Food Standards Agency
food.gov.uk

Andreas Klepsch
DG Sanco
European Commission

16 March 2012 NFU 788

INITIAL OPINION: **CHIA SEEDS: ADDITIONAL USES.**

Dear Andreas,

On 14 April 2011, the UK Competent Authority accepted an application from The Chia Company to extend the use of chia seeds as a novel food ingredient, in accordance with Article 4 of regulation (EC) 258/97.

The Advisory Committee on Novel Foods and Processes (ACNFP) reviewed this application and their opinion is attached. I apologise for the delay in submitting this opinion as the ACNFP's evaluation was extended while we obtained additional information from the applicant.

In view of the ACNFP's opinion, the UK Competent Authority considers that extending the use of chia seeds for the proposed food categories, meets the criteria for acceptance of a novel food defined in Article 3(1) of regulation 258/97.

I am copying this letter, and the ACNFP's opinion, to the applicant.

Yours sincerely,

(By e-mail only)

Dr Chris Jones
For the UK Competent Authority

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ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON AN APPLICATION UNDER THE NOVEL FOOD REGULATION FOR ADDITIONAL USES OF CHIA SEED

Applicant	**The Chia Company (Australia)** **262-272 Lorimer Street** **Port Melborne** **Vic 3207** **Australia**
Responsible Person	**April Halliwell**
EC Classification	**2.1**

1. An application has been submitted by The Chia Company (Australia) to extend the currently authorised use of chia seeds (*Salvia hispanica* L*) to include* a number of additional food products that commonly contain other seeds.
2. 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 purple or, less commonly, white. These flowers develop into seed pods which ultimately contain the seeds that are the subject of this application.
3. In 2009 an authorisation was issued to the Columbus Paradigm Institute S.A. for the use of whole or ground chia seeds in bread products at a maximum level of 5%. (Commission Decision 2009/827/EC). The Chia Company previously satisfied the Committee that their chia seeds are substantially equivalent to Columbus Paradigm's seeds and has gained authorisation to market their seeds for use in bread products by notifying the European Commission, in accordance with Article 5 of Regulation (EC) 258/97.[1]

I Specification of the Novel Ingredient (NI)

Dossier, pp 6-8

4. The proximate composition of the chia seeds is detailed below. This, together with information regarding the presence of contaminants such as heavy metals, was considered in the original applicant's application and again when the present

[1] The ACNFP's opinion isavailable via the Committee's website http://acnfp.food.gov.uk)

applicant submitted its request for the ACNFP's opinion on equivalence. As these data were reviewed by the Committee previously they are not reproduced in detail in this opinion but are available in the dossier.

Proximal Composition

Dry Matter	91-96%
Protein	20-22%
Fat	30-35%
Carbohydrate	25-41%
Crude Fibre (*)	18-30%
Ash	4-6%

*Crude fibre is the part of the fibre made mainly from indigestible cellulose, pentosans, and lignin

Discussion *The Committee accepted that the specification of the novel ingredient did not differ from that seen in previous applications and did not therefore give cause for concern.*

II Effect of the production process applied to the NI

Dossier pp8-10

5. The applicant describes the harvest and post harvest processing in detail in the dossier. In summary, the seeds, which originated from South America, are planted into prepared seedbeds and grown until the desired biomass is reached. This is achieved with the help of satellite imagery that indicates areas of higher and lower biomass so that targeted corrective measures (addition of plant nutrients) can be taken. Plant tissue tests are also taken during the growth stage to ensure the correct nutrition levels are obtained.
6. Post-harvest, the seed head is mechanically swathed to ensure even ripening and consistent oil yield in the seed. The seeds are transported to a seed cleaning facility where they are transferred into silos for fumigation with carbon dioxide, cleaned and then packed into finished products. The seeds are not further processed prior to use as a food ingredient and specific information related to post harvest handling is provided in Appendix 9 of the dossier.

Discussion *The Committee was satisfied with the proposed method of production is controlled and the post-harvest monitoring procedures offered sufficient reassurance that the applicant could ensure the quality of the product.*

III History of the organism used as the source of the NI

Dossier p10-11

7. The applicant refers to evidence of chia seeds being consumed for millennia in South America but acknowledges that that more recent use appears to have been restricted to local markets in rural South America until the 1990s, when

increased commercialisation led to exports to North America and, latterly, to Australasia and Europe. (Dossier Annex C).

8. The applicant also notes that EU authorisation is currently restricted to use in bread products at levels of up to 5% and that this is solely a reflection of the original applicant's marketing intentions. The use of chia seeds outside the EU is not restricted to bread products, a fact acknowledged by EFSA who noted that the increased worldwide use of chia seeds was a particular factor when it concluded in 2009 that the consumption of chia seeds was safe at the proposed level of use[2].

Discussion *The Committee noted that there was a substantial history of consumption of chia seeds and increasing use of the seeds elsewhere in the world*

IX Anticipated intake and extent of use of the NI

Dossier p11-16

9. The applicant intends to incorporate chia seeds into a number of food categories that commonly contain seeds and nuts. The proposed level of incorporation is based upon a Recommended Daily Intake of 2g of omega-3 fatty acids that has been set by the Australian Heart Foundation and the Food Safety Authority of Australia and New Zealand. (Dossier, Appendix 1). The applicant also proposes the marketing of pre-packed whole seeds. The proposed use categories are detailed below:

Proposed Food Uses

Proposed Category	**% Inclusion / Recommended Daily Intake**	**Chia seed Consumption per portion**
100% Packaged Chia Seed	15g Recommended intake per day	15g Chia Seed
Baked products (muffins, cookies, crackers and biscuits)	10%, 10g Chia per 100g total mix 'flour weight'	- Muffin 95g with 9.5g of Chia Seed - Cookie 40g with 4g Chia Seed - Cracker 40g with 4g Chia Seed - Biscuit 40g with 4g Chia Seed
Breakfast cereal	10%, 10g per 100g total mix	45g serving with 4.5g Chia Seed
Fruit, nut and seed mixes (sprinkles)	10%, 10g per 100g total mix	45g serving with 4.5g Chia Seed

10. Data from the UK National Diet and Nutrition Survey (NDNS) have been used to estimate the likely consumption of chia for the proposed range of products, and a

[2] http://www.efsa.europa.eu/en/efsajournal/pub/996.htm

summary of these figures are detailed below. The applicant recognised that the 2009 EFSA opinion does not highlight any toxicological issues related to the consumption of chia seeds and that the principal concern is likely to be in relation to potential allergenicity. In view of this the applicant has not carried out a highly detailed intake assessment, confining their analysis to published summary data from the NDNS database. Mean consumption is estimated to be 13.4 g/day, based on the assumption that a consumer is an average consumer of all the relevant foods, and that all these foods contain chia seed at the maximum level. The applicant suggests that "high level" consumption might be twice this figure.

Average potential Intake of Chia seed as calculated from UK NDNS for Bread, Breakfast Cereals, Baked Goods, Nuts, Savoury Snacks, and Confectionery Food Categories

All Respondents	Mean Consumption - (grams per day)							
Product Categories	Age Groups							
	19-24	25-34	34-49	50-64	All Consumers	% All Consumers	Chia % Inclusion	Grams of Chia Consumed / Day
Bread	94.3	102.7	101.6	101.4	100.9	99%	5%	5.0
Breakfast Cereal	16.4	26.4	28.1	37.6	29.0	67%	10%	2.9
Biscuits, buns, cakes, pastries & fruit pies	19.3	28.7	33.6	41.9	33.0	84%	10%	3.3
Nuts	0.9	2.3	2.3	2.1	2.1	20%	10%	0.2
Savoury snacks	12.4	9.9	7.0	3.6	7.4	56%	10%	0.7
Confectionary	15.9	12.3	12.3	8.6	11.7	62%	10%	1.2
SUM	159.1	182.3	184.9	195.1	184.1	65%		13.4

11. The applicant suggests that these figures will overestimate the consumption of seeds as it is unlikely that individuals will confine their consumption of foods within each category to those which contain chia seeds. The Committee noted that FSA experts in food chemical intake had recently advised that high level intake at the 97.5%ile can be estimated as three times the mean value, for individual foods[3]. The officials also noted however that the approach of summing the high level exposure for each food category to give an overall figure for high level consumption inevitably leads to overestimation because, in practice, it would not be possible for the same individuals to be high level consumers for every food category.

12. As noted above, the applicant also intends to market chia seeds *per se* to enable consumers to add chia seeds to products at home. The applicant states that this will give consumers the option of consuming chia seeds in their own choice of (for example) breakfast cereals and bakery products and intends that the level of consumption in such products will be in line with the RDI advice detailed above. In this regard the applicant will market 100% chia seed with appropriate labelling and intake advice will be clearly visible on the packaging.

[3] Initial opinion for taxifolin, available at http://acnfp.food.gov.uk

13. The applicant does not consider the resulting increase in consumption to be cause for concern and notes that the products that are the subject of this application are currently available elsewhere in the world (Dossier pp17-20). The applicant acknowledges the potential for individuals who are allergic to seeds to cross react with chia but notes that there is little evidence of this happening elsewhere in the world (see section XIII below).

Discussion *The Committee noted FSA officials' comments on the approach used by the applicant to estimate intake, and agreed that it led to a significant overestimation of likely consumption levels. Members also accepted that, while there was a requirement to estimate the likely level of consumption of any novel food, accurate intake values were of limited value for risk assessment purposes in the absence of a benchmark for the safe intake level. As reported in Section XIII (below) the arguments in support of extending the range of food categories are largely based on the evidence of safe (non-EU) food use. In view of this approach, the Committee accepted that the provision of more extensive intake information would not significantly add to that already presented in support of the safety of the seeds. The Committee also noted that food consumption can be systematically under-reported in dietary surveys, including the NDNS, and there are no accepted methods of correcting for this.*

The Committee also highlighted that the proposed food categories are products that would typically include products that contain other seeds, which is important when assessing the potential risk of cross-reactivity in people with existing food allergies (see below).

X. Information from previous human exposure to the NF or its source

Dossier p16-24

14. The applicant has provided a detailed review of chia-containing products that are on the market in non-EU countries, many of which are similar to those that are the subject of this application. The range of products is relatively large although it is not known how widely consumed each of these products is. Nevertheless, the relatively large number of newly launched products indicates increasing exposure to the seeds.

15. The applicant also notes that a number of products are being stocked by pan-Australian and New Zealand grocery chains and also cites data from the Australian Bureau of Statistics that, on a population basis, 30g of chia seeds were consumed by every Australia citizen during the 'last financial year'. (The applicant also mentions allergenic potential in this part of the dossier and this issue is considered in Section XIII below).

Discussion *The Committee noted that chia was becoming available in a wider range of products outside the EU, although the extent to which the seeds were consumed was not clear.*

XI Nutritional information on the novel food

Dossier p24-26

16. The applicant provides a detailed breakdown of the nutritional composition of the seed which is 20% protein and approximately one third fat, of which 80% is alpha-linoleic acid. The applicant contends that, as the seed is relatively rich in alpha-linoleic acid, it provides an important source of omega-3 fatty acids which are perceived to have health and nutritional benefits. The detailed nutritional profile can be found in the dossier (p24-25 and Appendix 2).

Discussion

The Committee observed that the omega-3 fatty acids in chia seed are in the form of alpha-linoleic acid, a nutritionally essential fatty acid that is required for synthesis of important fatty acids and eicosanoids, which has a different function to the long chain omega-3 fatty acids that are found in certain other foods e.g. in fish oils.

The Committee's assessment focuses on safety and labelling, it does not address any nutrition or health benefits that may be claimed for the novel ingredient or for foods that contain it. Nutrition or health claims may only be made if they are specifically authorised under EU Regulation (EC) No 1924/2006.

XII Microbiological Information

Dossier p26-27

17. The applicant's chia seeds are routinely tested for the presence of a range of microorganisms and mycotoxins. The results of these analyses, which were also reviewed as part of the applicant's earlier request for an opinion on equivalence and are not reproduced here, show only low levels of microbial contamination. According to the applicant the results are in compliance with relevant EU legislation.

Discussion *The Committee accepted that there was adequate provision to ensure that the seeds would not contain significant quantities of pathogenic or spoilage microorganism and that there was adequate testing employed to ensure the absence of mycotoxins.*

XIII Toxicological information

Dossier p27-29

18. The applicant does not present any safety studies that have been carried out on their seeds. The lack of toxicological studies is consistent with the original 2003

dossier. EFSA has noted that the data were limited but has concluded that ‘‘experience gained from previous and current use of chia seeds in non-EU countries can be regarded as supportive evidence of the safety of chia seeds’ (See footnote 2).

19. The applicant refers to a study carried out to determine whether chia seeds have any effect on the immune system in Wistar rats. The results of this study were presented at a Workshop on Immunonutrition in 2008 and are reported in a Nutritional Society Proceedings publication, and do not give any indication that consumption of the seeds affected body weight, thymus weight, thymocyte number, and IgE levels when compared with controls.

Discussion *The Committee accepted that, given the nature of the ingredient, the use outside the EU and the views of EFSA then there was scope for the applicant to extend the use categories without provision of additional safety studies. Members agreed that increased consumption of the seeds did not give cause for toxicological concern.*

Allergenicity and Labelling

20. In line with the conditions attached to the original authorisation, any products containing chia seeds will be clearly labelled as such. As noted above, there is a possibility that existing seed allergic individuals will cross react with chia seeds. The applicant acknowledges this concern and points out that the proposed food products are likely to also contain other seeds and nuts, so that such individuals would routinely avoid consuming them.

21. The applicant has approached a number of organisations in Australia and the US[4] to determine whether the increased marketing of the seeds has coincided with an increase in reports of allergy to chia. None of these organisations was aware of any reports of allergy to chia seeds, either in existing seed allergic individuals or otherwise (Dossier, Appendices 3, 4, 5 & 8). The applicant notes that this is not necessarily because chia is less allergenic than any other seeds, as it could be due to appropriate risk management strategies, such as clear labelling and incorporation of chia seeds into products that are already associated with seeds (including the sale of seeds in their own right). The applicant foresees that seed allergic individuals can continue to follow their normal diet if and when chia seeds are used in a wider range of foods.

Discussion. *The Committee noted that the seeds would be clearly labelled as such but the possibility of cross-reactivity in individuals who are allergic to seeds and nuts could not be discounted. This possibility was recognised during the earlier evaluation of chia seeds as a novel food. The Committee also noted that the additional food*

[4] Anaphylaxis Australia, Food Allergy and Anaphylaxis Network (US), Allergy Bureau of Australia, Asthma and Allergy Foundation of America

products that would incorporate chia seeds also contain other seeds or tree nuts and that, in the majority of cases, seed or tree nut allergic individuals would take care to avoid such products, even if they did not know specifically whether they should avoid consuming chia seeds. The Committee also highlighted the relative absence of studies quantifying the level of allergy to chia seeds amongst seed allergic individuals and suggested that such data could be useful in determining whether extending the use of chia seeds would restrict the choice of seed allergic individuals. The Committee also noted that chia seeds have little history of consumption in the European Union and it was therefore possible that extending the range of uses could, like any novel food containing protein, give rise to increased sensitisation in the wider population.

CONCLUSION

The Committee considered that the only issue of concern in relation to extending the use of chia seeds to the foods listed in paragraph 9 related to potential consumption by individuals with existing seed allergy. Despite evidence of historical use, the seeds were effectively new to markets across in the world and the true extent of allergenicity was not known. The applicant had considered the possibility of allergenicity and had sought to minimise this likelihood by careful consideration of the proposed food categories and liaison with relevant support groups.

Chia seed is not a known allergen and it is not subject to EU rules on mandatory declaration of allergens in food. The existing authorisation for the authorisation of chia seeds for use in bread products requires that there is reference to chia seeds on the label. The Committee was concerned that the use of chia in a wider range of foods, all carrying the same precautionary labelling, would result in a restriction of choice for people with existing seed allergies and this might in fact be unnecessary if there is actually no cross-reactivity between chia and other seeds

However the Committee also accepted that the risk management measures described by the applicant would be adequate to address safety concerns in relation to allergic reactions amongst known ‘at risk’ individuals.

If such an approach were to be considered the Committee noted the current dietary practices of nut and seed allergic individuals could not, in all cases, be relied upon to remove all risks resulting from cross-reactivity, and suggested that there would need to be increased awareness among these individuals. In order that this information is widely disseminated the Committee recommended that the applicant should proactively seek to work with consumer groups, allergy support groups and the relevant competent authorities in each Member State when they are seeking to place new products containing chia seeds on the market. It would also be advisable to inform allergy clinics so that they can report any cases of chia allergy to the relevant national authorities.

The Committee advised that the uncertainty could be reduced by research being carried out to determine the likelihood of different seed allergic individuals cross-reacting to chia seeds. In relation to potential changes in sensitisation across the population the Committee advised that the company should be proactive in reporting allergic reactions and specifically highlight any that occurred in individuals who had not previously demonstrated any symptoms of allergy to seeds.

March 2012