycolipids) and low levels of non-saponifiable lipids, e.g., sterols, carotenoids.

2.1 Named microbial omega-3 oils are derived from specific raw materials which are characteristic of the major microbial taxon from which the oil is extracted without altering the chemical form of the lipids. The microbial source of the omega-3 oil must have a history of safe use as food or as a production microorganism for omega-3 oils or be supported as a new source by sufficient scientific data on safety of the organism for its intended use.

2.1.1 *Cryptocodinium* oil is derived from *Cryptocodinium* microalgal species such as *Cryptocodinium cohnii* of the genus *Cryptocodinium* (family *Cryptocodiniaceae*) and is rich in DHA.

2.1.2 *Schizochytrium* oil is derived from microalgal species that are or have historically been classified under the genus *Schizochytrium* (family *Thraustochytriaceae*). These include species currently organized into the genus of *Aurantiochytrium*, *Hondae*, *Oblongichytrium*, and *Thraustochytrium*. The oil is characterized by high content of DHA (DHA oil) or by high contents of both EPA and DHA (EPA & DHA oil).

2.1.3 *Ulkenia* oil is derived from *Ulkenia* sp. (family *Thraustochytriaceae*) and is rich in DHA.

2.2 Concentrated microbial omega-3 oils are derived from microbial omega-3 oils described in Sections 2.1 which have been subjected to processes that may involve, but are not limited to hydrolysis, fractionation, winterization, molecular distillation, supercritical fluid extraction and/or re-esterification, and/or trans-esterification to increase the concentration of specific omega-3 fatty acids. *Concentrated microbial omega-3 oils* are primarily composed of fatty acid ethyl esters and/or re-esterified and trans-esterified triglycerides.

2.2.1 Concentrated microbial omega-3 oils contain at least 35 % w/w fatty acids as a sum of EPA and DHA.

² Microbial omega-3 oils can be considered as novel food in some countries, and it may be necessary to consider their authorization of use as foods for human consumption by the country of retail sale.

³ Microbial omega-3 oils derived from genetically modified microorganisms can require pre-market oversight in some countries.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Gas-Liquid Chromatography (GLC) ranges of EPA and DHA

Sample of *microbial omega-3* oils described in Sections 2.1 shall fall within the appropriate ranges specified in Table 1 (expressed as percentages of total weight, w/w).

3.2 Quality parameters

Note: The following parameters of this section do not apply to flavoured and intensely coloured microbial omega-3 oils where the added flavourings or the colour may interfere with the analytical determination: Peroxide Value, Anisidine Value, TOTOX, and Acid Value.

3.2.1 Microbial omega-3 oils (Section 2.1) shall comply with the quality parameters specified in Table 2.

4. FOOD ADDITIVES

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

The flavorings used in products covered by this Standard should comply with the *Guidelines for the Use of Flavourings* (CXG 66-2008).

5. CONTAMINANTS

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

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.

6. HYGIENE

6.1 General hygiene

It is recommended that the products covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969), and *Code of Hygienic Practice for the Storage and Transport of Edible Fats and Oils in Bulk* (CXC 36-1987).

6.2 Microbiological criteria

The products should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

7. LABELLING

The requirements of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), *Guidelines on Nutrition Labelling* (CXG 2-1985), and *Guidelines for use of Nutrition and Health Claims* (CXG 23-1997) apply to this standard.

7.1 Name of the food

The name of the microbial omega-3 oil shall conform to the descriptions provided in Section 2 of this Standard and at a minimum, shall include the name of the genus (section 2.1 to 2.3), e.g. Algal oil (*Schizochytrium sp.*).

7.2 Labelling on non-retail containers

The labelling of non-retail containers should be in accordance with the *General Standard for the Labeling of Non-Retail Containers of Foods* (CXS 346-2021).

7.3 Other labelling requirements

Labeling related to declaration of EPA and DHA content and related claims *should* be done in accordance with the regulatory requirements of the country of retail sale.

8. METHODS OF ANALYSIS⁴ AND SAMPLING

Provision	Method	Principle	Type
Fatty acid composition	ISO 12966-2 and 12966-4 and AOCS Ce 2-66 and AOCS Ce 1i-07		
EPA and DHA	Ph.Eur. 2.4.29, AOCS Ce1i-07 or USP 401		
Peroxide Value	AOCS Cd 8b-90 / ISO 3960 / NMKL 158 / European Pharmacopoeia 2.5.5		
p-anisidine value	European Pharmacopoeia 2.5.36/ AOCS Cd 18-90/ ISO 6885		
Acid value	AOCS Ca 5a-40 / AOCS Cd 3d-63 / ISO 660 / NMKL 38/ USP <401>, method I		
Unsaponifiable matter	ISO 3596 / AOCS Ca 6b-53 or ISO 18609		
Moisture and volatile matter	AOCS Ca 2c-25, ISO 662		
Moisture	ISO 8534, AOCS Ca 2e-84, AOCS Ca 2a-45		

⁴ The methods of analysis will be included in CXS 234-1999 after endorsement by CCMAS and the following text replace the Table.

***For checking the compliance with this standard, the methods of analysis and sampling contained in the Recommended Methods of Analysis and Sampling (CXS 234-1999) relevant to the provisions in this standard, shall be used.**

Table 1: EPA and DHA composition of named microbial omega-3 oils as determined by gas liquid chromatography from authentic samples (expressed as percentage of total weight, g/100g oil) (see Section 3.1 of the Standard)

Fatty acids	<i>Cryptocodinium</i> (section 2.1.1)	<i>Schizochytrium</i> (section 2.1.2)		<i>Ulkenia</i> (section 2.1.3)
		DHA Oil	EPA & DHA Oil	
C20:5 (n-3) Eicosapentaenoic acid (EPA)	< 1.0	≤ 7.0	≥ 10.0	< 1.0
C22:6 (n-3) Docosahexaenoic acid (DHA)	≥ 30.0	≥ 30.0	≥ 5.0	≥ 32

Table 2: Quality parameters of named microbial omega-3 oils and their concentrate (see Section 3.3 of the Standard).

Parameter	<i>Cryptocodinium</i>	<i>Schizochytrium</i> *	<i>Ulkenia</i>
Peroxide value (milliequivalent of active oxygen/kg oil)	≤ 5	≤ 5	≤ 5
Anisidine value	≤ 20	≤ 20	NA
Total oxidation number (TOTOX) ⁵	≤ 26	≤ 26	NA
Acid value (mg KOH/g oil)	≤ 3.0	≤ 3.0	≤ 0.5
Unsaponifiable matter (%)	≤ 4.5	≤ 4.5	≤ 4.5
Moisture and volatile matter (%)	NA	NA	≤ 0.05
Moisture (%)	≤ 0.1	≤ 0.1	NA

*Includes DHA oil and EPA & DHA oil types.

NA = not applicable

⁵ Total oxidation number (TOTOX) = 2 x Peroxide value + 1 x Anisidine value

Explanatory note: Oxidation of LCPUFA-rich oils is a sequential process: following an initial raise of peroxide value, the anisidine value rises. The peroxide value is therefore a parameter for primary oxidation products, the anisidine value for secondary oxidation products. The parameter TOTOX means "total oxidation of oil". The maximum allowed TOTOX value is set separately and lower than the sum of the individual possible maximum limits set for peroxide and anisidine values, to avoid both of these oxidation parameters being present at maximum levels.

APPENDIX

OTHER QUALITY AND COMPOSITION FACTORS

These quality and composition factors are supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet these supplementary factors, may still conform to the standard.

1. COMPOSITION CHARACTERISTICS

Total fatty acid composition by GLC (expressed as percentages of total fatty acids, w/w) are given in Table 3.

Table 3: Fatty acid composition of named microbial omega-3 oils as determined by gas liquid chromatography from authentic samples (expressed as percentages of total fatty acids, i.e., area %) (see Section 3.1 of the Standard)

Fatty acids	<i>Cryptocodinium</i>	<i>Schizochytrium</i>		<i>Ulkenia</i>
		DHA Oil	EPA & DHA Oil	
C12:0 lauric acid	NA	ND – 1.5	NA	NA
C14:0 myristic acid	9.0 – 18.0	ND – 14.0	ND – 4.0	1.5 – 4.5
C15:0 pentadecanoic acid	NA	ND – 2.0	0.1 – 0.4	1.2 – 1.6
C16:0 palmitic acid	8.0 – 16.0	9.0 – 49.0	14.0 – 25.0	32.2 – 33.5
C16:1 n-7 palmitoleic acid	1.0 – 3.0	ND – 8.5	NA	NA
C16:3 hexadecatrienoic acid	NA	ND – 0.4	NA	NA
C17:0 heptadecanoic acid	NA	ND – 1.5	NA	0.4 – 0.5
C17:1 heptadecenoic acid	NA	ND – 0.2	NA	NA
C18:0 stearic acid	0.3 – 1.0	ND – 2.0	1.0 – 2.5	0.5 – 2.0
C18:1 (n-7) vaccenic acid	ND – 0.3	ND – 10.0	NA	NA
C18:1 (n-9) oleic acid	10.0 – 25.0	ND – 31.0	ND – 6.0	NA
C18:2 (n-6) linoleic acid	ND – 2.5	ND – 7.0	ND – 3.0	NA
C18:3 (n-3) alpha-linolenic acid	NA	ND – 1.0	NA	NA
C18:3 (n-6) gamma-linolenic acid	ND – 1.0	ND – 0.5	NA	NA
C18:4 (n-3) stearidonic acid	NA	ND – 1.0	NA	NA
C20:0 arachidic acid	ND – 0.4	ND – 1.0	NA	NA
C20:1 eicosenoic acid (isomer not specified)	NA	NA	NA	NA
C20:1 (n-9) eicosenoic acid	ND – 0.2	ND – 0.2	NA	NA
C20:2 (n-6) eicosadienoic acid	NA	ND – 0.2	NA	NA
C20:3 (n-6) eicosatrienoic acid	ND – 0.1	ND – 3.0	NA	NA
C20:4 (n-6) arachidonic acid	NA	ND – 3.5	ND – 3.5	0.9 – 1.2
C20:4 (n-3) eicosatetraenoic acid	NA	0.4 – 2.0	NA	0.7 – 0.8
C20:5 (n-3) eicosapentaenoic acid	ND – 0.3	ND – 13.0	12.0 – 39.0	ND – 0.5
C22:0 behenic acid	NA	ND – 0.5	NA	NA
C22:1 (n-9) erucic acid	NA	NA	NA	NA
C22:1 (n-11) cetoleic acid	NA	ND – 1.5	NA	NA
C22:2 (n-6) docosadienoic acid	NA	ND – 0.6	NA	NA
C22:4 (n-6) docosatetraenoic acid	NA	ND – 0.2	NA	NA
C22:5 (n-3) docosapentaenoic acid	ND – 1.0	ND – 2.5	ND – 18.0	0.2 – 1.5
C22:5 (n-6) docosapentaenoic acid	ND – 1.0	ND – 25.0	0.5 – 3.5	8.0 – 14.0
C22:6 (n-3) docosahexaenoic acid	30.0 – 55.0	35.0 – 70.0	15.0 – 49.0	40.0 – 55.0
C24:0 lignoceric acid	NA	ND – 0.2	NA	NA
C24:1 (n-9) nervonic acid	NA	ND – 0.1	NA	NA

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

NA = not applicable or available

Note to Table 3. The purpose of Table 3 is only for use in confirming the authenticity of the respective oil types, based on the indicated ranges of diagnostic fatty acids. Microbial omega-3 oils are traded based on the accurately measured content of DHA and /or EPA, not for their fatty acid profiles. The ranges for EPA and DHA in Table 3 may vary from the requirements for minimum and maximum levels in g/100 g given in Table 1, which may be partly due to the difference in method of analysis and unit of quantitation.