

SUBSTANTIAL EQUIVALENCE OPINION

DHA Rich Algal Oil

The Food Safety Authority of Ireland (FSAI) received an application in April of 2017 from Polaris of France for an opinion on the substantial equivalence of its DHA- rich oil derived from a microalga (*Schizochytrium sp.*). The novel ingredient is compared to the existing DHA-rich algal oil marketed by DSM Nutritional Products and authorised for the EU market by Commission Implementing Decisions 2014/463/EU and (EU) 2015/545.

The novel DHA-rich algal oil is produced by an algal fermentation process using microalgae of the genus *Schizochytrium sp.* After fermentation, algal cells are disrupted by enzymatic hydrolysis using a protease (alcalase: CAS No. 9014-01-1, 21 CFR § 184.1027) from *Bacillus licheniformis*. The crude oil is recovered and refined without the use of organic solvents and with tocopherols added to aid oxidative stability before packaging in a nitrogen atmosphere. Polaris is certified to ISO 9001:2015 and ISO 22000:2005 standards. The novel ingredient is stable for 2 months at room temperature, 6 months at 0 – 10°C and 2 years at < -15°C. The applicant considers this ingredient to be novel and fall within the category of “*food and food ingredients consisting of or isolated from microorganisms, fungi or algae*” as set out in *Article 1.2 (d)* of the novel food Regulation EC No. 258/97.

Composition

The novel ingredient is a light yellow to orange coloured oil containing $\geq 38\%$ DHA. Certificates of analysis of three batches of Polaris DHA-rich algal oil demonstrate consistency of compliance with the specifications of the authorised comparators set out in Commission Implementing Decisions 2014/463 & 2015/545. Data on stability has been provided by the applicant and these results indicate a shelf life of up to 2 years under appropriate storage conditions.

Parameter	Novel Polaris DHA-rich oil	Decision 2014/463	Decision 2015/545
Acid value (Mg KOH/g)	≤ 0.5	0.5	-
Peroxide value (Meq/kg)	≤ 5.0	≤ 5.0	≤ 5.0
Moisture & volatiles (%)	≤ 0.05	≤ 0.05	-
Unsaponifiables (%)	≤ 3.5	≤ 4.5	≤ 3.5
Trans-fatty acids (%)	≤ 1.0	≤ 1.0	≤ 2.0
Free fatty acids (%)	≤ 0.25	-	≤ 0.4
Docosapentaenoic acid (DPA) n-6 (%)	≤ 7.5	-	≤ 6.0
DHA (%)	≥ 38.0	≥ 32.0	≥ 35.0

Nutritional value and Metabolism

The novel ingredient is compositionally very similar to the authorised DHA-rich algal oil and therefore it is reasonable to conclude that both oils will be similar in terms of nutritional value and metabolism.

Intended Uses

The novel Polaris DHA-rich algal oil will be used in the same food categories and at the same use levels as the authorised comparator, thereby offering an alternative source of the ingredient. The list of specified foods and specified levels of use are set out in Annex II of Commission implementing Decisions (EU) 2014/463 and 2015/545.

Level of undesirable substances

The applicant contends that there is minimal risk of microbial contamination during the controlled fermentation process producing the DHA-rich oil and that the high temperatures used in bleaching and deodorisation presents an antimicrobial barrier during the refinement stages. Results of batch analyses demonstrate satisfactory results for potential microbiological contaminants (Yeast, Mould, Coliforms, *E. coli*, *Staphylococci* and *Salmonella*), while heavy metal contaminants (arsenic, cadmium, copper, iron, lead and mercury) are within regulatory limits. The applicant has carried out additional checks for other potential environmental contaminants including aflatoxins, pesticides, PAH, dioxin and PCB, with no concerns identified.

Conclusion

The FSAI is satisfied from the information provided that the novel DHA-rich algal oil from *Schizochytrium sp.* is substantially equivalent to DHA-rich algal oil authorised for the EU market by Commission Implementing Decisions (EU) 2014/463 & 2015/545. The novel ingredient will be used in the same food categories and at the same maximum use levels as the authorised comparator. The designation of the novel food ingredient on the labelling of foodstuffs containing it shall be “oil from the micro-algae *Schizochytrium sp.*” in accordance with *Article 2* of Commission Decisions (EU) 2014/463 and 2015/545.