

Public summary of the dossier

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Novel food: Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae

With the present dossier the applicant requests the European Commission to extend the use in food supplement of the already authorised novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae to two population groups, i.e. children aged 3 to <10 years and adolescents aged 10 to <14 years.

Astaxanthin is a carotenoid produced by *Haematococcus pluvialis* algae. *H. pluvialis* can be cultivated either in closed systems, or in open ponds. After harvest the cells are dried, and the oleoresin is extracted. Then, astaxanthin is diluted and standardized. The production process has already been assessed and the ingredient is in the EU list of novel foods.

No changes in the identity and the production process of the novel food occurred. The compositional data and the specifications are maintained. The history of the novel food and data on its ADME, toxicology and allergenicity have already been assessed and the ingredient is authorised by Commission Implementing Regulation (EU) 2018/1023. Astaxanthin is considered safe for intakes below and up to the Acceptable Daily Intake (ADI) set by the EFSA FEEDAP Panel in 2019. Complementary analyses of the latest scientific literature did not reveal any emerging data questioning the current ADI for astaxanthin.

The applicant proposes an extension of the conditions of use of the already authorised novel food to children aged 3 to <10 years and adolescents aged 10 to <14 years, by setting maximum use levels of 2.2 mg astaxanthin per day (equivalent to 11-22 mg of oleoresin) and 5.6 mg astaxanthin per day (equivalent to 28-56 mg of oleoresin) in each group, respectively.

There are two dietary sources of exposure to astaxanthin: the background diet (fish and crustaceans), and the novel food which is the object of the dossier. Its use is authorised in the food supplement category.

The highest exposure estimates to astaxanthin from the diet were considered as reported by EFSA in 2020. As of the astaxanthin exposure from the novel food, the maximum use levels suggested in this dossier were considered. Estimates for combined intake levels for astaxanthin from the background diet and from food supplements were calculated, and the combined exposure scenario was compared to the ADI for astaxanthin.

The applicant suggests that for each of the two age groups it is possible to establish a maximum use level of the novel food that allows the combined exposure estimate of astaxanthin not to exceed the ADI.

Considering the proposed maximum daily doses of ATX for children aged 3 to <10 years and for adolescents aged 10 to <14 years and the absence of new relevant data concerning the toxicity of astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae, it can be acceptable to extend the conditions of use of the novel food in food supplements to these two population groups.