

Summary of the dossier: Application to change the conditions of use of Pasteurised *Akkermansia muciniphila* in the European Union

Applicant: The Akkermansia Company SA, Rue Granbonpré, 11 Bâtiment H, 1435 Mont-Saint-Guibert, Belgium

This application is submitted to request changes to the conditions of use of an already authorised novel food, pasteurised *Akkermansia muciniphila*, in the European Union (EU). Pasteurised *Akkermansia muciniphila* was authorised as a novel food in 2022 under Regulation (EU) 2022/168, for use at up to 3.4×10^{10} cells/day in food supplements and in foods for special medical purposes (FSMPs), for the adult population, excluding pregnant and lactating women.

The proposed changes to the conditions of use are to permit the use of pasteurised *Akkermansia muciniphila* in food supplements and FSMPs for the general population aged 12 years and above (*i.e.*, to include pregnant and lactating adult women, and to include adolescents aged 12 to 17 years), and use in general food categories (including: flavoured and unflavoured fermented milk based products, fruit smoothies, chewing gum, breakfast cereals, cereal bars, sweeteners, protein and nutrition bars, protein powders, fermented functional drinks, drink bases).

The limit that the European Food Safety Authority (EFSA) has considered to be safe is 4.89×10^8 cells/kg body weight/day, for all population groups; estimated high-level intakes of pasteurised *Akkermansia muciniphila* that are covered in this application for general food and beverage product use are below this limit. Similarly, the use levels proposed for the requested extension of use to food supplements and FSMPs for pregnant and lactating adult women, and for adolescents aged 12 to 17 years, result in body weight-relative intakes that do not exceed EFSA's safe level of 4.89×10^8 cells/kg body weight/day for any population group.

Therefore, EFSA's original risk assessment on pasteurised *Akkermansia muciniphila* is still valid for this change of use application, as exposure from the additional proposed uses is within the safe level of use derived by EFSA.

The available data support the safe use of pasteurised *Akkermansia muciniphila* in food supplements and FSMPs for the general population aged 12 years and above, and in general food and beverage categories.