

## ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OLEORESIN FROM DRIED BIOMASS FROM *Haematococcus pluvialis* ALGAE**Issue**

The Committee is asked to consider a draft opinion on whether Algal Industries dry biomass from oleoresin from *Haematococcus pluvialis* should be considered substantially equivalent to similar dry biomass from oleoresin from *H. pluvialis* already on the EU market. The Committee is asked if it agrees, that substantial equivalence has been demonstrated.

**Background**

- This dossier was considered at the last meeting of the Committee in February. The Committee noted batch to batch variation was very large, and compositional data differed between AstaReal's product and Algal Industries product and so sought further information to establish if substantial equivalence had been demonstrated. A comparison of previous substantial equivalent applications was provided (**Annex C**) which has showed that for Astaxanthin applications the proximate composition, and fatty acids have differed between the products being assessed and comparison products to a similar degree to that seen in this application.
- The oleoresin and carotenoid in Algal Industries product are largely within the ranges shown by the other oleoresin products already on the market. Previous applications had made the case for equivalence largely on the basis that the oleoresin contained a comparable amount of astaxanthin and other carotenoids when compared with the original algal meal product. At the time these applications were considered by the ACNFP the Committee had accepted that there would be differences between the overall gross composition of the meal and the oleoresin product being assessed.
- The Committee is asked to review the data on oleoresin and carotenoids in Algal Industries product to determine whether it is substantially equivalent to other products already on the EU market. The Secretariat has drafted a positive opinion for discussion. The opinion will be updated with the points raised in the discussion following the meeting.

- A non-confidential version of the application dossier has been placed on the FSA website to allow the public to input into the UK assessment. The consultation will end on 16 April, no comments have been received to date. Any comments we receive will be tabled at the ACNFP meeting for consideration by the Committee.

### **Committee Action Required**

- The Committee is asked whether it agrees that substantial equivalence has been established between Algalo Industries' oleoresin from dried biomass from *H. pluvialis* algae and an existing product, also produced from *H. pluvialis*, in accordance with Article 3(4) of Regulation (EC) 258/97.
- If not, the Committee is asked what additional information the applicant should supply in order to demonstrate equivalence.
- The Committee is also invited to comment on the draft opinion that has been prepared. (**Annex B**).

**Secretariat  
April 2017**

Annexes attached:

**Annex A: Application dossier and appendices**

**Annex B: Draft Opinion for comment**

**Annex C: Information on the specification of similar products that have been previously authorised.**