

Summary of the dossier: Betaine

Applicant: DuPont Nutrition Biosciences ApS, Langebrogade 1 Copenhagen K, DK-1411, Denmark

This is an application for authorisation to place on the market betaine extracted from sugar beet as a novel food to be used in foods destined for athletes (drink powders, isotonic ready to drink beverages, protein and cereal bars, meal replacements); in total diet replacements foods for weight control and foods for special medical purposes (excluding those for infants and young children) as defined in Regulation (EU) No 609/2013.

The applicant submitted a dossier in April 2015 pursuant Regulation (EC) No 258/97. With the entry into force of the new novel food Regulation (EU) 2015/2283 on 1 January 2018, the applicant adapted the dossier to the requirements of the new novel Regulation and in line with the EFSA opinion of October 2017 on the safety of betaine extracted from sugar beet. The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with the European Food Safety Authority (EFSA) guidance on the preparation and presentation of an application for authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283

Betaine is obtained from the processing of sugar beets. The application is supported by toxicological data and human studies demonstrating the safety of betaine in the intended food uses. The available studies show betaine is not genotoxic, and safety levels of 400 mg/person/day, could be derived from the available sub-chronic and chronic toxicity studies in experimental animals and the studies in human volunteers. Betaine is found in the food of a typical diet. Thus, the additional 400 mg/person/day, is the safe level of betaine as the total intake. No allergies from using betaine in foods has been reported. The intake estimates provided by the applicant indicate that the consumption of foods containing betaine will not exceed the safe intake levels both for the intended segments of the population and the non-intended segments of the population which could also consume betaine containing foods.