**PROPOSED DRAFT STANDARD FOR MICROBIAL OMEGA-3 OILS**

# **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 foods[[1]](#footnote-1). This standard does not apply to crude oils.

# **DESCRIPTION**

Microbial omega-3 oils means 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 also be achieved through strain selection and optimization of growth conditions. Microbial omega-3 oils may also be concentrated to adjust their LCPUFA content via physical, chemical or biological processes. Microbial omega-3 oils can also be blended with other edible oils; however, all specifications in this standard apply only to unblended 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-saponifiables, e.g., sterols, carotenoids. *Concentrated microbial omega-3 oils* are primarily composed of fatty acid ethyl esters and re-esterified triglycerides.

* 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 organism that is the source of the omega-3 oil must have a history of safe use as food or as a production microorganism.
     1. ***Crypthecodinium* oil**is derived from *Crypthecodinium* microalgal species such as *Crypthecodinium cohnii* of the genus *Crypthecodinium* (family *Crypthecodiniaceae*). The yellow to orange-coloured oil obtained from fermentation of *C. cohnii* is rich in DHA.
     2. ***Schizochytrium oil*** is derived from microalgal species tha 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 both EPA and DHA (EPA & DHA oil).
     3. ***Ulkenia oil*** is derived from *Ulkenia sp. (*family *Thraustochytriaceae)* and is rich in DHA.
  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 contain at least 35 % w/w fatty acids as sum of EPA and DHA.]

# **ESSENTIAL COMPOSITION AND QUALITY FACTORS**

* 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).

* 1. **Other essential composition criteria**
  2. **Quality parameters**

Note: this section does not apply to flavoured microbial omega-3 oils where the added flavourings may interfere with the analytical determination of oxidation parameters.

* + 1. Microbial omega-3 oils (Section 2.1) shall comply with the quality parameters specified in Table 2.

# **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*.*

*Note*: It is proposed that CCFO discusses 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. For the purpose of providing a draft standard with the proposal for new work, the primary concern is to ensure the list of food additives (i.e. antioxidants) is comprehensive.

*Note*: It is proposed that CCFO requests the Codex Committee on Food Additives (CCFA) that the *General Standard for Food Additives* (CXS 192-1995) Note 526 (related to ascorbyl esters INS 304) – “Except for use in products conforming to the Standards for Fish Oils (CXS 329-2017) at 2500 mg/kg” - is extended to microbial omega-3 oils once the Standard is adopted.

*Note*: It is proposed that CCFO requests CCFA that the *General Standard for Food Additives* (CXS 192-1995) 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 updated and extended to microbial omega-3 oils once the Standard is adopted.

*Note*: Rosemary Extract (INS 392) is not included in the *General Standard for Food Additives* (CXS 192-1995), but it is included in the amended Priority List of Substances Proposed for Evaluation by JECFA forwarded by the CCFA53 for endorsement by CAC46[[2]](#footnote-2). It is among the list of substances scheduled for evaluation or re-evaluation at the 100th meeting of the JECFA in June 2025.

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

# **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.

Note: For microbial omega-3 oils, the maximum limit for arsenic should be inorganic arsenic (As-in). The Notes/Remarks in General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) applicable to fish oils, in the table on arsenic in relation to edible fats and oils covered in page 45 of CXS 193-1995 should be extended to microbial omega-3 oils once the microbial omega-3 oil standard is adopted. The applicable note to fish oils reads as follows, “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.”

# **HYGIENE**

* 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).

# **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).

# **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.

# **Name of the food**

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

# **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).

# **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.

# **METHODS OF ANALYSIS AND SAMPLING**

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.

*Note*: CCFO will refer the following to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for endorsement:

List of methods of analysis and sampling for CCMAS review and update to CXS 234-1999

1. Determination of GLC ranges of fatty acid composition: According to ISO 12966-2 and 12966-4 and AOCS Ce 2-66 and AOCS Ce 1i-07
2. Determination of EPA and DHA: According to Ph.Eur. 2.4.29, AOCS Ce1i-07 or USP 401
3. Determination of peroxide value: According to AOCS Cd 8b-90 / ISO 3960 / NMKL 158 / European Pharmacopoeia 2.5.5/ AOCS Ja 8-87
4. Determination of p-anisidine value: According to European Pharmacopoeia 2.5.36/ AOCS Cd 18-90/ ISO 6885
5. Determination of acid value: According to AOCS Ca 5a-40 / AOCS Cd 3d-63 / ISO 660 / NMKL 38/ USP <401>, method I
6. Determination of unsaponifiable matter: According to ISO 3596 / AOCS Ca 6b-53 or ISO 18609
7. Determination of moisture and volatile matter: According to AOCS Ca 2a-45, ISO 662

***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 | *Crypthecodinium* (section 2.1.1.1) | *Schizochytrium (section 2.1.1.2)* | | *Ulkenia* (section 2.1.1.3) |
|  | 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 |

\*Methods to use to make a reliable quantification of EPA and DHA: Ph.Eur. 2.4.29, AOCS Ce1i-07 or USP 401.

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

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter | *Crypthecodinium* | *Schizochytrium\** | *Ulkenia* |
| Peroxide value (milliequivalent of active oxygen/kg oil) | ≤ 5 | ≤ 5 | ≤ 5 |
| Anisidine value | ≤ 20 | ≤ 20 |  |
| Total oxidation number (TOTOX)[[3]](#footnote-3) | ≤ 26 | ≤ 26 |  |
| Acid value (mg KOH/g oil) | ≤ [3.0] [1.0] | ≤ [3.0] [1.0] | ≤ 0.5 |
| Unsaponifiable matter (g/kg) | ≤ 4.5 | ≤ 4.5 | ≤ 4.5 |
| [Moisture and volatile matter (%)] |  |  | [≤ 0.05] |

\*Includes DHA oil and EPA & DHA oil types.

**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 | *Crypthecodinium* | *Schizochytrium* | | *Ulkenia* |
|  |  | DHA Oil | EPA & DHA Oil |  |
| C12:0 lauric acid |  | ND – 1.5 |  |  |
| C14:0 myristic acid | 9.0 – 18.0 | ND – 14.0 | 0.5 – 2.5 | 1.5 – 4.5 |
| C15:0 pentadecanoic acid |  | 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 |  |  |
| C16:3 hexadecatrienoic acid |  | ND – 0.4 |  |  |
| C17:0 heptadecanoic acid |  | ND – 1.5 |  | 0.4 – 0.5 |
| C17:1 heptadecenoic acid |  | ND – 0.2 |  |  |
| 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 |  |  |
| C18:1 (n-9) oleic acid | 10.0 – 25.0 | ND – 31.0 | ND – 6.0 |  |
| C18:2 (n-6) linoleic acid | ND – 2.5 | ND – 7.0 | ND – 3.0 |  |
| C18:3 (n-3) alpha-linolenic acid |  | ND – 1.0 |  |  |
| C18:3 (n-6) γ-linolenic acid | ND – 1.0 | ND - 0.5 |  |  |
| C18:4 (n-3) stearidonic acid |  | ND – 1.0 |  |  |
| C20:0 arachidic acid | ND – 0.4 | ND – 1.0 |  |  |
| C20:1 eicosenoic acid (isomer not specified) |  |  |  |  |
| C20:1 (n-9) eicosenoic acid | ND – 0.2 | ND – 0.2 |  |  |
| C20:1 (n-11) eicosenoic acid |  |  |  |  |
| C20:2 (n-6) eicosadienoic acid |  | ND – 0.2 |  |  |
| C20:3 (n-6) eicosatrienoic acid | ND – 0.1 | ND – 3.0 |  |  |
| C20:4 (n-6) arachidonic acid |  | ND – 3.5 | ND – 3.5 | 0.9 – 1.2 |
| C20:4 (n-3) eicosatetraenoic acid |  | 0.4 – 1.0 |  | 0.7 – 0.8 |
| C20:5 (n-3) eicosapentaenoic acid | ND – 0.3 | ND – 13.0 | ND – 39.0 | ND – 0.5 |
| C21:5 (n-3) heneicosapentaenoic acid |  |  |  |  |
| C22:0 behenic acid |  | ND – 0.5 |  |  |
| C22:1 (n-9) erucic acid |  |  |  |  |
| C22:1 (n-11) cetoleic acid |  | ND – 1.5 |  |  |
| C22:2 (n-6) docosadienoic acid |  | ND – 0.6 |  |  |
| C22:4 (n-6) docosatetraenoic acid |  | ND – 0.2 |  |  |
| 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 | 20.0 – 43.0 | 40.0 – 55.0 |
| C24:0 lignoceric acid |  | ND – 0.2 |  |  |
| C24:1 (n-9) nervonic acid |  | ND – 0.1 |  |  |

ND = non-detect, defined as ≤ 0.05%

1. 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. [↑](#footnote-ref-1)
2. REP23/FA, paragraph 143 and Appendix XI. [↑](#footnote-ref-2)
3. 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 that both of these oxidation parameters are present at maximum levels. [↑](#footnote-ref-3)