

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

OPINION ON AN APPLICATION UNDER THE NOVEL FOODS REGULATION FOR CHIA (*Salvia hispanica* L)

Applicant Robert Craig and Sons

Responsible Person David Armstrong

EC Classification 2.2

Introduction

1. An application was submitted by R Craig & Sons [M] Ltd. to the UK Competent Authority for authorisation of whole Chia (*Salvia hispanica* L) seed and ground whole Chia as a novel food ingredient in soft grain bread.
2. Chia (*Salvia hispanica* L) is a summer annual herbaceous plant belonging to the mint family (Labiatae). The seed of the Chia plant has a long history of consumption in South America and was a major part of the diet in pre-Columbian civilisations, mainly in the Aztec population. If approved in Europe, Chia seeds would provide consumers with an alternative source of the n-3 polyunsaturated fatty acid, alpha-linolenic acid. A number of studies carried out by one South American company suggest that incorporating Chia seeds into hens' diets results in eggs with an increased content of n-3 fatty acids, thereby providing another potential source of these fatty acids in the diet.
3. The applicant will import whole Chia seeds that are mechanically harvested from conventionally-grown crops in two locations: Peru and Argentina. The whole ground Chia to be marketed in the EU will be produced in the UK by milling the imported whole seeds.

I. Specification of the novel food

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4. Chia (*Salvia hispanica* L) is a summer annual herbaceous plant belonging to the Labiatae family.
5. Detailed compositional analyses of Chia seed are given in the application dossier for these analyses the applicant has tested four samples from four consignments of Chia from Peru, for proximate analysis, fatty acid composition and heavy metal content. Whilst details of the methods employed in the proximate analysis and heavy metal analysis are not given, fatty acid profiling was carried out to accredited procedures. Mineral, vitamin and carbohydrate analyses were also carried out on seed in Argentina. Although details of the methods of analysis are

not given, the applicant states that the analytical laboratory in Buenos Aires which carried out the analyses is a member of the Union of International Independent Laboratories and is approved by the UK Grain and Feed Trade Association to issue certificates of analysis for feed ingredients.

Discussion *The Committee was satisfied with the specification of the Novel Food.*

II. Effect of the production process applied to the novel food

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6. Whole Chia seeds are not processed in any way prior to their use as a food ingredient. The seeds are grown in Argentina and Peru under contract for the applicant who states that agronomic practices will be carried out to fully comply with EC legislation. Details of the cultivation conditions are given in the application.
7. Post-harvest, the seed is cleaned mechanically and not subjected to any chemical treatments. The seed is stored in sacks within a fully enclosed warehouse facility in preparation for shipment. Although the information on the storage and transport conditions is limited, following a request from the Committee concerning proposed conditions of handling, storage and shipment, the applicant submitted a proposed HACCP procedure the use of which would minimise batch to batch variation. The seeds are monitored during transport and storage whilst the proposed HACCP plan describes measures to be put in place to control temperature and humidity during storage and transport. The applicant has also provided data in respect of potential microbial contamination of Chia seed.

Discussion *The Committee was satisfied that the proposed method of production is controlled, and that the in-transport and in-process monitoring steps are appropriate to ensure a safe and consistent product. The Committee accepted the proposed HACCP procedures offered sufficient reassurance that the applicant would be able to ensure the quality of the product.*

III. History of the organism used as a source of the novel food

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8. Chia (*Salvia hispanica* L) seeds have a history of use as a food and a medicine, mainly by the Aztecs up until colonisation by the Europeans. Historically, Chia seeds were roasted and ground to form a meal called 'pinole', then mixed with water to form a porridge or made into cakes. Although grown only on a very small scale, and with rudimentary technological methods, Mexican Indian descendants are still producing this grain. Chia seeds are also used in a Mexican beverage 'chia fresca' in which the seeds are soaked in water and then flavoured with fruit juice and consumed as a drink.
9. An extensive research and development programme on Chia has been undertaken in South America to determine the feasibility of growing this crop on a commercial scale. This has resulted in the development of new production areas

and methods. Chia crops have been bred conventionally in South America and have not undergone genetic modification.

Discussion *The Committee noted that there was limited evidence of recent food use for this product.*

IX. Anticipated intake/extent of use of the novel food

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10. If approved, the applicant’s proposed use of Chia is for inclusion of the whole and ground seed as ingredients in soft grain bread. Based on data from the UK National Diet and Nutrition Survey of Adults Aged 19-64 years (2002), the applicant has estimated the amount of the novel ingredient that will be consumed as follows.

11. Pilot studies conducted by the applicant have determined that the level of Chia seeds or whole ground Chia included in the soft grain bread mix shall be 5%. On this basis, daily Chia consumption figures, calculated for British adults would give a mean intake of 2.1g/person/day. High level consumers could consume up to 12.9g/day (97.5th percentile; adult males).

12. In the UK, soft grain bread includes brands that are directly marketed for consumption by children. The applicant did not include estimates of Chia intake for different age groups, but the Food Standards Agency additionally provided estimates based on food consumption data from Diet and Nutrition Surveys of different age groups in Britain.

	Soft grain bread consumption (g/person/day)		Chia consumption (g/person/day)	
	Mean	High level (97.5 th percentile)	Mean	High level (97.5 th percentile)
Age 1½-4½	22	65	1.1	3.2
Age 4-18	29	86*	1.4	4.3*
Adult 19-64	43	231*	2.1	11.6*

* Note: with the exception of the youngest age group, the low number of consumers of soft grain bread in each survey means that the estimates of high level consumption may not be statistically valid. The figures can therefore only be used as a rough guide to the amount of Chia that would be consumed.

Discussion *As the proposed range of foods was narrow the Committee was content that the intended use of the product did not give any cause for concern, based on the scientific information currently available.*

X. Nutritional information on the novel food

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13. Chia seeds have an oil content of approximately 32%, which is rich in alpha-linolenic acid (approximately 60%). Seeds are also high in protein (21%), are a rich source of vitamins B, calcium, phosphorus, potassium, zinc and copper.

14. The UK Committee on Medical Aspects of Food and Nutrition Policy (COMA) recommended in 1994 that individuals should increase their intake of n-3 fatty

acids since raised intakes are associated with reduced risks of coronary heart disease. The main sources of n-3 fatty acids in the Western diet are oily fish, green vegetables and certain vegetable oils.

15. Alpha-linolenic acid is a significant contributor to the intake of n-3 polyunsaturated fatty acids (PUFA) and can be elongated and desaturated *in vivo* to its long-chain derivatives, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). However, in man the extent and regulation of this conversion is unclear¹.
16. Chia seed contains natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides) which confer a distinct technological advantage over alternative alpha-linolenic acid sources such as flaxseed, in terms of product stability and flavour quality.
17. Since Chia is intended to be used as a nutritional ingredient, any claims made on the food due to the inclusion of the seed or milled whole seed must comply with the general criteria for making nutrient content claims. Final products will need to be labelled with the ingredient name and the prescribed nutritional labelling according to Directive (79/112/EEC as amended).

Discussion *The Committee did not raise any concerns regarding the nutritional properties of the novel food.*

XII. Microbiological information on the novel food

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18. Samples were taken from four consignments of Chia seeds for microbiological analysis. No pathogenic organisms were detected. No substances inhibitory to BHK21 (C-13) cells were detected in a cytotoxicity assay.
19. No mycotoxins were detected in the screen carried out on a composite sample from the four Chia consignments (the applicant describes this analysis under scheme XIII).

Discussion *The Committee were content with the microbiological information supplied, but requested further information on the control of storage and transport, which would minimise the potential for foodborne spoilage microorganisms to develop. The applicant was able to supply this information and the Committee agreed that the proposed HACCP schema described sufficient measures that would control and monitor levels of moisture within the seeds during bulk storage and transport.*

¹ In 2002, the Food Standards Agency convened a group of expert scientists to review current research investigating whether n-3 PUFA from plant oils (alpha-linolenic acid) were as beneficial to cardiovascular health as the n-3 PUFA from marine oils (EPA and DHA). The group concluded that dietary intake of ALNA has been associated with a beneficial effect on coronary heart disease; however, the results from studies investigating the effects of ALNA supplementation on CHD risk factors have proved equivocal.

XIII. Toxicological information on the novel food

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20. A number of human clinical studies were carried out to assess the safety of this product, including an allergenicity study, a 4-week dietary intervention study and a 12-week randomised, single blind crossover feeding trial.
21. The applicant has also provided details of two 8-week trials in laying hens and one 28-day study in broiler chickens which investigated the effects of Chia on hens' egg yolk composition and chicken breast and thigh muscle.

Discussion *The Committee was satisfied with the toxicological data supplied by the applicant.*

Allergenicity

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22. An investigation into potential allergenicity of Chia was carried out at BIBRA International Ltd., Surrey, Southampton University and King's College London. The study described in the report was carried out to internationally accepted standards of Good Laboratory Practice but was not subject to any Quality Assurance inspection programme. The study is summarised below and more detailed information can be found in the application dossier.
23. No allergy-associated properties of Chia seed have been reported in the literature to date and no verifiable cases of patients with allergies to common UK food plants with any botanical relationship to Chia have been found. Chia belongs to the Labiatae, or Laminiaceae, family. The plants of this family include mint, sage, thyme, basil, pennyroyal, lavender, lemon balm, bergamot, oregano and savory. An allergic response to oregano and thyme is cited in the report, however this is related to the leaf of the plant rather than the seed. Consequently the investigation was targeted at the peanut and tree nut allergens as the most likely source of cross-reactivity.
24. An initial IgE binding screen was carried out against a panel of 30 individuals by Multiple Allergy Screening Test (MAST), selected on the basis of their reactivity to peanut. Sera from peanut allergic subjects showed low levels of serological binding to Chia protein in immunoblots, although this binding varied considerably between different serum samples. Inhibition studies indicated that IgE binding to Chia was specific. However, it was considered that the binding of IgE to Chia protein did not necessarily imply that there would be coincidental clinical reaction to Chia.
25. IgE binding of Chia was further analysed using sera from five double-blind placebo-controlled food challenge (DBPCFC) peanut sensitive individuals. None of these individuals were reported to have allergy to sesame seeds although one had sensitivity to mustard. Immunoblotting demonstrated some IgE binding in these sera, however this was concluded to be non-specific in nature. Furthermore

the applicant has suggested that Chia proteins may be highly glycosylated which could affect cross-reactivity.

26. Resistance to proteolytic digestion was investigated in Chia protein extracts using methodology based upon the recommendations of the 2001 Joint FAO/WHO expert consultation on foods derived from biotechnology. Immunoblot analysis demonstrated that all the Chia proteins were sensitive to peptic digestion with the exception of a 14kD band and protein bands below 6kD. The investigator suggests the 14kD band is non-specific cross-reactivity since this band was detected in the negative control serum.
27. Skin prick tests (SPT) were carried out on 12 individuals, selected because of sensitivity to peanut and tree nuts, to determine the clinical relevance of IgE binding activity observed in immunoblotting experiments. Two subjects gave positive SPT responses to Chia which were below the level of the histamine positive control challenge and therefore were considered of doubtful clinical significance. Both subjects were at the most broadly allergic end of the spectrum of sensitivities and both demonstrated sensitisation to sesame. Subsequent immunoblotting revealed a band that could represent an authentic IgE binding protein. This protein was shown to be susceptible to proteolytic digestion. The investigator speculates that this protein is related to sesame and its molecular weight could indicate it to be a profilin, a group of proteins associated with clinical food allergy.

***Discussion** The Committee requested further information regarding the allergenic potential of the novel food. The applicant recognised the potential for such cross-reactivity but was unable to provide the requested data, citing logistic difficulties in assembling the necessary panel of individuals with such allergies. The applicant proposed instead to control this risk by including a precautionary statement on the label of chia-containing foods, informing consumers that the product was not suitable for people suffering from sesame and mustard seed allergies. The applicant also pointed out that chia will be used in softgrain bread products which often contain other ingredients which make them unsuitable for this group of allergic consumers.*

The Committee was disappointed that the applicant was unwilling to conduct additional allergy studies, but accepted that this approach would control the risk associated with cross-reactivity, although was concerned that the use of precautionary labelling might unnecessarily restrict the range of products available to allergic consumers.

Human clinical trials

pp 22-24 of the application dossier

28. The effects of dietary intervention with Chia on selected markers of coagulation and immune function were investigated in humans. The 4-week placebo-controlled dietary intervention study with Chia was carried out in 100 healthy male and female subjects (21-65yr) at the University of Ulster, Northern Ireland. The full study report can be found in the application dossier. Subjects were then randomly allocated to one of four intervention groups and Chia supplements were

included at breakfast. Chia intake was 2.5g (n=25), 5g (n=25) or 10g (n=20) per day for 4 weeks. The control group (n=25) received 4g of sunflower seeds per day. Fasting blood samples were taken before and after the intervention period and were assessed for haematological parameters, plasma lipid profiles and lymphocyte subset typing. Additionally, full anthropometric data, a lifestyle and food questionnaire and a questionnaire monitoring any possible adverse effects of the novel food were administered to each subject.

29. Dose response effects of Chia were statistically analysed. Differences between groups were compared using one-way ANOVA, and differences within groups were compared using the paired t-test. According to the investigator, no significant health-related effects associated with consumption of high levels (10g) of Chia seed were detected. However, analysis of the adverse effects questionnaire revealed a significant effect of consumption of 5g per day on tiredness and fatigue. The study investigators concluded this to be an anomalous result since it was a single effect that was not dose-related. Consequently, no significant adverse effects on human health or well-being were seen after consumption of Chia, even at levels exceeding the anticipated mean daily intake.
30. The applicant also describes a human feeding trial carried out at the University of Toronto, Canada, on subjects with type-2 diabetes, investigating the effects of Chia on measures of glycaemic control and traditional and non-traditional risk factors of cardiovascular disease. A randomised single blind crossover trial using 20 subjects with type-2 diabetes was carried out for 12 weeks with individuals consuming 25g Chia/1000kcal. Fasting blood samples and blood pressure measurements were taken at 0 and 12 weeks.
31. The results suggested that when used as a food supplement, the consumption of Chia significantly lowered systolic blood pressure compared to controls and favourably altered coagulation factors. No adverse effects were reported including no change in bleeding times, liver function or kidney parameters and no adverse effects on glycaemic control.

Laying hen and broiler chicken trials

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32. The applicant presents three studies carried out at Queens University, Belfast, in laying hens and broilers, to assess the nutritional and compositional effects on foods produced from animals fed a diet enriched with Chia. These tests do not examine toxicological endpoints.
33. Two laying hen trials investigated the effects of Chia on hens' egg yolk composition by manipulating the feed. The main aim of the first study was to alter the fatty acid composition of the egg yolk by manipulating the hen's diet. The diets were carefully formulated to be isoenergetic and were supplemented with either 1.5% soya oil, 1.5% fish oil or 14% whole Chia seed. No adverse effects were observed, but again no specific toxicity tests were carried out.

Evaluation of n-3 enriched eggs in humans

p25 of the application dossier

34. This trial, carried out at the Northern Ireland Centre for Diet and Health at the University of Ulster, was intended to evaluate the bioavailability in humans of n-3 fatty acids in eggs produced by hens fed a modified diet supplemented with Chia. This study is not relevant to the assessment of Chia as an ingredient in food.

Additional information relevant to the application

p28 of the application dossier

35. The applicant has included information on the regulatory status of Chia seed as a food in the USA and Canada. Chia seed is considered to be exempt from pre-market regulatory evaluation in the USA and pre-market notification as a novel food in Canada. This regulatory information does not affect the evaluation of the current application since novel foods undergo a different regulatory process in the European Union.

Overall Discussion

36. The applicant has provided sufficient information of the proposed specification, intended use and microbiological safety measures, and indicated that on the basis of four samples analysed from four separate batches of seed, these criteria do not give rise to concern. The Committee noted that given the large transport distances involved and the nature of the product, a key element in preventing any undesirable substances from contaminating this product is adherence to the proposed HACCP procedure as described by the applicant.

37. With regard to the concerns about potential allergenicity, the applicant has indicated that they are unable to proceed with the additional studies that would offer further information regarding the allergenic potential of the seed. The Committee agreed with the applicant that mandatory product labelling, and the limited proposed use of the novel food would not present undue risk to the consumer. However, the Committee was in agreement that labelling on the basis that all individuals who have previously demonstrated symptoms of allergy when consuming other seed based products should not consume this product, restricted the choice of such individuals and could not be endorsed.

38. In addition, although the proposed labelling regime could be viewed as adequate to protect the consumer from potential harm when consuming this novel food, the Committee was cautious about agreeing to this approach particularly when the studies requested would better inform the public of the extent of the allergenic potential of the novel food.

Conclusion

The Committee is satisfied that in accordance with the criteria defined in Article 3(1) of Regulation (EC) 258/97, the evidence provided by the applicant demonstrates that the consumption of this product is not dangerous, misleading, or nutritionally disadvantageous to the consumer. With regard to the applicant's intention to use mandatory labelling to advise individuals of the potentially allergic nature of the novel

food, the Committee wish to note that that as the extent of allergenicity to this product remains unclear, this approach may be unduly restrictive of consumer choice. This issue is one of consumer choice and falls outside the scope of the safety criteria described in the regulation.

The Committee also advises that should this product be authorised then Member States should write and inform allergy clinics and allergy support groups of the introduction of this food these groups may then provide a useful source of on information on the prevalence of chia, and the potential cross-reactivity with existing food allergens.

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