

Imran Mohammed  
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21 June 2013

Dear Mr Mohammed

### **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

**Cc Arsalan Yunus, Infoods Ltd**

## ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

### OPINION ON SUBSTANTIAL EQUIVALENCE OF ARGENTINIAN CHIA SEED CONSIDERED UNDER ARTICLE 3(4) OF THE NOVEL FOODS REGULATION 258/97

**Applicant**                      Infoods Ltd  
   Unit 2,  
   Selbury Drive,  
   Leicester,  
   LE2 5NG  
   United Kingdom

**Responsible person**    Imran Mohammed

#### Introduction

1. In April 2013 a request was submitted by Infoods Ltd to the UK Competent Authority for an opinion on the equivalence of their chia seed grown in Argentina, compared with the existing chia seed cultivated in Australia, and marketed in the EU by The Chia Company.
2. Chia (*Salvia hispanica* L) 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 that contain chia seeds.
3. In 2003 an application was submitted to the UK for the use of chia seeds in certain types of bread but, 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 2009<sup>1</sup>. An application from The Chia Company, to extend the use of the seeds into products including baked goods and breakfast cereals was authorised in

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

January 2013 following a positive opinion by the UK in 2012<sup>2</sup>. Novel food 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. The dossier states that Infoods' chia seeds are grown and harvested in South America, and the applicant subsequently advised that they will be grown in Argentina. The seeds are not processed in any way prior to use as a food ingredient. If fertilisers are used these are restricted to 'natural fertilisers' and the applicant also advises that any irrigation systems employed are used carefully to minimise soil erosion. No pesticides are used and the applicant has carried out screens to confirm their absence (Dossier, Appendix 1). 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.

<b>Nutrient (%)</b>	<b>Infoods' Seed</b>	<b>The Chia Company Seed</b>
Dry matter	91.7 – 93.4	95.0 – 96.8
Protein	21.2 – 24.3	17.4 – 22.4
Fat	27.4 – 31.1	28.5 – 34.7

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

Carbohydrate	36.1 – 38.5	37.1 – 42.6
Fibre	35.3 – 41.7	32.8 – 40.2
Ash	4.6	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)	Infoods' Seed	The Chia Company Seed
Sodium	2.48 – 5.17	<0.1 – 6
Potassium	639 – 750	510 – 710
Calcium	510 – 581	500 – 640
Iron	5.91 – 7.37	5.70 – 15
Magnesium	298 – 360	310 – 430
Phosphorus	817 - 925	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 comparison of the fatty acid profile of their chia seed with the approved chia. (**Annex 1**, Table 4, p8). 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 seed<sup>3</sup>.

**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 Infoods' Argentinian chia seed and the Australian chia seed show that they have an equivalent composition.*

#### **b) c) Nutritional Value and Metabolism**

11. The applicant states that their chia seed contains around 20% protein and has an oil content of approximately one third of its weight, about 80% of which is alpha linolenic acid, making this ingredient a source of omega 3 fatty acids. The seeds contain about 5% soluble fibre and are a good source of vitamin B, minerals and antioxidants. These figures are similar to the existing product.

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

#### **d) Intended Use**

12. 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**

7. The applicant is of the view that the production process are sufficient to ensure that the levels of undesirable substances are below the specified

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

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 6 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 7 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*

## **(f) Additional information**

### **Toxicity and Safety Studies**

15. The applicant notes that the safety of chia seeds when used in bread at a maximum of 5% has been confirmed by EFSA. EFSA's 2009 opinion took into consideration a number of trials to assess the nutritional quality of chia, its effect on selected markers of coagulation and immune function in humans, and its potential allergenicity. The applicant regards the safety of chia seeds to have been reaffirmed when EU Member States assessed, and accepted, The Chia Company's 2011 request to extend the use of the seeds.

### **Conclusion**

16. The Committee concluded that Infods 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.

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

**June 2013**