

Summary of the dossier: Novel food application for specification change of oleoresin from *Haematococcus pluvialis* containing astaxanthin

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This is a novel food application for change in the specification of 'Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae' already included in the Union list of authorised novel foods (Commission Implementing Regulation (EU) 2017/2470).

The current authorisation specification for 'Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae' is listed in the Commission Implementing Regulation (EU) 2017/2470. It is authorised to be used only in food supplements for adults and children >14 years; with 40-80 mg/day of oleoresin, resulting in ≤ 8 mg astaxanthin per day. AstaReal AB seeks for the change of the specifications of 'Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae' concerning astaxanthin monoesters and diesters, astaxanthin 9-cis stereoisomer and protein.

According to the specification presented in Regulation (EU) 2017/2470, the range for astaxanthin monoesters in oleoresin is 79.8–91.5 w/w % of (total) carotenoids and the range of astaxanthin diesters is 0.16–19.0 w/w % of (total) carotenoids. Due to small changes in the algal cell maturation during the process, amount of astaxanthin diesters is increased and correspondingly, the amount of astaxanthin monoesters decreased. Thus, the range of relative amounts of astaxanthin monoesters is applied to be 66.7–91.5 % and astaxanthin diesters 0.16–32.5 %.

Additionally, AstaReal AB applies a specification change for the range of astaxanthin 9-cis stereoisomer. The range in the current authorised specification is 0.3–17.3 w/w % of (total) carotenoids. Similarly, as result of changes in the algal cell maturation phase, the amount of astaxanthin 9-cis stereoisomer is increased correlating the increased amount of astaxanthin diesters. Thus, a higher upper limit for astaxanthin 9-cis stereoisomer leading to a new range 0.3–30.0 w/w % is applied.

The protein content of AstaReal AB's oleoresin of *Haematococcus pluvialis* algae is slightly lower than in the current specification of 'Astaxanthin-rich oleoresin of *Haematococcus pluvialis* algae' listed in the Commission Implementing Regulation (EU) 2017/2470 due to enhanced method of analysis and purity of the product. The current minimum value 0.3 % is applied to be decreased to 0.0 %. Thus, the applied new value for protein would be 0.0-4.4 %.

These small specification changes of relative amount of astaxanthin monoesters and diesters do not have any effects on the safety, absorption and bioavailability of the oleoresin. Based on the scientific studies, before absorption astaxanthin mono- and diesters are hydrolysed.

Thus, in the circulation astaxanthin is found as a free, non-esterified form. Concerning the increased amount of astaxanthin cis-isomers; in general, cis-isomers are more bioavailable than trans-isomers. However, in humans, mainly cis-isomers are found indicating conformational changes from trans to cis-isomer at some point of the process or enhanced bioavailability of the cis-forms. Natural variation in astaxanthin isomers also exists.

Astaxanthin 13-cis stereoisomer have higher bioavailability and accumulation potential than 9-cis isomer of astaxanthin. The proposed small specification change of astaxanthin 9-cis isomer does not cause any changes in the safety of the novel food. Decreased amount of protein indicates the purity of the product and does not raise any safety concerns.