

APPENDIX

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods

Consultation request for a determination of novel food status pursuant to Article 4(2) of the above Regulation

Information pursuant to Article 7 of Implementing Regulation (EU) 2018/456

1. Name and description of the food concerned

Palmitoleic acid ethyl ester,
Concentrates from Alaska pollock fish oil (*Gadus chalcogrammus*)

Two concentrates from Alaska pollock fish oil (*Gadus chalcogrammus*) which contain at least 50% (in the case of the first product) and at least 70% (second product) palmitoleic acid ethyl ester after transesterification and distillation.

2. Novel food status

The products are novel.

3. Food category under which the food falls

The foods fall under the category in Article 3(2)(a)(v) of Regulation (EU) 2015/2283 (food isolated or produced from animals or their parts).

4. Justification

The documentation submitted did not provide any evidence that the foods in question were used for human consumption to a significant degree within the Union before 15 May 1997 (significant consumption).

The consultation exercise involving the senior German federal-state authorities responsible for food monitoring, EU Member State authorities and the European Commission likewise yielded no information indicating significant consumption of the products.

In the European Commission's Novel Food Catalogue, 'ethyl esters (concentrated from fish oils)' generally are only classified as not novel in food supplements.

The description in the Catalogue highlights the ethyl esters of long-chain ω -3 polyunsaturated fatty acids (PUFAs) – particularly eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) – as being characteristic, although this is not an exhaustive list.

The products under consideration here contain these fatty acids (PUFAs) only in very small quantities (0.2% or less). In their case, it is the ethyl ester of the ω -7 fatty acid palmitoleic acid that is the determining component for the values (50% and 70%).

They are therefore different from the product underlying the entry in the Novel Food Catalogue, which is considered to have a history of use as a food supplement before 15 May 1997.

For the products in question here, there is accordingly no information to indicate that they were used as a food supplement before 15 May 1997.