Food Standards Agency
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2 April 2014

Dear Mrs Heinimaa

INITIAL OPINION: DHA-rich oil from the microalgae *Schizochytrium*

In September 2013, the UK Competent Authority accepted an application from DSM Nutritional Products Ltd for the use of a Docosahexaenoic acid (22:6(n-3), DHA) rich algal oil as a novel food ingredient in accordance with Article 4 of Regulation (EC) 258/97.

This oil has been developed primarily as an additional source of DHA for infant and follow-on formulae. Approval is also sought for use in cereal-based and baby foods for infants and young children and, in addition, the applicant seeks authorisation for the same range of food uses that are currently permitted for other DHA and EPA rich oils, or for which approval is pending.

The Advisory Committee on Novel Foods and Processes (ACNFP) reviewed this application and their opinion is attached.

The Committee was satisfied that the proposed uses for this application will comply with current permitted levels for DHA in infant and follow on formula

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As the new DHA-rich oil will be an alternative to existing sources of DHA, the intake of DHA from these foods would not differ from current values.

The Committee also accepted that the other proposed uses were in line with current and pending authorisations for DHA and EPA rich oils from *Schizochytrium* sp.

In view of the ACNFP's opinion, the UK Competent Authority considers that DHA-rich oil from the microalgae Schizochytrium for the uses proposed by the applicant meets the criteria for acceptance of a novel food, as set out in Article 3(1) of Regulation 258/97.

Yours sincerely,

Dr Manisha Upadhyay

Novel Foods Unit
Food Safety Policy

cc William Turney (DSM Nutritional Products)

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON AN APPLICATION UNDER THE NOVEL FOOD REGULATION FOR DHA RICH OIL FROM THE MICROALGAE SCHIZOCHYTRIUM

Applicant	**DSM Nutritional Products Ltd**
Responsible Person	**William Turney**
EC Classification	**2.1**

1. An application has been submitted by DSM Nutritional Products Limited for the use of a Docosahexaenoic acid (22:6(n-3), DHA), rich algal oil as a novel food ingredient.

2. This is the sixth application made by this applicant[1] for oils rich in polyunsaturated fatty acids obtained from the microalgae *Schizochytrium sp.* This latest oil is obtained from another strain of the species and differs from previous applications in that it is proposed for use, primarily, in infant and follow on formula. Currently, DHA in infant formula is typically provided by the inclusion of fish (tuna) oil or a DHA rich oil from *Crypthecodinium cohnii.* Although other oils from *Schizochytrium sp.* have been authorised as novel ingredients, none of these authorisations includes the use of the oil in infant formulae or follow-on formula.

3. For the purposes of this opinion the novel ingredient will be referred to as **DHA-B**, which is the name used in the application dossier. **DHA-S** and **DHA-O** (both here and in the dossier) refer to the company's DHA rich, and DHA-EPA rich algal oils which have previously been authorised in the EU as novel ingredients[2]. The company has recently applied for an extension to the authorised uses of DHA-S and DHA-O and the decision on this application is pending (see section IX below)

[1] Previous applications were made by Martek Biosciences who are now part of DSM
[2] DHA-S is the DHA-rich oil authorised by Commission Decisions 2003/427/EC and \2009/778/EC. DHA-O is the DHA- and EPA-rich oil authorised by a letter from the Food Standards Agency dated 6 July 2012.

I Specification of the Novel Ingredient (NI)

Dossier p 13-25

4. The specifications for this oil (shown below) are consistent with, or exceed**,** the published specifications for DHA-S[3] algal oil. The applicant also analysed three batches of DHA-B to demonstrate compliance with the specifications (Dossier Table I.A-1).

Parameter	**Specification**
Free fatty acids (%)	Not more than 0.4
Peroxide value (meq/kg)	Not more than 5.0
Unsaponifiables (%)	Not more than 3.5
DHA (%)	Not less than 35
Arsenic (mg/kg)	Not more than 0.1
Cadmium (mg/kg)	Not more than 0.1
Copper (mg/kg)	Not more than 0.1
Lead (mg/kg)	Not more than 0.1
Mercury (mg/kg)	Not more than 0.4

5. The applicant has also carried out additional heavy metal and elemental quality control analyses and has compared the fatty acid profile of DHA-B with DHA-S (see Dossier, Tables I.B.3.1.1 and I.B.3.2.1). The applicant has also tested DHA-B for the presence of dioxins, dioxin-like polychlorinated biphenols (PCBs), polyaromatic hydrocarbons and pesticides. In each case the results were within the limits set in EU legislation. Acrylamide would not be expected to be formed during the production process, but the applicant has checked for its presence in DHA-B and no acrylamide was detected (limit less than 50µg/kg).

6. A 12 month stability trial was carried out under frozen storage conditions, which represents the conditions under which DHA-B is expected to be shipped and stored. This demonstrates that the stored oil conforms to specifications for DHA and peroxide values (Dossier 1, Table I.B.2.1).

Discussion *The Committee was satisfied that the composition of DHA-B did not give rise to any safety concerns.*

[3] The specifications for DHA-O and DHA-S are identical except that DHA-O has a lower minimum level of DHA (22.5% vs 32%) and contains at least 10% EPA.

II Effect of the production process applied to the NI

Dossier p31-37

7. The production process consists of 3 distinct stages (contained fermentation, oil recovery, and oil purification), which are proprietary and are described in detail in the Dossier, Sections II.A.1.1 to II.A.1.3. In brief, the production strain of *Schizochytrium* is fermented aerobically. The omega-3 oil accumulates within the cells, primarily as triglycerides, and the oil is recovered using an aqueous extraction process.

Discussion *The Committee accepted that the processing employed was closely monitored and given the range of parameters that had been analysed; the possibility of internal and external contamination was extremely small. The Committee noted that the oil extraction and purification processes differed to those employed for DHA-O and DHA-S because water, rather than organic solvents are used. However the applicant was able to reassure the Committee that the new production process would not result in other, unidentified, non-lipid based components being present in the final oil.*

III History of the organism used as the source of the NI

Dossier 38-40

8. The alga used in the production of DHA-B is a newly developed strain of the genus *Schizochytrium* which was selected by the applicant following a traditional strain selection process. The strain is derived from the production strain of the existing product DHA-O and was selected for its ability to produce DHA. Further improvements in productivity were obtained by optimisation of the fermentation process. The taxonomy of the production organism is as follows:
    - Kingdom – Chromista (Stramenopilia)
    - Phylum – Heterokonta
    - Class – Thaustochytridae
    - Order – Thaustochytriales
    - Family – Thaustochytridriaceae
    - Genus – Schizochytrium

9. The applicant provides a detailed overview of algal toxin production noting that, based on both published and unpublished studies; there have been no reports of toxic compounds, or association with toxic compounds, produced by organisms in the order Thraustochytrids. The company also notes that most of the toxic compounds produced by microalgae are produced by blue-green algae or dinoflagellates, which lie in a separate kingdom to *Schizochytrium.* Two toxic compounds, domoic acid and prymnesin, are known to be produced in the Chromista kingdom. However, these toxins are largely restricted to two genera (*Pseudonitzschia* and *Prymnesium*) which are in a separate class and phylum,

respectively, from the Thraustochytrids. Additional tests carried out by the applicant confirm that neither domoic acid nor prymnesin is present in *Schizochytrium* sp. (Dossier, Appendix 4).

Discussion *The Committee noted that Schizochytrium sp had previously been used to produce DHA rich oils. The Committee accepted additional information from the applicant which confirmed that the strain used for the production of DHA-B had been assigned a unique culture collection reference number[4] and, as there were no reports of toxins being produced by any members of the Class which includes the genus Schizochytrium, the use of the organism as a source of the oil did not therefore give cause for concern.*

IX Anticipated intake and extent of use of the NI

Dossier p.42-48

10. The applicant indicates that DHA-B has been developed primarily as an additional source of DHA for infant and follow-on formulae. Use of DHA-B in infant formula requires a novel food authorisation and, if approved, must also comply with the limits for DHA set out in Commission Directive 2006/141/EC[5], which regulates the composition of infant and follow-on formula.

11. Approval is also sought for use in cereal-based and baby foods for infants and young children as defined in Commission 2006/125/EC and, in addition, the applicant seeks authorisation for the same range of food uses that are currently permitted for DHA-O and DHA-S, or for which approval is pending. The proposed uses and use-levels are detailed below:

Proposed Food Uses and Use-Levels for DHA-B		**Current and pending appro (November 2013)**	
Food Category	**Proposed Use-Level (mg DHA/100 g unless otherwise stated)**	**DHA-S**	**DHA-O**
Food Supplements	3,000 mg DHA + EPA per daily dose as recommended by the manufacturer	Pending	Pending
	450 mg DHA per daily dose as recommended by the manufacturer for pregnant and lactating women	Pending	Approved
Foods intended for use in energy-restricted diets for weight reduction	250 mg DHA per meal replacement	Pending	Approved

[4] American Type Culture Collection (ATCC)
[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:401:0001:0033:EN:PDF

Proposed Food Uses and Use-Levels for DHA-B		Current and pending appro (November 2013)	
Food Category	**Proposed Use-Level (mg DHA/100 g unless otherwise stated)**	**DHA-S**	**DHA-O**
Other foods for particular nutritional uses (PARNUTS), as in Directive 2009/39/EC (European Parliament and the Council of the European Union, 2009) excluding infant and follow-on formula	200	Pending	Approved
Dietary foods for special medical purposes	In accordance with the Particular nutritional requirements of t persons for whom the products are intended	Approved	Approved
Sweet Biscuits	200	Pending	Approved
Bakery Products	200	Approved	Approved
Breads and Rolls	200	Approved	Approved
Breakfast Cereals	500	Approved	Approved
Cooking Fats	360	Proposed	Approved
Dairy Analogues (except drinks)	600	Approved	Approved
Dairy Products (except milk-based drinks)	600	Approved	Approved
Non-alcoholic Beverages (including dairy analogue and milk-based drinks)	80	Approved	Approved
Nutrition Bars	500	Approved	Approved
Spreadable Fats and Dressings	600	Approved	Approved
Infant formula and follow-on formula	Used in accordance with Commission Directive 2006/141/EC[1]	-	-
Food for Infants and Young Children	Used in accordance with Commission Directive 2006/125/EC[2]	-	-

[1] The DHA content shall not exceed that of n-6 long chain polyunsaturated fatty acids in accordance with Commission Directive 2006/141/EC.
[2] The lipid content shall not exceed 0.8 g/100 kJ in accordance with Commission Directive 2006/125/EC.

12. **Estimated intake**. The applicant does not estimate DHA-B intake by infants and young children for infant and follow on formula but the permitted levels would be in accordance with Commission Directive 2006/141/EC and, as DHA-B is an alternative source of DHA, levels would not be expected to differ unduly from current levels of intake in these foods. As noted above, in addition the primary use of DHA-B in infant and follow-on formula, the applicant also proposes that it be considered as a an alternative to existing PUFA-containing algal oils that are already permitted and/or awaiting approval. As the proposed uses and use-levels

of DHA from DHA-B are identical to those recently approved for DHA and EPA from DHA-O (with the exception of infant formula and follow-on formula, and other foods for infants and young children, see above), the consumption estimates generated in support of the DHA-O novel food application are applicable to DHA-B. These previous estimates, which are based on food consumption data from the UK National Diet and Nutrition Survey, are reproduced below.

13. These tables do not include the high dose food supplements which are the subject of an on-going request to extend the use of both DHA-O and DHA-S. In assessing this request, the Committee noted that if individuals consumed both fortified foods and high dose (3000mg) supplements this could result in high level consumption of DHA and EPA rich algal oil consumption of 4.72g/day.

Summary of the Estimated Daily Intake of DHA-from DHA-B from all Proposed Food Categories in the U.K. by Population Group – based on UK NDNS Data

Population Group	**Age Group (Years)**	**% User**	**Actual # of Total Users**	**All-Person Consumption**				**All-Users Consumption**			
				Mean (g)	**Percentile (g)**			**Mean (g)**	**Percentile (g)**		
					90	**95**	**97.5**		**90**	**95**	**97.5**
Children	1½ -4½	98.8	1,628	0.42	0.67	0.77	0.89	0.42	0.66	0.77	0.89
Young People	4-10	99.6	834	0.65	0.99	1.13	1.23	0.65	0.99	1.13	1.23
Female Teenager	11-18	97.8	436	0.67	1.05	1.20	1.31	0.67	1.05	1.17	1.30
Male Teenager	11-18	99.5	414	0.88	1.33	1.51	1.68	0.88	1.33	1.50	1.72
Female Adult	16-64	94.1	901	0.6	0.95	1.10	1.21	0.60	0.96	1.12	1.23
Male Adult	16-64	94.8	726	0.76	1.23	1.45	1.66	0.77	1.23	1.45	1.65

Summary of the Estimated Daily Per Kg Body Weight Intake of DHA-from DHA-B from all Proposed Food Categories in the U.K. by Population Group based on NDNS Data											
Population Group	**Age Group (Years)**	**% User**	**Actual # of Total Users**	**All-Person Consumption**				**All-Users Consumption**			
				Mean (mg/kg bw)	**Percentile (mg/kg bw)**			**Mean (mg/kg bw)**	**Percentile (mg/kg bw)**		
					90	**95**	**97.5**		**90**	**95**	**97.5**
Children	1½ -4½	98.8	1,628	29	47	54	62	30	48	54	62
Young People	4-10	99.6	834	25	39	44	49	25	39	44	49
Female Teenager	11-18	97.3	436	13	21	24	26	13	21	24	26
Male Teenager	11-18	99.3	414	16	26	28	32	16	26	28	32
Female Adult	16-64	91.6	901	8	14	16	19	9	14	16	19
Male Adult	16-64	91.4	726	9	15	17	20	9	16	18	20

Discussion *The Committee was satisfied that the proposed uses will comply with current permitted levels for DHA in infant and follow on formula and, as DHA-B is an alternative to existing sources of DHA, the intake of DHA from these foods would not differ from current values. The Committee also accepted that the other proposed uses were in line with current and pending authorisations for DHA and EPA rich oils from Schizochytrium sp.*

XI Nutritional information on the Novel Food

Dossier p.53-54

14. The applicant notes that DHA-B is compositionally similar to other DHA-rich oils that have been approved for use in food in the EU and DHA-B will be used as an alternative source of DHA to existing ingredients on the market.

Discussion *The Committee noted that the fatty acid profile of the product was broadly comparable with existing algal oil and fish oil derived products and, as such, would be unlikely to give rise to safety concerns. The Committee also noted that the applicant does not discuss the nutritional profile of the product in terms of its composition as a fat but, as it is almost entirely composed of triglycerides, a caloric value of 9 kcal will therefore be used on nutritional labels, in line with previous DHA rich algal oils.*

XII Microbiological Information

Dossier p.55-56

15. The applicant notes that the oil is subject to aqueous recovery and the product is pasteurised. The low water activity of the oil means that neither the source microorganism nor any microbial contaminants can survive and this is confirmed by microbial analysis (Dossier Table XII.A-1 p56).

Discussion *The Committee accepted the data provided in the application although Members regarded the possibility of contamination by Cyanobacteria to be one that should not be discounted. In regard to this point, Members were reassured by the quality control regime and confirmation from the applicant that that the fermentation proceeds in the absence of light under axenic*[6] *conditions. The Committee accepted that these measures were sufficient to ensure that any risk of Cyanobacterial contamination was no greater than for any other closed system fermentation process used in food production. The Committee also accepted additional data from the applicant which demonstrated the absence of detectable levels of mycotoxins for the proposed levels of use.*

XIII Toxicological information

Dossier p.75-73

16. The applicant has carried out extensive genotoxicity studies and a 90-day oral toxicity study in rats with an *in utero* phase. The 90-day and genotoxicity studies are summarised in the dossier and are available in full in Appendix 4 of the dossier.

17. The applicant originally intended to manufacture DHA-B using alcoholic extraction before switching to an aqueous process, in response to customer preference. In addition to reporting the studies on the water extracted DHA-B that is the subject of this application, the applicant has also included studies that were carried out on the alcohol extracted variant as these data may provide additional assurance of the safety of oil from this production strain. (Dossier Section X111.C.2.1)

18. **Genotoxicity and Mutagenicity studies.** These are detailed on p.62-64 of the Dossier, and are available in full at Appendix 4. The studies (including those where the alcohol extracted variant was used) are summarised in the following table:

[6] axenic: a pure culture of a single organism.

Summary of *in vitro* and *in vivo* Mutagenicity and Genotoxicity Studies on DHA-B				
Test System	**Type**	**Results**	**Concentration**	**Reference**
DHA-B (Aqueous Extraction)				
In vitro Studies				
Escherichia coli WP2uvrA	Mut (+/- S9)	Negative	31.6, 100, 316, 1,000, 2,500, or 5,000 µg/plate	BSL Bioservice Study No. 105886 – BSL, 2011a
Salmonella typhimurium TA98, TA100, TA1535, TA1537	Mut (+/- S9)	Negative	31.6, 100, 316, 1,000, 2,500, or 5,000 µg/plate	BSL Bioservice Study No. 105886 – BSL, 2011a
Human lymphocytes	CA (+/- S9)	Equivocal[a]	250, 500, 1,000, 2,500, or 5,000 µg/mL (4-hr; +/-S9) 250, 500, 1,000, 2,500, or 5,000 µg/mL (24-hr; -S9) 3,000, 4,000, or 5,000 µg/mL (4-hr; +/-S9) 400, 500, 750, or 1,000 µg/mL (4-hr; +/-S9)	BSL Bioservice Study No. 105887 – BSL, 2011b
In vivo Studies				
NMRI mice	MN	Negative	2,000 mg/kg bw (i.p. injection)	BSL Bioservice Study No. 105888 – BSL, 2011b
DHA-B (Alcoholic Extraction)				
In vitro Studies				
E. coli WP2uvrA	Mut (+/- S9)	Negative	50, 158, 500, 1,580, 4,000, or 5,000 µg/plate	Fedorova-Dahms *et al.,* 2011a; BSL Bioservice Study No. 101021 – BSL, 2010a
S. typhimurium TA98, TA100, TA1535, TA1537	Mut (+/- S9)	Negative	50, 158, 500, 1,580, 4,000, or 5,000 µg/plate	Fedorova-Dahms *et al.,* 2011a; BSL Bioservice Study No. 101021 – BSL, 2010a
Human lymphocytes	CA (+/- S9)	Negative	1,0, 2.5, or 5.0 µL/mL (4-hr; +/-S9) 1,0, 2.5, or 5.0 µL/mL (24-hr; -S9) 3, 4, or 5 µL/mL (4-hr; +S9)	Fedorova-Dahms *et al.,* 2011a; BSL Bioservice Study No. 101022 – BSL, 2010b
In vivo Studies				
NMRI mice	MN	Negative	2,000 mg/kg bw (oral)	Fedorova-Dahms *et al.,* 2011a; Bioservice Study No. 101023 – BSL, 2010b

bw = body weight; CA = chromosomal aberration; i.p. = intraperitoneal; MN = micronucleus; Mut = mutation; S9 = metabolic activation

[a] Increased frequency of chromosomal aberrations was observed at concentrations of 500 µg/mL and was greater in the absence of S9; however, no dose-response relationship was observed.

19. **Mutagenicitiy and Genotoxicity** The Ames test and the *in vivo* mouse micronucleus test were both negative and, although 'equivocal' results were seen in the *in vitro* mammalian chromosome aberration test, the applicant notes that *in vitro* genotoxicity assays may, on occasions, produce false positive (and false negative) results and highlights the view of the ICH[7](2011) that *"although positive in vitro data may indicate intrinsic genotoxic properties of a compound, appropriate in vivo data determine the biological significance of these in vitro signals in most cases."*

20. The Bacterial reverse mutation assay and the *in vivo* mouse micronucleus test were also both negative. This is consistent with results of the same mutagenicity/genotoxicity studies conducted on DHA-B obtained via isopropyl alcohol extraction, which is compositionally similar to DHA-B, the applicant suggests that it is highly unlikely that DHA-B has genotoxic potential despite the equivocal results obtained in the *in vitro* mammalian chromosome aberration test. The applicant also notes the findings of a number of investigators who have concluded that algal oils and algal biomass have no genotoxic potential.

21. The potential toxicity of DHA-B was investigated in a **90-day dietary toxicity study, preceded by an *in utero* phase**, in Sprague-Dawley CD IGS rats, conducted in accordance with the Organisation for Economic Cooperation and Development (OECD) Test Guideline No. 408 (OECD, 1998a). DHA-B was administered at dietary levels of 1% (low-dose), 3% (mid-dose), or 5% (high-dose) to F_0 rats (13 males and 26 females/group). Two control groups also were included in the study, one that received a standard low fat basal diet and one a basal diet supplemented with 5% tuna oil. A more detailed summary of this study is given on p.59-61 of the dossier and the complete study report is available at Appendix 5.

22. No test article-related mortalities were observed in parental animals at any period, and no clinical signs of toxicity were observed. No significant differences in body weight, body weight gain, or food consumption were observed during the pre-mating, mating, or gestation periods compared to basal diet controls. While a statistically significant decrease in food consumption was observed in dams receiving DHA-B during lactation this was comparable to that seen in the tuna oil control group and did not have effects on pups' general signs or weight gain.

23. Fertility and reproductive performance parameters of males and females were comparable between DHA-B groups and controls. No significant effects on mean gestation length, gestation index, number of implantation sites, number of corpora

[7] International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.

lutea, pre-implantation loss, post-implantation loss, stillbirth, live births, or viability indices were observed compared to controls.

24. No significant differences in litter loss, litter size, litter or pup weight, sex ratio, time and body weight to attainment of developmental indices and sexual maturity, or pup survival were noted compared to controls. A statistically significant lower body weight was observed in pups receiving the high dose DHA-B and the tuna oil control groups compared to the basal diet control from 14 days of age through to weaning, and in all DHA-B groups and the tuna oil controls following weaning. These reductions were not considered to be adverse because they were seen in the tuna oil control. Pups in all groups continued to thrive and gain weight and exhibited appropriate developmental landmarks for their age.

25. No test article-related macroscopic abnormalities were observed in 22 day old pups. In the parental animals, no adverse test article-related changes in macroscopic findings or organ weights were observed. Although yellow-discoloured peritoneal fat was observed in 17% of the high-dose dams, this was considered non-adverse and was consistent with previously reported studies with long-chain PUFAs. Taken together, there were no pre-mating, mating, reproductive, or early developmental effects attributed to DHA-B, and all indices remained within historical control values for age- and strain-matched rats.

26. No mortalities were observed and no clinical signs of toxicity were noted during the 90-day dietary phase. No test article-related ophthalmoscopic findings or test article-related differences in the functional observational battery or in motor activity were observed, compared to controls. No test article-related adverse changes in haematology, clinical chemistry, coagulation, or urinalysis parameters were observed, and all differences in these parameters from the basal diet control were determined to be within historical control data or without histological correlates and thus were deemed to be incidental.

27. Two instances of moderate granulomatous infiltration of retroperitoneal fat were observed in high-dose males and a similar incidence of minimal/moderate granulomatous infiltration was noted in the adipose issue of the mammary gland fat pad in 4 high-dose males and 2 high-dose females. These were considered to be possibly related to DHA-B but, as they are in line with several previous published studies on LC-PUFA oil, the authors considered these effects to be non-adverse as they are attributable to exposure to the high levels of dietary LC-PUFA and not to this specific oil.

28. Compared to the basal diet control, some changes in liver, heart, testes, kidney, and spleen weight were reported; however, these were without histological

correlates, without a dose relationship, and thus were deemed to be toxicologically insignificant by the authors.

29. Based on the results of this study, the authors derived a NOAEL of 3,278.9 and 3,788.4mg/kg body weight/day for male and female rats, the highest doses tested. The NOAEL derived from the study with DHA-B produced by alcoholic extraction was 4,122 and 4,399 mg/kg body weight/day for males and females, the highest dose tested

Discussion *The Committee accepted that the toxicological studies that were provided by the applicant were extensive and provided the necessary reassurance of safety for the proposed use categories. The Committee also noted that the nature and extent of toxicological studies carried out are consistent with the data provided in a previous novel food application for a refined arachidonic acid-rich oil which was also proposed for use in infant and follow-on formula. The previous application was evaluated by the Dutch authorities, whose report was accepted without objection and the arachidonic acid-rich oil was approved in December 2011*[8]*.*

Allergenicity and Labelling

30. The applicant highlights that allergic responses to microorganisms may be related to the presence of microbial toxins, which are not associated with *Schizochytrium sp.* The applicant notes that there is no indication that DHA-B would be associated with allergic reactions and potential allergy to the related oils was considered and was not regarded to pose a significant concern in previous applications[9]

Discussion *The Committee agreed that DHA-O was not an allergenic risk and that labelling similar to that of DHA-S adequately describes the product.*

Overall Discussion

The Committee was content that the applicant had provided sufficient scientific data to demonstrate that the proposed uses of DHA-B did not give rise to any safety concerns at the proposed levels of use. The Committee accepted that the toxicological studies were comprehensive and consistent with other novel algal oils proposed for use in infant and follow-on formula.

The Committee noted that the safety of DHA per se was reviewed in 2012 by EFSA in a wide ranging review of DHA and EPA from all dietary sources[10]*. This review established the tolerable upper intake level of EPA and DHA at 5 grams per day and the proposed uses for DHA-B were within this level. The Committee was therefore satisfied that the safety of DHA and other long chain polyunsaturated fatty acids is*

[8] http://ec.europa.eu/food/food/biotechnology/novelfood/arachidonic_acid_rich_oil_2011_en.pdf
[9] http://www.food.gov.uk/multimedia/pdfs/omegafinalopinion.pdf
http://www.food.gov.uk/multimedia/pdfs/dhaextfinalopinion.pdf
[10] http://www.efsa.europa.eu/en/efsajournal/pub/2815.htm

well documented and noted that a number of other algal oils obtained from the genus Schizochytrium sp that have been favourably assessed in recent years.

The Committee also highlighted that current policy in the UK is to encourage the intake of long chain n-3 polyunsaturated fatty acids and that this product may help consumers with low intakes to increase their consumption of n-3 fatty acids[11]*. It also provides an alternative to existing sources of long-chain PUFA in infant and follow-on formula.*

Conclusion

The Advisory Committee on Novel Foods and Processes is satisfied by the evidence provided by the applicant, DSM Nutritional Products Ltd that the range of uses for the novel ingredient (DHA rich algal oil from *Schizochytrium* sp., DHA-B) is acceptable.

March 2014

[11] Advice on fish consumption: Benefits and Risks; SACN/COT 2004