ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES
DRY BIOMASS AND OLEORESIN FROM *HAEMATOCOCCUS PLUVIALIS*

ISSUE

1. The Committee is asked to consider the information provided for an astaxanthin-rich oleoresin extracted from the algae *Haematococcus pluvialis.* The manufacturer of this product, Algalo Industries requests the opinion of the UK Competent Authority (CA) that this oleoresin should be considered substantially equivalent to an existing product produced by the Swedish company AstaReal AB (formerly registered as AstaCarotene AB) which is now owned by Fuji Chemical Industry Co. Ltd of Japan.

Background

2. *Haematococcus pluvialis* is rich in astaxanthin, a xanthophyll (oxygenated) carotenoid. It is consumed in the European Union as a food supplement.

3. Regulation (EC) 258/97 makes provision for novel foods or ingredients that are substantially equivalent to an existing product to be placed on the market once the applicant has notified the Commission. In all cases to date, the Commission has required that the applicant first obtain an opinion on equivalence from a Member State. Algalo Industries Ltd is requesting such an opinion from the UK Competent Authority.

4. According to article 3(4) of (EC) 258/97, the notification procedures applies to "foods or food ingredients…..which on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies….are substantially equivalent to existing foods or food ingredients as regards:

    - Composition
    - Nutritional value
    - Metabolism
    - Intended Use and
    - Level of undesirable substances contained therein.

5. Algalo have provided data which in their view demonstrates that their dry biomass and oleoresin is equivalent to the extract marketed by AstaReal AB.

6. The application dossier is attached as **Annex A** and contains confidential information

This application

7. Under Article 3(4) of the Novel Foods Regulation (EC) 258/97, the applicant is requesting an opinion from the UK Competent Authority on equivalence of its astaxanthin-rich oleoresin from *H. pluvialis* compared with AstaReal AB's product. Algalo have used open ponds, whereas AstaReal have used a closed system.

8. In previous applications the case for equivalence was made largely on the basis that the oleoresin contained a comparable amount of astaxanthin and other carotenoids when compared with the original algal meal product and it was accepted that there would be differences in the overall gross composition of the product compared with other extracts of oleoresin. An RP-HPLC analysis was carried out by the applicant and detected only the carotenoids astaxanthin and Lutein (Tables 1 and 2 – pgs 4 and 5 of Annex A).

9. The applicant has included a comparison of the fatty acid profile of their product (Figure 1 pg 7 and Table 5 pg 8 of Annex A). The applicant states that the fatty acid profile is comparable to AstaReal. Variations in the values are explained and include,analytical methods not standardised, batch to batch variations – depending on the cultivation conditions and season, and differences in oils used for dilution of the oleoresin – olive oil or MCT.

10. All the additives used in the production are authorised in the European Union for use in food (Table 11 pg 13 Annex A)

11. The applicant has also included a comparison of trace metals and heavy metals of their product. Differences with the AstaReal results are partly due to tap water being used for the analysis. The analysis is now carried out by reverse osmosis. Cultivation conditions also affect the mineral composition of the microalgae. The 2 strains of *H.pluvialis* used have slight differences in their phenotype and as a consequence differ slightly in their mineral content (Table 7 and 8 pgs 10 and 11Annex A).

12. The applicant has reported PCBs and pesticide residues were screened for and the negative results obtained are included in the dossier. There are no potential contaminants (Dossier Annex I)

13. The applicant has reported the microorganism levels are within the specification of the product. Two samples of pheophorbide, a known breakdown product of chlorophyll were tested and levels in the novel food were found to be equivalent to levels in AstaReal's product.

14. The existing product is available in the European Union as a food supplement with a maximum recommended consumption of astaxanthin of 4 mg/day. This application is for use in food supplements at a maximum consumption of 4mg/day.

15. A non-confidential version of the application will be placed on the FSA website to allow the public to input into the UK assessment and comments received after the ACNFP meeting will forwarded to Members for consideration.

COMMITTEE ACTION REQUIRED

16. The Committee is asked if whether the available data are sufficient to assess the applicant's claim of substantial equivalence has been established between Algalo Industries dry biomass and oleoresin from *H pluvialis* product and an existing product, also produced from *H pluvialis* in accordance with Article 3(4) of Regulation (EC) 258/97.

17. If so, the Committee is asked whether it agrees that substantial equivalence has been established.

18. The Committee's is asked what additional information the applicant should supply in order to demonstrate equivalence.

Secretariat
January 2017

Annexes attached:

Annex A: Application dossier and annexes.