

Summary of the application: *Schizochytrium* sp. (CABIO-A-2)

Applicant: CABIO Biotech (Wuhan) Co., Ltd., Wuhan Pharmacy Park, Jiangxia Avenue, Jiangxia Economic Development Zone, Wuhan, China

The subject of this novel food application is a *Schizochytrium* sp.-derived, docosahexaenoic acid (DHA)-rich oil manufactured by CABIO Biotech (Wuhan) Co., Ltd. This oil meets the specifications for *Schizochytrium* sp. oil specified in Regulation (EU) 2017/2470. This oil also meets the specifications for *Schizochytrium* sp. (T18) oil, which is authorized for use in infant and follow-on formula.

CABIO Biotech (Wuhan) Co., Ltd. requests authorisation of use for its *Schizochytrium* sp. (CABIO-A-2) derived oil to infant and follow-on formulas.

The *Schizochytrium* sp. (CABIO-A-2) used to produce the oil was isolated from a marine environment and the oil derived therefrom is manufactured using procedures that are standard in the food oil production industry. Analytical data on the strain and oil derived therefrom document the identity of the strain, composition of the oil, lack of undesirable substances in the oil, stability, and control of the production process. Moreover, the toxicity of DHA-rich algal oils produced from different strains of *Schizochytrium* sp. has been well documented through bacterial reverse mutation tests, in vitro chromosomal aberration tests, in vivo mammalian cell micronucleus tests, subchronic toxicity studies with rats, and developmental and reproductive toxicity studies with rats. Additionally, the digestion, absorption and metabolism of DHA have been extensively documented.

Because the production strain of the subject of this application is a member of *Schizochytrium* sp. and the resulting oil complies with the specifications for *Schizochytrium* sp. oil specified in Regulation (EU) 2017/2470, use of the *Schizochytrium* sp.-derived, docosahexaenoic acid (DHA)-rich oil manufactured by CABIO Biotech (Wuhan) Co., Ltd. in infant and follow-on formula is safe.