

SUBSTANTIAL EQUIVALENCE OPINION

DHA-rich Algal oil from *Schizochytrium* (T18)

The Food Safety Authority of Ireland (FSAI) received an application in October of 2015 from Mara Renewables Corp. of Canada for an opinion on the substantial equivalence of its DHA-rich oil from *Schizochytrium* T18 to a similar product previously authorised to DSM Nutritional Products through Commission Implementing Decision 2014/463/EC. The novel DHA-rich algal oil is produced by fermentation with the microalgae *Schizochytrium* sp. (strain T18) followed by enzymatic lysis of the microalgal cells, aqueous extraction and purification. The refined oil is a mixture of triglycerides containing polyunsaturated fatty acids (PUFAs), primarily (>35%) docosahexanoic acid (DHA) which is one of the omega 3 fatty acids commonly found in fish oils.

Composition

The novel algal oil and the authorised DSM comparator are derived from *Schizochytrium* sp. using very similar production and purification processes. The novel algal oil is produced by Algal Omega 3 Ltd. in the UK, with the main production differences being the use of a protease from *Bacillus licheniformis* to lyse the microalgal cells. This lysis allows the release of the oil which is then subject to an aqueous rather than a solvent based extraction process. *Bacillus licheniformis* is on the EFSA QPS list while the enzyme is currently used as a food enzyme in a number of Member States and has been submitted for addition to the EU enzyme list. A compositional comparison reveals almost identical specifications in terms of the parameters set out in Annex I of Decision 2014/463/EU. These include acid value, peroxide value, moisture and volatiles, unsaponifiables, trans-fatty acids and DHA content. The absence of protein or carbohydrate in the final product is demonstrated through batch analyses, while heavy metals such as arsenic, mercury, iron, copper and lead are either at insignificant levels or not detectable.

Nutritional Value and Metabolism

The novel DHA-rich algal oil and the authorised algal oil are both derived from *Schizochytrium* sp. and are compositionally equivalent. It follows therefore that the

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

Intended Uses

The applicant intends placing their DHA-rich algal oil on the EU market in the same food categories and at the same use levels as set out in Annex II of Decision 2014/463/EU for the authorised comparator.

Level of Undesirable Substances

The novel DHA-rich algal oil and the authorised comparator 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 analytical results for heavy metal analysis including arsenic, lead, mercury, copper and iron. The production and processing conditions are not conducive to the growth of microorganisms. However, the applicant operates routine microbiological testing regime for yeasts and moulds as well as coliforms, *E. coli*, *S. aureus* and Salmonella. Even though *Schizochytrium* sp. is not known to produce toxins, the source material and final product was also tested for the presence of a number of algal toxins which were not detected.

Conclusions

The FSAI is satisfied from the information provided by the applicant that DHA-rich algal oil marketed by Mara Renewables Corp. of Canada is substantially equivalent to the DHA-rich oil authorised by Commission Implementing Decision 2014/463/EC. The novel DHA-rich algal oil will be designated on the labelling or in the list of ingredients as “oil from the micro-algae *Schizochytrium* sp.” and will only be used in the food categories in accordance with the maximum use levels set out in Annex II of Commission Implementing Decision 2014/463/EC.