

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. A further application from Wow Foods and Drinks Ltd. to extend the use of the seeds in fruit juice and fruit juice blends, was authorised in September 2015 following a positive opinion from the Irish Competent Authority³.

5. Novel food authorisations are granted on an applicant-specific basis, so other companies seeking to market the same ingredient must gain separate approval. 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. Terrafertil UK Ltd is requesting such an opinion from the UK Competent Authority.

6. According to Article 3(4) of (EC) 258/97, the notification procedure 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 to their:
 - Composition
 - Nutritional value
 - Metabolism
 - Intended use, and
 - level of undesirable substances contained therein.”

7. Terrafertil UK Ltd has provided information to support the claim that their chia seeds, grown in Ecuador and Peru, are equivalent to an authorised source of chia seeds by The Chia Company and Wow Foods and Drinks Ltd. Terrafertil UK Ltd seek equivalence to use chia seeds in baked good and other products as listed in Commission Implementing Decision 2009/827/EC and Commission Implementing Decision 2013/50/EU, as authorised for supply by The Chia Company. Terrafertil UK Ltd also seeks equivalence to the extension of use of chia seeds into fruit juices as authorised for supply by Wow Foods and Drinks Ltd.

² Commission Decision 2013/50/EU

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

³ http://ec.europa.eu/food/safety/docs/novel-food_authorisation_2015_chia-seeds_2nd-extension_authorisation-letter_en.pdf

Evaluation

a) Composition

8. The dossier by Terrafertil states that chia seeds are grown and harvested in Ecuador and Peru and are not processed in any way prior to use as a food ingredient. During the growing process, the fields are visited at least weekly in order to evaluate the growth of the chia plants. The chia seeds are harvested mechanically, using machinery similar to that used for soy or wheat. Prior to entry into the field, the harvesting machines are cleaned thoroughly. Following harvest, the seeds are placed into new 800 kg bags, sealed and numbered to identify the specific field in order to maintain purity and traceability.
9. Post-harvest the chia seeds are mechanically cleaned and classified. No chemicals are used. The cleaning process removes flowers, leaves, stems, and other undesired parts of the plants. Following cleaning and classification, the chia seeds are generally packed into 25kg polypropylene bags. These bags are either then sent to warehouses for storage or directly to customers.
10. The applicant has compared the published composition of the approved chia seed with three separate batches of their seed from each source-country. This is summarised in the table below. Small variations can be seen, but the applicant does not regard these to be a cause for concern.

| Nutrient (%) | Terrafertil UK Ltd Ecuador | Terrafertil UK Ltd Peru | The Chia Company |
|--------------|----------------------------------|-------------------------------|---------------------|
| Dry matter | 92.6 - 92.7 | 92.7 - 93.1 | 95.0 - 96.8 |
| Protein | 23.1 - 23.9 | 21.7 - 21.9 | 17.4 - 22.4 |
| Fat | 26.9 - 27.8 | 26.7 - 28.1 | 28.5 - 34.7 |
| Carbohydrate | 36.6 - 38.0 | 38.4 - 39.8 | 37.1 - 42.6 |
| Fibre | 37.3 - 37.8 | 37.4 - 41.7 | 32.8 - 40.2 |
| Ash | 4.6 - 4.7 | 4.6 - 4.7 | 4.5 - 5.6 |

11. The applicant has also compared the fatty acid, vitamin and mineral concentrations of their chia seed with the approved chia. The mineral concentrations is summarised in the table below. Small variations can be seen, but the applicant does not regard these as important. 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 seed⁴.

| Minerals mg/100g | Terrafertil UK Ltd Ecuador | Terrafertil UK Ltd Peru | The Chia Company |
|---------------------|----------------------------------|-------------------------------|---------------------|
| Sodium | 1.59 - 2.3 | 1.76 - 2.26 | <0.1 - 6 |
| Potassium | 689 - 706 | 708 - 716 | 510 - 710 |
| Calcium | 508 - 517 | 528 - 534 | 500 - 640 |
| Iron | 6.46 - 6.79 | 6.38 - 6.63 | 5.7 - 15 |
| Phosphorus | 726 - 807 | 778 - 806 | 600 - 870 |
| Magnesium | 369 - 376 | 380 - 382 | 310 - 430 |

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 Terrafertil chia seed and the comparator's chia seed have an equivalent composition.

b) Nutritional Value and Metabolism

12. The applicant has compared the nutritional profile of its seeds with authorised chia (three separate batches from each source country were analysed, six in total) and found no significant nutritional differences between its chia seeds and those from The Chia Company and Wow Foods and Drinks Ltd.

13. The applicant's chia seed contains about 20% protein. 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 states that the Terrafertil UK's chia seeds are also a source of vitamins A, C, and E, calcium, phosphorus, potassium and zinc, and contain natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides).

⁴ <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 products.

c) Intended Use

14. The applicant intends to incorporate chia seeds into a range of foods (baked products (10%), breakfast cereal (10%), fruit, nut and seed mixes (10%) and bread (5%) in addition to marketing 100% packaged chia seeds as authorised for supply by The Chia Company. The applicant intends to incorporate whole, mashed or ground chia seeds in fruit juices or fruit juice blends at up to 15g/450ml as authorised for supply by Wow Foods and Drinks Ltd.

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

d) Level of undesirable substances

Chemical and Microbial Content

Chemical Contamination

15. The applicant provided results of heavy metal analyses (arsenic, cadmium and lead) for six separate batches of its seeds (three separate batches from each source country) and has compared these with data obtained for authorised chia by the Chia Company. The applicant also provided data relating to mycotoxins (Aflatoxin B1, B2, G1, G2 and Ochratoxin A) for six separate batches of its chia seeds (three separate batches from each source country). All results are comparable to those obtained by The Chia Company and Wow Foods and Drinks Ltd.

Microbial Contamination

16. The applicant presented microbiological data for the analyses of six separate batches of its seeds (three separate batches from each source country) and compared these to relevant data for authorised chia seeds. Data relating to yeasts and moulds, *E.coli*, *Salmonella*, coagulase positive Staphylococci, *Bacillus cereus*, Coliforms and Enterobacteriaceae were presented. No concerns were identified and the Ecuador and Peru results are comparable to those obtained by The Chia Company and Wow Foods and Drinks Ltd.

17. The applicant has expressed in their dossier how they will ensure safety of chia seeds that they plan to market in the future. Terrafertil UK state that they will request a certificate of analysis from the shipment lot before it is despatched, as well as inspecting supplier storage conditions on an annual basis.

***Discussion** The Committee was in agreement that the applicant's chia seeds are comparable to the comparator's seeds relating to the levels of undesirable substances in terms of chemical contaminants and microorganisms and no concerns were raised.*

Secretariat
March 2016