

OPINION ON SUBSTANTIAL EQUIVALENCE OF OLEORESIN FROM DRIED BIOMASS FROM *Haematococcus pluvialis* ALGAE CONSIDERED UNDER ARTICLE 3(4) OF THE NOVEL FOODS REGULATION 258/97

Applicant

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Introduction

1. A request was submitted by Algalo industries Ltd to the UK Competent Authority for an opinion on the equivalence of their oleoresin from the dried biomass from *Haematococcus pluvialis*, compared with the existing *H. pluvialis* astaxanthin-rich algal meal from AstaReal.
2. Astaxanthin is a carotenoid found in the algae *Haematococcus pluvialis* and is responsible of the pink coloration in the flesh of fish or crustaceans (e.g. salmon, shrimps), through the ingestion of astaxanthin.
3. *H. pluvialis* meal rich in astaxanthin is currently available to European consumers. A Swedish company, AstaCarotene¹, has been selling capsules containing dried *H. pluvialis* algae (Astaxin), since at least 1995.
4. The request addresses substantial equivalence in accordance with the five criteria set out in Article 3(4) of regulation 258/97: composition, nutritional value, metabolism, intended use and level of undesirable substances contained therein.

Evaluation

a) Composition

5. The applicant cultivates *H. pluvialis* algae in open bioreactors where conditions are controlled and astaxanthin synthesis is induced. On completion of astaxanthin synthesis, the cells are harvested and algal cells are precipitated in a centrifuge. It is freeze dried, food grade additives are added and the algal cells are cracked. The dry powder is vacuum packed. The oleoresin is extracted from the dried biomass by Supercritical Fluid CO₂ Extraction. It is collected and then while it is being homogenated, it is diluted and standardized into astaxanthin concentration of 10% with Olive oil.

The applicant has carried out a comparison of the proximate composition of AstaReal and their own *H. pluvialis* oleoresin product. The applicant has sought to summarise these data in Table 1 below.

Table 1: Comparison of the composition of the novel ingredient with the AstaReal product on the EU market.

Parameter (%) w/w	Algal oleoresin	AstaReal oleoresin
Fat	98%	95-102%
Protein	1.9%	0.03%
Carbohydrates	<1%	<1%
Fibre	<1%	<1%
Ash	0.1%	<0.1%

The applicant states the precise content of carbohydrates, fat and proteins and the ratio between these components is dependent on two factors

- a. The environmental/growth conditions of the algae, particularly the temperature. Usually the lower the temperature, the higher the fat content and the lower the carbohydrate in the oleoresin.
 - b. The specific strain of the *Haematococcus pluvialis* that is cultivated.
6. The applicant has explained the causes of the compositional differences seen when comparing AstaReal's oleoresin product with Algal Industries product. The applicant considers these to be due to the use of different strains of *H. pluvialis* and differing culture conditions. The extraction process is also done under slightly different conditions, the CO₂ being under a lower pressure.

Fatty Acids

7. The applicant has compared the fatty acid profile of their biomass and their oleoresin product with AstaReal's oleoresin product. The applicant states that the fatty acid profile is comparable to AstaReal's oleoresin product. The applicant argues the small differences are due to non-standardised analytical methods and batch to batch variations caused by cultivation methods, the oil used for diluting the oleoresin.

Carotenoid Profile

8. The applicant has compared the carotenoid profile of Algal Industries oleoresin product with AstaReal's oleoresin product. See Table 2 below.

Table 2 – Carotenoid Profile

Carotenoids (%) w/w	Algalo HPRA00	Algalo HPRAS1	Algalo Oleo301116	AstaReal Oleoresin
Astaxanthin concentration of which:				
Free Astaxanthin	1.98%	2.74%	2.03%	NA
Astaxanthin-monoesters	83.06%	76.08%	78.92%	NA
Astaxanthin-diesters	11.4%	19.68%	17.32%	NA
Trans astaxanthin	79.59%	72.07%	87.16%	≤78.2%**
9Z- astaxanthin	11.9%	12.88%	NA	17.5%
13Z- astaxanthin*	4.69%	13.45%	NA	4.3%

NA: not available

* : After de-esterification

** : Calculated

The applicant has used RP-HPLC analyses of its products and only detected astaxanthin and lutein. No other carotenoids, including canthaxanthin were detected. Astaxanthin in the oleoresin products accounts for 98% of the carotenoids in the algae.

Discussion: There was a large range of values for the proximate analysis of astaxanthin products already on the market. This novel ingredient is within the range of these values. The Committee noted that the novel ingredient is primarily produced as an oleoresin for its carotenoids in particular astaxanthin and fatty acids. The astaxanthin and astaxanthin mono acids levels in the novel ingredient are within the range of other products on the market. The characteristic fatty acids for this novel foods were similar in the Algalo Industries product to other products on the market.

b), c) Nutritional Value and Metabolism

9. The applicant states the composition of the product does not differ from its existing counterpart and so it is unlikely that there will be significant differences in its nutritional value or metabolism.

Discussion: The Committee was content with information provided on the nutritional value and metabolism of the product.

d) Intended Use

10. The applicant states the existing product is available in the European Union as a food supplement with a maximum recommended consumption of astaxanthin not exceeding 4mg. No other food uses are envisaged.

Discussion: The Committee considered Algalo Industries intended use of the product as an ingredient in food supplements at a maximum recommended consumption of 4gm was similar to the use of other similar products on the market.

e) Levels of Undesirable Substances

Trace metals

11. The applicant states the reason for the higher mineral content compared with the AstaReal product is that the analysed batches were produced with tap water which is “harder” in the north of Israel than in the production area of the comparator product. Production has since switched to using reverse osmosis water for production which contains fewer minerals. The additional minerals do not affect the safety of the product.

Heavy metals and other contaminants.

12. Three samples of algal meal and one of oleoresin were screened for heavy metals, dioxins and furans, dioxin-like PCBs, PCBs, PAHs and pesticide residues. The maximum level for lead and cadmium in food supplements is 3mg/kg. The maximum level for mercury in food supplements is 0.1mg/kg and the product was compliant with these standards. There are no limits for dioxins and PCBs in food supplements. The applicant states the TEQ values for octaCDD and octaCDF may represent analytical aberrations as there is no known source of these substances in algal biomass.

Microorganisms

13. AstaReal biomass is grown in closed tanks which are illuminated by artificial light and cultivation is at lower temperatures than Algalo Industries which use artificial light and then an open bioreactor only in the final stages of growth. The closed system is used to manage the risks of contamination with other microorganisms.

14. Pheophorbide a known breakdown product of chlorophyll, was tested in three samples of Algalo’s oleoresin, two of which were found to contain less than 10mg pheophorbide per 100g. Pheophorbide was detected at a level of 17mg/100g in one out of the three batches of AstaReal oleoresin analysed. The applicant states that the levels of pheophorbides in Algalo’s oleoresin product and its existing counterpart are consistent and are therefore equivalent.

15. DPA, a di-phenyl amine may be a contaminant of natural astaxanthin as it can be present in rubber parts, pipes and pumps used in production plants. Algalo’s oleoresin and intermediate products of the extraction process were found to contain no DPA above the limit of detection (0.5 mg/kg). There is no data available on DPA levels for AstaReal oleoresin products for comparison.

Discussion: The Committee didn’t raise any concerns about the trace metals, heavy metal contamination levels and micro-organism contamination levels

Conclusion:

16. The Committee noted that there was a large range of values for the proximate analysis of astaxanthin products. However, the Committee took account of previous applications where the case for equivalence had been 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 with this approach accepted by the ACNFP previously. In the case of Algalo Industries product the oleoresin, astaxanthin and astaxanthin mono acids and the characteristic fatty acids composition was similar to the composition of similar products already on the market
17. The Committee therefore concluded that Algalo Industries has demonstrated the equivalence of their Oleoresin product from dried biomass obtained from *H. pluvialis* with the existing Oleoresin products from dried biomass obtained from *H. Pluvialis* according to the criteria set out in Article 3(4) of the Novel Foods Regulation (EC) 258/97.
18. This opinion applies solely to the specified product, produced according to the processes described in the dossier, to be used by food supplement manufacturers with an astaxanthin content of no more than 4mg per capsule or tablet.