

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

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

Applicant COMPAÑÍA INVERSORA AGROPECUARIA S.R.L
and SalbaChia UK
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Introduction

1. In April 2013 a request was submitted by Company Inversora Agropecuaria S.R.L and its UK subsidiary company SalbaChia UK to the UK Competent Authority for an opinion on the equivalence of their chia seed grown in South America, 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 questions were raised by other EU Member States regarding the safety of the seeds. The applicant provided additional data that were scrutinised by the European Food Safety Authority (EFSA) before the seeds were authorised in 2009¹.
4. An application from The Chia Company, to authorise the use of the seeds in a wider range of products, including baked goods and breakfast cereals, was authorised in January 2013 following a positive opinion from the UK². Novel food authorisations are granted on an applicant-specific basis, so other companies seeking to market the same ingredient must gain separate approval.

¹ Commission Decision 2009/827/EC

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

² Commission Decision 2013/50/EU

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

- The current request proposes that the applicant's seeds and those from the Chia Company are substantially equivalent 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

- The dossier states that the applicant's chia seeds are grown and harvested in South America (Northern Argentina, Peru and Bolivia) and are not processed in any way prior to use as a food ingredient. The applicant has outlined current agricultural production practices for chia seeds and has highlighted that the seeds are grown contractually for SalbaChia UK Ltd and this company is able to specify herbicide/pesticide treatments that comply fully with EU legislation.
- The applicant has compared the published composition of the approved chia seed with three separate batches of their seed. This is summarised in the table below.

Nutrient (%)	CIA	The Chia Company
Dry matter	93.70 – 94.00	95.0 – 96.8
Protein	20.35 – 21.65	17.4 – 22.4
Fat	34.29 – 35.78	28.5 – 34.7
Carbohydrate	34.29 – 36.66	37.1 – 42.6
Fibre (soluble)	4.06-5.85	32.8 – 40.2
Fibre (insoluble)	27.56-31.13	
Ash	4.55 – 4.58	4.5 – 5.6

- The applicant has also compared the fatty acids, vitamins and minerals content of their chia seed with the approved chia. With the exception of sodium content, only small variations can be seen, but the applicant does not regard these to be a cause for concern.
- Sodium content of the applicants seeds (55.80-67.50 mg/100 g) would appear to differ from the sodium content of the Chia Company's approved seeds (<0.1-6 mg/100 g).
- In all of the above analyses, the applicant's data have been compared with published data on the approved product. 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 were sufficient to conclude that the applicant's chia seed and the Australian chia seed have an equivalent composition. The Committee noted a difference in sodium content between the two seeds and requested further information from the applicant to explain this variation. The applicant accounted for these differences by stating that sodium values differ greatly in all available analysis, as a result of the method of testing, humidity of the seed, soil type, local climate and time of harvest. The applicant highlighted that the sodium content of the Chia Company's approved chia seed ranged from <0.1 to 6 mg/100 g – a 60 fold seed to seed difference in variability. The applicant also highlighted that the sodium content of the recently assessed Nutrisure Ltd chia seed was below the limit of detection of < 50 mg/100 g; allowing for a wide range of sodium contents to be accepted within this limit. The Committee did not request any further information on this aspect and did not highlight any further concerns.*

b) c) Nutritional Value and Metabolism

11. The applicant has compared the nutritional profile of its seeds with authorised chia (three separate batches were analysed) and found no significant nutritional differences between its chia seeds and those from the Chia Company.
12. The applicant has also provided details of metabolism and stability studies for chia seeds in general. Chia seeds have an oil content of approximately one third of their weight, a significant percentage of which is alpha-linolenic fatty acid (an essential omega-3 fatty acid). The applicant's chia seeds are also a source of vitamin B, calcium, phosphorous, potassium and zinc, and contain natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides).

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

d) Intended Use

13. The applicant intends to incorporate chia seeds into a range of foods (bread products, breakfast cereal, fruit, nut and seed mixes and bread) in addition to marketing 100% packaged chia seeds. The applicant highlights that the proposed uses and use-levels are consistent with the authorisation given 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.*

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

e) Level of undesirable substances

Chemical and Microbial Content

Chemical Contamination

14. The applicant provided results of heavy metals analysis (arsenic, cadmium, mercury and lead) for three separate batches of its seeds and has compared these with data obtained for authorised chia by the Chia Company. The applicant also provided data relating to mycotoxins analysis (Aflatoxin B1, B2, G1, G2 and Ochratoxin A) for one batch of its chia seeds.

Microbial Contamination

15. The applicant presented microbiological data for one batch of its seeds and compared these to relevant data for authorised chia seeds. Analysis of *Bacillus cereus*, *S. aureus*, Salmonella species and *L. monocytogenes* were performed.

Discussion The Committee was in agreement that the applicant's chia seeds are comparable to the Chia Company's seeds relating to the levels of undesirable substances and no concerns were raised.

Conclusion

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

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