CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7.5 **CRD05**

Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FATS AND OILS
Twenty-Seventh Session
Virtual, 18 - 26 October 2021
PROPOSALS FOR NEW WORK
(Replies to CL 2019/54-FO)

PART V – PROPOSED AMENDMENT/REVISION TO THE CODEX STANDARD FOR FISH OILS (CXS 329-2017) – INCLUSION OF CALANUS OIL

DISCUSSION PAPER

(Prepared by Norway)

Proposed changes are indicated in BOLD and UNDERLINE

Background

1) Calanus oil is derived from the crustacean *Calanus finmarchicus,* a marine zooplankton. Calanus oil for human consumption has been marketed in Norway and the USA since 2012. Today, Calanus oil is exported to EU countries, USA and Canada. There is an interest for calanus oil in several countries worldwide, for example in Asia. But exporters experience problems due to the lack of a Codex standard accommodating for calanus oil and uncertainty in importing countries on how to perform quality control and authentication of calanus oil.

2) The Codex standard for fish oils (CXS 329-2017) was adopted in 2017. The following named fish oils are included: anchovy oil, tuna oil, krill oil, menhaden oil and salmon oil. A proposal to include calanus oil as a named oil had been considered, but at that time trade volume was too low. During the discussion on CXS 329-2017 it was agreed that additional named oils may be added at a later stage as trade becomes significant and fatty acid profiles are robustly documented. Based on new commercial harvesting quotas there is a potential to produce 15,000 tonnes of calanus oil annually. Due to specific properties of calanus oil, where the main lipid class is wax ester, not all essential quality criteria for unnamed fish oils are applicable to calanus oil. Thus, there is a need to accommodate for calanus oil in CXS 329-2017 to avoid trade impediments. The distinct properties of calanus oil makes it amenable for standardisation.

3) Calanus oil is, according to the definition for fish oils (unnamed) in CXS 329-2017 section 2.2. already covered by the standard. But this constitutes a problem for calanus oil, where the main lipid class is wax ester, whereas the main lipid class in fish body oils and cod liver oil is triglyceride. Due to the high amount of wax esters in calanus oil, not all essential quality factors for fish oils (unnamed) in the fish oil standard are applicable to calanus oil. Thus, there is a need to accommodate for calanus oil in CXS 329-2017 to avoid trade impediments. The distinct properties of calanus oil makes it amenable for standardisation.

4) The high amount of wax esters is specific for calanus oil and clearly distinguishes it from other fish oils. There is need to include calanus oil as a named fish oil, and to specify specific essential composition and quality factors for calanus oil, when that is justified. Wax esters can be analysed using method AOCS Ch 8-02. The method is applicable for calanus oil, however as the oil is not included in the validation data of the method, it is recommended that AOCS Ch 8-02 is included for calanus oil as a Type IV method in Recommended Methods of Analysis and Sampling (CXS 234-1999).

5) Including calanus oil as a named fish oil will reduce trade impediments and help governments in assessing the quality and the barriers and/or rejection of the product at the trade borders, and help manufacturers and traders documenting product authenticity and traceability.

6) The annual production of calanus oil has so far been based on research and development (R&D) harvesting quotas. Based on a scientific risk assessment **and a precautionary approach**, the Norwegian Directorate of Fisheries has issued **a total** annual commercial harvesting quota of 254,000 tonnes of *Calanus finmarchicus*. Together with a preliminary **annual total** quota of 100,000 tonnes set by the Faroe Islands, there is a potential to produce 15,000 tonnes of calanus oil annually. Even if only 50% of this volume is destined for human consumption, this is a high volume compared to many other fish oils already listed as named fish oils.

7) Harvesting and processing of *Calanus finmarchicus* started in 2007, based on R&D-quotas issued by the **Norwegian Ministry of Trade, Industry and Fisheries** ~~Norwegian Directorate of Fisheries~~. *Calanus finmarchicus* is a crustacean, defined as a zooplankton in the size-range 0.2-20 mm. The species can be found over the larger part of the northern hemisphere. However, the core area is the Norwegian Sea. It is the most numerous animal species in the Norwegian Sea and has the largest marine animal biomass production in the Northern hemisphere. Based on scientific risk assessment by the Institute of Marine Research (ISSN 0071 – 5638), the biomass is estimated to be 33 million tonnes (Directorate of Fisheries, Management Plan for *Calanus finmarchicus*, 2016). This is considered as the standing stock biomass of *Calanus finmarchicus* in the Norwegian Sea. This is the amount of calanus overwintering in the deep ocean, preparing for reproduction the next spring. The annual **new production** ~~yield~~ is estimated to be 190-290 million tonnes in the Norwegian Sea. The risk assessment addresses the ecological aspects related to **incidental mortality** ~~bycatch~~, potential food deficiency for predatory species, production, and standing stock size. The risk assessment is in line with the management principles adopted by the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR) management plan for krill in the Southern Ocean, and it was concluded that an adoption of this principle would be sustainable.

8) The Norwegian Ministry of Trade, Industry and Fisheries has issued a total commercial quota of 254,000 tonnes of *Calanus finmarchicus* per year in the period 2019-2029. The quota and other recommendations are based on the precautionary principle as regulated by the Norwegian Marine Resources Act. **Major sustainability and precautionary principles have been assessed and implemented in the Management Plan.** 254 000 tonnes represent less than **0.**1% of the estimated annual yield. 254,000 tonnes is 10% of the potential maximum sustainable yield as calculated by the Norwegian Institute of Marine Research (Broms *et al*., 2016).

9) All harvesting operations are subjected to monitoring through the use of Sailing Inspectors from the Directorate of Fisheries. The daily catch is reported to the Directorate of Fisheries. There are several measures developed and adopted to reduce incidental mortality. The fleet relocate if there is more than 10% bycatch in volume or avoid areas where previous years have demonstrated presence of larvae and juveniles.

10) The commercial sustainable harvesting and processing of *Calanus finmarchicus* is emerging in Norway and other countries (Faroe Islands (Denmark) and Iceland). Trading volumes of oil from *Calanus finmarchicus* are currently limited, since the management plan for the resource was only endorsed by the Norwegian Government as recently as the spring (first half) of 2019, as well as limitations in market access. However, based on the establishment of a **annual total** quota of 254,000 tonnes by the Norwegian Government, and a preliminary quota of 100,000 tonnes set by the Faroe Islands, a potential output of 15,000 tonnes of calanus oil may be produced.

11) Following harvesting of *Calanus finmarchicus*, the raw material is frozen on board the vessels for storage and processing on shore. Before processing, the raw material is inspected visually and analysed to ensure that the quality is consistent with a fresh product for food use. The frozen raw material is grounded and suspended in water in the presence of food grade enzymes to hydrolyze the proteins and aid release of the lipid fraction, then heated to deactivate the enzyme and sterilize the product. The lipid (oil) fraction is separated from the remaining solids (protein and shell/chitin) and water ("stick-water") fractions by decanting and centrifugation. Separation is repeated until there is no sedimentation (protein or water) identified in the lipid fraction. The resultant crude oil is then refined by conventional techniques such as evaporation and filtration to provide the finished, consumer ready oil. Calanus oil is packed under an inert (liquid nitrogen) atmosphere and stored in the dark.

12) Calanus oil is a ruby coloured, slightly viscous oil consisting primarily (> 80%) of monoesters of long-chain fatty acids including EPA (eicosapentaenoic acid), DHA (docosahexaenoic acid) and SDA (stearidonic acid), and long-chain fatty alcohols. In other words, unlike fish body oil or cod liver oil where the main lipid class is triglyceride, the main lipid class of oil from *Calanus finmarchicus* is wax ester. Minor components of the oil include triglycerides and other neutral lipids. The oil is naturally rich in astaxanthin, which in addition to dark red or ruby coloration also provides antioxidative protection.

Proposal

13) The proposed amendments will focus on including Calanus oil as a named fish oil in CXS329-2017, in the following sections:

- Section 2. Description – include calanus oil as a named fish oil and to define calanus oil according to the species it derives from and to the composition with a high amount of wax esters. 2.1.6 *Calanus oil* is derived from the species *Calanus finmarchicus.* Calanus oil consist mainly of wax esters.
- Section 3. Essential Composition and quality factors

- Section 3.1. GLC ranges of fatty acid composition (expressed as percentages of total fatty acids) - to include the GLC ranges of fatty acid composition for calanus oil in Table 1.
- Section 3.2 Other essential compositional criteria – to include minimum requirement for the content of wax esters in w/w % for calanus oil.
- Section 3.3. Quality parameters – to include calanus oil in section 3.3.2

- Section 8 Methods of Analysis and Sampling – Include AOCS Ch 8-02 in Recommended Methods of Analysis and Sampling (CXS 234-1999) for calanus oil as a Type IV method for analysis of wax esters.

Recommendation

14) The Committee is invited to consider this discussion paper and the project document in Appendix I and recommend to the 44th Session of the Codex Alimentarius Commission to approve new work for the Inclusion of Calanus oil derived from the species *Calanus finmarchicus* as a named fish oil in the Standard for Fish Oils (CXS 329-2017).

Additional information:

- Appendix II: all analytical results for the GLD ranges of fatty acid composition for calanus oil
- Appendix III: Additional background information.

Appendix I

PART V – PROPOSED AMENDMENT /REVISION TO THE CODEX STANDARD FOR FISH OILS (CXS 329-2017) - INCLUSION OF CALANUS OIL PROJECT DOCUMENT

(Prepared by Norway)

Proposed changes are indicated in BOLD and UNDERLINE

1. Purpose and scope of the proposed amendment

The purpose and scope of the proposed amendment to the *Standard for Fish Oils (*CODEX STAN 329-2017) is to include calanus oil derived from the species *Calanus finmarchicus* as a named fish oil, and where relevant amend other sections of the standard to accommodate for this inclusion.

2. Relevance and timeliness

Calanus oil for human consumption has been marketed in Norway and the USA since 2012. Today, Calanus oil is exported to EU countries, USA and Canada. There is an interest for calanus oil in several countries worldwide, as for example in Asia. But exporters experience problems due to the lack of a Codex standard accommodating for calanus oil and uncertainty in importing countries on how to perform quality control and authentication of calanus oil.

The Codex standard for fish oils (CXS 329-2017) was adopted in 2017. The following named fish oils are included: anchovy oil, tuna oil, krill oil, menhaden oil and salmon oil. During the discussion on CXS 329-2017 it was agreed that additional named oils may be added at a later stage as trade becomes significant and fatty acid profiles are robustly documented. Based on new commercial harvesting quotas there is a potential to produce 15,000 tonnes of calanus oil annually. Due to specific properties of calanus oil, where the main lipid class is wax ester, not all essential quality criteria for unnamed fish oils are applicable to calanus oil. Thus, there is a need to accommodate for calanus oil in CXS 329-2017 to avoid trade impediments. The distinct properties of calanus oil makes it amenable for standardisation.

Calanus oil is according to the definition for fish oils (unnamed) in CXS 329-2017 section 2.2. already covered by the standard. But this constitutes a problem for calanus oil, where the main lipid class is wax ester. Whereas the main lipid class in fish body oils and cod liver oil is triglyceride. Due to the high amount of wax esters in calanus oil, not all essential quality factors for fish oils (unnamed) in the fish oil standard are applicable calanus oil. Thus, there is a need to accommodate for calanus oil in CXS 329-2017 to avoid trade impediments. The distinct properties of calanus oil makes it amenable for standardisation.

The high amount of wax esters is specific for calanus oil and clearly distinguishes it from other fish oils. There is a need to include calanus oil as a named fish oil, and to specify specific essential composition and quality factors for calanus oil, when that is justified. Wax esters can be analysed using method AOCS Ch 8-02. As the method is applicable for calanus oil, but not included in the current validation data, it is recommended that AOCS Ch 8-02 is listed as a Type IV method for calanus oil for the determination of wax esters in Recommended Methods of Analysis and Sampling (CXS 234-1999).–

Including calanus oil as a named fish oil will reduce trade impediments and help governments in assessing the quality and the barriers and/or rejection of the product at the trade borders, and help manufacturers and traders documenting product authenticity and traceability.

Today's supply of EPA/DHA for human consumption may be as low as 30% of global demand, based on a recommended daily intake of 500 mg, according to a recent estimate (Hamilton *et al*. 2020). This gap is unlikely to be filled by traditional capture fisheries, due to a majority of stocks being considered fully exploited or overexploited. The gap may be filled by other resources, including such as krill (*Euphasia superba*) and *Calanus finmarchicus.*

The current annual trading volume of calanus oil is limited, estimated at around 25,000 kg. However, the value of calanus oil is high. The volume has been limited due to smaller R&D harvesting quotas and restricted market access. Based on the new commercial harvesting quotas issued in 2019, a potential output of 15,000 tonnes of calanus oil from may be produced. Even if only 50% of this volume is destined for human consumption, this is a high volume compared to many other fish oils already listed as named fish oils.

3. Main aspects to be covered

The proposed amendments to CXS 329-2017 include the following:

- include calanus oil as a named fish oil in section 2.1. Description Named fish oils;
- include the GLC ranges of fatty acid composition for calanus Oil in section 3.1., Table 1;

- specify additional essential compositional criteria for calanus oil in section 3.2.;
- include calanus oil in the section 3.3.2 Quality parameters; recommend that method AOCS Ch 8-02 is included for calanus oil as a Type IV method in *Recommended Methods of Analysis and Sampling* (CXS 234-1999), section 8, for the analysis of wax esters.

The details are as indicated in the Annex to this project document.

4. Assessment against the Criteria for the establishment of work priorities

General criterion

The proposed amendment of the Codex *Standard for fish oil* (CXS 329-2017) for inclusion of *calanus oil as a named fish oil* in the list of species under Section. 2.1. could support governments and traders in assuring product authenticity, traceability, and sustainability of resources, ensuring fair practices in the food trade and taking into account the identified needs for listing of calanus oil in the standard as experienced in several countries.

Criteria applicable to commodities

a) Volume and production and value of trade

According to GOED market report the total volume of fish oils, omega-3 ingredients for human consumption was 111,210 tonnes in 2018. Both the production and global trade of fish oil is increasing. In general fish oil production is taking place in some countries and regions with specialized processing and refining industry. Finished fish oil is then traded globally to countries in all regions. The global demand is increasing, the fastest growth is especially in Asian countries.

According to GOED the volume of calanus oil is limited, 17.000 kg in 2018. In 2019 the production was approximately 25.000 kg. But the value of calanus oil is very high, compared to many other fish oils. **This is due to the amount of research and development necessary at the early stages of product development. As the volume increases, pricing is expected to develop accordingly.**

Both volume and value for several fish oils are listed in the table below.

Annual production and value of fish oils in 2018 (GOED market report 2019)

	Volume (tonnes)	Value (millions USD)
Common refined oils	40,754	188
Concentrated oils	20,711	485
Menhaden oil	9,405	19
Cod liver oil	8,490	45
Salmon oil	5,285	34
Tuna oil	4,531	196
Krill oil	856	102
Calanus oil	17	5

By the end of 2021, the production of calanus oil will be approximately 52. 000 kg, doubling the volume from 2019. Of this volume, on average 50 % is sold in Europe (EU and Norway) and 50 % in the United States of America.

Based on the annual commercial harvesting quotas, there is a potential to produce 15,000 tonnes of calanus oil annually.

Consumption of calanus oil has been mainly as dietary supplements. Between 2008 and 2021 223.800 kg of calanus oil was manufactured and traded, resulting in the consumption of about 500 million capsules.

b) Diversification of national legislation and apparent resultant impediments to international trade

National legislation for fish oil for human consumption which accommodates for market access also for calanus oil is in place in some countries. In other regions, as for example Asia there is a lack of national legislation for calanus oil with their specific properties. Due to the high amount of wax esters, the quality parameters

established in CXS 329-2017 for named fish oils and unnamed fish oils primarily composed of glycerides of fatty acids, are not all applicable for calanus oil. Trade impediments are experienced, especially in the Asian market, due to the lack of a Codex standard accommodating for calanus oil and the uncertainty on how to control the quality and the authentication of calanus oil. Response from trading partners indicate that competent authorities in importing countries would welcome an international standard for calanus oil.

c) International or regional market potential

Based on the annual commercial harvesting quotas issued in 2019 for *Calanus finmarchicus*, the potential annual production may be 15,000 tonnes of calanus oil.

Norway exports calanus oil to EU countries, USA and Canada. There is an interest for calanus oil in several countries worldwide as for example in Asia. But market access is hindered to the lack of standardisation.

d) Amenability of the commodity to standardisation.

Calanus oils is derived from the crustacean *Calanus finmarchicus,* and according to the definition for fish oils (unnamed) in CXS 329-2017 section 2.2. already covered by the standard. But this constitutes a problem for calanus oil, where the main lipid class is wax ester. Whereas the main lipid class in fish body oils and cod liver oil is triglyceride. Due to the high amount of wax esters in calanus oil, not all essential quality factors in the fish oil standard are applicable calanus oil. Thus, there is a need to accommodate for calanus oil in CXS 329-2017 to avoid trade impediments. The distinct properties of calanus oil makes it very amenable for standardisation.

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

Not applicable.

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

Not applicable.

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

So far, no similar work by other international organizations has been encountered.

5) Relevance to the Codex strategic objectives

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

The proposed amendment of the Codex *Standard for Fish oil* (CXS 329-2017) responds to the need for having an updated and relevant standard for this commodity–

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

The proposed amendment will simply update the existing *Codex standard for fish oil* (CXS329-2017) to include calanus oil as a named fish oil.

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

None.

8. Identification of any need for technical input to the standard so that this could be planned for

None

9. Proposed timeline for completion of the amendment.

A period of four years is foreseen in the completion of the proposed amendment of *Codex standard for fish oil* (CXS329-2017). If new work is adopted at CCFO 27 and by CAC 44 in 2021; it is anticipated an adoption at step 5 at CCFO 28, and at step 8 at CCFO 29 and CAC 48 in ~~2023~~ **2025.**

Annex

PROPOSED DRAFT AMENDMENTS/REVISION IN THE STANDARD FOR FISH OILS CXS 329-2017

(Inclusion of calanus oil)

Proposed amendments to CXS 329-2017 for the inclusion of calanus oil are indicated in **bold** and underlined.

2.1 Named fish oils are derived from specific raw materials which are characteristic of the major fish or shellfish taxon from which the oil is extracted.

2.1.6 *Calanus oil* is derived from the species *Calanus finmarchicus.* Calanus oil consist mainly of wax esters.

Rationale: Calanus oil is primarily composed of wax esters and differs from traditional fish oils which are primarily composed of glycerides of fatty esters. This should be specified, in line with additional information provided for krill oil.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 GLC ranges of fatty acid composition (expressed as percentages of total fatty acids)

Sample of fish oils described in sections 2.1 and 2.3 shall fall within the appropriate ranges specified in Table 1. Supplementary criteria, for example national geographical and/or climatic variations may be considered, as necessary, to confirm that a sample is in compliance with the Standard.

The proposed GLC ranges of the fatty acid composition for calanus oil are to be included Table 1.

Table 1. Supplementary criteria

Fatty acids	*Calanus* oil section 2.1.6[1]
C14:0 Myristic acid	**5.5-9.1**
C15:0 Pentadecanoic acid	**0.2-0.5**
C16:0 Palmitic acid	**4.3-5.8**
C16:1 (n-7) Palmitoleic acid	**1.5-3.7**
C17:0 Heptadecanoic acid	**ND-0.2**
C18:0 Stearic acid	**0.3-0.7**
C18:1 (n-7) Vaccenic acid	**0.2-0.4**
C18:1 (n-9) Oleic acid	**1.0-2.3**
C18:2 (n-6) Linoleic acid	**0.3-0.7**
C18:3 (n-3) Linolenic acid	**0.5-2.0**
C18:3 (n-6) γ-Linolenic acid	**0.1-0.3**
C18:4 (n-3) Stearidonic acid	**4.3-9.2**
C20:0 Arachidic acid	**ND-0.2**
C20:1 (n-9) Eicosenoic acid	**1.3-2.8**
C20:1 (n:11) Eicosenoic acid	**ND-0.7**
C20:4 (n-6) Arachidonic acid	**0.1-0.3**
C20:4 (n-3) Eicosatetraenoic aicd	**0.0-0.7**
C20:5 (n-3) Eicosapentaenic acid	**4.9-9.7**
C21:5 (n-3) Heneicosapentaenoic acid	**0.2-0.4**
C22:1 (n-9) Erucic acid	**ND-0.3**
C22:1(n-11) Cetoleid acid	**1.8-4.3**
C22:5 (n-3) Docosapentaenoic acid	**0.0-0.9**

[1] The fatty acid composition of calanus oil is given as g/100g oil

C22:6 (n-3) Docosahexaenoic acid	**3.5-7.2**

ND = non-detected, defined as ≤0.05%

NA = not applicable or available

Rationale: The proposal for GLC ranges of fatty acid composition is based on the analysis of 20 different batches.

3.2 Other essential compositional criteria

For calanus oil the content of wax esters shall be at least 80w/w %.

Rationale: Calanus oil consists mainly of wax esters. As this clearly distinguishes calanus oil from other fish oils, minimum content of wax esters should be included as an essential compositional criterion for calanus oil.

3.3.2 *Fish oils with a high phospholipid concentration of 30% or more such as krill oil (Section 2.1.3)* ***and oils with a high wax ester concentration of 80% or more such as calanus oil (Section 2.1.6)*** *shall comply with the following:*

Acid value	≤ 45 mg KOH/g
Peroxide value	≤ 5 milliequivalent of active oxygen/kg oil

Rationale: Due to the high amount of wax esters calanus oil has similar properties as krill oil with regard to acid value and oxidation parameters.

METHODS OF ANALYSIS AND SAMPLING

Include the following method of analysis

AOCS Ch 8-02 in Recommended Methods of Analysis and Sampling (CXS 234-1999) for calanus oil -

Typing: **Type IV method**