

CODEX COMMITTEE ON FATS AND OILS

28th Session

Kuala Lumpur, Malaysia

19 - 23 February 2024

European Union Comments

Agenda Item 6:

**Proposed draft Amendment/Revision to the *Standard for Fish Oils*
(CXS 329-2017): Inclusion of Calanus Oil
(CX/FO 24/28/9 and CL 2023/62-FO)**

*European Union Competence.
European Union Vote.*

The European Union (EU) thanks Norway and the EWG for the preparation of this work.

In the EU, foods falling under the Novel Food Regulation are subject to a pre-market authorisation that involves a safety assessment by EFSA, covering, among others, the production process. Similar to any other novel food (NF) that are authorised in the EU, a procedure that includes a food safety assessment must be established and implemented.

The EU notes that the proposed Standard consists mainly of qualitative parameters. However, the EU is of the view that safety-related specifications (e.g., astaxanthin esters levels) and the conditions under which the calanus oil may be used should be included. In the EU and based on the acceptable daily intake (ADI) established by EFSA, calanus oil is only authorised in food supplements, excluding food supplements for infants and young children, with maximum levels of:

- 1,0 g/day (< 0,1 % astaxanthin esters, resulting in < 1,0 mg astaxanthin per day) for the general population, excluding infants and young children.
- 2,3 g/day (from 0,1 % to ≤ 0,25 % astaxanthin esters, resulting in ≤ 5,75 mg astaxanthin per day) for the general population older than 14 years of age.

Moreover, the EU legal act authorising this novel food establishes additional labelling requirements for calanus oil to ensure that consumers only use the food supplements intended for their age group, and to warn consumers not to use this novel food supplement, when other food supplements containing astaxanthin esters are consumed on the same day:

- a) if other food supplements containing astaxanthin esters are consumed on the same day.
- b) by infants and children younger than 3 years.
- c) by children younger than 14 years, if the ingredient contains ≥ 0,1 % astaxanthin.

Equally, the maximum level of trans fatty acids should also be specified. For calanus oil, in the EU, the legal limit is set at <1%

The specifications of calanus oil laid down in EU legislation are:

Water: < 1,0 %

Wax esters: > 85 %

Total fatty acids: > 46 %

Eicosapentaenoic acid (EPA): > 3,0 %

Docosahexaenoic acid (DHA): > 4,0 %

Total fatty alcohols: > 28 %

C20:1 n-9 fatty alcohol: > 9,0 %

C22:1 n-11 fatty alcohol: > 12 %

Trans fatty acids: < 1,0 %

Astaxanthin esters: \leq 0,25 %

Peroxide value (PV): < 3,0 meq. O₂/kg