**Development of a Standard for Microbial Omega-3 Oils (CXS xxx-xxxx)**

**Comments on the second version of the draft standard**

**Background**

1. The CCFO28 agreed to submit the proposal to develop a Codex standard for microbial omega-3 oils for approval by CAC47, and establish an electronic working group (EWG), chaired by the United States of America and co-chaired by China to prepare the draft standard for comments at Step 3 and consideration by CCFO29.
2. Codex members and observers were invited to participate and register to join the EWG by August 2, 2024.
3. Twenty-six members (Australia, Brazil, Canada, China, Colombia, Egypt, European Union, 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 Stated of America, and Uruguay) and three observers (FIA, GOED, and USP) participated in the EWG.
4. The new work was approved by CAC47 in November 2024.
5. The EWG was invited for first round of consultation on the standard draft in August 2024 and received comments from six members and one observer.
6. The standard draft was revised accordingly and posted on the EWG forum along with the round 1 comments summary and response form in February 2025 for round 2 consultation.

**Draft standard revision (second version)**

1. Six members (Brazil, Canada, European Union, Malaysia, Norway, United States of America) and one observer (GOED) submitted comments during round 2 review. The EWG comments from round 2 are summarized and discussed in Annex I.
2. The draft standard was revised after considering the EWG comments. The revised version of the draft standard is available as tracked changes and clean copy for further review.
3. The EWG is invited for round 3 review and comments on third version of the draft standard.

**Annex I**

**Summary of Response from Round 2 Comments and Discussion**

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| 1.Is there is need for specific scientific advice for this draft standard, in addition to the ongoing work by FAO and WHO? |
| |  |  | | --- | --- | | **Response** | **No. of responses** | | Yes | 1 | | No | 5 | | Unanswered | 1 |   The EWG was asked for the feedback on whether specific scientific advice is needed for the draft standard beyond ongoing FAO/WHO work. Overall, the responses indicated that there is no need for scientific advice from FAO/WHO, as most countries have their own mechanism for safety evaluation of new ingredients, and there is ongoing work by FAO/WHO that addresses assessment of foods produced by precision fermentation. One of the responses indicated the need for safety assessment for new food sources and production systems including microbial omega-3 oils and suggested that the proposed standard should consider different production processes and species/strains used in microbial omega-3 oil production.  **Chair’s proposal:** The majority of the respondents agree with not needing specific scientific advice from FAO/WHO. Also, in 2025, FAO published “Precision Fermentation – With a Focus on Food Safety”, which can serve as a reference point for countries interested in adopting relevant food safety regulatory approaches for foods derived from precision fermentation. Based on the responses and recent FAO report, the Chair proposes to not request specific scientific advice from FAO/WHO on microbial omega-3 oils. |
| 2. Should there be a provision or information added to the draft standard on use of species/strain and production process, or their safety assessment at national level? If yes, please comment on the provision that should be added to the relevant section of the standard draft. |
| |  |  | | --- | --- | | **Response** | **No. of responses** | | Yes | 3 | | No | 3 | | Unanswered | 1 |   The EWG provided comments that addressed whether provisions or information should be added on meeting requirements at national levels that relates to either the species or strain used, production process, or any safety assessment. Some responses favored the addition of safety provisions at a national level in the draft standard, whereas some did not favor it. The comments that did not favor adding provisions to assess safety considering the strain and production process raised concern that such provisions could limit future innovation due to restrictions.  **Chair’s proposal:** Although foods produced by precision fermentation are considered novel foods, these products have been commercialized for many years and many countries/regions already have regulatory mechanisms in place for these foods (at least 16 of the 23 countries/regions that provided their regulatory framework in the FAO consultation; see the [FAO report](https://openknowledge.fao.org/handle/20.500.14283/cd4448en) published recently in 2025 for more details). The report also noted that the majority of food safety hazards identified in their production are similar to those in conventional food production. The report can help provide relevant information on associated food safety hazards that can be further used by countries to develop regulatory strategies for foods derived from precision fermentation. The Chair agrees with the comments that the provision should not be restrictive to innovation. Based on the responses and already existing mechanism for regulation of these foods by many countries, the Chair proposes to add below general provision as footnote in the standard to encourage countries to adopt a regulatory framework, if one doesn’t exist for microbial omega-3 oils, while ensuring it is not restrictive to strain or production process.  **“As microbial omega-3 oils can be considered as novel food in some countries, it may be necessary to consider their authorization for use as foods for human consumption by the country of retail sale.”** |
| 3. Do you agree or not with the need and practicality to add relevant species used for microbial omega-3 oils as annex |
| |  |  | | --- | --- | | **Response** | **No. of responses** | | Yes | 2 | | No | 5 | | Unanswered | 0 |   This question specifically requested feedback from the EWG on adding relevant species used for microbial omega-3 oils as an annex to the standard. Many of the responses did not agree to add all relevant species currently used in production of microbial omega-3 oils, as it may not be a practical approach and could result in often updating the standard in order to avoid limiting innovation and making the standard restrictive.  **Chair’s proposal:** The Chair agrees that adding all species and strains used in production of microbial omega-3 oils can be a cumbersome task that could result in continuously updating the standard to accommodate new species/strains in a timely manner. However, the Chair also agrees that the species/strains should be safe for use in producing microbial omega-3 oils. Adding a provision to consider authorization for their use by the country of retail sale can help ensure that there are mechanisms in place by the countries to ensure safety of these oils. Based on the responses, the Chair proposes to not add list of all species and strains used in microbial omega-3 oil production and note the below provision to ensure micro-organisms used in oil production are safe.  **“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. 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.”** |
| 4. Do you agree with the addition of parameter LCPUFA (minimum or range) to the fatty acid composition Table? |
| |  |  | | --- | --- | | **Response** | **No. of responses** | | Yes | 2 | | No | 4 | | Unanswered | 1 |   The EWG provided response to the question on need for the additional parameter LCPUFA. Many of the responses did not favor inclusion of the additional parameter of LCPUFA when fatty acid composition is provided in the standard, as LCPUFA could be determined from fatty acid composition. One of the responses commented to shorten the fatty acid profile by focusing on main fatty acids only.  **Chair’s proposal:** Based on the responses, the Chair proposes to include complete fatty acid composition that can help estimate LCPUFA. There is no need for addition of parameter LCPUFA as it could be estimated from the fatty acid composition. Based on the responses in context of “substantial level” of LCPUFA in the description of microbial omega-3 oils in Section 2, the Chair proposes to include that they contain at least 15% w/w fatty acids as sum of EPA and DHA. Similarly, a description is added for concentrated microbial omega-3 oils to contain at least 35% w/w fatty acids as sum of EPA and DHA. |
| 5. Are there any known biological processes used to concentrate microbial omega-3 oils to adjust their LCPUFA content (revised draft currently lists only physical and chemical processes)? If yes, please explain. |
| |  |  | | --- | --- | | **Response** | **No. of responses** | | Yes | 3 | | No | 3 | | Unanswered | 1 |   Regarding the use of biological processes for concentration of LCPUFA, the use of enzymes and strain engineering were noted in the responses by the EWG as biological processes used in concentration of microbial omega-3 oils.  **Chair’s proposal:** Since there are known biological processes identified in the responses, the Chair proposes to include ‘biological’ in the draft standard and remove the square brackets to read “Microbial omega-3 oils may also be concentrated to adjust their LCPUFA content via physical, chemical or biological processes.” |
| 6. Do you agree or not with the need for having a complete fatty acid composition? If yes, please elaborate if it should be included as an essential composition factor in the main text or other composition factor as annex to the standard draft? |
| |  |  | | --- | --- | | **Response** | **No. of responses** | | Yes | 3 | | No | 3 | | Yes and No | 1 |   The EWG provided feedback on the need for a complete fatty acid composition table and its appropriate place within the standard. There were mixed responses to this question, with an equal number of responses for the need to include a complete fatty acid composition table as not. The responses not in favor of inclusion noted that the complete fatty acid profile may not be an accurate representation of oils currently traded and that only those fatty acids essential for oil characterization should be included. The reason for inclusion was to authenticate the oil and identify oil substitution/dilution with other oils. Amongst those in favor, many responses noted that such a table would be more suitable as annex than part of main text of the standard since the essential fatty acids are already included as a separate table in the main text.  **Chair’s proposal:** Based on the responses, it is clear that including the complete fatty acid composition in the main text of the standard is not favored by the EWG. Regarding, addition as an annex or not, all fats and oils standards have fatty acid composition, as it is one of their defining compositional characteristics. Although EPA and DHA are the fatty acids that are the most important fatty acids for microbial omega3 oils, other fatty acids can be helpful in oil authenticity. The EWG can decide to shorten the list of fatty acids to be included in the fatty acid table, but its inclusion provides further information on oil composition. Also, having a complete fatty acid composition table helps in estimation of LCPUFA when it is not an additional parameter in the standard, as discussed above for question # 4. The Chair proposes to include the fatty acid composition table as an annex to the standard. |
| 7. Do you agree with the addition of other microbial omega-3 oils (*Ulkenia* oil, *Isochrysis galbana* oil*, Phaeodactylum tricornutum* oil, *Crypthecodinium* oil) to the standard? If yes, please comment on which oils should be added to the standard and availability of data on their composition (EPA, DHA, fatty acids)? |
| |  |  | | --- | --- | | **Response** | **No. of responses** | | Yes | 4 | | No | 1 | | Unanswered | 2 |   Regarding the microbial omega-3 oils from other species, many of the responses agreed to add those microbial omega-3 oils to the standard, as some of them may be authorized for use in food by some countries/regions. However, the responses also noted that these oils should meet the trade volume criteria listed in CX/FO 24/28/12.  **Chair’s proposal:** Chair agrees with the responses that if the oil is currently traded in sufficient volume and is used as a food, it should be considered within the scope of the standard and be added to the list of microbial omega-3 oils in the standard. However, if there is a current lack of compositional and quality parameter data for those oils, it may be appropriate to collect data for those oils before having the discussion on their inclusion. The current version of the standard draft lacks data on many parameters for the oils from many microbial sources listed in the draft*.* There is information provided by the EWG on fatty acid composition of *Crypthecodinium*, *Schizochytrium* and *Ulkenia* oil, and these oils are retained in the revised standard draft.The Chair proposes to not include *Nannochloropsis,* *Isochrysis galbana* and *Phaeodactylum tricornutum* in the standard draft at this time, unless the EWG can provide the information on their composition, quality and sufficient trade criteria. Further the Chair also proposes to remove section 2.3 on blended oil as there is no criteria established to differentiate or characterize the blends. Blends could be assessed by the standard for named microbial omega-3 oils used as ingredient in producing blended oils. The Chair also notes that a minimum amount of EPA and/or DHA should be established for concentrated oils in section 2.2. |
| 8.Do you agree with the appropriateness of the EPA and DHA value listed in Table 1? If more than one value/range is listed in square brackets, please comment on the appropriate value? |
| |  |  | | --- | --- | | **Response** | **No. of responses** | | Yes | 5 | | No | 1 | | Unanswered | 1 |   In response to the inquiry regarding Table 1, the majority of the EWG comments supported the table for EPA and DHA, and some of the responses suggested an appropriate range/value for EPA and DHA.  **Chair’s proposal:** The table for EPA and DHA should be retained in the standard draft, and the EPA and DHA levels should be inclusive to all currently traded oils used in human consumption. The EPA and DHA ranges should be revised accordingly. |
| 9. The EWG is invited to (1) provide quality parameters for the proposed new oils from *Ulkenia*, *Isochrysis galbana* and *Phaeodactylum tricomutum*, (2) comment on the appropriate parameter value from the square brackets, and (3) need for TOTOX and moisture content as quality parameters for microbial omega-3 oils. |
| Since the EWG responses did not include any data on Isochrysis galbana and Phaeodactylum tricomutum, the Chair proposes to not include these sources of microbial omega-3 oil at this time. Although some parameters were provided for *Ulkenia* oil, it is not known if the trade volume is sufficient to meet the criteria for inclusion in the standard. Also see comments to Questions # 7.  Based on the responses, TOTOX was generally favored as a quality parameter. Since the EWG did not provide any data or comment relating to moisture content as quality parameter, it may be appropriate to either remove it from the standard or retain in square bracket until there is enough data to support its inclusion as quality parameter.  **Chair’s proposal:** Based on unknown trade amount and incomplete data on composition/quality, the Chair proposes to not include oils from *Nannochloropsis*, *Isochrysis galbana* and *Phaeodactylum tricomutum* at this time. Also, TOTOX is retained as a quality parameter and moisture content is retained in square bracket until there is sufficient data to support its inclusion in the standard. Anisidine value and TOTOX are retained as ≤ 20 and ≤ 26, respectively, to align with industry standards. For reference, similar values are also reported in the standard for fish oils (CXS 329-2017). As the acid value of ≤ 0.5 was suggested as not feasible for many oils from *Schizochytrium* and *Crypthecodinium*, the Chair proposes to retain the alternate values of ≤ 3.0 and ≤ 1.0 in square bracket for further discussion by the EWG. |
| 10. The EWG is invited to comment on the appropriate food category for microbial omega-3 oils in the *General Standard for Food Additives* (CXS 192-1995). Should CCFO request CCFA to add microbial omega-3 oils to existing food category 02.1.3 or create a new food category to include food additives for microbial omega-3 oils? Should fish oils and microbial omega-3 oils be combined into one new food category based on their similar usage? EWG is also invited to comment on extending the current Notes 526 and 527 in CXS 192-1995 for fish oil standard to include microbial omega-3 oil standard. |
| The EWG provided feedback on the appropriate food category classification for microbial omega-3 oils in CXS 192-1995. The responses generally agreed to have consultation between CCFO and CCFA to incorporate microbial omega-3 oils as a GFSA food category, preferably combining fish oils and microbial omega-3 oils into one category based on their similarities noted by many responses. Similarly, CCFO should discuss Notes 526 and 527 with CCFA to cover microbial omega-3 oils.  **Chair’s proposal:** The Chair agrees with the EWG and recommends CCFO to consult with CCFA to include microbial omega-3 oils as a GFSA food category along with the current category of fish oils and extend the Notes 526 and 527 to include microbial omega-3 oils. |
| 11. The EWG is invited to comment on specific (e.g., maximum levels for inorganic arsenic) or general referral to CCCF regarding contaminants in microbial omega-3 oils. |
| Regarding the matter of contaminant specifications in microbial omega-3 oils, the EWG responses generally agreed to refer to CCCF for establishing MLs for microbial omega-3 oils depending on the applicability, available occurrence data, and methods for contaminant quantitation in microbial omega-3 oils. The Chair agrees with the EWG and propose that this matter be discussed with CCFO for referral to CCCF.  **Chair’s proposal:** The Chair agrees with EWG and recommends CCFO to consult with CCCF regarding establishing appropriate MLs for microbial omega-3 oils. |
| 12. The EWG is invited to comment on any other labelling requirements for microbial omega-3 oils that should be listed in section 7.3. |
| There were not many comments from the EWG on a labelling requirement. Suggestions included labeling should be in accordance with current Codex labeling standard (CSX 1-1985, CXG 2-1985, CXS 346-2021) and Codex Guidelines on Nutrition and Health Claims. Also, it should be clarified that any declaration of EPA/DHA and related claims should be in accordance with national regulations.  **Chair’s proposal:** The Chair agrees with the comments and propose to revise the standard draft accordingly. Section 7.3 is revised to add below provision.  **“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.”** |
| 13. The EWG is invited to review the methods listed, any related modifications (e.g., footnote on Peroxide Value in Table 3), and comment on their suitability to refer to CCMAS for endorsement. |
| The EWG provided feedback on methods listed for microbial omega-3 oils. The responses generally agreed with the methods listed in the standard draft. The commonly used method of analysis for EPA and DHA content in microbial omega-3 oils is according to Ph.Eur. 2.4.29, AOCS Ce1i-07 or USP 401 and thus is listed as a separate method for their quantitation in Table 1 of the standard. The fatty acid determination by GLC will also give a measure of EPA and DHA, but not all methods referenced in context of fatty acid characterization and are used as a definitive measure of EPA and DHA. The fatty acid table is now included as an annex to the standard draft (see comments to question # 6).  For determination of polar lipids, it was suggested to revise standard to clarify that “polar lipids” are measured as acetone-insoluble matter. Alternatively, ISO 2420: 2022 (equivalent to AOCS Cd 20-91) should be listed for polar compounds.  For determination of neutral lipids, it was suggested that the listed methods are not equivalent in measuring neutral lipids. One response suggested to list AOCS Ca 9f-57 for measuring neutral lipids as one or more methods currently listed measure acylglycerols and not other neutral lipids such as sterols and wax esters.  For determination of moisture, it was suggested that AOCS Ca 2a-45 may be better as ISO 662 method is uses oven-drying, which may cause oxidative changes.  For determination of peroxide value, it was suggested to also add AOCS Ja 8-87.  **Chair’s proposal:** The Chair proposes to revise the method list accordingly and recommend the CCFO to refer the listed methods to CCMAS for endorsement. The methods for determination of polar and neutral lipids have been removed from the revised draft since they were associated with *Nannochloropsis* oil, which is also removed from the revised draft. |