

Ms Laila Mantecón Gálvez

Fitoplancton Marino S.L.
Dársena comercial s/n
El Puerto de Santa María
11500 Cádiz (Spain)

Subject: *Authorisation of extension of use of freeze-dried microalgae *Tetraselmis chuii* to include their use in food supplements*

Madrid, 8 November 2017

Dear Ms Mantecón,

I am pleased to be able to inform you of the result of your request for an assessment before dried microalgae *Tetraselmis chuii* (TetraSOD®) are placed on the market in food supplements as a novel ingredient, in accordance with Articles 4 and 6 of Regulation (EC) No 258/97 on novel foods and novel food ingredients.

On 18 April 2017, you submitted a request on behalf of Fitoplancton Marino S.L. to the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN), the competent body designated to assess novel foods in Spain, with a view to marketing freeze-dried microalgae *Tetraselmis chuii* in food supplements as a novel food.

On 24 May 2017, AECOSAN's Scientific Committee issued an initial assessment report (AECOSAN-2017-001, published on AECOSAN's website and in the Journal of AECOSAN's Scientific Committee No 25), in which it concluded that, based on the information provided, there was no indication that consumption of the freeze-dried marine microalgae *Tetraselmis chuii* as a food supplement under the conditions proposed by the applicant might have adverse health effects, and that the novel food met the criteria for acceptance laid down by Regulation (EC) No 258/1997.

The European Commission forwarded the initial assessment report to all Member States on 10 July 2017. Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97, neither the Commission nor the Member States presented any reasoned objections to the product being marketed, although the British and German authorities did make some comments which you then addressed. There are therefore no objections to freeze-dried microalgae *Tetraselmis chuii* being placed on the market in food supplements as a novel food.

On the basis of the initial assessment report, it is therefore established that the extension of use of freeze-dried microalgae *Tetraselmis chuii* to include their use in food supplements as a novel food complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97. The product to be marketed must correspond to the product assessed and meet the conditions set out in the Appendix to this letter and the applicable legislative provisions.

Fitoplancton Marino S.L. may therefore market freeze-dried microalgae *Tetraselmis chuii* for the use indicated in the Appendix provided the conditions laid down therein are met.

In order not to confuse consumers, in accordance with the legislation on the food information provided to consumers, the product must comply with the specific labelling requirements set out in this letter.

The name 'freeze-dried microalgae *Tetraselmis chuii*' or 'freeze-dried microalgae *T. chuii*' must appear on the label when the product is sold neat and in the list of ingredients of foods containing it.

A copy of this letter will be forwarded to the European Commission for transmission to all other Member States and for general publication, as appropriate.

Yours sincerely,

THE EXECUTIVE DIRECTOR

(signature)

Teresa Robledo de Dios

APPENDIX

Description, specification and uses of freeze-dried microalgae *Tetraselmis chuii*

DESCRIPTION OF FREEZE-DRIED MICROALGAE *Tetraselmis chuii*

The freeze-dried product is obtained from the marine microalgae *Tetraselmis chuii*, belonging to the *Chlorodendraceae* family, cultivated in sterile sea water in closed photobioreactors isolated from the surrounding external environment.

SPECIFICATION OF FREEZE-DRIED MICROALGAE *Tetraselmis chuii*

Parameter	Specification
Identity by 18S rDNA nuclear marker (sequence analysed not less than 1 600 base pairs) compared to the National Center for Biotechnology information (NCBI) database.	Not less than 99.9 %
Moisture	Not more than 7 %
Proteins	35-40 %
Ash	14-16 %
Carbohydrates	30-32 %
Fibre	2-3 %
Fat	5-8 %
Saturated fatty acids	29-31 % of total fatty acids
Monounsaturated fatty acids	21-24 % of total fatty acids
Polyunsaturated fatty acids	44-49 % of total fatty acids
Iodine	Not more than 15 mg/kg

USES OF FREEZE-DRIED MICROALGAE *Tetraselmis chuii*

Food category	Maximum use level
Food supplements	250 mg/day

SPECIFIC LABELLING, PRESENTATION AND ADVERTISING REQUIREMENTS

The statement 'Contains negligible amounts of iodine' must be included.