Summary of the dossier: *Anaerobutyricum soehngenii* CH106

Applicant: Caelus Pharmaceuticals BV, Rondweg 50, 3474 KG Zegveld, The Netherlands

This is an application for the authorisation of *Anaerobutyricum soehngenii* CH106 as a novel food in the form of a food supplement on the European market.

All the information in this dossier has been prepared and presented according to guidelines set forth in the technical report of the European Food Safety Authority (EFSA), implementation date 27 March 2021, titled "Administrative guidance for the preparation of applications of novel foods pursuant to Article 10 of regulation (EU) 2015/2283".

The novel food is a lyophilized powder, containing cells of the bacterium *Anaerobutyricum soehngenii* CH106 that have been produced through fermentation. Caelus Health (Caelus) intends to market the novel food containing *A. soehngenii* CH106 for use as a food supplement for adults at a use level of up to 3 x 10^9 Active Fluorescence Units (AFU)/ serving up to 3 servings daily.

The information in this dossier is provided to show that the product is safe for use under the intended dosage. A full genome sequence was performed to show that *A. soehngenii* CH106 does not carry any transferable antibiotic resistance markers and is free of potential toxicity and virulence factors. Additionally, studies showed that allergenicity potential of the novel food is highly unlikely and not to be expected.

A. soehngenii CH106 was shown to be non-toxic in *in vitro* genotoxicity studies (mammalian cell micronucleus test and bacterial reverse mutation test). A 90-day subchronic toxicity study was carried out and showed that the product was well tolerated at even the highest dose. Based on this a NOAEL of 4.7 x 10^{10} AFU, containing no less then 1.0 x 10^{11} total cells/kg body weight/day could be established. With a maximum exposure level of 9 x 10^9 AFU/day in human adults this provides a margin of exposure of at least 365.

Human studies performed with *A. soehngenii* and related species showed no adverse events that could be related to the test item. Likewise, no adverse effects could be identified in literature.

Together, the evidence presented in this application supports the safe use of *A. soehngenii* CH106 under the proposed conditions of use.

All studies relating to safety of the novel food which are mentioned in this report have been commissioned prior to the effective date of the 'Transparency Regulation' [Regulation (EU) 2019/1381 - transparency and sustainability of the EU risk assessment in the food chain] of March 27 2021.