Application for consultation to determine the status of a novel food, pursuant to art. 4(2) of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods

Recipient Member State:

Główny Inspektorat Sanitarny (The Chief Sanitary Inspectorate) – Poland.

Name and description of the novel food:

The request concerns Tributyrin.

Tributyrin is a triglyceride obtained by formal acylation of the three hydroxy groups of glycerol by butyric acid. It is a triglyceride and a butyrate ester.

As a result of verification of the available data, the Applicant did not identify data confirming consumption to a significant degree of this product as food before 15 May1997 in the European Union.

Status:

The product is novel food.

Novel food category:

Art. 3(2)(a)(i) of the regulation (EU) 2015/2283 - food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997.

Reasons statement:

Tributyrin is obtained through chemical synthesis. There is no information available indicating that it was used for human consumption to a significant degree in the European Union before 15th of May 1997.

Conclusion:

Tributyrin is a novel food, and therefore it falls within the scope of Regulation (EU) 2015/2283 on novel foods, unless it is considered as flavouring referred to the Regulation No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods.