

SUBSTANTIAL EQUIVALENCE OPINION

Astaxanthin-Rich Oleoresin from *Haematococcus pluvialis*

(INNOBIO[®] Astaxanthin Oleoresin)

The Food Safety Authority of Ireland (FSAI) received an application in May of 2016 from InnoBio[®] Ltd. in China for an opinion on the substantial equivalence of its astaxanthin product (InnoBio[®] Astaxanthin Oleoresin) to a similar astaxanthin product which was authorised for the EU market (Zanthin[®] produced by US Nutra) by a substantial equivalence opinion in 2004. The novel ingredient falls 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 and so qualifies for the simplified procedure under *Article 3.4*.

Astaxanthin is a naturally occurring carotenoid pigment found in marine animals, plants, fungi and bacteria. Similar to the EU-authorised comparator, InnoBio[®] Astaxanthin Oleoresin is derived from the common green algae *Haematococcus pluvialis*. The only notable difference in the production process is the use of ethyl acetate for extraction of the novel ingredient compared to super-critical carbon dioxide for the EU-authorised comparator, along with an ethanol wash. The applicant has demonstrated that InnoBio[®] Astaxanthin Oleoresin is stable for up to 12 months when stored under cool (<10°C) and dry conditions, protected from light, heat and oxygen.

The applicant intends to market the novel ingredient in food supplements at usage levels similar to those of the EU-authorised comparator (2-4mg/day).

Composition

Similar to the EU-authorised comparator, the common green algae *H. pluvialis* is used in the production of InnoBio[®] Astaxanthin Oleoresin and was obtained from the Freshwater Algae Culture Collection at the Institute of Hydrobiology in China. The novel ingredient is produced to consistent specifications (5 to 20%) in compliance with current Good Manufacturing Practices (cGMP) and in accordance with HACCP principles. The novel ingredient is primarily composed of fat and astaxanthin, with only minor levels of carbohydrate, protein, ash and moisture present. The authorised astaxanthin comparator

contains approximately 89.2% fatty acids, comparing favourably with the novel ingredient which contains between 86.3% and 92.6% fat. The fatty acid profile of the novel ingredient is similar to the existing counterpart, with linoleic, oleic, α -linolenic, and palmitic acids being the most abundant fatty acids present in both. The carotenoid and astaxanthin profiles for the novel and authorised ingredients are also similar.

Nutritional Value and Metabolism

The novel and EU-authorised astaxanthin products contain similar levels of the primary nutritional constituents including fat, astaxanthin, protein, carbohydrate and dietary fibre. The proposed intake of the novel astaxanthin will be similar to that for the authorised comparator. Therefore, the nutritional value and metabolism of both products would not be expected to differ significantly.

Intended uses

The applicant intends placing InnoBio[®] Astaxanthin Oleoresin on the EU market as an ingredient in food supplements in the form of tablets, soft gel or hard gel capsules. The final ingredient will be formulated into food supplements to provide a maximum recommended dose of 2-4 mg/day, which the applicant estimates is within the range of current use.

Level of Undesirable Substances

The novel ingredient is produced under controlled conditions which limit the potential for environmental contamination. Batch analyses demonstrate that levels of heavy metals (lead, arsenic, cadmium and mercury), microbial contaminants (such as yeasts, moulds, *Staphylococcus aureus*, *Escherichia coli* and *Salmonella*) and environmental contaminants such as dioxins, dioxin-like PCBs, benzo(a)pyrene and pesticide residues are within regulatory limits for food supplements where detected. Residual ethyl acetate and ethanol levels are well within specified limits and are therefore not a safety concern.

Conclusions

The FSAI is satisfied from the information provided that InnoBio[®] Astaxanthin Oleoresin is substantially equivalent to the EU-authorised astaxanthin (Zanthin[®]) in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances.