Summary of the dossier: Pasteurised *Akkermansia muciniphila*

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This is an application for authorisation of pasteurised *Akkermansia muciniphila* for use in food supplements and in foods for special medical purposes in the European Union (EU).

The application has been prepared in accordance with the requirements of Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, the European Food Safety Authority (EFSA) Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 and EFSA's Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283.

The novel food consists of pasteurised *Akkermansia muciniphila. Akkermansia muciniphila* is a human gut commensal non-motile and non-spore-forming elliptical bacterium, accounting for 1 to 5% of healthy intestinal microbiota. The strain *Akkermansia muciniphila* Muc^T (=ATCC BAA-835) was isolated from the healthy human intestinal tract.

The production process for pasteurised *Akkermansia muciniphila* consists of an anaerobic fermentation followed by pasteurisation, concentration of the bacterial cells and freeze-drying to make the final powder. The manufacturing process follows HACCP certification. Analyses have shown the lack of contaminants, such as microbiological contaminants, heavy metals and pesticides.

The application is also supported by a number of toxicological studies, which aim to demonstrate the safety of this novel food. As demonstrated by *in vitro* antimicrobial resistance studies, pasteurised *Akkermansia muciniphila* presents a minimal potential for horizontal spread and does not pose any strain-specific risk in terms of antimicrobial resistance pattern. Pasteurised *Akkermansia muciniphila* was demonstrated to be non-genotoxic in the standard battery of *in vitro* tests (bacterial reverse mutation test and *in vitro* mammalian cell micronucleus test) and was well tolerated in several sub-acute studies (in rats and mice) and a 90-day study (in rats). Furthermore, there were no adverse effects in a human safety study where live or pasteurised *Akkermansia muciniphila* was consumed in supplements at 1×10^{10} cells/day for 12 weeks.

Together, the weight of the available evidence on pasteurised *Akkermansia muciniphila* supports the safe use of the ingredient under the proposed conditions of use.