

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 expanding conditions of use and changes in additional specific labelling requirements of already authorized Novel Food - *Yarrowia lipolytica* yeast biomass.

The subject of this application is request for an extension of use of *Yarrowia lipolytica* yeast biomass to the following foods:

- meal replacement products - Children from 10 years of age, adolescents, adults (men and women): 20 000 mg NF/100 g of product (not more than 6000 mg per day); - Children from 3 to 9 years of age: 20 000 mg NF/100g of product (not more than 3000 mg per day),
- meal replacement products for weight control - Children from 10 years of age, adolescents, adults (men and women): 20 000 mg NF/100 g of product (not more than 6000 mg per day); - Children from 3 to 9 years of age: 20 000 mg NF/100g of product (not more than 3000 mg per day),
- fortified foods - Adults (men and women): 20 000 mg NF/100 g of product (not more than 6000 mg per day).

The proposed quantities do not exceed the quantities already assessed by EFSA during the *Yarrowia lipolytica* yeast biomass Safety Assessment procedure (doi: 10.2903/j.efsa.2019.5594). The category of consumers is also the same.

The second subject of this application is to change specific labelling requirements from “*Yarrowia lipolytica* yeast heat-killed biomass” to “*Yarrowia lipolytica* inactive yeast”.

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 (such as B1, B2, B3, B5, B7, B9 and B12), E vitamin and a high proportion of unsaturated fats (over 90% of the total fat content), and wealth of micro and macroelements (including Calcium, Phosphorus, Sodium, Iron, Copper, Magnesium, Potassium, Manganese, Zinc & Iodine).

Yarrowia lipolytica yeast biomass has been positively assessed by EFSA (EFSA Journal 2019;17(2):5594) with particular interest on safety for consumers. Scientific evidences shows full safety with any impurities, i.e. heavy metals or microbial parameters, which has been confirmed in expert opinions on the nutritional values and consumption of heavy metals and microbiological parameters, including target groups and acceptable consumption standards acc. to the National Institute of Hygiene in Warsaw and Instytut Żywności i Żywienia im. prof. dr med. Aleksandra Szczygła in Warsaw (Prof. Aleksander Szczygiel, Ph.D, Memorial Institute of Food and Nutrition). Additionally, EFSA has granted QPS status for *Yarrowia lipolytica* inactive yeast biomass in 2018 (EFSA Journal 2018;16(7):5315).

Consumption safety is also confirmed by the toxicity tests of *Yarrowia lipolytica* yeast biomass. One of the largest toxicity studies was an unprecedented study carried out in the 1970's by BP at the independent Centraal Instituut voor Voedingsonderzoek (CIVO) institute. The cited studies were conducted on a variety of animal species (mice, rats, chickens, and even quails) that were administered *Y.lipolytica* yeast biomass (up to 30% of diet), not only for acute, subchronic and chronic toxicity but 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.