

Application for consultation to determine the status of a novel food, pursuant to Article 4(2) of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25th November 2015 on novel food, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1–22).

Recipient Member State:

Główny Inspektor Sanitarny (Chief Sanitary Inspector) - Poland.

Name and description of the food product concerned:

Liposomal vitamin C intended for food supplements, foods for special medical purposes, containing: L-ascorbic acid and plant based excipients: inulin and sunflower lecithin. The manufacturing process used in production: spray drying and homogenization. The average size of the particles is not smaller than 100 nm.

Status:

Not a novel food.

Novel food category (where applicable):

Not Applicable.

Reasons statement:

All ingredients and the technological process used applied the liposomal vitamin C had been used before 15th May 1997 in food industry in the European Union's countries. Moreover the liposomal vitamin C was available on the EU's market as a food/ food supplement. Following information provided by member states, the Chief Sanitary Inspector is aware that a history of consumption exists for this product – liposomal vitamin C as a food/ food supplement in the EU prior to 15th May 1997 and therefore it does not fall within the scope of the Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25th November 2015 on novel food.

Conclusion:

Based on the data received, history of consumption (HOC) in the European Union's countries prior to 15th May 1997. The liposomal vitamin C does not imply changes on the structure, nutritional value, metabolism of vitamin C and the average size of the particles is not smaller than 100 nm therefore do not fall within the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods.