

Summary of the application: *Yarrowia lipolytica* yeast biomass

Applicant: Skotan S.A., ul. Dyrekcyjna 6 41-506 Chorzów, Poland

The subject of this application is a request for extension of use of *Yarrowia lipolytica* yeast biomass as a novel food and changes of additional specific labelling requirements.

On the basis of Commission Implementing Regulation (EU) 2019/760 authorising the placing on the market of *Yarrowia lipolytica* yeast biomass as a novel food under Regulation (EU) 2015/2283 the *Yarrowia lipolytica* yeast biomass is authorized for use in food supplements (excluding food supplements for infants and young children) with maximum level of 6 g/day for children from 10 years of age, adolescents and general adult population and 3 g/day for children from 3 to 9 years of age. In accordance with the same Regulation *Yarrowia lipolytica* yeast biomass should be labelled in the foodstuffs as “*Yarrowia lipolytica* yeast heat-killed biomass”.

The subject of this application is to extend the use of *Yarrowia lipolytica* yeast biomass in following foods: Dairy products and analogues, Fruit and vegetables, Cereals and cereal products, Bakery wares, Meat, Fish and fisheries products, Eggs and egg products, Salts, spices, soups, sauces, salads and protein products, Foods intended for particular nutritional uses as defined in Regulation (EU) 609/2013, Beverages, Ready-to-eat savouries and snacks, Desserts, Processed foods not covered by categories, excluding foods for infants and young children in recommended portions as presented:

- Children from 10 years of age, adolescents, adults – 20g/100g of product (not more than 6 grams per portion of product),
- Children from 3 to 9 years of age – 20g/100g of product (not more than 3 grams per portion of product).

Furthermore, Skotan S.A. requests a change of specific labelling requirements from “*Yarrowia lipolytica* yeast heat-killed biomass” to “*Yarrowia lipolytica* inactive yeast”.

Biomass of *Yarrowia lipolytica* yeast is classified in the category ‘Food consisting of, isolated or produced from microorganisms, fungi or algae’. *Yarrowia lipolytica* Strain A-101 yeast is characterized by very good nutritional values, including high content of: protein (about 45-50%), beta-glucan, vitamins of group B, E vitamin and a high proportion of unsaturated fats, and wealth of micro and macroelements.

*Yarrowia lipolytica* yeast biomass has been positively assessed by EFSA (EFSA Journal 2019;17(2):5594) with particular interest on safety. Moreover, EFSA has granted QPS status for *Yarrowia lipolytica* inactive yeast biomass in 2018 (EFSA Journal 2018;16(7):5315). Safety is also confirmed by the toxicity tests of *Yarrowia lipolytica* yeast biomass by unprecedented study carried out in the 1970’s at CIVO. The cited studies were conducted on a variety of animal species that were administered *Y. lipolytica* yeast biomass (up to 30% of diet) for acute, subchronic, chronic toxicity and also for multi-generational impact of administration of the yeast (effects on reproduction and development). There were neither negative effects of ingestion nor toxicity, genotoxic, carcinogenic or reproductive and developmental effects.