

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

CHIA SEEDS EXTENSION OF USE FOR CHOCOLATE - DOSSIER 227

ISSUE

1. The Spanish Competent Authority (CA) has prepared an initial assessment report on an application for the extension of use of chia seeds under the Novel Foods Regulation (EC) No 258/97. The additional uses proposed are as an ingredient in chocolate.
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 17 October the European Commission forwarded the initial opinion of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) on an application made by Sanchis Mira SA under Article 4 of the Regulation for the extension of use of Chia seeds as an ingredient Chocolate as defined in the EU Chocolate Regulation.
4. The Commission has requested the views of Member States on the Spanish CA's initial opinion. Member States have until 15 December to submit any comments and/or reasoned objections to the Spanish assessment.
5. The Spanish initial opinion is attached as **Annex A**, the Application dossier is attached as **Annex B**. **Annex A and B** contain protected information.

This application

6. The applicant intends to extend the authorised uses of chia seeds as an ingredient in chocolate. The chia seeds used in the product are supplied by Jules BROCHENIN S.A who received authorisation for their chia seeds in the current permitted uses in March 2015. The intention is for the chia seeds to add crunchy sensory qualities of the chocolate rather than providing health benefits.
7. The applicant details the production process which includes how the seeds are produced and harvested as well as the chocolate production. The proposed product would have 3% chia seeds at the manufacturing stage. The applicant

also intends to include 15% cranberries in the product. The applicant has considered the potential impact on the composition of the seeds both the addition of the chocolate at 27-33°C and the cooling of the product to set the chocolate. No changes in composition were identified. The applicant explains that they have a HACCP system in place for the product.

8. The applicant has undertaken stability studies for the product. The product retained its qualities over the 8 month testing period. The tests included analysis for microorganisms and the applicant considers the product was stable over the testing period when subjected to variable temperatures of 0-25°C.
9. An estimate of intake was based on data at EU level on chocolate consumption. To estimate the maximum consumption of chia seeds from the additional use in chocolate, the highest 95th percentile consumption from the data from Slovenia of 200g/day was used. The estimate assumes that all chocolate consumed contained 3% chia as added at manufacturing stage. This resulted in additional exposure to chia seeds of 6g of seed per day.
10. The applicant notes this does not exceed the 15g per day recommended maximum intake level for chia seeds as required to be labelled on chia seeds sold as such. Analysis of the total exposure to the novel ingredient from all proposed and authorised uses was not calculated.
11. The initial opinion highlights that as an extension of use the toxicological safety is largely based on the original authorisation. However, the Spanish CA has undertaken a literature search to identify the additional data on the safety of chia has become available since the authorisation. They suggest these do not indicate safety concerns. The applicant has also analysed the levels of undesirable substances including mycotoxins and moulds in the chia seeds and found that the specification limits for these parameters are not being exceeded.
12. The Spanish Opinion refers to a recent case of anaphylaxis caused by consumption of chia seed¹. However, given the cases are currently few; the Spanish CA is content that the potential allergenicity concern is managed by labelling of the ingredient.

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.

¹ García Jiménez, S., Pastor Vargas, C., de las Heras, M., Sanz Maroto, A., Vivanco, F. and Sastre, J. (2015). Allergen characterisation of chia Seeds (*Salvia hispánica*), a new allergenic food. *Journal of Investigational Allergology and Clinical Immunology*; 25 (1), pp: 55-82.

Annexes attached:

Annex A Initial Opinion of the Spanish Authority – Official Sensitive

Annex B Application dossier for the approval of the extension of use of chia seeds