

Application for the Approval of Allulose as a Novel Food Ingredient in the European Union

Ingredient: Allulose

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CJ-Tereos Sweeteners Europe SAS wishes to market allulose, a naturally occurring monosaccharide (C-3 epimer of D-fructose), as an ingredient in the European Union (EU). Allulose has sweetness 70% that of sucrose but with almost no caloric value and is intended for use as a food ingredient in sugar- or energy-reduced foodstuffs.

While allulose is a naturally occurring saccharide, it has almost no caloric value. Under Annex II of Regulation (EC) 1333/2008, allulose does not fit within the definition of a food additive identified under Article 3, which states that the following are 'not considered to be food additives': "i) monosaccharides, disaccharides or oligosaccharides and foods containing these substances used for their sweetening properties". As such, approval is sought for allulose as a Novel Food ingredient under Regulation (EU) 2015/2283.

Allulose occurs in 2 forms: a crystalline form and a syrup form. It is produced by the epimerisation of fructose at the C-3 position, in a reaction catalysed by D-psicose 3-epimerase, which is contained within a non-viable, immobilised cell system. Fructose solution is added into the immobilised cell system, which is subjected to decolourisation with carbon, ion exchange purification (to remove impurities), then evaporation to produce a syrup (containing both allulose and fructose). Allulose is separated from other sugars using separation chromatography and then evaporated again, which produces the syrup form of allulose. The liquid form is crystallised, centrifuged, then washed and dried to produce the crystalline form of allulose. Batch data for both forms demonstrate a consistent product that aligns with the proposed specification.

Allulose has a long history of safe consumption at low amounts, as it occurs in small quantities in a variety of commonly consumed foods and beverages (including cakes, dried fruits, and condiments), with estimated daily intakes from these "natural" sources alone of approximately 206 mg/day. Furthermore, allulose is permitted for use as an ingredient in various jurisdictions globally (including the United States, Colombia, Japan, Korea, Mexico, and Singapore) and has been consumed in these jurisdictions for several years.

As allulose has almost no caloric value, it is proposed to be used as direct replacement for sugars. Foods containing allulose are intended for consumption by the general population seeking products with a reduced sugar content.

Absorption, distribution, metabolism, and excretion (ADME) studies demonstrate that allulose is absorbed in a virtually identical manner to fructose following oral consumption, but is not metabolised into energy, instead being rapidly excreted unchanged in urine. Additionally, allulose has been demonstrated to be involved in fat catabolism, amongst other potentially beneficial effects.

Allulose is non-genotoxic as assessed in *in vitro* and *in vivo* studies. Allulose was generally well tolerated in preclinical toxicity studies (acute, subchronic, and chronic) conducted in rodents and dogs.

Together, the weight of the available evidence on allulose support the safe use of the ingredient under the proposed conditions of use.