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Use of *Yarrowia lipolytica* Yeast Biomass as a Novel Food and a Novel Food Ingredient
(Summary of the Dossier)

The subject of this application is a request for authorization to use *Yarrowia lipolytica* yeast biomass as a novel food and a novel food ingredient as a component of food supplements and a component of selected foods in the form of yeast cells, dried and deprived of metabolic activity. 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 (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 is intended for the general population but mainly adult men and women (with particular emphasis on the eating habits of vegans and vegetarians). For the estimated dosage, including destination and age groups, see Table 16 (and also below).

Table 16. Recommended dosage taking into account age groups and food categories.

Type of consumer category	Dosage as a component of food supplements (code A03RQ)	Dosage in other food categories
Adults: Men and women over 18 YO	2-3 g/day (5 g /day max.)	3-6 g/ day (1-2 tsp) (18 g/day max.)
Youth between 10 and 17 YO	2-3 g/day (5 g /day max.)	3-6 g/ day (1-2 tsp) (18 g/day max.)
Children from 36 months to 9 YO	1-2 g/day (3 g/day max.)	1.5-3 g/day (0.5-1 tsp) (6 g/day max.)

The main purpose of the reported Novel Food is to use it as a component of food supplements with specific functionalities, in the form of soft capsules, hard capsules, tablets or loose powder (according to the FoodEx system classification in Group 18 – Products for special nutritional use). In addition, *Yarrowia lipolytica* yeast biomass is expected to be used as a conventional food additive being the nutrition and flavour additive to conventional foods classified according to the FoodEx system to Groups: No. 2 – Vegetables and vegetables products, No. 4 – Legumes, nuts and oilseeds, No. 7 – Fish and other seafood, No. 8 – Milk and dairy products, No. 9 – Eggs and egg products, No. 16 – Herbs, spices and condiments, No. 17 – Food for infants and small children, No. 19 – Composite food, No. 20 – Snacks, desserts, and other foods.

Due to the use of *Y.lipolytica* yeast biomass mainly as a component of food supplements, the requirements for maximum permissible levels of heavy metals were adopted in accordance with Regulation (EC) no. 629/2008. The microbiological requirements adopted for *Y.lipolytica* yeast biomass were prepared on the basis of Pharmacopoeia 7.0 for non-sterile products. Storage test results did not show any negative changes in any parameter during the 12 months of storage. An expert opinion on the consumption of heavy metals and microbiological parameters, including target groups and acceptable consumption standards acc. to the National Institute of Hygiene in Warsaw, fully confirms safety of consumption of *Yarrowia lipolytica* yeast biomass in suggested applications and dosages.

Due to its unique and valuable properties, *Yarrowia lipolytica* yeast is increasingly used in biotechnology, the US Food and Drug Administration (FDA) has granted GRAS (Generally Recognized As Safe) status to many commercial scale processes performed with its involvement. The *Yarrowia lipolytica* strain is considered a classic in Biosafety Class 1 (no toxicity). *Yarrowia lipolytica* species is listed as one of the most common and extremely important in dairy products and sausages and maturing hams, according to EFSA's paper from 2007 [EFSA 2007; 587] and is included in the list of species considered for QPS status (Qualified Presumption of Safety) [EFSA 2013; 11(8)]. 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.

Due to fact that application was submitted on 17th July 2017 the scientific and research unit that maintained preliminary review for *Yarrowia lipolytica* yeast biomass as a novel food and a novel food ingredient was Instytut Żywności i Żywienia im. prof. dr med. Aleksandra Szczygła in Warsaw (Prof. Aleksander Szczygiel, Ph.D, Memorial Institute of Food and Nutrition).