



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

30 July 2025

RE: Public Consultation No. 1,324, dated April 17, 2025 - Proposal for a Normative Instruction Establishing the Specifications for the Identity, Purity and Composition of Ingredients Authorized for Use in Food

Submitted electronically at <https://pesquisa.anvisa.gov.br/index.php/576786>

Dear Mr. Meirelles Fernandes Pereira and Mr. Rodrigues Mota:

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 industry, with a mission to use science-based information to promote the consumption of and enable access to quality EPA & DHA from all sources for a positive impact on public health. Our 200+ members represent the entire supply chain from fisheries and crude oil suppliers to refiners, concentrators and brands. Our activities focus on maintaining quality standards, educating consumers and healthcare professionals, advancing science, and advocating for members with governments and non-governmental organizations (NGOs) throughout the world.

GOED appreciates the opportunity to provide comments regarding [Public Consultation No. 1,324, dated April 17, 2025 - Proposal for a Normative Instruction that establishes the specifications for the identity, purity and composition of ingredients authorized for use in food.](#)

Our comments focus primarily on our concern that a large number of demonstrably safe algae oils from Schizochytrium (hereafter referred to as Schizochytrium oils) are not adequately represented in the Normative Instruction. We have also included several unrelated but important comments.

Schizochytrium Oils are Not Adequately Represented

GOED is concerned that many safe Schizochytrium oils have been inadvertently left out of the Normative Instruction and could have the unintended consequence of impeding free trade. Below we propose two solutions for your consideration.

1) Expand the annexes to include other Schizochytrium oils.

In Annexes I and II of the Proposal, ANVISA provides specifications for different Schizochytrium oils, but the annexes are incomplete. Annex I establishes the list of ingredients that must meet the approved identity, purity and composition specification and includes one Schizochytrium oil (i.e. listed in Annex I as Oil from *Aurantiochytrium*¹ sp. NH6181). Annex II establishes the list of ingredients that must meet the specifications of identity, purity and composition of approved references (e.g. [Commission Implementing](#)

¹Schizochytrium oil is derived from microalgal species that are or have historically been classified under the genus Schizochytrium. These include species currently organized into other genera, including Aurantiochytrium.



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[Regulation \(EU\) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation \(EU\) 2015/2283 of the European Parliament and of the Council on novel foods](#), Food Chemicals Codex (FCC), and the United States Pharmacopeia (USP)) and includes three Schizochytrium oils.

Absent from these annexes are Schizochytrium oils that are permitted to be sold in the European Union, United States or associated with pharmacopeial monographs. We believe this limits consumer choices of a range of Schizochytrium oils that have been demonstrated to be safe and suitable for a range of intended uses. While the United States is not specifically mentioned in Article 19 of [Resolution RDC No. 839 of 12/14/2023](#), it is our understanding that the resolution allows for equivalence assessments by foreign regulatory authorities (e.g. United States). For this reason, in the United States, the Schizochytrium oils that have been the subject of a Generally Recognized as Safe (GRAS) Notification or New Dietary Ingredient Notification (NDIN) and received a letter of no objection or letter of acceptance of the NDIN for filing, respectively, should be included in the annexes.

Annex II includes the following three Schizochytrium oils: *Schizochytrium* sp. microalgae oil, *Schizochytrium* sp. T18 microalgae oil, and *Schizochytrium* sp. ATCC 20888 microalgae oil, the first two of which are included in *Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods*. Among the Schizochytrium oils that are included in the Union list, but missing from either Annex I or II, and thus should be added, are the following:

- *Schizochytrium* sp. oil rich in DHA and EPA (Use includes “food supplements” and other categories)
- *Schizochytrium* sp. (CABIO-A-2) oil (Use includes only “Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013”)
- *Schizochytrium* sp. (FCC-3204) oil (Use includes only “Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013” and “food supplements”)
- *Schizochytrium* sp. (WZU477) oil (Use is limited to “Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013”)
- *Schizochytrium limacinum* (TKD-1) oil (Use is limited to “Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013”)

2) Adopt a single specification based on work by the Codex Alimentarius Commission (CAC).

Currently, an electronic working group (EWG) of the Codex Committee on Fats and Oils (CCFO) is working on the development of a standard for microbial omega-3 oils, including Schizochytrium oils. GOED is a member of the EWG, as is Brazil. We propose a specification based on GOED’s last feedback to the EWG. While the work remains in progress and may not be the specification that is ultimately adopted, what we are proposing is



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based on occurrence data from our membership, which includes Schizochytrium oil producers and brand owners.

EPA and DHA content of Schizochytrium Oils (expressed by weight in g/100 g oil)

Fatty Acids	DHA Oil	EPA & DHA Oil
EPA	≤ 5.0	≥ 10.0
DHA	≥ 30.0	≥ 5.0

Quality Parameters of Schizochytrium Oils

Parameter	Value
Peroxide Value (milliequivalent of active oxygen/kg oil)	≤ 5
Anisidine Value	≤ 20
Total oxidation number (TOTOX)	≤ 26
Acid Value (mg KOH/g oil)	≤ 3
Unsaponifiable matter (g/100g)	≤ 4.5

Other Comments

- In Annex II, the entries for Cod Liver Oil and Krill Oil should, like the entry for Fish Oil, include a reference to the Codex Standard for Fish Oils (CXS 329-2017).
- *Ulkenia* sp. algae oil is listed in Annex II. FCC and USP are listed as references, but there is no USP monograph for this oil type. Thus said, we recommend removing the option of complying with USP.
- Annex I includes "DHA and EPA obtained from omega-3 lysinate." We propose renaming to "EPA and DHA lysinate" or "EPA and DHA lysine complex," because EPA and DHA are not obtained from lysinate, rather the lysinate of EPA and/or DHA are the lysine salts of EPA and DHA, produced from EPA and DHA free fatty acid concentrates (we don't know the exact production details).
- In Annex I, *Aurantiochytrium* NH6181 oil is listed with a peroxide value of ≤ 10 mEq/kg oil. We suggest considering a maximum peroxide value of ≤ 5 mEq/kg for alignment with other international standards, which typically set a maximum peroxide value of ≤ 5 mEq/kg oil for Schizochytrium oils.



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- Ingredients listed in the Normative Instruction and those included in ANVISA's search tool - [Approved New Foods, New Ingredients, Probiotics and Enzymes](#) – should be aligned to ensure naming consistency, prevent misinterpretation and allow each ingredient to be easily found in both sources (or enable accurate identification of each substance across both sources).

Thank you in advance for your consideration of GOED's comments. Should you have any questions, please do not hesitate to contact us.

Sincerely,

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

Harry B. Rice, PhD
Vice-President, Regulatory & Scientific Affairs

A handwritten signature in blue ink, appearing to read "Gabriela A. Cortez R.".

Gabriela A. Cortez R., MSc
Regulatory & Technical Support Manager

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

Gerard Bannenberg, PhD
Director, Technical Compliance & Outreach