

Summary of the application: L-Fucose

Applicant: Setenta e Três Mil e Cem, Lda, sited in Rua Ivone Silva, Edifício Arcis, 6, 4º, 1050-124 Lisboa, Portugal

This application for a novel food authorisation of the monosaccharide L-Fucose under Regulation (EU) 2015/2283.

L-Fucose is intended to be used in a variety of foodstuff products such as dairy products, infant and follow-on formulae and flavoured drinks to be consumed by general population. The proposed maximum use level of the Novel Food L-Fucose depends on the specific food category and ranges from 30 mg/L to 250 mg/L in the final food product.

L-fucose is a hexose-deoxy-sugar endogenous in mammals and is one of the eight essential monosaccharides to humans. This rare sugar is involved in a wide array of biological functions. L-fucose is also a building block in several natural occurring oligo- or polysaccharides. This monosaccharide has been consumed to a significant degree by humans for centuries. This sugar can be found as free monosaccharide or as part of macromolecules covalently bound to other sugars or proteins, which are metabolized by humans. Infants and young children consume L-fucose via breast milk as free L-fucose and as a building block in Human Milk Oligosaccharides. Adults consume L-fucose mainly as bound in fucosylated carbohydrates (e.g. fucoidan) and glycoproteins and as free L-fucose produced by intestinal microbiota. As source of bounded L-fucose, fucoidan ingredients are currently available for use in dietary supplements and for inclusion in pet, livestock and aquaculture feed supplements. As a free sugar or as part of polysaccharide fibres and other macromolecules, L-fucose is present in a balanced diet because it can be found as part of very differentiate foods, ranging from fruits, vegetables, plants, seaweeds and mushrooms and as part of oligosaccharides and glycans in the animal kingdom as in human breast milk at concentrations of 20 to 30 mg/L.

Humans can metabolize L-Fucose, which is endogenously synthesized in its activated metabolite - GDP-L-Fucose - that works as a donor in a metabolic process called fucosylation, an enzyme-promoted glycosylation performed by a specific protein called *Fucosyltransferase*. The synthesis of GDP-L-fucose can be done in two ways: The de novo pathway, in which L-Fucose is synthesized enzymatically through GDP-D-mannose and the salvage pathway where L-fucose is derived from existing glycoconjugates or from dietary sources, is taken into cells via a specific transport protein.

The Novel Food is produced by hydrolysis of a Fucose-rich polysaccharide expelled to medium during microbial fermentation, using a patented invention.

The application is supported by a number of studies and scientific data, which aim to demonstrate the safety of this novel food. No adverse effects were observed in toxicological studies provided. Moreover, L-Fucose is not genotoxic or mutagenic. The results of the 13-week dietary toxicity study provided with an in utero phase, together with the negative genotoxicity results, support the safety of L-fucose dietary consumption in humans at suggested acceptable daily intakes (ADI) of 5 mg/kg bw. The anticipated average ranges of dietary daily intake to L-Fucose (mg/kg bw) based on the individual data from the EFSA Comprehensive Food Consumption Database using the FAIM tool in all population groups are below the ADI. Moreover, these ranges are below the estimated daily intake levels of L-Fucose from breast milk in infants.

Based on the submitted evidence, the applicant concludes that the Novel Food L-Fucose does not raise safety concerns at the proposed uses.