Summary of the dossier

Applicant: Tate & Lyle Ingredients France SAS, 2 avenue de l'horizon, 59650 Villeneuve d'Ascq, France

Tate & Lyle proposes to market allulose (also known as psicose), a naturally occurring rare sugar produced by the enzymatic epimerisation of D-fructose, as a novel food, functioning as a low calorie sweetener in a variety of food and beverage products in the European Union (EU). The allulose manufactured by Tate & Lyle is highly purified (>95% purity); it is available as both a crystalline powder and as a syrup. Allulose is a monosaccharide, a C-3 epimer of D-fructose, and it has approximately 70% of the sweetness as sucrose. Epimerisation renders allulose to be almost completely non-metabolizable; therefore, it provides only a fraction of the calories of sucrose (i.e., <0.4 kcal/g). Allulose is present at small quantities in certain commonly consumed foods, including dried fruits (e.g., dried figs and raisins), as well as some processed products (e.g., select bakery products, seasonings, and sauces) (Oshima et al., 2006).

In the EU, "monosaccharides, disaccharides or oligosaccharides and foods containing these substances used for their sweetening properties" are excluded from the definition of a food additive, as defined in Article 3 of Regulation (EC) 1333/2008. Moreover, even though allulose has a long history of consumption as part of existing foodstuffs, these intakes through natural sources are very low, and enzymatically synthesised and purified forms of allulose as proposed hereunder has not been consumed to a significant degree in the EU before May 1997. As such, approval is sought for allulose as a novel food ingredient under Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods, 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 (hereafter referred to as EU 2015/2283).

Allulose is obtained by the epimerisation of D-fructose in a reaction that is catalysed by D-psicose 3 epimerase. The D-fructose is produced from corn syrup using suitable food enzymes. Following the epimerisation reaction, a series of purification steps involving ion-exchange resins, filtration, and vacuum evaporation are applied to generate the highly pure allulose ingredient (>95% purity).

Allulose has been authorised in other jurisdictions (Mexico, Chile, Colombia, Costa Rica, and Singapore, United States) for similar conditions of use as those proposed in the EU. Allulose preparations that are produced by the enzymatic epimerisation of D-fructose by other manufacturers are also commercially available. These allulose preparations are added as a sweetener in a variety of food and beverage intended for consumption by the general population. Tate & Lyle's allulose syrup and crystalline products have been on the market since 2015. Allulose was first listed on the US FDA's GRAS Notification listing in 2012.

Allulose is intended to be used as an ingredient added directly to foods as consumed and as an ingredient in processed foods and dishes. While allulose is not specifically intended to replace another food, it will allow for reduced calorie versions of the same foods.

Studies examining the metabolic fate of allulose following oral intake have been conducted in both rats and humans. Overall, it is apparent that allulose is well absorbed (approximately 70 to 85%) following oral intake, but only small amounts are metabolised or fermented and allulose is rapidly excreted predominantly as unchanged allulose in the urine and faeces. Minor metabolites include glucose and fructose.

As stated in Section 2.10.1 of the Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283, the tiered approach to the safety assessment of food additives (described in the EFSA Guidance for submission for food additive evaluations (EFSA, 2012)] is the also the default approach for safety assessment of novel foods. Using this tiered approach, allulose was determined to be non-genotoxic in two in vitro studies in bacterial and mammalian test systems; Tier 2 test was therefore not required. In preclinical (acute, subchronic, chronic, and developmental) toxicity studies in dogs and rats, allulose was well-tolerated.

A number of clinical studies are available on allulose including those published in the peer-reviewed literature as well as those conducted specifically on Allulose, brand Dolcia Prima®. These studies were conducted to either investigate the effect of allulose on the glycaemic and insulin response or gastrointestinal tolerance. Studies cover various age groups including children, both genders, and healthy and diabetic populations. Based on these studies, allulose is safe for human consumption at 30 g/day (the highest amount tested in the study) and up to 63 g/day (based on 0.9 g/kg body weight/day in a 70-kg adult), when consumed in portions throughout the day (as one would typically, based on multiple meals or snacks throughout the day), and up to 28 to 42 g (based on 0.4 to 0.6 g/kg body weight/day in a 70-kg adult) can be consumed in one sitting.

In summary, allulose is a naturally available sweetener similar to fructose and is already present in our current foods. Animal and human studies have not suggested any adverse pathological effects with allulose at intake levels relevant to human consumption. Similar to some other sweeteners in the market, gastrointestinal intolerance to allulose occurs at very high doses.