# MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY AECOSAN – Spanish Consumer Affairs, Food Safety and Nutrition Agency Executive Director

Mr Carlos Unamunzaga Escosura Fitoplancton Marino S.L. Dársena comercial s/n 11500 El Puerto de Santa Maria

Subject: Authorisation to market Tetraselmis chuii

4 March 2014

Dear Mr Unamunzaga,

I am pleased to inform you of the result of your request for initial assessment for marketing of dried microalgae *Tetraselmis chuii*, in accordance with Articles 4 and 6 of Regulation (EC) No 258/97.

On 6 May 2011 you submitted a request to the Spanish Food Safety and Nutrition Agency (now the Spanish Consumer Affairs, Food Safety and Nutrition Agency), the competent body designated to assess novel foods in Spain, with a view to marketing dried microalgae *Tetraselmis chuii* as a novel food.

On 27 September 2013, the AESAN Scientific Committee issued its initial assessment report (AESAN-2013-001, published in the journal of the AESAN Scientific Committee No 18). That report concludes that dried microalgae *Tetraselmis chuii* meets the criteria for acceptance as a novel food in accordance with Article 3(1) of Regulation (EC) No 258/97.

The Commission forwarded the initial assessment report to all Member States on 12 November 2013. Within the 60 day period laid down in Article 6(4) of the Regulation no reasoned objections to the marketing of this product were presented by the Commission or the Member States, though certain comments were made by the German, British and Hungarian authorities to which you responded. There are therefore no objections to the placing on the market of dried microalgae *Tetraselmis chuii*.

On the basis of the initial assessment report, it is therefore established that dried microalgae *Tetraselmis chuii* conforms to Article 3(1) of Regulation (EC) No 258/97. The marketed product must correspond to the product assessed and meet the conditions laid down in the Annex to this letter and the applicable legislative provisions.

Fitoplancton Marino S.L. may therefore market dried microalgae *Tetraselmis chuii* for the uses indicated in the Annex and in accordance with the conditions laid down therein.

The description 'dried microalgae *Tetraselmis chuii*' or 'dried microalgae T. chuii' must appear on the labelling of the product itself and on the list of ingredients of food products containing it.

This letter will be forwarded to the European Commission for transmission to all other Member States and general publication as appropriate.

Yours sincerely,

The Executive Director

#### **ANNEX**

## Description, specifications and uses of Tetraselmis chuii

#### **DESCRIPTION OF DRIED MICROALGAE** Tetraselmis chuii

The dried product is obtained from the marine microalgae *Tetraselmis chuii*, belonging to the Chlorodendraceae family, cultivated in sterile sea water in closed photobioreactors insulated from the outside air.

#### SPECIFICATIONS OF DRIED MICROALGAE Tetraselmis chuii

Parameter	Specification
Identified by means of nuclear marker rDNA 18 S	Not less than 99.9 %
(sequence analysed no less than 1,600 base	
pairs) in the National Centre for Biotechnology	
information (NCBI) database	
Humidity	Not more than 7 %
Proteins	35-40 %
Ashes	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
lodine	Not more than 15 mg/kg

### **USES OF DRIED MICROALGAE** Tetraselmis chuii

Food category	Maximum use level
Sauces	Dried <i>Tetraselmis chuii</i> content 20 % (250
	mg of dried Tetraselmis chuii/day)
Special salts	Dried <i>Tetraselmis chuii</i> content 1 %
Condiment	250 mg/day