Notification in accordance with Article 5 of Regulation (EC) No 258/97 regarding Novel Foods and Novel Food Ingredients

Presentation of data to demonstrate substantial equivalence between a novel food or food ingredient (dry biomass and oleoresin from Haematococcus pluvialis produced by Algalo Industries Ltd) and an existing counterpart (Haematococcus pluvialis product produced by AstaCarotene AB)

Submitted by:

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ISRAEL

January 2017

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Introduction

Algalo Industries Ltd wishes to market dry biomass and oleoresin from *Haematococcus pluvialis* produced by closed cultivation and purified by supercritical CO_2 extraction in the EU for use in dietary supplements. The company wishes to make a notification in accordance with Article 5 of Regulation (EC) No 258/97 regarding novel foods and novel food ingredients, using the simplified procedure products that can be shown to be substantially equivalent to existing foods. This procedure requires a positive opinion from a competent authority in one of the EU member states and the company is directing this request for a substantial equivalency opinion to the UK Food Standards Agency and the Advisory Committee on Novel Foods and Processes (ACNFP).

This application follows Guidelines provided by the ACNFP for the presentation of data to demonstrate substantial equivalence between a novel food or food ingredient and an existing counterpart[1]. In this case the novel food will be dry biomass and oleoresin from *Haematococcus pluvialis* produced by Algalo Industries Ltd in a closed cultivation system and purified by supercritical CO2 extraction. The existing counterpart is the existing *Haematococcus pluvialis* 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. AstaReal AB, has marketed its Astaxin™ product in the EU since at least 1995[2]. .

Data to demonstrate substantial equivalence between a novel food or food ingredient and an existing counterpart

(a) Administrative information

Administrative information	
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Name of the novel food or food ingredient:	Algalo dry biomass and oleoresin from *Haematococcus pluvialis*
Date of the application:	January 2017

(b) Composition

Specification

The commercial specification for *Haematococcus pluvialis* algae dried biomass produced by Algalo Industries Ltd is provided at Annex A to this submission. The specification for algal biomass marketed by Fuji under the trade name BioReal is available in the Premarket Dietary Ingredient Notification for Astaxanthin present in Haematococcus pluvialis submitted to the US FDA[3]. The commercial specification for *Haematococcus pluvialis* oleoresin produced by Algalo Industries Ltd and marketed by Frutarom (in January, 2016, Frutarom Ltd, acquired 50% of Algalo's shares) is provided at Annex B to this submission.

Source organism

The source organism for the novel food and the existing counterpart is the microalgae *Haematococcus pluvialis.*

Methods used for preparation of the novel product

A detailed description of the method of production of Algalo *Haematococcus pluvialis* algae dried biomass is provided at Annex C (CONFIDENTIAL). Single-cell colonies of the microalgae *Haematococcus pluvialis* are grown in test tubes in the inoculation room, in sterile conditions. The *Haematococcus* culture is transferred to plastic sleeves and from there to an array of Algalo's proprietary photo-bio-reactors (PBRs). At an adequate algae cell density, the *Haematococcus* "green" culture is divided and diluted to the outdoors "Red Stage" PBRs and subjected to stress conditions, which elicit the production and accumulation of the carotenoid natural astaxanthin in the algae cells. The *Haematococcus* cells are collected from the "Red Stage" PBRs and the algal cells are precipitated in a centrifuge. The precipitate is packed in plastic bags and stored frozen (-20° C) for transfer to a sub-contractor's facilities for freeze drying. After drying food grade silicon dioxide, ascorbyl palmitate and rosemary extract are mixed with the dry biomass and the algal cells are cracked by a proprietary air pressure milling process. At this point the dried biomass is refrigerated ready for shipping.

The oleoresin is prepared by supercritical CO_2 extraction of the dried biomass and standardized to an astaxanthin concentration of 10% with olive oil. Natural tocopherol and oil soluble rosemary extract are added as anti-oxidants. At this point the oleoresin is refrigerated ready for shipping.

The existing counterpart AstaReal Haematococcus meal is prepared in Sweden in a very similar process involving cell culture, growth in a photo-bioreactor, induced to form the red phase, harvested, crushed and dried[4]. AstaReal also supply an oleoresin containing 10% astaxanthin produced by non-solvent supercritical carbon dioxide extraction[5].

The difference between the two production methods is believed to be limited to the design of the bioreactor. The Algalo photo-bio-reactors are a closed to the atmosphere which results in lower levels of some contaminants, the ability to highly control and optimize culture condition and, other advantages of closed systems for microalgae cultivation. In contrast, Algalo's proprietary PBR design has the advantage of low installation and operating costs characterizing some open systems.

AstaReal cultivation is performed with artificial lighting and artificial light/dark cycle, whereas Algalo's cultivation process is performed with natural sunlight and natural seasonal day/night

cycle. This results in lower overall concentration of astaxanthin in the algal cells. The lower average concentration does not affect the quality or the doses of the active agent (astaxanthin) in the final products.

Another minor difference between the two production methods resides in the milling process, intended to break the cell walls and to make the Astaxanthin readily available. Algalo performs the milling on dry *Haematococcus* cysts (alplanospores), whereas, BioReal mills wet algal paste. Algalo's milling process is believed to be safer for it does not use beads for mechanical milling, but only air pressure. Moreover, natural astaxanthin is safely packed and protected inside the Haematococcus cysts during the drying process, which is applied on algal paste, consisting of unbroken cysts.

Composition of the final product

Carotenoids

Algalo Industries Ltd has compiled a report on the composition and quality of Algalo's Products (Annex D – CONFIDENTIAL). Certificates of analysis of three recent batches of dried algal meal are provided at Annex E and summarised in Table 1.

The average composition of three batches of algal biomass marketed by Fuji under the trade name BioReal is available from the Premarket Dietary Ingredient Notification for Astaxanthin present in *Haematococcus pluvialis* submitted to the US FDA[3]. Additional information about the isomerisation of astaxanthin is available from the EFSA NDA Panel Opinion on the safety of astaxanthin-rich ingredients (AstaREAL A1010 and AstaREAL L10) as novel food ingredients[6]. Levels of astaxanthin in AstaReal batches reported in the NDA Opinion were higher than those reported to FDA, suggesting some batch-to-batch variation.

Table 1. Carotenoid composition of Algalo biomass compared with data for the existing counterpart.

	Algalo HPRA1 & 2prot31716	**Algalo HPRA3 & 5prot030816**	**Algalo HPRA6 & 7prot080816**	**AstaReal**
Astaxanthin	2.97%	2.92%	3.22%	3.8%[3] / 5.16%[6]
Of which:				
Free-Astaxanthin	3.71%	3.49%	4.9%	1.3%[3]
Astaxanthin-monoesters	89.46%	79.81%	91.4%	81.6%[3]
Astaxanthin-diesters	4.51%	15.25%	3.7%	18.4%[3]
Trans- astaxanthin*	83.21%	81.31%	84.09%	---
9Z-astaxanthin*	8.06%	8.65%	7.6%	12%[6]
13Z-astaxanthin*	3.97%	5.56%	3.7%	7%[6]

* After de-esterification

The results for three separate batches of super-critical fluid-CO_2 (SCF-CO_2) extracted Algalo oleoresin gave an average astaxanthin concentration of 13.63% (Annex D). Certificates of analysis of three recent batches of oleoresin are provided at Annex F and summarised in Table 2.Astaxanthin in oleoresin is standardised to 10% with olive oil before distribution. Data on the degree of esterification of the AstaReal oleoresin were unavailable. However, analyses of comparable products showed that the ratio was likely to be very similar (see Annex D).

Table 2. Carotenoid composition of Algalo oleoresin compared with data for the existing counterpart.

	Algalo HPRA00	**Algalo HPRAS1**	**Algalo Oleo301116**	**AstaReal**
Astaxanthin concentration	10.91%	15.78%	10.15	10.61%[6]
Of which:				
Free-Astaxanthin	1.98%	2.74%	2.03%	n/a
Astaxanthin-monoesters	83.06%	76.08%	78.92%	n/a
Astaxanthin-diesters	11.4%	19.68%	17.32%	n/a
Trans-astaxanthin*	79.59%	72.07%	87.16%	≤78.2% **
9Z-astaxanthin*	11.9%	12.88%	CHECK	17.5%[6]
13Z-astaxanthin*	4.69%	13.45%	CHECK	4.3%[6]

* After de-esterification

** Calculated.

The applicant has used RP-HPLC analyses (using the method of the USP monograph and USP standards) of our products and detected only Astaxanthin and Lutein. No other carotenoids including canthaxanthin were detected. Astaxanthin in the products accounts for about 98% of the carotenoids in the algae. Other producers, which cultivate their algae in open systems may contain other carotenoids as well.

The applicant has also reported results for pheophorbide, as detailed in the USP monograph for natural astaxanthin and we have demonstrated that products are compliant. As a control for those analyses, purified pheophorbide to spike all samples.

Total composition

The total fat, protein carbohydrate, fibre and ash content of the dried algal biomass (Annex G, Table 3) and oleoresin (Table 4) can be compared with equivalent data from the EFSA NDA Opinion on AstaReal products. Certificates of analysis are provided in Annex H.

Table 3. Total composition of Algalo biomass compared with data for the existing counterpart.

	Algalo biomass	**AstReal biomass**
Fat	35%	45 - 50%
Protein	13%	9 - 12%
Carbohydrates	40%	20 - 30%
Fibre	40%	10%
Ash	≤5%	1.5 - 2.5%

Table 4. Total composition of Algalo oleoresin compared with data for the existing counterpart.

	Algalo oleoresin	**AstaReal Oleoresin**
Fat	98.0%	95 - 102%
Protein	1.9%	<0.03%
Carbohydrates	<1%	<1%
Fibre	<1%	<1%
Ash	0.1%	<0.1%

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

1- The environmental/growth conditions of the algae, particularly on the temperature. Usually the lower is the temperature the higher is the fat content and lower is the carbohydrate content. And

2- The specific strain of the *Haematococcus pluvialis* that is cultivated.

AstaReal biomass is grown in closed tanks, which are illuminated by artificial light. Their cultivation and production is performed at lower temperatures. Algalo, as described, is using an array of PBR's that are exposed to Sunlight. The "red stage" of the cultivation is done at about 30 degrees Celsius. Under these conditions the algae accumulate less fat and more carbohydrates. There may also be some slight strain differences in carbohydrates, fat and proteins ratios. As a result, the "algal meal" product of Algalo contains more carbohydrates and dietary fibers, but an equal amount of natural astaxanthin.

Algalo's oleoresin contains a little higher level of proteins because the extraction process is done under slightly different conditions than that of AstaReal. The CO_2 (solvent) pressure 600 bars, whereas AstaReal extract under 700 bars. Under such conditions fewer proteins are extracted. In additions, different additives (lecithin, Rosemary extract, ascorbyl palmitate) in the extracted biomass, will protect proteins in the extraction process.

Given the dosages of astaxanthin used (up to 40 mg of oleoresin per day), the differences are insignificant from the perspective of the consumer.

Fatty acid profiles

The relative proportions of fatty acids for Algalo biomass, Algalo oleoresin and AstaReal biomass are summarised in Table 5. The comparison in more easily made from a bar chart (Figure 1). Certificates of analysis are provided in Annex H.

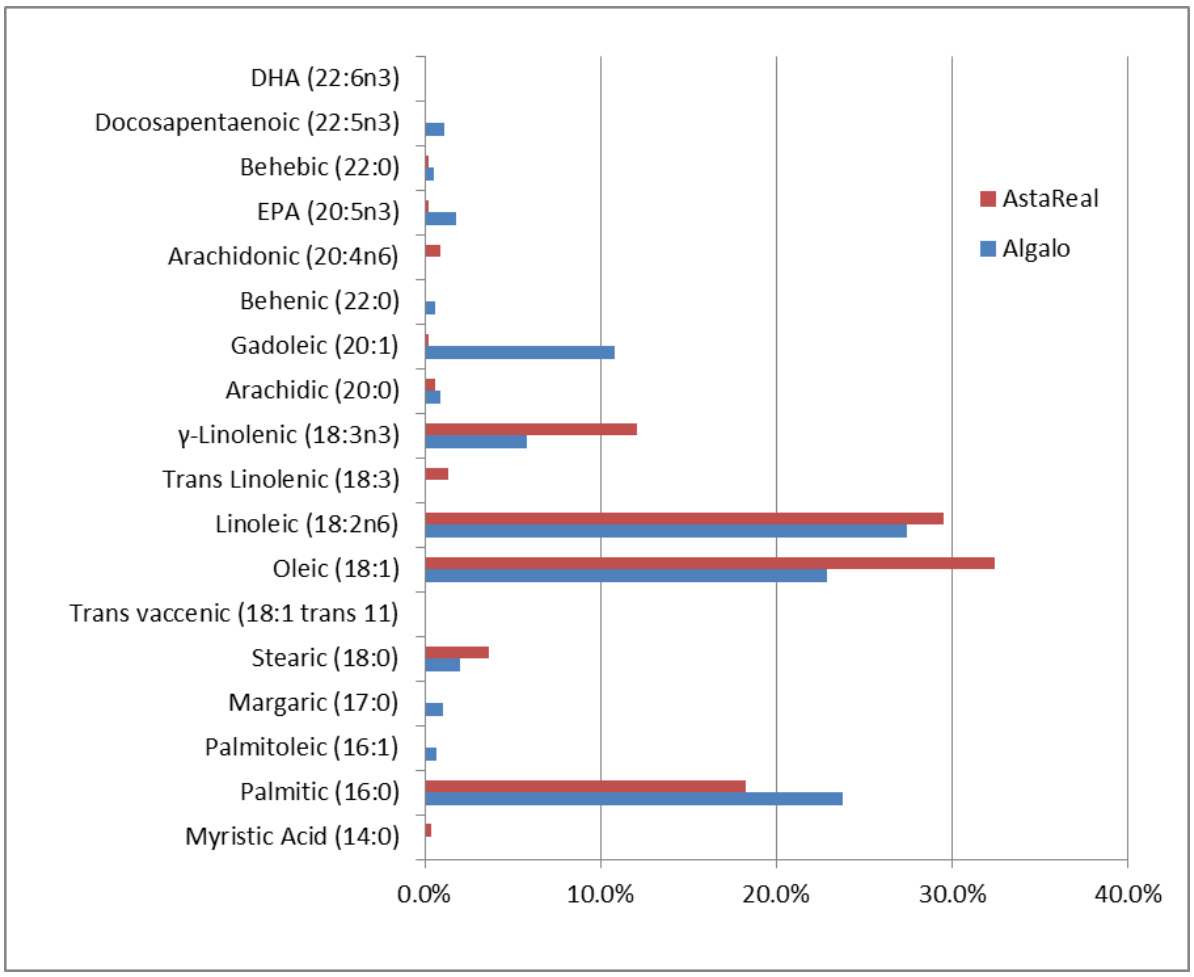

Figure 1. Bar chart of fatty acid profiles of Algalo biomass and oleoresin compared with data for the existing counterpart.

Table 5. Fatty acid profiles of Algalo biomass and oleoresin compared with data for the existing counterpart.

	Algalo biomass	**Algalo oleoresin**	**AstaReal biomass**
Caproic (6:0)	<0.1	<0.1	
Caprylic (8:0)	<0.1	<0.1	
Capric (10:0)	<0.1	<0.1	
Lauric (12:0)	<0.1	<0.1	
Myristic Acid (14:0)	<0.1	0%	0.4%
Pentadecanoic (15:0)	<0.1		
Palmitic (16:0)	23.8%	6%	18.2%
Palmitoleic (16:1)	0.7%	0%	
Margaric (17:0)	1.0%	0%	
Stearic (18:0)	2.0%	2%	3.6%
Trans vaccenic (18:1 trans 11)	<0.1	<0.1	
Oleic (18:1)	22.9%	12%	32.4%
Oleic trans (18:1)	<0.1	19%	
Linoleic (18:2n6)	27.4%	17%	29.5%
Trans Linolenic (18:3)	<0.1		1.3%
γ-Linolenic (18:3n3)	5.8%	27%	12.0%
Arachidic (20:0)	0.9%	1%	0.6%
Gadoleic (20:1)	10.8%	10%	0.2%
cis-11-Eicosenoic (20:1)	<0.1		
cis-11,14-Eicosadienoic (20:2n6)	<0.1		<0.1
Behenic (22:0)	0.6%	1%	
Arachidonic (20:4n6)	<0.1	1%	0.9%
EPA (20:5n3)	1.8%	3%	0.2%
Heneicosanoic (21:0)	<0.1		
Behebic (22:0)	0.5%	<0.1	0.2%
Docosapentaenoic (22:5n3)	1.1%		
DHA (22:6n3)	<0.1	1%	<0.1
Lignoceric (23:0)	<0.1	1%	
Tetracosenoic (24:1)	0.8%	<0.1	
Nervonic (24:1n9)	0.4%		
Unknown	<0.1		
	%	%	%

Small differences exist between the lipid profiles of Algalo products and AstaReal biomass. These are due to the following factors:

1- Analysis. The analytical methods used are not standardized and cannot be used for direct comparison, particularly at such low levels. The equipment and methods are not sensitive enough. To compare the profiles accurately, one would need to perform the analyses at the same laboratory at the same time. This is not feasible

2- Batch to batch variations. Each batch of algae and oleoresin has slightly different fatty acids profiles, depending on the cultivation conditions and the season.

3- Olive oil. The variability in oleic acid is probably resulting from the oil used for dilution of the oleoresin. For standardization we use olive oil. Fuji uses MCT, or Safflower oil..

4- Cultivation conditions. The differences in LC-PUFA concentrations are a consequence of the cultivation conditions (especially temperature, cultivation time and light source, etc.).

It is important to emphasize that none of these minor differences has any effect on the quality or the safety of the marketed products.

Maximum limits for the presence of known or potential contaminants.

Potential metal contaminants

Maximum levels for heavy metals provided in the product specification for biomass are provided in Table 6.

Table 6. Maximum levels of trace metals in Algalo biomass.

	Limit
Arsenic	≤ 1 mg/kg
Lead	≤ 1 mg/kg
Mercury	≤ 0.1 mg/kg
Cadmium	≤ 0.1 mg/kg

(c) Nutritional value

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.

(d) Metabolism

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.

(e) Intended use

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 would be for food supplements with a daily consumption of astaxanthin not exceeding 4 mg. No other food uses are envisaged.

(f) Levels of undesirable substances

The quantities of trace and heavy metals reported in Algalo biomass, Algalo oleoresin and AstaReal biomass are summarised in Table 7. Certificates of analysis are provided in annexes H a to e.

Table 7. Levels of trace metals in Algalo biomass and oleoresin compared with data for the existing counterpart.

	Algalo biomass	**Algalo oleoresin**	**AstaReal biomass**
Aluminum (Al)	7	2<	27
Antimony (Sb)	<0.1	0	
Arsenic (As)	<0.2	0.6	<0.05
Barium (Ba)	10.3	<0.2	
Beryllium (Be)	<0.1	<0.2	
Boron (B)	21	<2	
Cadmium (Cd)	<0.1	<0.1	0.01
Calcium (Ca)	15214	32	13500
Chromium (Cr)	3	0.3	5
Cobalt (Co)	<0.2	0.2	
Copper (Cu)	34.3	3	4.4
Iodine (I)	<10	<10	0.4
Iron (Fe)	237	4	100
Lead (Pb)	<1	<0.2	0.03
Lithium (Li)	<0.2	<0.2	
Magnesium (Mg)	1506	17	350
Manganese (Mn)	78.3	0.5	70
Mercury (Hg)			<0.02
Molybdenum (Mo)	0.2	0.2	
Nickel (Ni)	0.3	<0.2	
Phosphorus (P)	3828	8	2400
Potassium (K)	2356	<2	2300
Selenium (Se)	<0.2	<0.2	<0.03
Silicon (Si)	<0.1	0	
Silver (Ag)	<0.2	<0.2	
Sodium (Na)	236	4	
Sodium (Na)			260
Strontium (Sr)	30	<0.2	
Sulfur (S)	1731	2	
Tin (Sn)	0.5	<0.5	
Titanium (Ti)	0.2	<0.2	
Vanadium (V)	1.2	<0.2	
Zinc (Zn)	71	0.5	13
	mg/kg	mg/kg	mg/kg

The analysed batches were produced with tap water, which is “harder” in the north of Israel. This explains the higher mineral content compared to AstaReal product. Since that time production has switched to using reverse osmosis (RO) water for production, which contain less minerals (apart of those nutrients we add to the cultivation media). These additional minerals do not affect the safety of the biomass.

Heavy metals and other contaminants.

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 (Annexe I and J and Table 8). The levels of all contaminants are lower that limits set for certain contaminants[7] and for pesticides[8] in European regulations.

Table 8. Screening results for heavy metals, dioxins and furans, dioxin-like PCBs, PCBs, PAHs and pesticide residues

		Algalo algal meal			Oleoresin	
Metals		HPRA6 & prot080816	HPRA1 & 2prot31716	HPRA3 & 5prot030816	Oleo301116	
	Lead	0.78	0.65	0.68	0.09	mg/kg
	Cadmium	<0.01	<0.01	<0.01	<0.01	mg/kg
	Mercury	<0.005	<0.005	<0.005	0.012	mg/kg
	Arsenic	0.4	0.2	0.03	<0.1	mg/kg
	Chromium	0.71	1.0	0.88	0.6	mg/kg
Dioxins and furans						
	PCDD/F TEG (upper-bound)	0.196	0.193	0.242	0.34	pg/g
	PCDD/F TEG (lower-bound)	0.0877	0.0818	0.136	0.0783	pg/g
Dioxin-like PCBs						
	PCB TEQ (upper-bound)	0.0662	0.121	0.0647	0.177	pg/g
	PCB TEQ (upper-bound)	0.00049	ND	ND	ND	pg/g
Dioxins, furans and PCBs						
	PCDD/F + PCB (upper-bound)	0.263	0.313	0.307	0.517	pg/g
	PCDD/F + PCB (lower-bound)	0.0881	0.0818	0.136	0.0783	pg/g
PCBs						
	PCB (upper-bound)	0.64	1.17	0.627	1.71	ng/g
	PCB (lower-bound)	ND	ND	ND	ND	ng/g
PAH						
	Benzo(a)anthracene	<0.5	<0.5	<0.5	<0.5	µg/g
	Benzo(a)pyrene	<0.5	<0.5	<0.5	<0.5	µg/g
	Benzo(a)fluoranthene	<0.5	<0.5	<0.5	<0.5	µg/g
	Chrysene	<0.5	<0.5	<0.5	<0.5	µg/g
	Sum PAH 4	NA	NA	NA	NA	µg/g
Pesticides						
	OCs, pyrethroides	ND	ND	ND	ND	ND
	NCI-GHT	ND	ND	ND	ND	-
	OPs	ND	ND	ND	ND	ND
	ONs	ND	ND	ND	<0.01-6.0	mg/kg

The maximum level for lead (Pb) and cadmium (Cd) in food supplements is 3 mg/kg. The maximum level for mercury (Hg) in food supplements is 0.1 mg/kg. There are no limits for dioxins and PCBs in food supplements. TEQ values for octaCDD and octaCDF appeared raised in some samples. These substances have a toxicological equivalence factor of 0.0003 and so have minimal effect on total TEF. There is no known source of these substances in algal biomass and so they may represent analytical aberrations.

Contamination with bacteria, yeasts and moulds is tested in the biomass before extraction, because if the biomass is contaminated with bacteria it is not appropriate for human consumption. Microbiological tests were performed on the biomass by an accredited by the Israeli microbiological laboratory (Table 9). Certificates of analysis are provided in Annex H.

Table 9. Levels of microorganisms reported in Algalo biomass and product specification.

	Algalo biomass	**Specification**
Total counts (cfu/g)	330	≤ 10^4 CFU/gr
Yeasts (cfu/g)	<10	≤ 10^2 CFU/gr
Moulds (cfu/g)	<10	≤ 10^2 CFU/gr
Coliforms (cfu/g)	<10	≤ 10 CFU/gr
E. coli (cfu/g)	<10	
Salmonella (10g)	absent	absence

Pheophorbide is a known breakdown product of chlorophyll. Pheophorbide samples were tested in two samples of Algalo's oleoresin and found to contain less than 10 mg pheophorbide per 100g (Table 10).

Table 10. Levels of pheophorbide in Algalo oleoresin

Sample	**Pheophorbide mg/100g**
Pheo 0 #1	7.9
Pheo 0 #2	4.3

The presence of pheophorbide a, was reported in the EFSA NDA Panel Opinion on Scientific Opinion on the safety of astaxanthin-rich ingredients (AstaREAL A1010 and AstaREAL L10) as novel food ingredients. According to the applicant, the chlorophyll content of *H. pluvialis* is low and thus the amount of pheophorbides in the product is likely to be very low. Pheophorbide was detected at a level of 17 mg/100 g in one out of three batches of AstaREAL oleoresin analysed.

The levels of pheophorbides in the novel food product and the existing counterpart are therefore equivalent.

Traces of di-phenyl amine DPA may contaminate natural astaxanthin cultivated in photo-bio-reactors because it can be present in rubber parts, pipes and pumps used in the production plants. DPA is also a pesticide and anti-mycotic agent that is used in the citrus, apple and pear industries to inhibit post-harvest rot.

Algalo oleoresin, as well as the intermediate products of the extraction process, were found to contain no DPA above the limit of detection (0.5 mg/kg). No data on DPA levels are available for the AstaReal products.

(g) Other relevant data

The safety of astaxanthin was reviewed by the EFSA FEEDAP panel in 2014[9],[10] who recommended setting an ADI value of 0.034 mg/kg bw for astaxanthin. The EFSA NDA Panel noted in their opinion on AstaReal products that the maximum intake of 4 mg astaxanthin per day could exceed the ADI by approximately two- to three-fold.

All the additives used in production are authorised in the EU for use in food (Table 11).

Table 11. Additive used in the production of algalo biomass and oleoresin

Ingredient	Official name	E-number
Food grade silicon dioxide	Silicon dioxide	E551
Ascorbyl palmitate	Fatty acid esters of ascorbic acid	E304
Rosemary extract	Extracts of rosemary	E392
Natural tocopherol	Tocopherol-rich extract	E306
Oil soluble rosemary extract	Extracts of rosemary	E392

Conclusion

The novel food that is the subject of this application (dry biomass and oleoresin from *Haematococcus pluvialis* produced by Algalo Industries Ltd) is produced from the same organism using very similar production techniques and has a similar composition to the existing counterpart (*Haematococcus pluvialis* product produced by AstaCarotene AB). Some small variation can be seen in values such as the astaxanthin concentration, degree of esterification or isomer formation and the overall composition of proximates in both products. However, these differences reflect natural variations in a cultured product and may also include some degree of analytical uncertainty. Variations in the concentration of astaxanthin in the final algal meal or oleoresin product would be adjusted during manufacture of the food supplement and reflected in the labelling and use recommendations for the final product. From the perspective of the consumer of nutritional supplements any differences are minor and irrelevant from a nutritional and safety perspective.

The introduction of an ADI value for astaxanthin by the EFSA FEEDAP panel may result in a modification of usage recommendations for all *Haematococcus pluvialis* products at some time in the future.

References

[1] Food Standards Agency (2005). ACNFP guidelines for the presentation of data to demonstrate substantial equivalence between a novel food or food ingredient and an existing counterpart. Download from: http://acnfp.food.gov.uk/acnfppapers/inforelatass/guidance-presentation-data Accessed July 2016.

[2] AstaReal History. http://www.astareal.com/company/history Accessed July 2016.

[3]Fuji Chemical Industry Co., Ltd. 2005. Typical analysis results for AstaCarox™ V1010 Haematococcus algae meal. Excerpted from: Premarket notification for a new dietary ingredient:

Astaxanthin present in Haematococcus pluvialis algal biomass. United States Food and Drug Administration, Docket 95S-0316, RPT274. 1 p. https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwj2jIzJ3ITOAhVFWhoKHSwfBqUQFggjMAA&url=http%3A%2F%2Fwww.fda.gov%2Fohrms%2Fdockets%2Fdockets%2F95s0316%2F95s-0316-rpt0274-01-vol210.pdf&usg=AFQjCNF0ajwX4Rx11AbJEJ_IfmVK7TFS7Q&bvm=bv.127521224,d.d2s Accessed July 2016.

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[5] AstaReal oleoresin. http://www.astareal.se/products/bulk-products/oleoresin Accessed July 2016.

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