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PROPOSALS FOR NEW WORK
(Replies to CL 2021/96-FO)

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

DISCUSSION PAPER
(Prepared by 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

[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.

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 *Obloblichytrium actosporum*, 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 Nannochloropsis species used for the production of omega-3 rich oils is *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

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*

[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.

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

The Committee is invited to consider at its 28th Session this discussion paper and the project document in Appendix I and to agree to recommend to the 46th Session of the Codex Alimentarius Commission to approve new work for the elaboration of a Standard for Microbial Omega-3 Oils.

[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
(Prepared 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,

[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.

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.

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-seventh edition, 2019) and the structures of existing Codex Standards for fats and oils:

[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.

- 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.

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

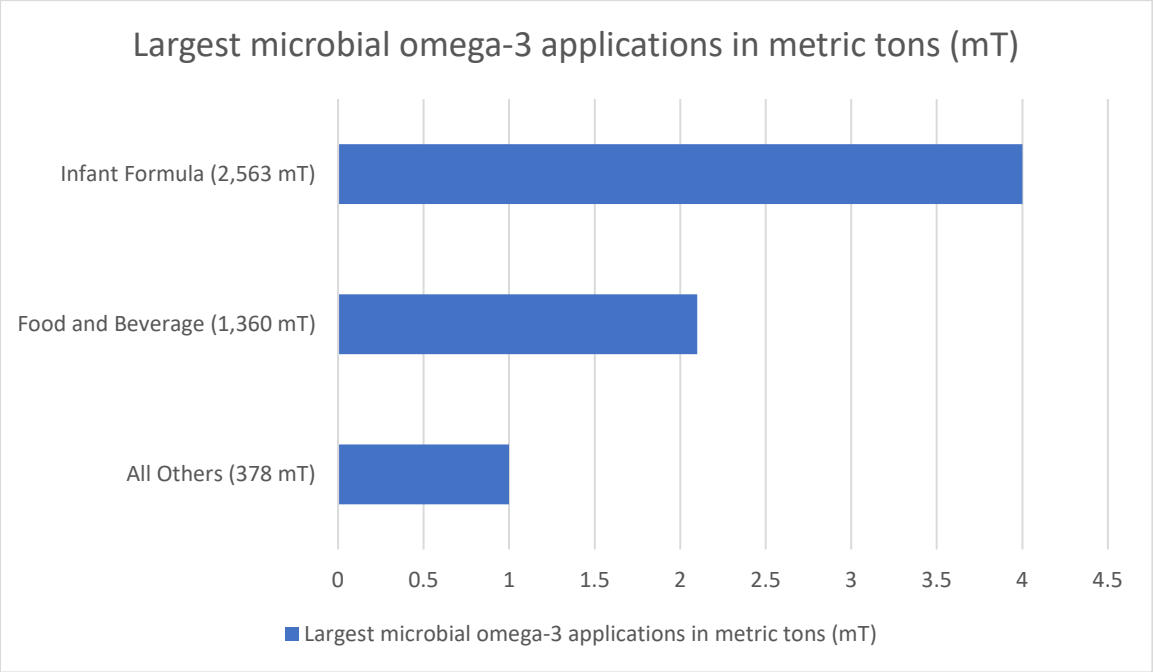
Microbial omega-3 oils for human consumption are a high value commodity. The international trade in processed microbial omega-3 oils suitable for human consumption reached over 4,301 metric tons and 213.7 million USD in 2021. Both the production and global trade of microbial omega-3 oil is increasing, 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, Global Organization for EPA and DHA Omega-3s (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:

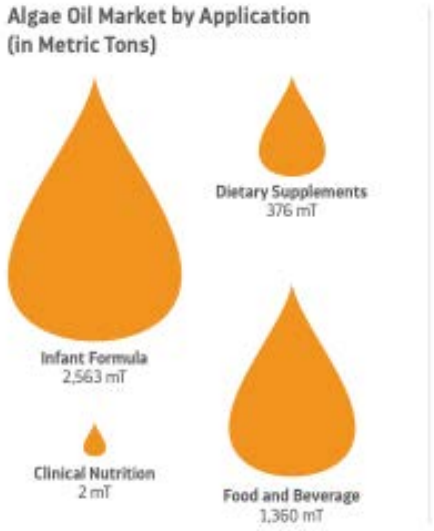
In 2021, by Application:

Infant formula, the largest application, uses 59.6% 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 31.6% 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% of the volume (and 3.4% 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 12.3%.

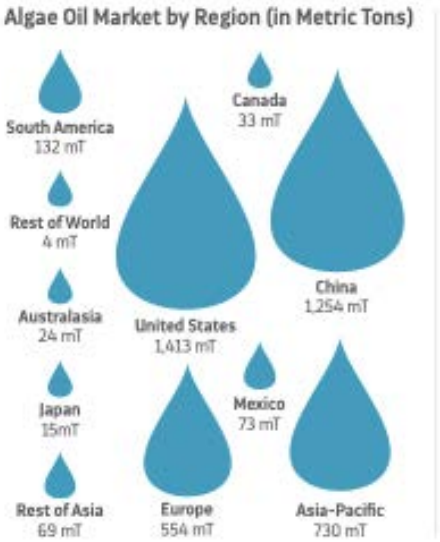
The following figures provide further detail of microbial omega-3 growth in trade volumes by application:[11]

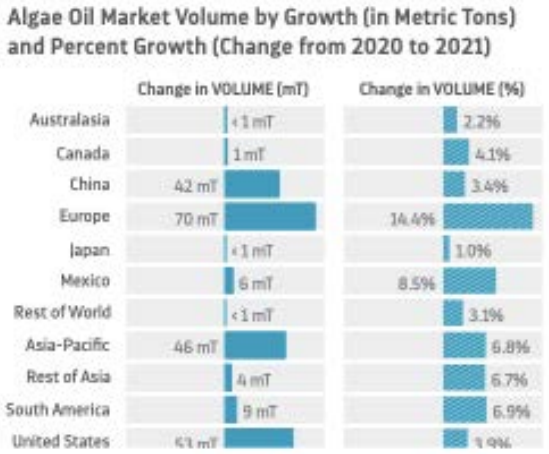


In 2021, by Region:

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

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

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

· Volumes 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 (mT)	2020-21	To 2024 (average)
Australasia	24	2.2%	2.2%
Canada	32	4.1%	4.3%
China	1,212	3.4%	3.4%
Europe	484	14.4%	10.7%
Japan	15	1.0%	1.0%
Mexico	4	8.5%	8.5%
Rest of the World	4	-	-
Asia-Pacific	684	6.8%	6.9%
Rest of Asia	65	6.7%	6.8%
South America	124	6.9%	7.1%
USA	1,361	3.9%	4.1%

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

Forecast by application:

	2021 volume (mT)	2020-21	To 2024 (average)
Infant Formula	2,493	2.8%	2.9%
Food and Beverage	1,241	9.6%	8.0%
Dietary Supplements	335	12,2%	12.8%
Clinical nutrition	2	5.9%	5.9%

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:

2023	Agreement to undertake new work by the 28th Session of the CCFO.
2023	Approval of new work by the 46th 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 due to the COVID pandemic the usual order of meeting dates have been affected.*