Summary of the application: Cellobiose

Applicant: SAVANNA Ingredients GmbH; Dürener Straße 67, 50189 Elsdorf, Germany

This application for authorisation of a novel food in accordance with Article 10 of Regulation (EU) 2015/2283 concerns cellobiose, which consists of two glucose molecules linked by a beta-1.4 glycosidic bond. This disaccharide occurs naturally in honey and developing corn seeds and is an integral building block of cellulose, the main component of plant cell walls.

The product is manufactured by a two-step enzymatic conversion from sucrose and glucose to obtain cellobiose, which is subsequently purified and crystallized. The purity of the final product is at least 99%.

Since cellobiose was not consumed to a significant degree within the EU prior to May 15th, 1997, it falls under Article 3(2) (i) of the Novel Food Regulation (EU) 2015/2283: (i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997.

The identity of the product has been verified by NMR and HPLC techniques.

The product shall be used as food ingredient in various foods categories to replace sucrose or lactose, or function as low-calorie sweetener. Additionally, cellobiose is intended to be used as filler and carrier for flavours or high intensity sweeteners in various foods and beverages.

The safety of the novel food is supported by chemical and microbial analyses of five independently manufactured product batches. The specifications comply with EU regulations on microbial criteria (Regulation (EC) 2073/2005) and other contaminants in foodstuffs (Regulation (EC) 1881/2006).

Based on product-specific stability studies, the applicant proposes a shelf life of two years.

The safety of the novel food was further studied by an in-vitro mutagenicity assay (OECD 471), an in-vitro genotoxicity assay (OECD 487) and a sub-chronic oral toxicity study in rats (OECD 408). These studies did not reveal any indications for mutagenic, genotoxic or sub-chronic oral toxic effects at the doses investigated. Accordingly, the OECD 408-compliant study established a NOAEL equivalent to ~ 6852 and ~ 8043 mg cellobiose per kg body weight and day for males and females, respectively, the highest doses investigated. The studies complied with GLP standards.

In healthy humans, cellobiose is only absorbed in very minor amounts. Degradation of cellobiose by intestinal enzymes is also very low and a side reaction of lactase. Intravenous gavage of cellobiose showed almost complete recovery in the urine, indicating negligible metabolism. Cellobiose is degraded by intestinal microbes and confers its nutritional value indirectly via SCFAs released during microbial fermentation. This led to a nutritional value of 2 kcal/g cellobiose.

Literature data as well as a human tolerance study performed by the applicant indicated the tolerable dose of cellobiose consumption to be 20 g cellobiose daily for single-use and 15 g twice daily (30 g total) for repeated consumption.

No indication for an allergenic potential of cellobiose was identified.

The application has been prepared in accordance with the requirements of Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283, 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, and EFSA's Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283.

Overall, by means of analytical, toxicological as well as human data, it was demonstrated that the novel food is safe for humans and devoid of any hazards that would arise from the product itself, the production process or the raw materials.

The applicant requests protection of proprietary data according to Article 26 of regulation (EU) 2015/2283.