

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

CHIA SEED (*Salvia hispanica* L) FROM NUTRISURE LTD**Issue**

The Committee is asked to consider information provided by Nutrisure Ltd (Supernutrients), who have requested the opinion of the UK Competent Authority on whether their chia seeds should be considered substantially equivalent to chia seeds that are already on the EU market. The Committee is asked if it agrees that substantial equivalence has been demonstrated.

Background

1. Chia is a summer annual herbaceous plant belonging to the Labiatae family. It grows from a seedling to develop lush green foliage before it produces long flowers which are either purple or, less commonly white. These flowers develop into seed pods to produce chia seeds. Today, chia is grown commercially in several Latin American countries and Australia, but they have not been consumed to a significant degree in Europe.
2. In 2003 an application was submitted to the UK for the use of chia seeds in certain types of bread and, following a positive UK initial opinion, a number of concerns were raised by other EU Member States regarding the safety of the seeds. The applicant subsequently provided additional data that were scrutinised by EFSA before the seeds were authorised in 2009¹. An application, from a company called The Chia Company, to extend the use of the seeds into products including baked goods and breakfast cereals was authorised earlier this year following a positive opinion by the UK in 2012². Novel food authorisations are granted on an applicant specific basis, so other companies seeking to market the same ingredient must gain separate approval.
3. Regulation (EC) 258/97 makes provision for novel foods or ingredients that are substantially equivalent to an existing product to be placed on the market once the applicant has notified the Commission. In most cases, the Commission requires that the applicant first obtain an opinion on equivalence from a Member State. Nutrisure Ltd is requesting such an opinion from the UK Competent Authority.

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:294:0014:0015:EN:PDF>

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:021:0034:0035:EN:PDF>

4. According to Article 3(4) of (EC) 258/97, the notification procedures applies to “foods or food ingredients...which on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies...are substantially equivalent to existing foods or food ingredients as regards their:
 - Composition
 - Nutritional value
 - Metabolism
 - Intended use, and
 - level of undesirable substances contained therein”.
5. Nutrisure Ltd has provided information to support the claim that their chia seeds, grown in Argentina, are equivalent to The Chia Company’s seeds which are grown in Australia. The application dossier and appendices are attached at **Annex 1**.
6. The Chia Company originally claimed equivalence to authorised seeds which were grown in South America for use in bread products at up to 5%. In the request to the UK for an opinion they highlighted a 2009 EFSA opinion³ which noted that there was little difference between chia seeds sourced from the South American countries and Australia. A favourable UK opinion on equivalence was issued in 2010. The Chia Company submitted a full novel food application to the UK in 2011 to extend the uses of its chia seeds into a range of other products. The ACNFP issued a positive opinion in 2012 and EU approval for this wider range of uses was granted earlier this year.
7. The application dossier will be published on the Agency’s website for a 21-day public consultation. Any comments received will be forwarded to the Committee.

Evaluation

a) Composition

Annex 1, p. 1-2 and Appendix 1

8. The applicant indicates that their chia seeds are grown and harvested in Argentina. The seeds used for cultivation have been selected for resistance to pests and are not processed in any way prior to use as a food ingredient. In their 2011 request for an opinion on equivalence, The Chia Company advised that the original source of their seeds were seed stock from Mexico and Bolivia.

³ <http://www.efsa.europa.eu/en/efsajournal/doc/996.pdf>

9. The applicant has compared the published composition of the approved chia seed with 3 batches of their seed. (**Annex 1**, p 6 and Appendix 1). This is summarised in the table below.

Nutrient (%)	Nutrisure Seed	TCC Seed
Dry matter	91.2-92.7	95.0 – 96.8
Protein	19.5 – 22.6	17.4 – 22.4
Fat	27.3 -28.8	28.5 – 34.7
Carbohydrate	36.9 – 39.2	37.1 – 42.6
Fibre	28.8 – 33.0	32.8 – 40.2
Ash	4.5 – 4.7	4.5 – 5.6

10. The applicant has also compared the mineral content of their chia seed with the approved chia and this is summarised in the table below. The applicant has not provided a comparison of the amino acid content of their chia seed with TCC's chia but states that the overall nutritional value is consistent with the approved chia.

Mineral (mg/100g)	NutrisureSeed	TCC Seed
Sodium	<50	<0.1 – 6
Potassium	460 - 520	510 – 710
Calcium	430 - 460	500 – 640
Iron	5.5 – 6.6	5.70 – 15
Magnesium	230 - 270	310 – 430
Phosphorus	520 - 640	600 – 870

11. Although some of the components analysed fall slightly outside of the range of the approved chia seed, the Secretariat notes that there were similar variations in The Chia Company's 2011 request for an opinion on equivalence
12. The applicant has also included a basic comparison of the of the fatty acid profile of their chia seed. (**Annex 1**, Table 2 and Appendix.) In all of the above analyses, it should be noted that the applicant's data are being compared with published data on the approved product. It is therefore possible that the reported differences could be due to different method of analysis. This pragmatic approach for whole seeds was also adopted for The Chia Company's 2011 request.

b), c) Nutritional Value and Metabolism

Annex 1, p. -2-3

13. The applicant states that their chia seed have comparable levels of protein and an oil content of approximately one third of its weight, about 60% of which is α -linolenic acid, making this ingredient a source of n-3 fatty acids. The seeds have similar mineral and vitamin profiles o the existing product.

d) Intended Use

Annex 1, p. 3

14. The applicant will limit the use of chia seed to bread products (max 5%), baked products (max 10%), breakfast cereals (max 10 %), fruit, nut and seed mixes (max 10 %), pre-packaged Chia seed (max 15 g per day). This is consistent with the authorisation given to Columbus Paradigm in 2009 and to The Chia Company earlier this year.

e) Levels of Undesirable Substances

Annex 1, p. -3-4

Chemical and Microbial Content

15. The applicant is of the view that the production process are sufficient to ensure that the levels of undesirable substances are well below the specified limits and equivalent to the approved chia seeds. The applicant has carried out a heavy metal and mycotoxin screen to support this statement. (Annex 1, Table 5 and Appendix). Results of tests for microbial content are also provided and these are at, or below those seen for The Chia Company's seeds (Annex 1, Table 6 and Appendix).

Committee Action Required

16. The Committee is asked whether it agrees that substantial equivalence has been established between Nutrisure's chia seed and an existing product, from The Chia Company, in accordance with Article 3(4) of Regulation (EC) 258/97.

17. If so, the Secretariat proposes to draft an opinion incorporating the ACNFP's comments on this application which will be cleared by Chairman's action before the next Committee meeting in February 2014.

18. If not, the Committee is asked what additional information the applicant should supply in order to demonstrate equivalence.

**Secretariat
November 2013**

Annex attached:

Annex 1: Application dossier and appendices