

## **Summary of the dossier**

Applicant: Petiva Europe SA, Zoning Industriel C, 1 rue Adolphe Quetelet, Belgium

Name and description of the novel food : Allulose, an epimer of Fructose

The applicant, Petiva Europe SA, submits an application in order to include Allulose in the Union list of novel foods.

Nature produces a large gamut of sugars in very different quantities; the most ubiquitous are Glucose and Fructose which are both structural building blocks and an energy source. The most notorious sugar is Saccharose (also known as sucrose), a dimer of Fructose and Glucose usually extracted from sugar beet or sugar cane.

Nature also produces, in very small amounts, some other sugars which are often referred to as “rare sugars”. These rare sugars are formed by conversion of some of the most abundant sugars to other forms of sugars through enzymatic processes which have been discovered and isolated in the late nineties by Prof K. Izumori in Japan and are called D-psicose-epimerase. This epimerase does not change the chemical formula or even the primary structure of fructose but does rearrange its 3D appearance.

Allulose, an epimer of Fructose, is one of the “rare sugars” that are formed through such enzymatic process. More specifically, in the case of Allulose, the Hydroxyl and Hydrogen of Carbon n° 3 of fructose are switched in 3D.

Allulose is found in foodstuff and has always been present in conventional foods, albeit in small quantities. It is present in natural foods (e.g. dried fruits, such as dried figs and raisins), as well as in confectionary products such as fried dough and brown sugar cookies. For example, brown sugar contains approximately 71.1 mg /100 g of Allulose, and ketchup contains approximately 39.8 mg/ 100 g of Allulose. These foods are consumed frequently across many population distributions all over the world with no known adverse effects linked to Allulose. The human body is used to the presence of Allulose in foods, and human metabolism is capable of handling it without adverse reaction. However, Allulose is present in such small quantities in conventional foods that no specific human metabolic pathway has been developed for it, unlike for Glucose and Fructose, that are used as main energy sources in humans and other living organisms. As a result, unlike other sugars, Allulose is not an energy source and its calorie content is close to zero. However, just like other sugars, Allulose has a sweet taste -rather close to that of Glucose, with no aftertaste- and it is perfectly safe and can replace sugar in all its uses (drinks, baking, cooking, etc.) It is colourless and it browns when heated.

Human toxicological tolerance to Allulose is similar than that to regular sugars (Glucose, Fructose, Saccharose). Allulose is not chemically extracted or produced or altered, it is not GMO based, it does not contain nor is associated with heavy metals, soy, sodium, lactose, gluten or artificial flavours. Allulose has excellent shelf life and is stable even in harsh conditions. Scientific reports indicate Allulose has near zero calories, low glycaemic index, does not induce illnesses, has anti-oxidant, anti-microbial properties and is tooth friendly. It is also reported Allulose, when mixed with standard commercial sugars, reduces their glycaemic index.

New technological developments (such as those used by the applicant) allow safe production of Allulose in industrial quantities.

Allulose has been first commercially introduced in larger quantities in the human food chain in Japan, where it is commercialized as an ingredient of a product called “Rare Sugar Sweet”. It has been also approved in other countries such as USA (where it has GRAS status), New Zealand, Canada and Australia, South Korea, Singapore, Chile and reportedly as well in Mexico and Columbia, thus covering already a market of more than 800 million people.

To date, there has not been a single warning resulting from the increased use of Allulose in human diet. On the contrary, D-Allulose has been recognized as a 'FOSHU' foodstuff in Japan (i.e. a food with specific health benefits pursuant to the Japanese food regulations) and the Singapore Ministry of Health considers it as a public health tool.

The available evidence on Allulose demonstrates that under the proposed conditions of use, Allulose does not pose a safety risk to human health.