

Summary of the application: *Schizochytrium* sp. (TKD-1)

Applicant: ATK Biotech Co., Ltd., 109 Husong Road, Shitan Industrial Park, Shizi Town, Quanjiao County, Chuzhou City, China

The subject of this novel food application is a *Schizochytrium limacinum*-derived, docosahexaenoic acid (DHA)-rich oil manufactured by ATK Biotech Co., Ltd. This oil meets the specifications for *Schizochytrium* sp. oil specified in Regulation (EU) 2017/2470, as well as the specifications for *Schizochytrium* sp. (T18) oil, which is authorized for use in infant and follow-on formula per Regulation (EU) No 609/2013.

ATK Biotech Co., Ltd. therefore requests authorisation of use for its *S. limacinum* TKD-1 oil to infant and follow-on formulas following the conditions of use defined in Regulation (EU) No 609/2013.

The *S. limacinum* TKD-1 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.

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 and *S. limacinum* has been recommended for the Qualified Presumption of Safety (QPS) list with the qualification 'for production purposes only'.

Because the production strain of the subject of this petition is a member of *Schizochytrium* sp. and the resulting oil complies with the specifications for *Schizochytrium* sp. (T18) oil, use of the *Schizochytrium* limacinum-derived, docosahexaenoic acid (DHA)-rich oil manufactured by ATK Biotech Co., Ltd. in infant and follow-on formula is safe.