Public summary

D-tagatose is a monosaccharide that can be found in very small quantities in dairy and various fruits. It is approximately 90 % as sweet as sucrose and can be used in similar applications. D-tagatose consumption has been associated with numerous physiological benefits including improvements in glycemic and dental health. Due to its low natural abundance, D-tagatose is produced synthetically for commercial use as an ingredient in foods and beverages.

D-tagatose manufactured from galactose or fructose is currently approved for use in food in many countries, including the UK, EU, US, Canada and Mexico. These approved production methods utilise enzymatic processing aids to facilitate bioconversion to D-tagatose.

D-tagatose produced from maltodextrin is currently approved for use in food in the US, Canada and Mexico. Bonumose, Inc. of 1500 State Farm Blvd, Charlottesville, VA 22911, USA submits this application to request a modification of the D-tagatose specification outlined in Commission Implementing Regulation 2017/2470 establishing the Union list of novel foods such that production by “enzymatic conversion of maltodextrin” be included in the Description. Maltodextrin is a well-known food ingredient with an established history of safe use. Conversion of maltodextrin to D-tagatose is achieved through the use of 7 immobilised enzymes, one of which has a history of safe use in food production.

The other 6 enzymes used in D-tagatose production are derived from non-toxic, non-pathogenic organisms and expressed in a non-toxic, non-pathogenic strain of *Escherichia coli* that has an established history of use in the food and biotechnology industries. Fermentation and enzyme purification is carried out using conventional methods to yield enzymatic processing aids of sufficient purity and stability that support efficient, commercialisable D-tagatose production. Structural analyses using three allergen databases and one toxin database indicate that none of these enzymes are likely to be potential allergens or cross-react with potential allergens. The enzymes are immobilised on a food-safe carrier to convert food-grade maltodextrin into D-tagatose. Enzyme purification and immobilisation ensures that no residual microorganisms or enzymes are present in D-tagatose, and thus there is no consumer exposure to the processing aids or the materials used in the production of the processing aids.

Following its enzymatic conversion from maltodextrin, downstream processing of D-tagatose is carried out using standard methods of sweetener processing according to GMP using food-safe materials and processes in accordance with the applicable parts of US 21 CFR §§ 110 and 117 and Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food to ensure efficient production of a safe food product. All processing and filtering aids used in the manufacturing process are considered safe and suitable according to Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food. Quality control measures are built into the process, facilitating the production of a high-quality food product with very low risk for potential impurities such as microorganisms, residual

carbohydrates, enzymatic processing aids, and materials used in the production of those processing aids.

Final product testing of D-tagatose produced at the pilot scale demonstrates its compliance with the Food Chemicals Codex monograph for D-tagatose as well as the chemical identity, purity and heavy metal content of the existing D-tagatose specification in Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. Other parameters attesting to its high quality are its compliance with limits set on microorganisms, protein and aspects related to processing aid production.

Because of the alignment of the specifications for D-tagatose produced from galactose and fructose with D-tagatose produced from maltodextrin, D-tagatose produced by the latter process does not alter the results of the existing D-tagatose risk assessment for safety. The intended uses of D-tagatose produced from maltodextrin are identical to those listed in the current D-tagatose specification. Thus, incorporation of D-tagatose produced from maltodextrin into the commercial food supply would not alter the results of the existing risk assessment for its anticipated dietary intake.

This application does include a proposed modification to the specific labelling requirements of D-tagatose such that the common name of “Tagatose” be allowed as an alternative to the chemical name “D-tagatose” on the foodstuff label to improve consumer understanding of food stuff ingredients.

Overall, there is no evidence to suggest that D-tagatose or any elements of its production from maltodextrin present a safety risk to consumers. Therefore D-tagatose produced by this method is safe for human consumption and it should be approved as a novel food.