CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 8.2

CX/FO 24/28/12
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FATS AND OILS

Twenty-Eighth Session

Kuala Lumpur, Malaysia

19-23 February 2024

PROPOSALS FOR NEW WORK

(Replies to CL 2021/96-FO)

Background

1. The 27th Session of the Codex Committee for Fats and Oils discussed how it could better manage its work and agreed to:
   (i) Continue to use the existing project document for submission of proposals for new work and or amendments to existing fats and oils standards.

   (ii) Request the Codex Secretariat to issue a CL to call for proposals for new work including amendments to existing standards well in advance of each session of CCFO and with a specific deadline within which proposals should be submitted. Submissions in response to the CL should include both a discussion paper and proposed project document. Submissions received after the deadline would not be considered by that session but by the following session of the Committee; and

   (iii) Establish an in-session working group at each session of the CCFO Proposals.
2. The Circular Letter CL 2021/96-FO was issued in December 2021 with an initial deadline of 30 September 2022 which was later extended to 30 June 2022.

Proposal(s)

3. In reply to CL 2021/96-FO, one (1) proposal from Global Organisation for EPA and DHA omega 3s (GOED) on microbial omega-3 oils was submitted, is hereby attached as Appendix I.

APPENDIX I

PROPOSAL FOR NEW WORK ON A STANDARD FOR MICROBIAL OMEGA-3 OILS

DISCUSSION PAPER

(Prepared by Global Organisation for EPA and DHA omega 3s (GOED))

Introduction

Microbial omega-3 oils, also known as derived from single-celled microalgae organisms, have been increasingly considered as a sustainable commodity with huge potential to address specific needs of food and nutrition. Production of edible oils by fermentation and other technologies have become an economically and technologically viable solution to produce a great diversity of high-value bioactive compounds, including n-3 polyunsaturated fatty acids (PUFA).

The n-3 PUFA, especially eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), possess an array of biological activities that may contribute to the prevention of coronary heart disease, reduce other cardiovascular risk factors and possibly other degenerative diseases of aging.[1]

Microbial omega-3 oils are characterised by a high content of EPA and/or DHA, which makes them an important ingredient in an increasing variety of foods and food supplements. A rapid uptake in the acceptance by consumers and increased consumption of oils produced by microbial omega-3 organisms, known for their specific compositions rich in EPA and DHA, is a more recent phenomenon observed in many countries.

Today, microbial omega-3 oils are presented to the consumer in fortified foods, foods for plant-based diets, several types of foods for special dietary uses - such as foods for special medical purposes, infant formula or follow-up formula products - and food supplements.

Microbial omega-3 oils for human consumption are a high value commodity. The international trade in processed microbial omega-3 oils suitable for human consumption reached over 4,301 metric tons and 213.7 million USD in 2021. Both the production and global trade of microbial omega-3 oils are increasing, as growth in the demand as well as trade of this commodity is projected to continue. Further detail on the projected continued growth in global production, demand and trade of microbial omega-3 oils is provided in section 4 of the project document that is found in Appendix I to this discussion paper.

Distinct types of microbial omega-3 oils

Microbial omega-3 oils originate from different microbial species and have distinct chemical compositions.

Schizochytrium is a type of protist (*Heterokonta/Stramenopiles*) from the class *Labyrinthula*, order *Traustochytriida*, family *Traustochytriaceae*, genus *Schizochytrium*. Schizochytrium species are often characterized as microalgae (photosynthetic eukaryotes invisible to the naked eye). One of the Schizochytrium species used for the production of omega-3 rich oils is *Schizochytrium limacinum,* although the species name requires further confirmation. Due to a complex nomenclature and taxonomic name changes, species with basionyms such as *Aurantiochytrium limacinum*, *Aurantiochytrium mangrovei*, *Oblongichytrium minutum* and *Oblongichytrium octosporum*, and *Hondae sp.* can be considered part of the Schizochytrium definition.

Nannochloropsis oculata is a type of protist (*Heterokonta/Stramenopiles*) from the phylum *Ochrophyta*, class *Eustigmatophydeae*, order *Eustigmatales*, family *Monopsidaceae*, genus *Nannochloropsis*. Nannochloropsis species are characterized as microalgae. The primary Nannochloropsis species used for the production of omega-3 rich oils today are *Nannochloropsis salina and Nannochloropsis oculata*.

Crypthecodinium cohnii is a type of protist from the superphylum *Alveolata*, phylum *Dinoflagellata*, class *Dinophyceae*, order *Peridiniales*, family *Crypthecodiniaceae*, genus *Crypthecodinium*. *C. cohnii* is characterized as a non-photosynthetic microalgae.

These distinct types of microbial omega-3 oils are increasingly used in a wide variety of food applications and consumer demand is driving growing international trade. However, due to the lack of an international standard, microbial omega-3 oils are traded with differing levels of information. This makes it difficult for authorities to judge whether a particular type of oil is acceptable, and consumers are unable to make an informed choice.

Microbial omega-3 oils pharmacopeial monographs or regulations

[1] Food and Agriculture Organization of the United Nations. FAO Food and Nutrition Paper 91. Fats and fatty acids in human nutrition. Report of an expert consultation. Joint FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition held in Geneva from 10 to 14 November 2008. https://www.fao.org/3/i1953e/I1953E.pdf.

There is a limited number of examples of pharmacopeial monographs or regulations on microbial omega-3 oils, including the following:

Australia has developed monographs on DHA-rich oil derived from microalgae *Schizochytrium* sp.,[2] DHA/EPA rich Schizochytrium algal oil[3] and EPA-rich *Nannochloropsis* oculata oil.[4] In addition, the US Pharmacopeia has developed monographs on Schizochytrium Oil (Formerly called "DHA Algal Oil, Schizochytrium"), DHA Algal Oil, *Ulkenia*, *Crypthecodinium cohnii* Oil and USP Schizochytrium Oil.

In addition, regulatory guidelines and standards have been adopted in Australia — Compositional Guideline for DHA/EPA rich Schizochytrium algal oil[5] and Compositional Guideline for DHA-rich oil derived from microalgae *Schizochytrium sp*.[6]- and in China, GB 26400-2011 National Food Safety Standard for Food Additive Docosahexaenoic Acid Grease (Fermentation Process). In Latin America, both Chile and Brazil (the latter in food supplements specifically) have authorized edible oils from *Schizochytrium* sp. without establishing specifications. Furthermore, in the European Union *Schizochytrium* sp. oil has been authorised as a novel food for various food applications.

Proposal

It is therefore proposed to develop an inclusive Codex Standard for microbial omega-3 oils that can be easily updated to include other microbial omega-3 oils as newer types of oils are developed and brought to the market and increase in importance in international trade.

Establishing a Codex Standard for microbial omega-3 oils containing quality and compositional factors will ensure fair practices in trade in these commodities as well as ensure consumers' health protection, which are the purpose and goals of the Codex Alimentarius.

The purpose and scope of this new work is to establish an overarching Standard providing a harmonised description containing quality and compositional factors for microbial omega-3 oils, for use as an ingredient in foods and food supplements where these are regulated as food.

Recommendation

CCFO28 is invited to consider this discussion paper and the project document in Appendix I and to agree to recommend to the 47th Session of the Codex Alimentarius Commission (CAC47) to approve new work for the elaboration of a Standard for Microbial Omega-3 Oils.

[2] Link available at: https://www.tga.gov.au/resources/resource/compositional-guidelines/dha-rich-oil-derived-microalgae-schizochytrium-sp.
[3] Link available at: https://www.tga.gov.au/resources/resource/compositional-guidelines/dhaepa-rich-schizochytrium-algal-oil.
[4] Link available at: https://www.tga.gov.au/resources/resource/compositional-guidelines/epa-rich-nannochloropsis-oculata-oil.
[5] Link available at: https://www.tga.gov.au/sites/default/files/cm-cg-dha-epa-rich-schizochytrium-algal-oil.pdf.
[6] Link available at: https://www.tga.gov.au/sites/default/files/cm-cg-dha-rich-oil-derived-from-microalgae-schizochytrium.pdf.

Appendix I

PROPOSAL FOR NEW WORK ON A STANDARD FOR MICROBIAL OMEGA-3 OILS

PROJECT DOCUMENT

(Submitted by GOED)

1. The purposes and the scope of the standard

The purpose and scope of this new work is to establish an overarching Standard providing a harmonised description containing quality and compositional factors for microbial omega-3 oils, for use as an ingredient in foods and food supplements where these are regulated as food.

2. Its relevance and timeliness

Microbial omega-3 oils have specific compositions, rich in eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which makes them an important ingredient in an increasing variety of foods and food supplements.

The consumption of oils produced by microbial omega-3 organisms, known for their specific compositions rich in EPA and DHA, is a more recent phenomenon observed in many countries. Microbial omega-3 oils are added to foodstuffs, and consumer awareness, as well as trade, is increasing.

Today, microbial omega-3 oils are presented to the consumer in fortified foods, foods for plant-based diets, several types of foods for special dietary uses — such as foods for special medical purposes, infant formula or follow-up formula products — and food supplements.

However, there is a lack of knowledge among consumers and national authorities on appropriate quality and compositional factors for microbial omega-3 oils in general, or between different types of microbial omega-3 oils. As trade in microbial omega-3 oils has increased rapidly, with volume at over 4,301 metric tons (according to data for the year 2021), an international standard is required to enable fair practices in trade.

Examples of internationally traded microbial omega-3 oils currently on the market include those from the genera Schizochytrium, Nannochloropsis and Crypthecodinium, among others:

- Oil from Schizochytrium is composed of triglycerides rich in DHA, or rich in DHA and EPA, as the major polyunsaturated fatty acid components.[7] It has a light yellow to orange appearance. It is obtained from fermentation of *Schizochytrium* sp., followed by solvent extraction, aqueous extraction methods or enzymatic hydrolysis methods, and further refining using traditional technologies applied for vegetable or animal based fats and oils.
- Oil from Nannochloropsis has a dark green appearance and is obtained from the fermentation of *Nannochloropsis oculata*, followed by extraction methods and is composed of a mixture of glycolipids, phospholipids and triglycerides, with >24% of fatty acids being EPA.[8]
- Oil from *Crypthecodinium cohnii* is composed of triglycerides with a high level of DHA by weight, with DHA constituting almost all the polyunsaturated fatty acid fraction. The color of the oil is light yellow to orange. The oil is obtained by fermentation of *C. cohnii*, and may be refined using winterization, bleaching, and deodorization.

Microbial omega-3 oils from other single-cell microalgae species have been developed in the past or are under current development or are currently traded. Examples are oils from *Euglena and Cryptecodinium cohnii*, which is used for infant nutrition. Some microbial omega-3 oils that have been traded in the past are oils from *Ulkenia*.

Currently, due to the lack of an international standard, microbial omega-3 oils are traded with differing levels of information. This makes it difficult for authorities to judge whether a particular type of oil is acceptable, and consumers are unable to make an informed choice.

In this regard, it is therefore proposed to develop an inclusive Codex Standard that can be easily updated to include other microbial omega-3 oils as newer types of oils increase in importance in international trade.

[7] US Pharmacopeia - Food Chemical Codex (FCC). USP-FCC Schizochytrium Oil. https://online.foodchemicalscodex.org/uspfcc/document/6_GUID-DE13986B-B98E-413F-B133-8516D1F776E7_50101_en-US?source=TOC.

[8] Australian Government. Department of Health and Aged Care. Therapeutic Goods Administration. EPA-rich Nannochloropsis oculata oil. https://www.tga.gov.au/resources/resource/compositional-guidelines/epa-rich-nannochloropsis-oculata-oil.

Establishing a Codex Standard for microbial omega-3 oils containing quality and compositional factors will ensure fair practices in trade in these commodities as well as ensure consumers' health protection, in line with Codex Alimentarius purpose and goals.

The Codex Alimentarius Commission has developed Standards for almost all fats and oils commonly used in food. However, microbial omega-3 oils are increasingly important foodstuffs, for which up to now no specific Codex Standard has been developed, which means that no quality standards for these types of oils are applicable globally. Neither the *Codex Standard for Edible Fats and Oils not Covered by Individual Standards* (CXS 19-1981) nor the *Standard for Named Animal Fats* (CXS 211-1999) nor the *Standard for Fish Oils* (CXS 329-2017) adequately cover the specific nature of microbial omega-3 oils.

3. The main aspects to be covered

The proposed new work to establish a Standard for microbial omega-3 oils includes the following sections, following the format for Codex Commodity Standards provided by the Codex Procedural Manual (Twenty-eighth edition, 2023) and the structures of existing Codex Standards for fats and oils:

- Scope
- Description
- Essential composition and quality factors
- Food additives
- Contaminants
- Hygiene
- Labelling
- Methods of analysis and sampling
- Tables with characteristic lipids/fatty acid composition of the described oils.

Further detail on the main aspects to be covered and addressed by the proposed new work are indicated in the Annex to this project document.

4. An assessment against the criteria for the establishment of work priorities

General criterion

The Codex Alimentarius Commission has a mandate of protecting consumers' health and ensuring fair practices in food trade. The proposed new Standard for microbial omega-3 oils, containing quality and compositional factors, will meet this criterion by promoting consumer protection from the point of view of health, food safety and ensuring fair practices in the food trade, assuring product authenticity and traceability, taking into account the identified needs of developing countries.

Criteria applicable to commodities

a) Volume of production and consumption in individual countries and volume and pattern of trade between countries

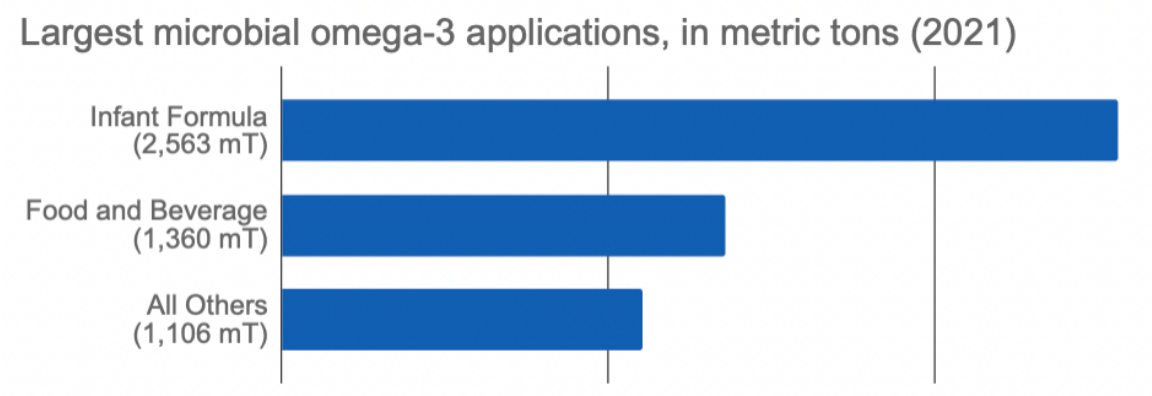
Microbial omega-3 oils for human consumption are a high value commodity. The international trade in processed microbial omega-3 oils suitable for human consumption reached over 5,029 metric tons and 264.6 million USD in 2021. Both the production and global trade of microbial omega-3 oil is increasing, as growth in the demand as well as trade of this commodity is projected to continue.[9]

Microbial omega-3 strain selection and growth condition are optimized to produce a certain type of omega-3 (high EPA, high DHA, etc.), and can be grown by fermentation in tanks, or grown in open ponds (raceway ponds) or photobioreactors.

Microbial omega-3 oils are used mainly for segments where the ingredient characteristics justify it: fortified infant formula and foods, usually for a high content of DHA, and specialized food supplements, in particular for consumers wishing to consume omega-3 oils of a non-fish origin.

The figure below shows that the largest microbial omega-3 oil volume is used by two applications, infant formula and food and beverage:[10]

[9] Market survey data, Global Organization for EPA and DHA Omega-3s (GOED).
[10] Market survey data, GOED.



Traditionally, microbial omega-3 oils have been used in food supplements tailored to specific groups of users (like vegetarian/vegan consumers, or people concerned about fish allergies) and have been high in DHA. As shown above, infant formula is now the largest application followed by food and beverage. In recent years, the production volume of high-EPA microbial omega-3 oils has increased, and it is likely that the resulting innovation will attract new consumer segments. In this regard, advances in production methods and declining prices are starting to make these oils attractive to a larger audience.

All geographic markets grew in volume, but the fastest increases (as a percentage of the demand) were observed in the developing markets, driven by increased penetration into infant formula.

Microbial omega-3 oils trade growth

Microbial omega-3 oils trade volumes, and projected continued growth in global production, demand and trade of microbial omega-3 oils, are described as follows:

In 2021, by Application:

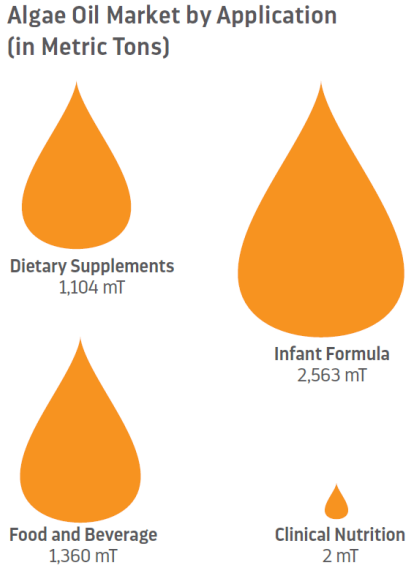
Infant formula, the largest application, uses 51.0% of microbial omega-3 oil volume, growing at an annual rate of 2.8%, particularly in Asian countries.

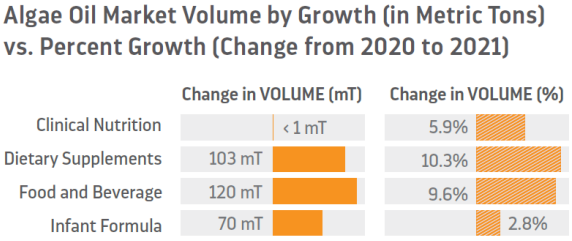
The next application, food and beverage, commands 27.0% of the volume of microbial omega-3 oils, and grew at a healthy 9.6%, driven by rapid growth in the large European market. An increased focus on prevention has resulted in the demand for healthy (including fortified) foods. The US market and the demand in the Asia-Pacific region also grew at a rapid pace.

Microbial omega-3 oils have traditionally represented a small fraction of the oil volumes used in food supplements, but they are gaining momentum. In 2021, these oils comprised less than 1.6% of the volume (and 9.4% of the value) of omega-3 ingredients used in this sector. The major obstacle to larger representation has been their higher cost, but advances in production methods — and therefore more manufacturers coming onstream with algal/protist capacity — and economies of scale have resulted in more competitive pricing. Additionally, consumer interest in plant-based ingredients and a growing variety of strains and compositions have helped microalgae achieve a global growth rate of 10.3%.

The following figures provide further detail of microbial omega-3 growth in trade volumes by application:[11]

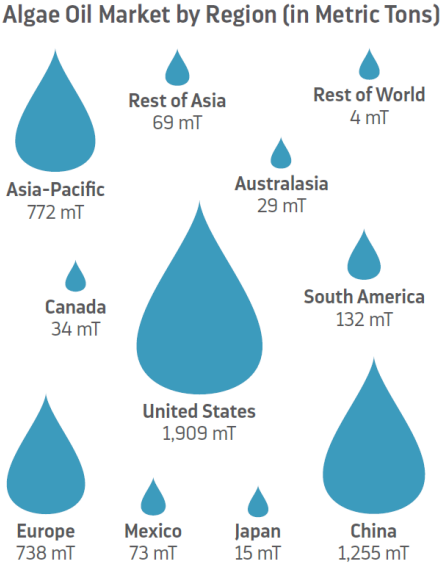
[11] Market survey data, GOED.

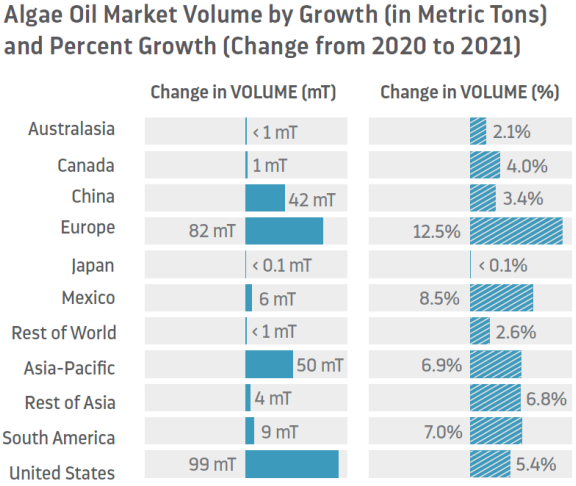




In 2021, by Region:

The following figures provide further detail of microbial omega-3 growth in trade volumes by region:[12]





[12] Market survey data, GOED.

2021, by Region and Application:

The following tables provide further detail of microbial omega-3 growth in trade volumes, in metric tons, mT, and value in millions of US dollars, by region and application:[13]

· Volumes in mT:

	Infant Formula			Food and Beverages			Dietary Supplements			Clinical Nutrition		
	2020	2021	Change	2020	2021	Change	2020	2021	Change	2020	2021	Change
Australasia	10	10	1.0%	12	13	3.2%	1	1	2.2%	-	-	-
Canada	8	8	-1.3%	16	17	5.7%	8	9	6.2%	-	-	-
China	1,025	1,059	3.3%	162	168	4.1%	25	26	4.0%	-	-	-
Europe	114	115	1.1%	255	301	17.9%	115	137	19.9%	-	-	-
Japan	-	-	-	13	13	0.8%	2	2	2.0%	-	-	-
Mexico	4	4	4.9%	63	69	8.7%	-	-	-	-	-	-
Rest of the World	-	-	-	3	4	3.2%	< 1	< 1	2.9%	-	-	-
Asia-Pacific	394	414	5.3%	201	218	8.9%	89	97	8.8%	-	-	-
Rest of Asia	20	20	4.1%	43	47	8.1%	2	2	2.2%	-	-	-
South America	41	42	2.2%	80	88	9.4%	2	2	3.1%	-	-	-
USA	878	890	1.4%	392	423	8.0%	90	98	9.6%	2	2	5.9%

Volumes in metric tons (mT)

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[13] Market survey data, GOED.

Volumes of trade in millions of US dollars

	Infant Formula			Food and Beverages			Dietary Supplements			Clinical Nutrition		
	2020	2021	Change	2020	2021	Change	2020	2021	Change	2020	2021	Change
Australasia	$0.4	$0.4	-2.0%	$0.7	$0.7	0.2%	$0.1	< 0.1	-0.8%	-	-	-
Canada	$0.3	$0.3	-4.2%	$0.9	$1.0	2.6%	$0.6	$0.6	3.1%	-	-	-
China	$44.8	$45.0	0.3%	$9.6	$9.7	1.1%	$1.8	$1.8	0.9%	-	-	-
Europe	$5.0	$4.9	-1.8%	$15.2	$17.3	14.4%	$8.3	$9.6	16.4%	-	-	-
Japan	-	-	-	$0.7	$0.7	-2.1%	$0.1	$0.1	-1.0%	-	-	-
Mexico	$0.2	$0.2	1.8%	$3.8	$4.0	5.5%	-	-	-	-	-	-
Rest of the World	-	-	-	$0.2	$0.2	0.2%	< 0.1	< 0.1	< 0.1%	-	-	-
Asia-Pacific	$17.2	$17.6	2.2%	$11.9	$12.6	5.7%	$6.4	$6.8	5.7%	-	-	-
Rest of Asia	$0.9	$0.9	1.1%	$2.6	$2.7	5.0%	$0.2	$0.2	-0.8%	-	-	-
South America	$1.8	$1.8	-0.8%	$4.8	$5.1	6.3%	$0.1	$0.1	0.1%	-	-	-
USA	$38.4	$37.8	-1.5%	$23.3	$24.4	4.9%	$6.5	$6.9	6.4%	$0.1	$0.1	2.8%

Volumes in millions of US dollars (MM US$)

Forecast

These are the volumes by region and by application for 2021, followed by the growth rate from 2020-2021 and then the average annual growth rate expected to be seen to 2024:[14]

Forecast by region:

	2021 volume (Tons)	2020-21 (Percentage change)	To 2024 (average)
Australasia	29	2.1%	2.1%
Canada	34	4.0%	4.3%
China	1,255	3.4%	3.4%
Europe	738	12.5%	9.6%
Japan	15	<0.1%	0.7%
Mexico	73	8.5%	8.5%
Rest of the World	4	2.6%	2.6%
Asia-Pacific	772	6.9%	7.0%
Rest of Asia	69	6.8%	6.8%
South America	132	7.0%	7.2%
USA	1,909	5.4%	5.6%

Forecast by application:

	2021 volume (Tons)	2020-21 (Percentage change)	To 2024 (average)
Infant Formula	2,563	2.8%	2.9%
Food and Beverage	1,360	9.6%	8.0%
Dietary Supplements	1104	10.3%	10.1%
Clinical nutrition	2	5.9%	5.9%

[14] Market survey data, GOED.

b) Diversification of national legislations and apparent resultant or potential impediments to international trade

As no internationally harmonised standard for microbial omega-3 oils exists, difficulties in and impediments to trade occur. Microbial omega-3 oils are currently traded with various levels of detail concerning their source, composition and quality. As there are variations possible in the degree of processing, chemical forms of the oil, fatty acid profile requirements, quality requirements and addition of additives, it is difficult for national authorities to judge whether individual shipments are acceptable.

Currently, pharmacopeial monographs, guidelines, standards and regulations exist for microbial omega-3 oils in Australia, China, the European Union, the USA, Brazil and Chile, providing orientation or authorising the use of microbial omega-3 oils with different levels of information in a variety of food applications.

This new work will assist in providing an internationally harmonized approach for quality and compositional factors as well as the labelling and trade in microbial omega-3 oils, embracing future innovation.

c) International or regional market potential

Today, both the production of microbial omega-3 oils, as well as the consumption of finished omega-3 rich food products containing such oils already occurs globally.

d) Amenability of the commodity to standardisation

Microbial omega-3 oils are approved for sale in different parts of the world, so therefore are a commodity amenable to standardization by the Codex Committee on Fats and Oils, CCFO.

e) Coverage of the main consumer protection and trade issues by existing or proposed general standards

The Codex Alimentarius Commission has developed Standards for almost all fats and oils commonly used in food. However, microbial omega-3 oils are increasingly important foodstuffs, for which up to now no specific Standard has been developed. Neither the *Codex Standard for Edible Fats and Oils not Covered by Individual Standards* (CXS 19-1981) nor the *Standard for Named Animal Fats* (CXS 211-1999) nor the *Standard for Fish Oils* (CXS 329-2017) adequately cover the specific nature of microbial omega-3 oils.

f) Number of commodities which would need separate standards indicating whether raw, semi-processed or processed

There are several types of microbial omega-3 oils. The proposal is to develop an inclusive Codex Standard that can be easily updated to include other microbial omega-3 oils as newer types of oils increase in importance in international trade. Therefore, the work will cover a commodity that encompasses the various relevant microbial omega-3 oils.

g) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)

There is no existing work already undertaken on an international standard for the food use of microbial omega-3 oils. In addition, so far no similar work by other international organizations has been discovered. A Codex Standard covering all necessary quality and compositional factors is therefore required.

5. Relevance to the Codex strategic objectives

The proposed new work to establish a Standard for microbial omega-3 oils containing quality and compositional factors will ensure fair practices in trade in these commodities as well as ensure consumers' health protection, in line with Codex Alimentarius purpose and goals.

The objective, as described above, is in line with the Codex Strategic Plan 2020-2025, adopted by the 42nd Session of the Codex Alimentarius Commission. In this regard, the new work proposal will contribute particularly to Goals 1, 2 and 3:

Goal 1: *"Address current, emerging and critical issues in a timely manner."*

Goal 2: *"Develop standards based on science and Codex risk-analysis principles."*

Goal 3: *"Increase impact through the recognition and use of Codex Standards."*

6. Information on the relation between the proposal and other existing Codex documents as well as other ongoing work

The Codex Alimentarius Commission has developed Standards for almost all fats and oils commonly used in food. However, microbial omega-3 oils are increasingly important foodstuffs, for which up to now no specific Standard has been developed. Neither the *Codex Standard for Edible Fats and Oils not Covered by Individual Standards* (CXS 19-1981) nor the *Standard for Named Animal Fats* (CXS 211-1999) nor the *Standard for Fish Oils* (CXS 329-2017) adequately cover the specific nature of microbial omega-3 oils.

The proposed new work to establish a Standard for microbial omega-3 oils will take into account the provisions of relevant general subject standards, such as: the *General Principles of Food Hygiene* (CXC 1-1969), the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) and the *General Standard for Food Additives* (CXS 192-1995).

7. Identification of any requirement for and availability of expert scientific advice

No expert advice other than that which is to be found in the CCFO is required at this time.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

No technical input other than that which is to be found in the CCFO is required at this time.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years

The proposed timeline for completion of the new work would be as follows:

February 2024	Agreement to undertake new work by the 28th Session of the CCFO.
2024	Approval of new work by the 47th Session of the CAC.
2025	The Proposed Draft Standard will be submitted for consideration and agreement at Step 5 by the 29th Session of the CCFO.
2025	Adoption of Draft Standard at Step 5 by the 48th Session of the CAC.
2027	The Draft Standard will be submitted for consideration and final agreement at Step 8 by the 30th Session of the CCFO.
2027	Final adoption of Draft Standard at Step 8 by the 50th Session of the CAC

** Further detail will be provided on the months of the CCFO and CAC meeting dates when there is more clarity in this regard, since at this time as a result of the COVID pandemic the usual order of meeting dates have been affected.*

Annex

PROPOSED DRAFT STANDARD FOR MICROBIAL OMEGA-3 OILS

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 foods.

2. DESCRIPTION

Microbial omega-3 oils are oils that contain a substantial level of long-chain omega-3 polyunsaturated fatty acids (omega-3 LCPUFA), including but not limited to, C20:5 (n-3) eicosapentaenoic acid (EPA) and/or C22:6 (n-3) docosahexaenoic acid (DHA) and/or C22:5 docosapentaenoic acid (DPA; either as n-6 or n-3).

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 chemical or physical refining of that crude oil, and concentration of the refined oil. Microbial omega-3 oils may also be subjected to additional processing steps, e.g. solvent extraction, saponification, re-esterification, and trans-esterification. Microbial omega-3 oils may also be concentrated or blended to adjust their LCPUFA content via physical or chemical processes.

Microbial omega-3 oils can be composed of glycerides of fatty acids (including triglycerides, phospholipids, and glycolipids); whereas *concentrated microbial omega-3 oils* are primarily composed of fatty acid ethyl esters and re-esterified triglycerides. Microbial omega-3 oils may contain other lipids and unsaponifiable constituents that are naturally present.

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.

2.1.1 *Schizochytrium oil* is derived from *Schizochytrium* species (such as *Schizochytrium limacinum)* of the genus *Schizochytrium* (family *Traustochytreaceae*). The following genus are considered to be included: *Schizochytrium*, *Aurantiochytrium*, *Hondae* and *Oblongichytrium*.

2.1.2 *Nannochloropsis oil* is derived from the species *Nannochloropsis salina*, *Nannochloropsis gaditana*, *Nannochloropsis oceanica* and *Nannochloropsis oculata*, of the genus *Nannochloropsis (*family *Eustigmatales)*. The genus *Microchloropsis* is considered included within the same genus. *N. gaditana* and *N. salina* are considered strains of the same species.

2.2 Microbial omega-3 oils (others) are derived from one or more species of microorganisms producing oils with a preponderance of DHA, or a preponderance of EPA, or a combination of EPA and DHA with or without DPA.

2.3 Concentrated microbial omega-3 oils are derived from microbial omega-3 oils described in Sections 2.1 to 2.2 which have been subjected to processes that may involve, but are not limited to hydrolysis, fractionation, winterization and/or re- esterification, and/or trans-esterification to increase the concentration of specific omega-3 fatty acids.

2.4 Blends containing *Schizochytrium* oils, *Nannochloropsis* oils, other microbial omega-3 oils and concentrated microbial omega-3 oils, mentioned in sections 2.1 to 2.3.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Gas-Liquid Chromatography (GLC) ranges of fatty acid composition (expressed as percentages (w/w))

Sample of *microbial omega-3* oils described in sections 2.1 and 2.2 shall fall within the appropriate ranges specified in Table 1. (*Schizochytrium* Oils) and Table 2. (*Nannochloropsis* Oils).

3.2 Other essential compositional criteria

Other than concentrated microbial omega-3 oil as defined in section 2.3, the minimum content of polar lipids in *Nannochloropsis* oil is 15%. The polar lipid composition may include, but is not limited to, glycolipids, phospholipids, and betaine lipids. To determine polar lipid content method AOCS Ja 4-46 “Acetone-insoluble Matter” should be used.

3.3 Quality parameters

Note: this section does not apply to flavored or intensely-colored microbial omega-3 oils, such as

Nannochloropsis oils (Section 2.1.2) where the added flavorings or naturally-present color and free fatty acid may interfere with the analytical determination of oxidation parameters or Acid Value and unsaponifiable matter content.

3.3.1 *Microbial omega-3 oils and concentrated microbial omega-3 oils (Section 2.1. to 2.4)*

Schizochytrium Oil:

Peroxide value	≤ 5 milliequivalent of active oxygen/kg oil
Anisidine value	≤ 20
Total oxidation number (TOTOX)[15]	≤ 26
Acid Value	≤ 3.0%
Unsaponifiable Matter	≤ 4.5%

Nannochloropsis Oil:

Peroxide value	≤ 5 milliequivalent of active oxygen/kg oil
Moisture	≤ 3.0%

Note: For oils with a significant level of polar lipids, such as *Nannochloropsis* oils, it is necessary to employ methods using a solvent that can dissolve both the fat and the more polar phospholipids and glycolipids. Hence for Peroxide Value methods based on chloroform/acetic acid solvent should be used.

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.

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 305, 306) – "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 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[16]. Additional studies have been conducted and final reports and consequently data are expected to be available by December 2023.

Note: For *Nannochloropsis* oils, green tea extract (epigallo-catechin gallate (EGCG)) is used as an antioxidant. Currently, it is not included in the *General Standard for Food Additives* (CXS 192-1995). Once the Standard for microbial omega-3 oils is adopted, it is proposed that CCFO requests CCFA to

[15] 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.
[16] REP23/FA, paragraph 143 and Appendix XI.

consider this matter, for which a call for data to manufacturers of green tea extract may be required to be launched.

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.

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."*

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) and of the *Guidelines on Nutrition Labelling* (CXG 2-1985) apply to this standard.

7.1 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 2.4), *e.g.* Algal oil (Schizochytrium *sp*.)

7.2 Labelling on non-retail containers

Information on the above labelling requirements shall be given either on the container or in accompanying documents, except that the name of the food, lot identification and the name and address of the manufacturer or packer shall appear on the container.

However, lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark, provided that such a mark is clearly identifiable with the accompanying documents.

7.3 Other labelling requirements

To be discussed by CCFO

8. 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: Once the Standard for microbial omega-3 oils is adopted, it is proposed that CCFO refers the following to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for discussion: adoption of Ph. Eur. 2.4.29 (composition of fatty acids in oils rich in omega-3 acids).

Table 1: Fatty acid (FA) composition of* Schizochytrium *oils (Section 2.1.1) (triglycerides) categories as determined by gas liquid chromatography (expressed as percentage of total fatty acids) (see Section 3.1 of the Standard)

Fatty Acid	Shorthand notation	DHA Oil	EPA & DHA Oil
Eicosapentaenoic acid (EPA)	20:5 n-3	NA	≥ 5.0*
Docosahexaenoic acid (DHA)	22:6 n-3	≥ 30.0*	≥ 5.0*

* Limit is expressed as % (w/w). Methods to use to make a reliable quantification of EPA and DHA: Ph.Eur. 2.4.29, AOCS Ce1i-07 or USP 401.

** *Schizochytrium* oils may also contain DPA n-6 (22:5 n-6) and DPA n-3 (22:5 n-3).

Table 2: Fatty acid (FA) composition of* Nannochloropsis *oils (Section 2.1.2) as determined by gas liquid chromatography (expressed as percentage of total fatty acids) (see Section 3.1 of the Standard)

2A. *Nannochloropsis* oils fatty acid criteria

Fatty acids	**Nannochloropsis oils (as % (w/w)**
Eicosapentaenoic acid (EPA)	≥ 15*
Docosahexaenoic acid (DHA)	≤ 0.3*

2B. *Nannochloropsis* oil lipid class criteria

Fatty acids	**Nannochloropsis oils (as % (w/w) of total lipids)**
Polar Lipids	≥ 15
Neutral lipids	0.5 - 35

Table 3: Fatty acid (FA) composition of concentrated* Nannochloropsis *oils (Section 2.3) as determined by gas liquid chromatography (expressed as percentage of total fatty acids) (see Section 3.1 of the Standard)

3.A. Concentrated *Nannochloropsis* oils fatty acid criteria

Fatty acids	***Concentrated Nannochloropsis* oils (as % w/w)**
Eicosapentaenoic acid (EPA)	≥ 30
Docosahexaenoic acid (DHA)	≤ 0.3