

SUBSTANTIAL EQUIVALENCE OPINION

Astaxanthin oil from *H. pluvialis* - Supercritical CO₂ Extraction

The Food Safety Authority of Ireland (FSAI) received an application in October of 2016 from the Beijing Ginkgo Group (BGG) in China for an opinion on the substantial equivalence of its astaxanthin-rich oleoresin from *Haematococcus pluvialis* (Astaxanthin Oil - Supercritical CO₂ Extraction) to a similar astaxanthin product (Zanthin[®] produced by US Nutra) which was authorised for the EU market via a substantial equivalence opinion from the UK authorities in 2004. Similar to the authorised comparator, the novel astaxanthin is derived from an algal biomass (*Haematococcus pluvialis*).

Haematococcus pluvialis is a microalga that is rich in astaxanthin, a naturally occurring xanthophyll carotenoid pigment found in marine animals, plants, fungi and bacteria. The microalgae are cultivated within closed tubular photobioreactors and harvested at a defined growth stage before being freeze-dried and packaged. The algal biomass is subject to cellular disruption for 2 to 3 hours and the lipid fraction is extracted using supercritical CO₂. The material is purified and standardised with food-grade vegetable oil where necessary to ensure a minimum content of 5-10% astaxanthin. The production process is carried out in accordance with HACCP principles. The novel ingredient is stable in bulk storage for at least 9 months when stored in a sealed, airtight container protected from light, at temperatures not exceeding 4°C.

The applicant wishes to market the novel product as an ingredient in food supplements consistent with the current use and use levels of other astaxanthin-rich oleoresins from *H. pluvialis* already on the EU market. The applicant considers the novel ingredient to fall under the category: *Foods and food ingredients consisting of or isolated from micro-organisms, fungi, or algae*” as set out in *Article 1.2(d)* of the novel food Regulation EC No 258/97.

Composition

The novel ingredient is a dark red viscous oil which is primarily composed of fat (approx. 85%), astaxanthin (up to 11%) with only minor levels of carbohydrate, protein, moisture and ash present. The carotenoid profiles are largely similar to the authorised comparator, with most (approximately 98%) of the astaxanthin present in the esterified form (primarily mono-ester up to 80% and di-ester approx. 20%) with minimal levels free astaxanthin present. The

fatty acid profiles of the novel ingredient and its existing counterpart are comparable, with palmitic, oleic, linoleic and linolenic acid being the most abundant fatty acids in both. Tocopherol, an authorised food additive is added as a stabilising agent.

Nutritional Value and Metabolism

The novel astaxanthin is predominantly in the mono-ester (approximately 80%) and di-ester ($\leq 20\%$) forms, with only minor amounts in the free form. There are no significant compositional differences evident between the novel and authorised products therefore, it is reasonable to assume that the nutritional value and metabolism will also be similar.

Intended uses

BGG's Astaxanthin is intended to be placed on the EU market as an ingredient in food supplements (tablets as well as soft and hard gel capsules) at the "current levels of usage" as for the authorised comparator.

Level of Undesirable Substances

The novel ingredient is cultivated in a closed system and therefore the potential for external contamination is extremely low. Batch analyses demonstrate that heavy metals including lead, cadmium, mercury and arsenic comply with specifications and are within regulatory limits. Batch analyses also demonstrate that certain microorganisms (yeast, mould, Coliforms, *Escherichia coli* and *Salmonella*) as well as aflatoxins and polyaromatic hydrocarbons (PAHs) are within specifications.

Haematococcus pluvialis naturally contains small amounts of canthaxanthin which has been assigned an ADI of 0.03 mg/kg body weight by EFSA. Assuming a maximum daily intake of the novel ingredient at 4mg of astaxanthin/day, this which would result in an exposure level of 44 μ g (0.044mg) of canthaxanthin per day (0.0007mg/kg bw/day for a 60kg adult) which is not considered to pose a significant safety concern.

Conclusions

The FSAI is satisfied from the information provided that astaxanthin oil (supercritical CO₂ extraction) produced by Beijing Ginkgo Group (BGG) in China is substantially equivalent to the EU-authorised astaxanthin-rich oleoresin (Zanthin[®] produced by US Nutra) in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances.