



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](mailto: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<sup>1</sup>

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<sub>22</sub>H<sub>42</sub>O<sub>2</sub>) 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;**

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<sup>1</sup> [http://food.fda.moph.go.th/law/data/announ\\_moph/P421.pdf](http://food.fda.moph.go.th/law/data/announ_moph/P421.pdf)



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- **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,

A handwritten signature in blue ink, appearing to read "Harry B. Rice".

Harry B. Rice, PhD  
VP, Regulatory & Scientific Affairs  
[harry@goedomega3.com](mailto:harry@goedomega3.com)

A handwritten signature in black ink, appearing to read "Gerard Bannenberg".

Gerard Bannenberg, PhD  
Director, Technical Compliance & Outreach  
[gerard@goedomega3.com](mailto:gerard@goedomega3.com)



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## 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:  $\geq 35.0$
- 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%20Functiona1%20Food%20Code.pdf](https://www.mfds.go.kr/files/upload/eng/7_Health%20Functiona1%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



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- <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/nhp/nd-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.



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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](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](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](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



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- 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](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](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](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](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](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



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- 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](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](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](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](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>



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- 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](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<sup>1</sup> 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 & Respostas 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](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](https://www.minsal.cl/sites/default/files/files/DECRETO_977_96%20actualizado%20a%20Enero%202015(1).pdf) which references Resolución exenta N°586 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>

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<sup>1</sup> <https://www.foodchemicalscodex.org/fcc-forum>