GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

21 March 2024

Thailand Food and Drug Administration
Food Division
Standard Setting Group
88/24 Tiwanon Road
Talat Khwan Subdistrict
Mueang District
Nonthaburi, Thailand 11000
food.publichearing@gmail.com
Google Form link

RE: Notification of the Ministry of Public Health (No. ...) B.E..... Issued under the Food Act B.E. 2522 Regarding Oils and Fats (No. 2)[1]

To Whom It May Concern:

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide EPA and DHA omega-3 industry, with a mission to increase consumption of EPA and DHA omega-3s around the world. The membership is built on a quality standard unparalleled in the market and members must comply with quality and ethics guidelines that ensure members produce quality products that consumers can trust. Our 200+ members and partners represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands.

Regarding the (Draft) Notification of the Ministry of Public Health (No. …) B.E. …. Issued under the Food Act B.E. 2522 Regarding Oils and Fats (No. 2), GOED appreciates the opportunity to provide comments, which will focus on algal oil derived from *Schizochytrium sp*.

While GOED appreciates the Food and Drug Administration's (FDA) flexibility to permit companies to submit documentation for approval on a case-by-case basis for oils and fats whose chemical and physical characteristics and fatty acid compositions differ from those specified in Announcement of the Ministry of Public Health (No. 421) B.E. 2564 (2021) Issued under the Food Act B.E. 2522 (1979) about Oils and Fats,[2] GOED's preference, as noted in our two previous attached letters from 23 August 2021 and 20 October 2022, is the removal of the ranges for all fatty acids other than EPA and DHA.

The inclusion of fatty acid profiles other than for EPA and DHA is unnecessarily prescriptive and has the potential to create a barrier to free trade of historically safe and suitable oils. EPA and DHA are the characterizing fatty acids of relevance and, with the exception of erucic acid

[1] https://food.fda.moph.go.th/media.php?id=581011565529145344&name=draft-421.pdf
[2] https://en.fda.moph.go.th/media.php?id=517782071406632960&name=P421_E.pdf

(C22:1 n-9) in infant formula, GOED is not aware of any safety concerns related to any of the fatty acids that may be present in algal oil derived from *Schizochytrium sp*. Also, while stipulating fatty acid ranges and profiles for fish and vegetable oils may be considered a way to deter fraud, this is not an issue for algal oil derived from *Schizochytrium sp*.

Since GOED's last communication with the FDA, the 28th Session of the Codex Committee on Fats and Oils (CCFO28) agreed to submit for approval to the Codex Alimentarius Commission GOED's Proposal for New Work on a Standard for Microbial Omega-3 Oils,[3] which includes Schizochytrium oils. With the Proposal for New Work, we submitted a Proposed Draft Standard for Microbial Omega-3 Oils with fatty acid ranges for only EPA and DHA as follows:

Fatty Acid	DHA Oil	EPA & DHA Oil
EPA	Not applicable	≥ 5.0*
DHA	≥ 30.0*	≥ 5.0*

*Limit is expressed as % (w/w)

While this Proposed Draft Standard served only as an example of what a Codex standard could look like and may not resemble the standard that is ultimately adopted, it does represent the feedback from our membership producing and selling these oils globally.

In summary, GOED encourages you to update the specifications for algal oil derived from *Schizochytrium sp*. to include fatty acid ranges for only EPA and DHA. GOED appreciates your consideration of the above comments and would be happy to answer any questions.

Sincerely,

Harry B. Rice, PhD
VP, Regulatory & Scientific Affairs
harry@goedomega3.com

Gerard Bannenberg, PhD
Director, Technical Compliance & Outreach
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[3] https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-709-28%252FReport%252FFinal%252520Report%252FREP24_FOe_COMPILED.pdf (see Appendix XII)

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

20 October 2022

Thailand Food and Drug Administration
Standards Group
Food Division
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Talat Khwan Subdistrict
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Nonthaburi, Thailand 11000
food.publichearing@gmail.com
link to Google Form https://docs.google.com/forms/d/1Gih-R1BRPBPokI5flGjD8ZgNEIrgdQzJgFPIz0z77Jg/viewform?edit_requested=true

RE: (Draft) Notification of the Ministry of Public Health (No. …) B.E. …. Issued under the Food Act B.E. 2522 about Oils and Fats[1]

To Whom It May Concern:

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide EPA and DHA omega-3 industry, with a mission to increase global consumption of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The membership is built on a quality standard unparalleled in the market and members must comply with quality and ethics guidelines that ensure members produce quality products that consumers can trust. Our 160+ members represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands.

Regarding the (Draft) Notification of the Ministry of Public Health (No. …) B.E. …. Issued under the Food Act B.E. 2522 about Oils and Fats, GOED appreciates the opportunity to provide comments, which focus on the proposed modifications to the fatty acid requirements for 'oil from algae *Schizochytrium* sp.'

For 'oil from algae *Schizochytrium* sp.,' EPA and DHA, in particular, are the characterizing fatty acids of relevance; therefore, GOED is grateful of your expansion of the fatty acid ranges for both EPA and DHA. We view this as the most important change necessary to maintain free trade of commercially available 'oil from algae *Schizochytrium* sp.'

Globally, 'oil from algae *Schizochytrium* sp.' with different concentrations of EPA and DHA are permitted for sale in a wide range of applications (e.g. infant formula, dietary/food supplements, etc…). While stipulating fatty acid ranges and profiles for fish and vegetable oils is considered a way to deter fraud, this is not an issue for oils from algae. In addition, with the exception of erucic acid ($C_{22}H_{42}O_2$) in infant formula, GOED is not aware of any safety concerns related to

[1] https://www.fda.moph.go.th/sites/food/FileNews/DRAFT/65_Oil/2_421.pdf

any of the fatty acids that may be present in 'oil from algae *Schizochytrium* sp.' Therefore, GOED views the inclusion of fatty acid profiles to be unnecessarily prescriptive and it has the potential to create a barrier to free trade of historically safe and suitable 'oil from algae *Schizochytrium* sp.' For this reason, GOED recommends removing the ranges for all fatty acids except EPA and DHA.

While not all specifications for oils from algae *Schizochytrium* sp. limit the fatty acids of interest to EPA and DHA, any reference to additional fatty acids is limited. Globally, there are many oils from *Schizochytrium* sp. with specifications that focus primarily on EPA and DHA. Examples of such oils can be found in the letter GOED sent to Thailand FDA on 23 August 2021. For your reference, a copy of that letter has been provided following this letter.

To highlight just one example, the United States Pharmacopeia's (USP) Food Chemicals Codex (FCC) current monograph entitled *DHA from Algal (Schizochytrium) Oil*[2] includes EPA and DHA, in addition to dihomo-gamma-linolenic acid, arachidonic acid, and docosapentaenoic acid (DPA). The monograph contains specifications for four broad classes of Schizochytrium oils each characterized by their contents of DHA and EPA, but it does not include a long list of minor fatty acids that would preclude meeting the specification by a potential portion of the marketed Schizochytrium oils.

Fatty acid	Shorthand notation	Type I – acceptance criteria	Type II – acceptance criteria	Type III – acceptance criteria	Type IV – acceptance criteria
EPA	20:5 n-3	NMT 3.9	NMT 3.5	NLT 10.0	NMT 20.0
DHA	22:6 n-3	NLT 30.0	NLT 35.0	NLT 20.0	NLT 35.0
DPA n-6	22:5 n-6	NMT 16.5	NMT 25.0	NMT 3.5	NMT 6.0
Dihomo-gamma-linolenic acid	20:3 n-6	NMT 2.8	NMT 1.0	NMT 1.0	NMT 1.0
Arachidonic acid	20:4 n-6	NMT 1.3	NMT 3.5	NMT 3.5	NMT 3.5

Limits are specified as wt/wt%

While GOED is not recommending the inclusion of fatty acids other than EPA and DHA be included in Thailand's specification, our point is that reference to fatty acids other than EPA and DHA should be limited to as few as possible. The inclusion of any other fatty acids will require

[2] https://online.foodchemicalscodex.org/uspfcc/document/6_GUID-DE13986B-B98E-413F-B133-8516D1F776E7_50101_en-US?source=TOC

acceptance of wide fatty acid ranges to ensure that all companies that want to register to sell their safe and suitable oils from *Schizochytrium* sp. in Thailand have the ability to do so. In fact, if any fatty acids other than EPA and DHA are included in Thailand's specification, we recommend that they be associated with only an upper limit and not include a lower limit (as exemplified in the above table).

GOED notes that you have added a condition to be able to submit documentary evidence to the Food and Drug Administration for approval on a case-by-case basis for oils and fats whose chemical and physical characteristics and fatty acid composition differ from those specified in the notification for a number of reasons. While GOED's preference is that you remove the ranges for all fatty acids other than EPA and DHA, GOED supports the inclusion of this condition, because it has the potential to maintain free trade for those oils whose fatty acid compositions may deviate from the published ranges.

GOED appreciates your consideration of the above comments and would be happy to answer any questions.

Sincerely,

Harry B. Rice, PhD
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Gerard Bannenberg, PhD
Director, Technical Compliance & Outreach
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GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

23 August 2021

Thailand Food and Drug Administration Secretary-General, Dr. Paisarn Dunkum
88/24 Tiwanon Road
Nonthaburi, Thailand 11000
food@fda.moph.go.th

RE: Announcement of the Ministry of Public Health (No. 421) B.E. 2564 (2021) Issued under the Food Act B.E. 2522 (1979) about Oils and Fats[1]

Dear Dr. Dunkum:

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide EPA and DHA omega-3 industry, with a mission to increase consumption of EPA and DHA omega-3s around the world. The membership is built on a quality standard unparalleled in the market and members must comply with quality and ethics guidelines that ensure members produce quality products that consumers can trust. Our 160+ members represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands.

Regarding Announcement of the Ministry of Public Health (No. 421) B.E. 2564 (2021) Issued under the Food Act B.E. 2522 (1979) about Oils and Fats, specifically 'algal oil from *Schizochytrium* sp.,' it has come to GOED's attention that the majority of, if not all, commercially available algal oils from *Schizochytrium* sp. cannot comply with the stipulated fatty acid profile requirements detailed in Annex 5 (Composition of fatty acid as a %-age of total fatty acids in oil and fat). This impedes the sale of *Schizochytrium* algal oils in Thailand.

Globally, algal oils from *Schizochytrium* sp. with different concentrations of EPA and DHA are permitted for sale in a wide range of applications (e.g. infant formula, dietary/food supplements, etc…). While stipulating fatty acid ranges and profiles for fish and vegetable oils is considered a way to deter fraud, this is not an issue for algal oils. In addition, with the exception of erucic acid ($C_{22}H_{42}O_2$) in infant formula, GOED is not aware of any concerns related to any of the fatty acids that may be present in algal oils from *Schizochytrium* sp. Thus said, GOED views the inclusion of fatty acid profiles to be unnecessarily prescriptive and creates a barrier to free trade of historically safe and suitable algal oils from *Schizochytrium* sp.

For algal oils from *Schizochytrium* sp., EPA and (in particular) DHA are the characterizing fatty acids of relevance; therefore, **GOED proposes the following:**

- **EPA specifications be changed from a range of 6.0-7.0% (%-age of total fatty acids) to allow for any concentration;**

[1] http://food.fda.moph.go.th/law/data/announ_moph/P421.pdf

- **DHA specifications be changed from a range of 41.0-46.0% (%-age of total fatty acids) to a minimum concentration of 20% (%-age of total fatty acids); and**
- **ranges for all other fatty acids, which have not been reported to present any safety issues, be removed.**

Not only would this change allow for the sale of current algal oils from *Schizochytrium* sp., but it serves to embrace future innovation. This proposal is based on an internal survey of specifications from producers of algal oils from *Schizochytrium* sp. that have been approved for sale in different parts of the world. This survey can be found in the annex following the body of this letter.

GOED appreciates your consideration of the above comments and looks forward to further discussion on this topic in order to come to an acceptable resolution for the companies selling safe and suitable algal oils from *Schizochytrium* sp. in Thailand.

Sincerely,

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Gerard Bannenberg, PhD
Director, Technical Compliance & Outreach
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GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Annex
Survey of Global Specifications for Algal Oils from *Schizochytrium* sp.

ASIA

China

GB 26400-2011 National Food Safety Standard for Food Additive Docosahexaenoic Acid Grease (Fermentation Process)

- DHA: ≥ 35.0
- EPA: not mentioned

South Korea

According to the Health Functional Food Code, "Edible oil containing omega-3 fatty acid" can be made from "seaweeds," which GOED understands to include algae. The sum of EPA and DHA is specified as 300 mg/g.
https://www.mfds.go.kr/files/upload/eng/7_Health%20Functioanl%20Food%20Code.pdf

AUSTRALIA

- Compositional Guideline for DHA-rich oil derived from microalgae *Schizochytrium* sp.
  https://www.tga.gov.au/sites/default/files/cm-cg-dha-rich-oil-derived-from-microalgae-schizochytrium.pdf
  - DHA: not less than 35% (w/w)
- Compositional Guideline for DHA/EPA rich *Schizochytrium* algal oil
  https://www.tga.gov.au/sites/default/files/cm-cg-dha-epa-rich-schizochytrium-algal-oil.pdf
  - DHA: not less than 24% (w/w)
  - EPA: not less than 12% (w/w)

EUROPE

European Union

While each algal oil is associated with a unique fatty acid profile, the focus of the EFSA opinions is on either the level of DHA alone or levels of DHA and EPA.

- Scientific Opinion on the extension of use for DHA and EPA-rich algal oil from *Schizochytrium* sp. as a Novel Food ingredient
  - https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3843
  - Applicant: DSM Nutritional Products
  - Adopted 18 September 2014
    - DHA: minimum of 22.5%
    - EPA: minimum of 10%
- Safety of *Schizochytrium* sp. oil as a novel food pursuant to Regulation (EU) 2015/2283

  - https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6242
  - Applicant: Progress Biotech bv
  - Adopted 31 August 2020
    - DHA: ~44%
    - EPA: <1%
- Safety of oil from *Schizochytrium limacinum* (strain FCC-3204) for use in food supplements as a novel food pursuant to Regulation (EU) 2015/2283
  - https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6345
  - Applicant: Fermentalg
  - Adopted 24 November 2020
    - DHA: >55%
    - EPA: <1%
- Safety of oil from Schizochytrium *limacinum* (strain FCC-3204) for use in infant and follow-on formula as a novel food pursuant to Regulation (EU) 2015/2283
  - https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6344
  - Applicant: Fermentalg
  - Adopted 24 November 2020
    - DHA: >55%
    - EPA: <1%

NORTH AMERICA

Canada

- In 2006, in response to Novel Food Notification 131, Health Canada did not object to the sale of a DHA rich oil (35% by weight DHA) from *Schizochytrium* sp. as a food ingredient for the general population.
- While the EPA/DHA specifications are unclear, GOED is aware of non-novel determinations for:
  - DHA-rich algal oil sourced from *Schizochytrium* sp. strain T18
  - DHA-rich oil sourced from *Schizochytrium* sp. FCC-3204
  - DHA-rich oil sourced from *Schizochitrium* sp. strain DHF
- In multiple ingredient fixed oil products, *Schizochytrium* oils with an EPA content up to 3.9% and DHA content from 22 to 55% are permitted. http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=multiple.oil&lang=eng

United States

Generally Recognized as Safe (GRAS) Notifications

In the United States, many algal oils from *Schizochytrium* sp. are permitted to be sold for a number of intended uses. The first such oil was acknowledged (i.e. letter of no objection) by the United States FDA over 20 years ago. Since that time, the Agency has sent 12 additional letters of no objection in response to GRAS Notifications.

While each algal oil GRAS Notification includes a unique fatty acid profile, the majority of FDA's letters of no objection focus only on the level of DHA.

- GRN 41 Martek Biosciences Corporation (now DSM Nutritional Products) https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=41&sort=GRN_No&order=DESC&startrow=1&type=basic&search=dha
    - Intended Use: term infant formula
    - Filing Date: March 1, 2000
    - Date of Closure: May 17, 2001
        - DHA: 40%
        - EPA: <1%
- GRN 137 Martek Biosciences Corporation (now DSM Nutritional Products) https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=137&sort=GRN_No&order=DESC&startrow=1&type=basic&search=schizochytrium
    - Intended Use: ingredient in the food categories listed in 21 CFR 184.1472(a)(3) and in the additional food categories listed in GRN 000105 (i.e. soy protein bars; processed vegetable drinks; hard candy; soft candy; non-dairy and powdered cream substitutes; jams and jellies; milk, dry and powdered mixes; milk-based meal replacements; flavored milk and milk products; and non-dairy milk, imitation and soy milk)
    - Filing Date: August 21, 2003
    - Date of Closure: February 12, 2004
        - DHA: 35%
        - EPA: <3%
- GRN 553 DSM Nutritional Products https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=553
    - Intended Use: preterm and term infant formula
    - Filing Date: December 23, 2014
    - Date of Closure: June 19, 2015
        - DHA: minimum 35%
        - EPA: maximum 10%
- GRN 677 Mara Renewables Corporation https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=677
    - Intended Use: preterm and term infant formula
    - Filing Date: November 21, 2016
    - Date of Closure: May 2, 2017
        - DHA: minimum 35%
        - EPA: < 2%
- GRN 731 Linyi Youkang Biology Co., Ltd. https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=731&sort=GRN_No&order=DESC&startrow=1&type=basic&search=dha
    - Intended Use: infant formula

  - Filing Date: October 16, 2017
  - Date of Closure: April 6, 2018
    - DHA: 50 g/100g
    - EPA: <1g/100g
- GRN 776 Fermentalg
https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=776&sort=GRN_No&order=DESC&startrow=1&type=basic&search=dha
  - Intended Use: infant formula
  - Filing Date: May 14, 2018
  - Date of Closure: October 26, 2018
    - DHA: min 350 mg/g
    - EPA: <1 mg/g
- GRN 777 Fermentalg
https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=777&sort=GRN_No&order=DESC&startrow=1&type=basic&search=dha
  - Intended Use: infant formula
  - Filing Date: May 14, 2018
  - Date of Closure: October 26, 2018
    - DHA: min 550 mg/g
    - EPA: <1 mg/g
- GRN 836 Xiamen Huison Biotech Co., LTD
https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=836&sort=GRN_No&order=DESC&startrow=1&type=basic&search=schizochytrium
  - Intended Use: Ingredient in gelatin desserts or salads, and vegetable oils
  - Filing Date: March 7, 2019
  - Date of Closure: September 3, 2019
    - DHA: 50—60%
    - EPA: <1%
- GRN 843 Fermentalg
https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=843&sort=GRN_No&order=DESC&startrow=1&type=basic&search=dha
  - Intended Use: Ingredient in food categories listed in 21 CFR 184.1472(a)(3)
  - Filing Date: April 10, 2019
  - Date of Closure: October 18, 2019
    - DHA: min 350 mg/g (35%)
    - EPA: <1mg/g (1%)
- GRN 844 Fermentalg
https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=844&sort=GRN_No&order=DESC&startrow=1&type=basic&search=dha
  - Intended Use: Ingredient in food categories listed in 21 CFR 184.1472(a)(3)
  - Filing Date: April 10, 2019
  - Date of Closure: October 18, 2019

    - DHA: min 550 mg/g (55%)
    - EPA: <1mg/g (1%)
- GRN 862 BASF Corporation
https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=862&sort=GRN_No&order=DESC&startrow=1&type=basic&search=dha
    - Intended Use: in milk- and soy-based infant formula
    - Filing Date: July 22, 2019
    - Date of Closure: June 15, 2020
        - DHA: ≥ 380 mg/g (38%)
        - EPA: < 2 mg/g (2%)
- GRN 913 Mara Renewables Corporation
https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=913&sort=GRN_No&order=DESC&startrow=1&type=basic&search=dha
    - Intended Use: ingredient in the food categories listed in 21 CFR 184.1472(a)(3)
    - Filing Date: April 13, 2020
    - Date of Closure: November 10, 2020
        - DHA: min 35%
        - EPA: <1%
- GRN 933 Hubei Fuxing BioTechnology, Co., Ltd.
https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=933&sort=GRN_No&order=DESC&startrow=1&type=basic&search=dha
    - Intended Use: ingredient in the food categories listed in 21 CFR 184.1472(a)(3)
    - Filing Date: July 21, 2020
    - Date of Closure: November 13, 2020
        - DHA: ≥ 36%
        - EPA: <1%

New Dietary Ingredient (NDI) Notifications

Below are NDI Notifications which received positive responses from the FDA. While each algal oil is associated with a unique fatty acid profile, the focus of the FDA is on only EPA and DHA.

- NDI 17 - SeaGold DHA-rich oil from *Schizochytrium* sp.
    - Notifier: Monsanto
    - Date Received by FDA: December 22, 1997
    - https://downloads.regulations.gov/FDA-1998-S-1294-0004/attachment_1.pdf
        - DHA: 35%
        - EPA: 13%
- NDI 679 - DHA and EPA Algal Oil derived from fermentation of the microalgae *Schizochytrium* sp.
    - Notifier: Martek Biosciences
    - Date Received by FDA: November 17, 2010
    - https://www.regulations.gov/document/FDA-1995-S-0039-0312

    - DHA: minimum 225 mg
    - EPA: minimum 100 mg
- NDI 813 - DHA Algal Oil from *Schizochytrium* (DHA-B)
    - Notifier: DSM Nutritional Products
    - Date Received by FDA: November 25, 2013
    - https://downloads.regulations.gov/FDA-2014-S-0023-0015/attachment_1.pdf
        - EPA+DHA: Minimum 40%

United States Pharmacopeia's Food Chemicals Codex

Currently, the monograph for "DHA from Algal (*Schizochytrium*) Oil" from the United States Pharmacopeia's Food Chemicals Codex stipulates DHA and EPA ranges (area %) of 30-40% and 1.3-3.9%, respectively, but the monograph is undergoing revision via the Food Chemicals Codex Forum[1] with a proposal to expand the monograph with new *Schizochytrium* oil types that contain significant concentrations of EPA that range from 3.5 to 20.0%, in addition to DHA (20.0-35.0%).

SOUTH AMERICA

Brazil

Brazil has authorized edible oils from *Schizochytrium* sp., but has not established specifications. See Agência Nacional de Vigilância Sanitária (ANVISA) Perguntas & Repostas Suplementos Alimentares 7ª edição - 5 de abril de 2021 which mentions that both DHA and EPA can be obtained from *Schizochytrium* sp. https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/alimentos/perguntas-e-respostas/suplementos-alimentares.pdf/@@download/file/Suplementos%20Alimentares_7%C2%AA%20edi%C3%A7%C3%A3o.pdf

Chile

Chile has authorized edible oils from *Schizochytrium* sp., but did not establish specifications. See Reglamento Sanitario de los Alimentos DTO. N° 977/96 (D.OF. 13.05.97) https://www.minsal.cl/sites/default/files/files/DECRETO_977_96%20actualizado%20a%20Enero%202015(1).pdf which references Resolución exenta Nº586 de 12.02.12 del Ministerio de Salud, publicada en el Diario Oficial de 27.09.12 "Autoriza la obtención de aceites comestibles a partir de los frutos de Vitellaria Paradoxa y Shorea Stenoptera y de la Microalga *Schizochytrium* SP". https://www.bcn.cl/leychile/navegar?i=1044151

[1] https://www.foodchemicalscodex.org/fcc-forum