SUBSTANTIAL EQUIVALENCE OPINION

Astaxanthin-Rich Oleoresin from *Haematococcus pluvialis* (AstaZine)

The Food Safety Authority of Ireland (FSAI) received an application in May of 2016 from the Beijing Gingko Group (BGG) in China for an opinion on the substantial equivalence of its astaxanthin-rich oleoresin (AstaZine) to astaxanthin-rich oleoresin (Zanthin® produced by US Nutra) which was authorised for the EU market via a substantial equivalence opinion issued by the UK authorities in 2004. Similar to the authorised comparator, the novel astaxanthin is derived from an algal biomass (*Haematoccocus pluvialis*).

Haematoccocus pluvialis is a microalga that is rich in astaxanthin, a naturally occurring xanthophyll carotenoid pigment found in marine animals, plants, fungi and bacteria. Production of the novel ingredient is carried out in two main steps. The microalgae are cultivated in a closed system and harvested at a defined growth stage before being freeze-dried and packaged. The *H. pluvialis* biomass then undergoes cellular disruption and the lipid fraction is extracted using ethanol, followed by a series of purification steps to yield a dark red viscous oil made up primarily of fat (~ 87%) and approximately 10% astaxanthin which is predominantly in the esterified form (~98%). The astaxanthin rich oleoresin is then standardised to the required astaxanthin content (5% or 10%) with vegetable oil, while tocopherol is added as a stabilising antioxidant. The production process is carried out in accordance with HACCP principles.

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 within the category of "*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. 87%), astaxanthin (up to 10%) and minor levels of carbohydrate, protein, moisture and ash. The carotenoid profiles are largely similar to the authorised comparator, with most (approximately 98%) of the astaxanthin present in the esterified form. The applicant has

demonstrated that the novel ingredient is stable for at least 18 months, and possibly longer, at temperatures not exceeding 4°C when protected from air and light.

Nutritional Value and Metabolism

The novel astaxanthin is predominantly in the mono-ester (80-90%) and di-ester (10-20%) forms, with only minor amounts in the free form. There are no significant compositional differences evident between the novel and authorised products with fatty acid and carotenoid profiles being similar. Therefore, it is reasonable to assume that the nutritional value and metabolism will also be similar.

Intended uses

Beijing Gingko Group intends placing AstaZine 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" for the authorised comparator in the EU.

Level of Undesirable Substances

The novel ingredient is produced in a controlled environment and so opportunities for contamination with microorganisms or environmental contaminants are limited. Batch analyses demonstrate that heavy metals including lead, cadmium, mercury and arsenic are either not detected or are present at insignificant levels and within regulatory limits. Batch analysis of the final product also demonstrates that certain microorganisms (yeast, mould, Coliforms, *Staphylococcus aureus, Escherichia coli* and *Salmonella*) are well within specifications. Due to the closed production system, pesticide residues or environmental pollutants like polyaromatic hydrocarbons would not be expected. Pesticide residues were not detected while levels of benzo[a]pyrene were within the limits permitted in food supplements. In the EU, ethanol may be used as an extraction solvent in compliance with GMP. In the absence of regulatory limits, the applicant has a specification of <5,000 ppm (0.5%) for residual ethanol, with batch analyses indicating levels of at <500 ppm (0.05%).

Canthaxanthin is a carotenoid found at low levels in *Haematococcus pluvialis* (approximately 0.12% in AstaZine) and has been assigned an ADI of 0.03 mg/kg bw by EFSA. A maximum daily intake of AstaZine in food supplements of 40 mg oleoresin (4 mg astaxanthin/day) would result in an exposure to canthaxanthin of approximately 48µg/day (0.8µg/kg bw/day for a 60kg adult), which would not pose a significant safety concern.

Conclusions

The FSAI is satisfied from the information provided that the astaxanthin-rich oleoresin (AstaZine) produced by the Beijing Gingko Group (BGG) in China is substantially equivalent to the authorised astaxanthin-rich oleoresin (Zanthin®) in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances.