SUBSTANTIAL EQUIVALENCE OPINION

Astaxanthin (AstaMarin™)

The Food Safety Authority of Ireland (FSAI) received an application in June of 2014 from Fenchem Biotek Ltd. in China for an opinion on the substantial equivalence of its astaxanthin product (AstaMarin™ – 5% & 10% Oleoresin) to astaxanthin oleoresin already on the EU market in dietary supplement form (BioAstin® 5% & 10% Oleoresin). BioAstin® is on the EU market by virtue of a substantial equivalence opinion obtained by the Cyanotech Corporation from the UK authorities in 2006. Fenchem Biotek Ltd. intends their novel product to be marketed in dietary supplements similar to the comparator which is sold in capsule and tablet form.

Astaxanthin is a naturally occurring carotenoid pigment found in marine animals, plants, fungi and bacteria. Similar to the production of the comparator product, the novel astaxanthin is derived from the common green algae *Haematoccocus pluvialis* using a standard process outlined by the applicant and which uses supercritical CO_2 as the only solvent to extract the carotenoid.

Composition

The applicant maintains their own pure strain of *H. pluvialis* and the production process is subject to HACCP principles. Along with the astaxanthin content, the compositional specifications provided includes data on the levels of ash, protein, fibre, fat and carbohydrate, all of which are at similar levels in both the novel AstaMarin™ and the BioAstin® products. Fatty acids, amino acids and a number of vitamins and minerals are also at comparable levels. The applicant has demonstrated that AstaMarin™ is stable for at least two years.

Nutritional Value and Metabolism

The novel and comparator astaxanthin oleoresin products contain similar levels of the major nutritional components including protein, fat, carbohydrate and fibre and therefore the nutritional value and metabolism of both products would not be expected to differ significantly.

Intended Uses

Similar to the existing BioAstin® product, the applicant intends to market the novel AstaMarin™ product for use in dietary supplements as hard and soft gel capsules and tablets. The applicant contends that the BioAstin® product is marketed as a 5% and

10% oleoresin with a recommended intake of 2 – 12 mg/day. The Cyanotech Corporation application dossier seeking a substantial equivalence opinion for their astaxanthin (BioAstin®) stated that they were aware of no reports of adverse reactions to astaxanthin dosages of 2-12 mg/day, but the dossier did not propose a specific recommended dosage. The substantial equivalence opinion by the UK authorities from 2006 that allowed BioAstin® on the market refers to the level of astaxanthin present in each capsule or tablet at 4 mg but is silent on a specific recommended daily dosage. Therefore, for the purposes of this opinion the recommended daily intake for AstaMarin™ can only be taken as "current levels of usage" rather than a specific value of 2 – 12 mg/day. In any event, the recommended daily intake of astaxanthin in the EU has been addressed in a novel food assessment published by EFSA in June 2014 and this may have an effect on future recommended daily intakes of astaxanthin within the EU.

Level of Undesirable Substances

The applicant notes that the algal source is cultivated in a closed system and that only CO_2 is used as a solvent in the production of AstaMarin™ with no other chemicals involved. Therefore detailed information on chemical residue analysis is not provided. The applicant provides data relating to microbial (Yeasts/moulds, *Salmonella*, *E. Coli* and *Staphylococcus*) and chemical (Dioxins and PCB congeners) contaminants as well as heavy metals (arsenic, cadmium, lead and mercury) are provided, and the applicant intends that such monitoring will continue as part of the quality control system.

Conclusions

The FSAI is satisfied from the information provided by the applicant that astaxanthin (5% and 10% Oleoresin) marketed by Fenchem Biotek Ltd. (AstaMarin™) is substantially equivalent to the astaxanthin product (BioAstin®) permitted on the EU market by substantial equivalence opinion in 2006 to the Cyanotech Corporation. The products are substantially equivalent with respect to composition, nutritional value, metabolism and undesirable substances while the recommended daily intake for AstaMarin™ will be the same as for the existing BioAstin® product.