SUBSTANTIAL EQUIVALENCE OPINION

Astaxanthin-Rich Oleoresin from *Haematococcus pluvialis* (AstAlphy™)

The Food Safety Authority of Ireland (FSAI) received an application in March of 2017 from Yunnan Alphy Biotech Co., Ltd. of China for an opinion on the substantial equivalence of its astaxanthin-rich (5% and 10%) oleoresin (AstAlphy™) to astaxanthin-rich oleoresin (AstaREAL®L10) which was authorised for the EU market by a substantial equivalence opinion issued by the Swedish Competent Authority in 2006. Similar to the authorised comparator, the novel astaxanthin is derived from an algal biomass (*Haematoccocus pluvialis*).

The manufacturing process begins with the closed cultivation of *H. pluvialis*, followed by astaxanthin production in photobioreactors for 2-3 weeks where environmental stress (high light and nutrient depletion) induces the algal cells to accumulate astaxanthin. Extraction of the dried *H. pluvialis* is carried out using supercritical carbon dioxide to yield an oleoresin fraction containing 8-12 % astaxanthin. Astaxanthin levels of the intermediate oleoresin are normalised to 10% by blending with a commercially available product containing 10% astaxanthin. In order to produce the 5% astaxanthin product, the astaxanthin-rich oleoresin is diluted with food-grade safflower oil. AstAlphy™ is stable for at least 24 months and the applicant recommends that it is stored in a tightly sealed container at room temperature under dark and dry conditions.

The novel ingredient is manufactured to good manufacturing practices (GMP) at a facility that has a HACCP (Hazard Analysis Critical Control Points) plan in place. The applicant wishes to market the novel 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 oily substance composed primarily of fat (up to 99%), with only residual amounts of protein, carbohydrate and moisture present. Similar to the existing comparator, the astaxanthin in AstAlphy™ is predominantly the all-*trans* astaxanthin isomer, with

lower levels of the 9-*cis*-astaxanthin and 13-*cis*-astaxanthin isomers also present. The initial astaxanthin-rich oleoresin extract of *H. pluvialis* is diluted using safflower oil to yield AstAlphy™5%. The novel ingredient contains relatively high levels of certain fatty acids including palmitic, linoleic, alpha-linolenic and oleic acids. The other carotenoid found in the oleoresin extract is beta-carotene, but canthaxanthin, lutein and zeaxanthin are not present at any appreciable levels.

Nutritional Value and Metabolism

The composition of the novel ingredient is similar to its authorised comparator and therefore no significant differences in nutrition or metabolism are expected.

Intended uses

AstAlphy™ is intended for use as an ingredient in food supplements (hard or soft gel capsules) on the European market at doses similar to the existing counterpart.

Level of Undesirable Substances

H. pluvialis is cultivated in a closed system which minimises the potential for contamination. Analytical data from three batches of AstAlphy™ 10% demonstrates that the levels of heavy metals (mercury, lead, arsenic and cadmium), microbial contaminants (including yeasts, moulds, *Escherichia coli, Staphylococcus aureus, Bacillus cereus, Clostridium perfringens and Salmonella*) and pesticide residues do not identify any cause for concern.

Conclusions

Based on the information provided, the FSAI is satisfied that AstAlphy™ produced by Yunnan Alphy Biotech Co., Ltd. in China is substantially equivalent to the authorised comparator (AstaREAL® L10) in terms of composition, nutritional value, metabolism, intended uses and level of undesirable substances.