

Hilary Lloyd

Ocean Nutrition Canada Limited
101 Research Drive
Dartmouth
Nova Scotia B2Y 4T6
Canada

16 March 2012

Dear Ms Lloyd

**OPINION ON THE SUBSTANTIAL EQUIVALENCE OF A DHA RICH OIL
FROM MICROALGAE**

The Advisory Committee on Novel Foods and Processes (ACNFP) has now completed your request for an opinion on the substantial equivalence of your algal oil with the existing algal oil which received an authorisation under (EC)258/97 in 2003 and 2009 (decisions 2003/427/EC and 2009/778/EC respectively).

I am pleased to inform you that, in view of the positive opinion given by the ACNFP, the Food Standards Agency, UK Competent Authority for all novel food issues, is content that your algal oil meets the criteria for equivalence, as defined in Article 3(4) of regulation (EC) 258/97.

This opinion is issued on the basis that your oil will be used in accordance with the conditions of use and food categories detailed in decisions.

Please note that, in accordance with Article 5 of (EC) 258/97, you should notify the European Commission when you intend to market your algal oil ingredients when they are first marketed. You should send this to Mr Andreas Klepsch at the following address:

**European Commission
DG SANCO
Rue de la Loi 200
B-1049
Brussels
Belgium**

Aviation House
125 Kingsway
London WC2B 6NH
T 020 7276 8572
E chris.jones@foodstandards.gsi.gov.uk

If you have any other queries, please do not hesitate to contact me.

Yours sincerely,

Dr Chris Jones

Novel Foods Unit

cc James Peach Ocean Nutrition

John Howlett

Enc.: ACNFP opinion

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON SUBSTANTIAL EQUIVALENCE OF A DHA RICH OIL FROM MICROALGAE CONSIDERED UNDER ARTICLE 3(4) OF THE NOVEL FOOD REGULATION (EC) 258/97

Applicant **Ocean Nutrition Canada Limited**
101 Research Drive
Dartmouth
Nova Scotia B2Y 4T6
Canada

Responsible Person **Hilary Lloyd**

Background

1. In November 2011 a request was submitted by Ocean Nutrition Canada Ltd to the UK for an opinion on equivalence on their DHA rich algal oil compared with the existing DHA rich algal oil from *Schizochytrium sp* marketed by Martek.
2. A number of applications have been made under the novel foods regulation (EC) 258/97 for algal oils that are rich in DHA (docosahexaenoic acid). Of particular relevance to the current request are the oils produced from microalgae of the genus *Schizochytrium* and the Committee first considered an application for the authorisation of an oil from this source in 2001-2 Following its authorisation in 2003¹, the applicant company Martek (*formerly* Omega-Tech) successfully sought an extension of use, which was authorised in 2009²
3. The current request addresses substantial equivalence according to the five criteria set out in Article 3(4) of Regulation (EC) 258/97: composition, nutritional value, metabolism, intended use and the level of undesirable substances.

Evaluation

a) Composition

4. The applicant cultivates the algae (*Schizochytrium sp* ONC-T18) using a heterotrophic fermentation process, carried out in the absence of light under

¹ Commission Decision of 5 June 2003 authorising the placing on the market of oil rich in DHA (docosahexaenoic acid) from the microalgae *Schizochytrium sp.* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (2003/427/EC)

² Commission Decision of 22 October 2009 concerning the extension of uses of algal oil from the micro-algae *Schizochytrium sp.* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (2009/778/EC)

axenic³ conditions, which, in their view, is broadly the same as the process employed by Martek. The applicant controls a number of operating parameters (temperature, aeration, pH, etc) to ensure maximal biomass production and the harvested biomass is dried prior to oil extraction using an EU permitted extraction solvent (propan-2-ol). The oil produced by Martek is extracted using hexane.

5. Once the crude oil is extracted from the biomass it undergoes a number of refining processes that are common to the edible oil industry. Specific details of the extraction and refining process can be found in Annex 1 of the application dossier. EU permitted antioxidants are added to the refined oil to ensure stability and the oil is packaged in airtight containers.
6. The applicant has assessed compositional equivalence in two ways: by evaluating the similarity of the production organisms from a taxonomic perspective and by comparing relative quantities of key components in each of the oils.
7. The **taxonomic** evaluation was carried out to provide reassurance that the production strain ONC-T18, originally classified in the genus *Thraustochytrium*, was sufficiently closely related to *Schizochytrium* to support a request for an opinion on equivalence. This evaluation concluded that, based on morphological, biochemical and ribosomal DNA analysis, strain ONC-T18 is more correctly classified within the genus *Schizochytrium*. This evaluation is attached at Annex 4 of the application dossier, together with an additional independent review. The Committee notes that there is an ongoing taxonomic discussion regarding classification within microalgal family *Thraustochytriaceae* but, irrespective of the eventual outcome of this discussion, the strain used by Ocean Nutrition would appear to be closely related to the organism used in the production of Martek's oil.
8. In terms of **composition** the applicant regards their oil to be within the specification for Martek's (Tables 1 & 2 and Annex 2 of the application dossier, summarised below). The applicant also refers to a proximate analysis (tabulated in Annex 2 of the application dossier, summarised below), noting that the oil is 'free' from protein and carbohydrate (limit of detection 0.1%). Although this may not provide evidence of the total absence of protein, the detection limit is consistent with that used for Martek's oil.

Specification of DHA rich oil from *Schizochytrium* sp ONC-T18

	Specification	Test Method
Colour	Report Actual	Gardner colour

³ Axenic: not contaminated by or associated with any other organisms.

Acid Value	Max. 0.5 mg KOH/g	AOCS CD 3D-63
Peroxide Value (PV)	Max. 5 meq/kg	AOCS Cd 8-53
Moisture and Volatiles	Max 0.01%	AOCS Ca 2d-25
Unsaponifiabiles	Max 3.5%	AOCS Ca 6a-40
Trans-fatty acids	Max 1%	AOAC 996.06
DHA (Area %)	Min 35% Min 350 mg/g	EP 2003:1352 Method 2.4.29
Residual propan-2-ol	Max 1 mg/kg	POS SOP IN-LS-113
Elemental Analysis		
Arsenic	<0.1 mg/kg	US EPA 200.8
Copper	<0.05 mg/kg l	SO 8294 Equivalent
Mercury	<0.04 mg/kg	US EPA 245.6
Lead	<0.01 mg/kg	US EPA 200.8

Proximate Analysis of DHA rich oil from *Schizochytrium* sp ONC-T18

Nutritional Parameters	Units	Average (of 3 lots) values
Energy	KJ /100g	3765
Moisture	g/100g	ND
Ash	g/100g	ND
Fat	g/100g	100
Calories	/100g	900
Protein	g/100g	ND
Carbohydrate	g/100g	ND

ND: Not detected

9. A specification for Martek's oil was published in the original 2003 authorisation Decision (reproduced in Table 2, p9 of the application dossier). The applicant's oil meets this specification but, as it includes only a limited number of fatty acids, the applicant has provided a detailed lipid profile of the two oils in order to give additional reassurance that they are equivalent. This analysis, detailed in the Table below, was carried out on three independent batches and includes a side-by-side analysis of a sample of Martek's oil. To complete the comparison the applicant also includes the data set that was submitted in the original application

(final column). The applicant concludes that the results of this analysis indicate a relatively high degree of similarity with Martek's oil.

Discussion

*In regard to the **compositional data** the Committee accepted the applicant's view that the differences between a commercial sample of Martek's oil (Column 6 in the Table) and their product was likely to be due to the effect of blending the commercial product with vegetable oil to obtain a consistent product that was within the published specification. However, Members requested additional reassurance from the applicant regarding the degree of variability seen both between the Martek and the applicant's oils and between individual batch analyses was typical. The applicant provided a further breakdown of the composition of individual samples and Members accepted that the differences observed were relatively minor..*

*In regard to the **taxonomic** evaluation the Committee questioned whether the production strain was truly a member of the genus Schizochytrium. In their response, the applicant noted that this evaluation was carried out, in line with the ACNFP guidelines, to provide reassurance that the production strain ONC-T18 was sufficiently closely related to Schizochytrium to enable a request for an opinion on equivalence to be considered. The applicant also noted that neither their, nor Martek's production strains have been formally assigned to the genus Schizochytrium using binomial nomenclature. The Committee accepted that, although the expert opinions did not necessarily confirm that the productions strains were members of the same genus, the applicant had provided reassurance that they were sufficiently closely related.*

Fatty Acid (by Area %)	Formula	Ocean Nutrition Oil*			Martek's oil*	Original application Omega-Tech(Martek) (2001)**
		(lot) 22629	22630	22740		
Laurate	12:0	1.1	1.0	1.2	Trace	0.40
Myristate	14:0	13.9	13.2	14.2	4.5	10.11
Palmitate	16:0	26.1	27.0	26.6	13.5	23.68
Palmitoleate	16:1n7	2.0	1.7	3.7	0.2	1.76
Stearate	18:0	0.8	0.8	0.8	0.9	0.45
Oleate	18:1n9	0.7	0.3	0.3	17.1	Not Reported
Vaccenate	18:1n7	1.9	1.5	2.9	0.3	Trace – 1.36n
Linoleate	18:2n6	0.2	Trace	Trace	1.4	Trace -0.85
Octadecatetraenoate	18:4n3	0.2	0.2	0.2	0.3	Not Reported
Dihomo-gamma Linolenate*	20:3n6	0.1	0.1	Trace	0.3	2.21
Arachidonate	20:4n6	0.2	0.3	0.2	1.0	0.94
Eicosatetraenoate	20:4n3	0.5	0.5	0.4	0.8	0.87
EPA	20:5n3	0.8	1.0	0.8	1.2	2.63
Docosapentaenoate	22:5n6	8.0	8.2	7.5	15.9	13.50
DHA	22:6n3	40.8	41.3	38.6	39.6	35.00
Other		2.8	3.0	2.6	3.3	6.24
* as measured by Ocean Nutrition Canada ** as measured by Omega-Tech						

b), c) Nutritional Value and Metabolism

10. The applicant is of the view that, as their oil has an identical proximate analysis and a similar lipid profile, there will be negligible difference in terms of nutritional value and metabolism compared with Martek's oil.

Discussion: The Committee noted that although there were differences in the composition of the oil compared with the existing product (e.g. EPA and arachidonic acid) these were not significant in terms of safety.

d) Intended Use

11. The applicant intends to market their oil in accordance with the authorised uses that are specified in the two Decisions mentioned in paragraph 2, above.

Discussion: The Committee was content that the intended use of the oil would be consistent with those permitted for the existing product.

e) Levels of Undesirable Substances

12. The applicant's oil is routinely tested to ensure compliance with the specification which includes limits for arsenic, copper iron, mercury, lead and trans-fatty acids. These limits, which are at least as stringent as for Martek's oil, are detailed in the specification (Tables 1 and 2 of the application dossier).

13. The applicant notes that the fermentation, extraction and refining processes minimise the risk of microbial contamination, and that tests to check for the presence of contaminating, (including pathogenic) organisms are carried out as part of the quality control regime. The microbiological limits, which are as stringent as those employed for Martek's oil, are as follows:

Coliforms	max 10 MPN/g
<i>E. coli</i>	negative
Aerobic Plate Count	<1000 CFU/g

Yeasts and Moulds	<100 CFU/g
Salmonella	negative/25g
<i>S. aureus</i>	<10 CFU/g

14. The applicant has also considered the possibility of toxin production, noting that there are no reports of toxin production in any of the genus in *Thraustochytriaceae*. Nevertheless, the applicant has screened samples of both the oil and the algal biomass for a wide range of algal toxins. This screen indicates that none of the toxins tested was present in either test material (Annex 5 of the application dossier).

Discussion: The Committee was content that the applicant had appropriate quality control procedures in place to minimise the risk of contamination.

Conclusion

12. The Committee concluded that Ocean Nutrition has demonstrated the equivalence of their DHA rich algal oil with Martek's existing algal oil, according to the criteria set out in Article 3(4) of the Novel Foods Regulation (EC) 258/97.

13. The Committee therefore concluded that the DHA rich algal oil produced by Ocean Nutrition can be considered to be substantially equivalent to the existing DHA rich algal oil produced by Martek.

14. This opinion applies solely to the use of DHA rich algal oil as an ingredient in same products as detailed in Commission Decisions 2003/427/EC and 2009/778/EC and subject to the same maximum level of incorporation.

March 2012