Public Summary of Whole cell heat-killed non-GMM *Mycolicibacterium aurum* Aogashima DSM33539 (officially known as *Mycobacterium aurum* Aogashima)

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The application is submitted pursuant to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, for the authorisation of whole cells of heat-killed (dead) *Mycolicibacterium aurum* Aogashima (DSM33539) officially classified as *Mycobacterium aurum* Aogashima) suspended in water as a food supplement. *M. aurum* is a saprophytic, non-pathogenic bacteria ubiquitous to the environment originally belonging to the *Mycobacterium* genus. The food supplement is intended to be taken in daily doses of 0.33 ml (9.9 µg of *M. aurum* Aogashima) by the general population except for infants below 3 years. A literature search covering compositional data, the safety and history of the microorganism was conducted to support this application.

M. aurum is a rapid-grower non-pathogenic environmental species originally isolated from a sample of soil from Japan and designated a new species in 1966 (Tsukamura, 1966). This ubiquitous, saprophytic mycolicibacterium can be found free-living in wet environments, including marshland, rotting vegetation, mud and free water and, most importantly, has been shown to colonise pipes supplying water for industrial and domestic use.

M. aurum Aogashima is grown under high sanitary conditions aligned with the EU principles on food safety. The final product is a heat inactivated whole cell preparation of M. aurum (DSM33539) and, therefore, contains no viable cells. The product can remain stable for at least 24 months from its production.

The product does not have previous history of consumption in the EU and is classified as “Food consisting of, isolated from or produced from microorganisms, fungi or algae”. The safety of the product was evaluated in three toxicological studies: one reverse mutation (Ames), one micronucleus test and one 90-day sub-chronic oral toxicity study in rats. All studies were GLP-compliant and were carried out following the corresponding OECD guidelines. No safety concerns were identified in any of the studies and the daily dose was found to be several folds below the NOEL. The genome of the production strain was also found to be free of virulence factors and antimicrobial resistance.