Summary of the application: Arachidonic acid-rich oil from the fungus Mortierella alpina

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This application requests the authorisation of an Arachidonic acid-rich oil from the fungus Mortierella alpina (ARA-rich oil) derived from two further strains, namely (i) JDW-646 and (ii) CNCM I-4642. Therefore, the applicant seeks for a modification of the specification of the Union list (Regulation (EU) 2017/2470) with regard to these strains. In addition, an increase of the limit for unsaponifiable matters from ≤1,5% to ≤ 3,5% is also requested. The use of ARA-rich oils (20:4 n-6) from the fungus Mortierella alpina is well known and the ingredient has been used for many years as an ingredient in infant and follow-on formula. The first novel food authorisation was already granted in 2008, which was followed by several other approvals with other strains. In addition, one ARA oil was already marketed before 1997 and is therefore not considered as novel at all. "Oil from Mortierella alpina" or "Mortierella alpina oil" is presently authorised in infant formula, follow-on formula and foods for special medical purposes for infants as defined in Regulation (EU) No 609/2013. BASF ARA-rich oil is planned to be used the same food categories with the same use levels than already authorised according to Regulation (EU) No 609/2019 and concretised in Regulation (EU) 2016/127 (1% of the total fat content). The toxicity of ARA-rich oils produced from different strains of Mortierella alpina has been well documented over the last decades. In addition to former authorisation procedures, an update of the literature has been conducted and did not reveal any safety concerns. Furthermore, the analysis of potential impurities, process impurities, byproducts, residues or microbiological contaminants did not give rise to any concern. The higher limit of unsaponifiable matter corresponds to the specification of a non-novel food ARA-rich oil. Therefore, for these and other reasons, the rather higher limit of unsaponifiable matters in ARA oil does not give cause to safety concerns. In summary, BASF ARA-rich oil does not give cause to any safety concerns.