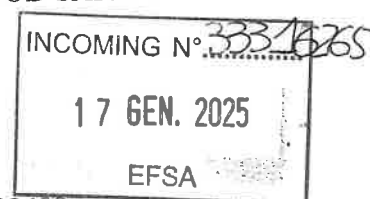




EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Directorate E – Food safety, sustainability and innovation
E2 - Food processing technologies and novel foods



Brussels,
SANTE/E2/IB/amf (2025)633409

Dear Ms Afonso,

Subject: Request for a scientific opinion on the safety of supplemental docosahexaenoic acid (DHA)

On 24 September 2024, EFSA adopted a scientific opinion on the “Safety of an extension of use of oil from *Schizochytrium limacinum* (strain FCC-3204) as a novel food pursuant to Regulation (EU) 2015/2283”¹. In its opinion, EFSA concluded that the novel food oil from *Schizochytrium limacinum* (strain FCC-3204) is safe under the new intended use.

In the same opinion, EFSA provided intake estimates of docosahexaenoic acid (DHA) from the authorised novel food sources (excluding food supplements) showing that the anticipated intake estimates of DHA from the authorised uses ranged from 0.1-2.4 g/day (mean intake) and from 0.3-4 g/day (95th percentile intake). According to these data, the intake of DHA from the authorised uses could be above 1g DHA /day, the safe level of intake established by the NDA Panel in 2012 in its “Scientific Opinion related to the tolerable upper intake level of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA)”².

In light of the above, the Commission would like to request EFSA to reassess the safe level of intake for DHA and to establish a Tolerable Upper Intake Level for DHA, for all population groups, at the latest by end of June 2026, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002³.

Please find herewith the background and the terms of reference for this request.

My services remain at your disposal for further information. You can contact [REDACTED] who is responsible for this dossier in Unit E2 ‘Food processing technologies and novel foods’

¹ EFSA Journal. 2024;22:e9043.

² EFSA Journal, 10(7), 2815.

³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Ms Ana Afonso, Head of Unit
Nutrition and Food Innovation Unit (NIF)
European Food Safety Authority
Via Carlo Magno 1A
43126 Parma
ITALY

and [REDACTED], who is the relevant contact point in Unit E1 'Farm to fork strategy'.
Their respective phones and e-mail addresses are indicated below.

Yours sincerely,

Sabine Pelsser
Head of Unit

Annex: Request for a scientific opinion on the safety of supplemental
docosahexaenoic acid (DHA)

[REDACTED]

[REDACTED]

ANNEX

European Commission request to the European Food Safety Authority

FOR A SCIENTIFIC OPINION ON:

THE SAFETY OF SUPPLEMENTAL DOCOSAHEXAENOIC ACID (DHA)

1. BACKGROUND

On 24 September 2024, EFSA adopted a scientific opinion on the “Safety of an extension of use of oil from *Schizochytrium limacinum* (strain FCC-3204) as a novel food pursuant to Regulation (EU) 2015/2283”⁴. In its opinion, EFSA concluded that the novel food oil from *Schizochytrium limacinum* (strain FCC-3204) is safe under the new intended use.

The above-mentioned opinion refers to EFSA’s “Scientific Opinion related to the tolerable upper intake level of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA)” adopted by the EFSA NDA Panel in 2012.

In its 2012 opinion, EFSA concluded that a tolerable upper intake level for DHA could not be established. However, the Panel noted that supplemental intakes of EPA and DHA combined at doses up to 5 g/day, and supplemental intakes of EPA alone up to 1.8 g/day, do not raise safety concerns for the adult population. The Panel also considered that supplemental intakes of DHA alone up to about 1 g/day do not raise safety concerns for the general population (safe level of intake). Limited data were available on the effects of long-term supplementation with DHA alone at higher doses. The Panel noted that specific dietary recommendations for DHA for European adults and children were well below this amount.

In the recent 2024 opinion, EFSA provided anticipated intake estimates of DHA from the authorised novel food sources (excluding food supplements) showing that the anticipated intake of DHA from the authorised uses ranges from 0.1-2.4 g/day (mean intake) and from 0.3-4 g/day (95th percentile intake). According to these data, the intake of DHA from the authorised uses could be above 1g DHA /day, the safe level of intake established by the NDA Panel in 2012 scientific opinion.

2. TERMS OF REFERENCE

In accordance with Article 29(1)(a) of Regulation (EC) 178/2002, the European Commission asks the European Food Safety Authority to provide a scientific opinion on the safety of supplemental docosahexaenoic acid (DHA).

In particular, EFSA is requested to:

- reassess the safe level of intake of 1g/day for supplemental DHA alone established for the general population by the NDA Panel in 2012, in view of the scientific data that has become available since then. To that end, EFSA is requested to review new available data of long-term supplementation with DHA alone at doses at or above the current safe level of intake of 1g/day;

⁴ EFSA Journal. 2024;22:e9043.

- establish a safe level of intake or, if data allows, a Tolerable Upper Intake Level for supplemental DHA alone for all population groups and, as appropriate, for specific vulnerable subgroups of the population.

