Summary of the dossier: Algal meal and oleoresin of *Haematococcus pluvialis* containing astaxanthin
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This is a re-submitted novel food application for the authorisation of AstaREAL A1010, algal meal of Haematococcus pluvialis (powder) and AstaREAL L10, oleoresin of Haematococcus pluvialis (oil and encapsulated oil), manufactured by the company AstaReal AB. The ingredients are produced from Haematococcus pluvialis, a microalga naturally rich in the carotenoid pigment astaxanthin.

Astaxanthin content is 5.0–5.6 % in AstaREAL A1010 powder, 10.0–11.1 % in AstaREAL L10 oil and 2.5–2.7 % in AstaREAL EL25 (encapsulated form of L10). The ingredients are to be used in 1) Unflavoured milk pasteurised and sterilised including UHT (ultra-heat-treated); 2) Unflavoured fermented milk products including natural unflavoured buttermilk (excluding sterilized butter milk) non-heat-treated after fermentation; 3) Flavoured fermented milk products including heat-treated products; 4) Dairy analogues, including beverage whiteners; 5) Fruit juices as defined by Directive 2001/112/EC; and 6) Fruit and vegetable nectars as defined by Directive 2001/112 EC and similar products.

This application follows a previous application, in 2014, for which EFSA NDA Panel provided unfavourable opinion. The main safety concern was related to observed liver toxicity effects of astaxanthin in female rats in chronic toxicity study ; based on EFSA FEEDAP Panel opinion (2014). The acceptable daily intake (ADI) derived by the FEEDAP Panel was set to the level 0.034 mg/kg body weight (bw). In the original application, the ADI was exceeded by the anticipated intake levels of astaxanthin and this was the reason for the unfavourable opinion. That safety concern was also in focus of recent EFSA NDA Panel opinion (2020) on safety astaxanthin in food supplements in which a new ADI for astaxanthin was set to be 0.2 mg/kg bw. Previously applied anticipated intake of astaxanthin via the foods enriched with astaxanthin ingredients now falls within the set ADI. AstaReal AB therefore re-applies for the authorisation of astaxanthin to be used in the same food categories as proposed before. Additionally, AstaReal provides new mechanistic in vitro and transcriptomics data that strongly suggest that liver toxicity observed in female rats are species specific to rats and not relevant to humans. Based on that, the applicant also proposes more appropriate safety factors for calculating the ADI for astaxanthin, leading to the ADI of 0.4 mg/kg bw/day.