

Summary of the dossier: Heat-killed *Mycobacterium manresensis*.

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This is an application for authorisation to place on the market the heat-killed bacteria *Mycobacterium manresensis* for use in food supplements. The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with 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.

The Novel Food consists of heat-killed *Mycobacterium manresensis*. No product containing heat-killed *M. manresensis* is available on the EU market. The novel food is to be used in food supplements at a daily intake of 10^4 to 10^5 heat-killed bacilli per day for 14 days. The target population is healthy adults (older than 18 years) and excluding pregnant and lactating women and persons with diagnosed tuberculosis who are not under the standard chemotherapy treatment.

Mycobacterium manresensis has been isolated from the Cardener River in Manresa, Catalonia, Spain, and is a fast-growing mycobacterium that belongs to the *Mycobacterium fortuitum* group. The strain has been deposited in two public Culture Collections, in Spain and in Belgium.

The manufacturing process of *M. manresensis* is composed of 5 consecutive steps and follows the HACCP certification. Analyses have shown the lack of contaminants, such as microbiological contaminants, heavy metals and pesticides. The stability of *M. manresensis* has been demonstrated over 24 months. Experiments on the antibiotic susceptibility showed that *M. manresensis* is susceptible or resistant to antibiotics in a similar pattern that other *M. fortuitum* species. Moreover, the risk of horizontal gene transfer has been investigated and has been found to be very unlikely.

The application is also supported by a number of toxicological studies, which aim to demonstrate the safety of this novel food. A bacterial reverse mutation test and an *in vitro* mammalian cell micronucleus test have shown the lack of genotoxicity of *M. manresensis*. A 28-day oral toxicity study conducted in rats and a 90-day toxicity study conducted in pigs have demonstrated the lack of toxicity of heat-killed *M. manresensis*. Moreover, a virulence assay in severely immunocompromised SCID mice and a bioinformatics assessment of *M. manresensis* have confirmed the lack of virulence of the bacteria. Finally, a human study has investigated the safety of oral administration of heat-killed *M. manresensis*, without highlighting any safety concerns. To conclude, heat-killed *M. manresensis* is well-characterized and compliant with European Regulations. Moreover, the product has been shown to be safe and does not present consequently any potential hazard for the European population.