

Glenn Turner

Nutrisure Ltd (Supernutrients)

North Barn
Manor Farm
Southstoke
Bath

9 January 2014

Dear Mr Turner

OPINION ON THE SUBSTANTIAL EQUIVALENCE OF CHIA SEED

The Advisory Committee on Novel Foods and Processes (ACNFP) has now completed your request for an opinion on the substantial equivalence of your chia seed with the chia seed which received an authorisation under (EC) 258/97 earlier this year (decision 2013/50/EC).

I am pleased to inform you that, in view of the positive opinion given by the ACNFP, the Food Standards Agency, UK Competent Authority for all novel food issues, is content that your seeds meets the criteria for equivalence, as defined in Article 3(4) of regulation (EC) 258/97.

This opinion is issued on the basis that your seeds will be used in accordance with the conditions of use and food categories detailed in decisions.

Please note that, in accordance with Article 5 of (EC) 258/97, you should notify the European Commission when you intend to market your chia seeds when they are first marketed. You should send this to Mrs Sirkku Heinimaa at the following address:

**European Commission
DG SANCO
Rue de la Loi 200
B-1049
Brussels
Belgium**

If you have any other queries, please do not hesitate to contact me.

Yours sincerely,

Dr Chris Jones

Novel Foods Unit

authorisations are granted on an applicant specific basis, so other companies seeking to market the same ingredient must gain separate approval.

4. The current request addresses substantial equivalence according to the five criteria set out in Article 3(4) of Regulation (EC) 258/97: composition, nutritional value, metabolism, intended use and the level of undesirable substances.

Evaluation

a) Composition

1. Nutrisure Ltd chia seeds are grown and harvested in Argentina. The seeds are not processed in any way prior to use as a food ingredient. 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 their seed stock were originally imported from Mexico and Bolivia.
2. The applicant has compared the published composition of the approved chia seed with 3 batches of their seed. (Dossier, 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

3. 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 the Chia Company's chia but states that the overall nutritional value is consistent with the approved chia.

Mineral (mg/100g)	Nutrisure Seed	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

4. The applicant notes that some of the components analysed fall slightly outside of the range of the approved chia seed but does not regard these differences to be substantive.
5. The applicant has also included a basic comparison of the fatty acid profile of their chia seed with the approved chia. (Dossier, Table 2 and Appendix). Small differences in some of the fatty acids are also seen but the applicant does not highlight these as a cause for concern.
6. 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, in part, to different methods of analysis. This pragmatic approach is in line with a previous request for an opinion on equivalence between two sources of chia seed³.

Discussion: *The Committee was satisfied that minor differences observed between the seeds were likely to be due to differing growing conditions and agreed that the data provided were sufficient to conclude that Nutrisure's Argentinian chia seed and the Australian chia seed show that they have an equivalent composition.*

b) c) Nutritional Value and Metabolism

7. 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 to the existing product.

³ <http://www.food.gov.uk/multimedia/pdfs/chiacompdraftopinion.pdf>

Discussion: *The Committee was content with information provided on the nutritional value of the chia seed, compared with the existing product.*

d) Intended Use

11. 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 in 2013.

Discussion: *The Committee was content that the intended uses of the chia seed are consistent with those permitted for the existing product.*

e) Level of undesirable substances

Chemical and Microbial Content

8. The applicant is of the view that the production process are sufficient to ensure that the levels of undesirable substances are 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. (Dossier, Table 5 and Appendix 1). Results of tests for microbial content are also provided and these are at or below those seen for The Chia Company's seeds (Dossier, Table 6 and Appendix 1).

Discussion *The Committee was content that the applicant had quality control procedures in place to minimise the risk of contamination of the chia seeds.*

Conclusion

15. The Committee concluded that Nutrisure Ltd has demonstrated the equivalence of their chia seed with the existing chia seed according to the criteria set out in Article 3(4) of the Novel Foods Regulation (EC) 258/97.

16. The Committee therefore concluded that the chia seed produced by Nutrisure Ltd. can be considered to be substantially equivalent to the existing chia seed produced by The Chia Company.

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