

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES
TETRASELMIS CHUII EXTENSION OF USE- DOSSIER 216

ISSUE

1. The Spanish Competent Authority (CA) has prepared an initial assessment report on an application for the extension of use of dried *Tetraselmis chuii* (TetraSOD®) as a food supplement under the Novel Foods Regulation (EC) No 258/97.
2. The Committee is asked whether it agrees with the initial opinion and whether it would like to make any further comments on this application. The Committee's advice will form the basis for the UK's formal response to the Commission.

Background

3. On 10 July the European Commission forwarded the initial opinion of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) on an application made by Fitoplancton Marino, S.L. under Article 4 of the Regulation for the extension of use of dried *Tetraselmis chuii* (TetraSOD®) as a food supplement.
4. The Commission has requested the views of Member States on the Spanish CA's initial opinion. Member States have until 8 September to submit any comments and/or reasoned objections to the Spanish assessment.
5. The ACNFP were consulted by email on the original application for *Tetraselmis chuii* for use in sauces and condiments on 18 December 2013. At that time the ACNFP agreed with the Spanish CA that the novel ingredient was safe. This view was shared by other Member States with no objections raised to the initial assessment and these uses were authorised.
6. The application dossier is attached as **Annex A**, the Spanish Initial Assessment Report is attached as **Annex B** and the letter to the European Commission detailing the UK's comments on the original application for the novel ingredient in the existing authorised uses at **Annex C**. **Annex A, B and C** contain protected information.

This application

7. The applicant intends *Tetraselmis chuii* marketed as TetraSOD® to be used as a powder in food supplements for healthy adults with a recommended intake of a maximum of 250mg per day.
8. On the previous application, the Spanish CA noted in its opinion that the novel food does not provide any added nutritional value to foods. The Committee at that time noted that the list of proposed uses for this novel ingredient did not include food supplements. The Committee considered that the novel ingredient should not be put into food supplements as it was not a significant source of iodine. Member's views are sort on whether they still hold this opinion and whether the additional use of the novel food ingredient meets the criteria for authorisation under the regulation.
9. The opinion suggests that the composition and production process for the novel ingredient remains the same as previously authorised. In the initial opinion no microbiological concerns were expressed. Stability analysis was undertaken for Lyophilised and powdered *Tetraselmis chuii* to confirm its stability for at least 2 years storage at temperatures below 25°C.
10. A NOAEL of 2500mg/kg bw/day was calculated for the product from the 90 day study on rats. Based on this value the applicant calculated the ADI for dried *Tetraselmis chuii* to be 25mg/kg bw/day (1750mg/day for a 70kg adult). The increase of 250mg/day, which is the recommended maximum daily intake of dried *Tetraselmis chuii* in food supplements, means the total maximum intake, taking into account the uses already authorised of 800mg/day. This is below the ADI calculated by the applicant.
11. The Spanish Opinion raised no allergenicity issues. The result of the analysis of the sulphite content was 15mg/kg in dried *Tetraselmis chuii*. The product labelling includes the wording "contains sulphites" as laid down in Regulation (EU) 1169/2011.

COMMITTEE ACTION REQUIRED

- Members are asked whether they agree with the initial opinion from the Spanish CA, and whether they wish to make any comments on the application.

- The Committee's advice will form the basis for the UK's formal response to the opinion of the Spanish CA.

**Secretariat
July 2017**

Annexes attached:

Annex A Application dossier for the approval of the extension of use of dried *Tetraselmis chuii* (trade name TetraSOD®) as a food supplement – Official Sensitive.

Annex B Initial Opinion of the Spanish Authority – Official Sensitive

Annex C UK comments to the European Commission on the original dossier for the novel ingredient - Official Sensitive