

SUBSTANTIAL EQUIVALENCE OPINION

DHA-rich Algal oil (BioDHA algal oil)

The Food Safety Authority of Ireland (FSAI) received an application in June of 2013 from Bioplus Life sciences Pvt. Ltd. in India for an opinion on the substantial equivalence of its DHA-rich algal oil (BioDHA algal oil) to a similar product previously authorised to Martek Biosciences Corporation through Commission Decisions 2003/427/EC and 2009/778/EC. The applicant considers the ingredient to be novel and fall within the category of “foods and food ingredients consisting of, or isolated from micro-organisms, fungi or algae” as set out in *Article 1.2(d)* of the novel food Regulation EC No. 258/97.

Similar to the Martek DHA-rich algal oil, BioDHA algal oil is extracted from dried marine microalgae (*Schizochytrium* sp.) grown in contained conditions. The production process for the novel ingredient is very similar to the Martek DHA-rich oil, yielding a product with almost identical specifications. BioDHA algal oil will be designated as “DHA-rich oil from the microalgae *Schizochytrium* sp” or “oil from the micro-algae *Schizochytrium* sp.” in line with Commission Decisions 2003/427/EC and 2009/778/EC respectively. BioDHA algal oil will be used in the food groups and at the use levels set out in the relevant Annexes of Commission Decisions 2003/427/EC and 2009/778/EC.

Composition

BioDHA algal oil and the authorised Martek comparator are derived from *Schizochytrium* sp. using very similar production and purification processes. A compositional comparison reveals almost identical specifications in terms of the level of protein, moisture, arsenic, ash etc, as specified in Annex I of Commission Decision 2003/427/EC. The applicant demonstrates batch consistency with respect to composition, along with six months product stability under various temperature and humidity conditions.

Nutritional Value and Metabolism

BioDHA algal oil and the authorised algal oil are both derived from *Schizochytrium* sp. using similar processes, with the result that the composition of both products is

almost identical. Therefore the nutritional value and metabolism of the novel ingredient is not expected to be any different to the authorised DHA-rich algal oil. The applicant demonstrates this similarity in a comparison of the primary nutrients including fatty acids, sterols and unsaponifiables.

Intended Uses

The applicant intends placing BioDHA algal oil on the EU market in the same food categories as the authorised comparator. The range of food categories and maximum use levels are set out in the Annexes of Commission Decisions 2003/427/EC and 2009/778/EC.

Level of Undesirable Substances

BioDHA algal oil and the authorised product are produced from the same raw material using a largely similar process and therefore it can be assumed that there will not be any significant differences in the levels of undesirable substances. The applicant demonstrates satisfactory results for lead analysis in BioDHA algal oil along with a microbiological profile similar to that for the authorised DHA-rich oil.

Conclusions

The FSAI is satisfied from the information provided by the applicant that BioDHA algal oil from Bioplus Life sciences is substantially equivalent to the Martek DHA-rich oil authorised by Commission Decisions 2003/427/EC and 2009/778/EC. BioDHA algal oil will be designated on the labelling or in the list of ingredients as “oil from the micro-algae *Schizochytrium* sp.” or “DHA-rich oil from the micro-algae *Schizochytrium* sp.”. BioDHA algal oil will only be used in the food categories and to the maximum use levels set out in Commission Decisions 2003/427/EC and 2009/778/EC.