

Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the safety of chia (*Salvia hispanica* L.) seed and ground whole chia seed as a novel food ingredient intended for use in bread

(Request N° EFSA-Q-2005-059)

(adopted on 5 October 2005)

SUMMARY

This Opinion refers to an application for placing on the European Union market of chia (*Salvia hispanica* L.) seed and ground whole chia seed as a novel food (NF) ingredient intended for use in bread.

The Panel has been requested to consider whether the authorisation of chia as a food ingredient for bread is likely to have an effect on public health and to focus on the concerns of a scientific nature raised by various Members States (MS). In particular, the Panel has been asked to address the question of whether the safety of chia may be established without additional toxicological studies.

The compositional data on chia seeds provided by the applicant are not sufficient to perform a full nutritional assessment. From the data provided by the applicant there is no evidence of adverse effects of whole chia seed and whole ground chia seeds. There are uncertainties with regard to the potential allergenicity of chia. The presence in the intended NF ingredient of constituents which might exert anti-nutritional or toxic effects cannot be excluded. Adequate toxicological information on chia seed is not available and the human data provided to the Panel are limited. Therefore the safety of chia cannot be established from the available information and additional studies are required.

KEY WORDS

Chia seeds, novel food, bread, food safety.

BACKGROUND

In June 2003, R Craig and Sons Ltd., Northern Ireland (UK) submitted a request under article 4 of the Novel Foods Regulation (EC) N° 258/97 to the authorities of the UK for placing on the market chia (*Salvia hispanica* L.) seed and ground whole chia seed as a food ingredient.

On 7 May 2004, the authorities of the UK forwarded their initial assessment report of the product concerned to the European Commission. The initial assessment report was carried out by the Food Standards Agency (UK), which had reached the conclusion that this product was not dangerous, misleading or nutritionally disadvantageous to the consumer.

In accordance with article 6 (4) of the Novel Foods Regulation, the European Commission forwarded the initial assessment report to Member States (MS) on 16 July 2004. MS submitted

comments and/or presented reasoned objections within the 60-day period provided for in the authorization procedure.

Several MS supported the conclusion of the initial assessment report carried out by the UK authorities. However, some MS objected to the same conclusion, raising scientific concerns with regard to the risk assessment and/or claiming lack of relevant data. The main concerns/suggestions raised by the competent authorities of the MS are on the following aspects:

- Insufficient toxicological information;
- allergenicity; and
- analytical methodology.

In view of the divergent opinions of the MS and the Community interest in this matter, the European Commission has decided to seek the opinion of the EFSA.

TERMS OF REFERENCE

In accordance with Article 29 (1) (a) of Regulation (EC) N° 178/2002, the European Commission requests the European Food Safety Authority to issue a scientific opinion on the use of chia seed and ground whole chia seed as a novel food ingredient within the context of Regulation (EC) N° 258/97.

The Authority is asked to specify whether the authorisation of chia as a food ingredient for bread is likely to have an effect on public health and to focus on the elements of a scientific nature in the comments/objections raised by the MS to the Initial Assessment Report. In particular, EFSA should consider whether the safety of chia may be established without additional toxicological studies, as has been requested by some MS.

ASSESSMENT

The application was considered to belong to category (e) of the Novel Foods Regulation. In accordance with the Commission Recommendation 97/618/EC, the ingredient concerned belongs to Class 2, Complex Novel Foods (NF) from a non-GM source. This class comprises complex NF derived from sources which have not been genetically modified. Intact plants, animals and microorganisms used as foods as well as food components (e.g. complex carbohydrates, fats, proteins or those substances collectively described as dietary fibre) are included. Furthermore, it corresponds to sub-class 2.2 because the source of the NF has no history of food use in the Community. For this reason this Opinion will be an assessment of the safety data provided by the applicant to comply with the information required for novel foods (EC, 1997) of Class 2, i.e. information requirements I, II, III, IX, XI, XII and XIII as detailed in the following text.

In this assessment, the original data submitted by the applicant, the initial assessment report (ACNFP, 2004), the comments and objections provided by the MS and the applicant's response to MS have been taken into account.

I. Specification of the novel food (NF)

Specification of the origin and the composition of the novel food (NF) are needed to ensure the identity of the product tested/evaluated and the product to be marketed.

Chia (Salvia hispanica L.) is a summer annual herbaceous plant belonging to the Labiatae family.

Regarding the composition of chia seed, the applicant refers to analysis of four consignments that have been received from Peru, where the crop is being grown commercially. These batches have been analysed for proximate parameters (dry matter, protein, oil, crude fibre and ash) and fatty acids. A fatty acid profile was presented by the applicant showing that 58.7% of the fatty acids are α -linolenic acid, making chia seeds a particularly rich source of omega-3 fatty acids. Analyses of minerals, vitamins, carbohydrates, fat and amino acids were also carried out.

The four samples of chia seed from Peru were analysed for the heavy metals arsenic, cadmium, mercury and lead and found to comply with the maximum levels set in Regulation 466/2001/EC for cadmium and lead in ingredients with comparable food use like cereals (0.1 mg/kg and 0.2 mg/kg, respectively). Mean levels of arsenic and mercury (0.102 mg/kg and <0.01 mg/kg, respectively) also do not raise concern.

The methods of analyses applied were not given in the original dossier. However, the applicant has provided additional information on some of the methods (mineral, carbohydrate and vitamin analyses) and confirmed that these studies were carried out in laboratories accepted by relevant UK bodies.

In a mycotoxin screen of a composite sample from four consignments of chia seed provided by the applicant, the concentrations of aflatoxin B_1 , B_2 , G_1 and G_2 , ochratoxin, zearalenone, deoxynivalenol and T-2 toxin were below the limits of detection of the method applied. However, the method used for the assay does not comply with the standard laid down in the relevant EU legislation on food contaminants regarding aflatoxins and ochratoxin A (Directive 1998/53/EC amended by Directive 2002/27/EC, Directive 2002/26/EC) and also does not give adequate assurance in the case of the other mycotoxins.

No specific data on composition of ground material has been provided by the applicant.

II. Effects of the production process applied to the NF

According to the applicant, whole chia seeds are not processed in any way prior to their use as a food ingredient. The seeds are grown contractually for the applicant who is claimed to have the right to specify what herbicide/pesticide treatments are used in order to comply fully with EU legislation.

The chia seed is sown mechanically at a seeding rate of 3 to 5 kg/hectare. The seed is not treated chemically in any way prior to sowing, but a herbicide Trifluralin [2,6-dinitro-N, N-dipropyl 4-(trifluoromethyl) benzeamine; α , α , α -trifluor-2,6-dinitro-N N-dipropyl-p-toluidine] may be applied to the ground prior to sowing at a rate of 2 litres/hectare. No insecticide is applied. At sowing, the fertilizer consisting of diammonium phosphate is applied mechanically, localised in rows. Between 30 and 45 days following sowing, 150 kg/hectare of urea is applied, also mechanically and localised in rows.

The crop is allowed to ripen naturally. However, should there be a requirement to speed up the ripening process; paraquat is used at a rate of 1 litre/hectare. The seed is mechanically harvested.

Post-harvest, the seed is cleaned mechanically and not subjected to any chemical treatments. In the production of whole ground chia, the whole seeds are passed through a variable speed Christy Briton hammer mill (manufactured by Christy Hunt Ltd.). To ensure that no vegetative material is present, a strict quality control system has been used to remove flowers, leaves and other parts of the plant thereby eliminating any risk posed by components of the leaves or flowers. The seeds are stored in sacks within a fully enclosed warehouse facility in preparation for shipment.

A multi-residue screen for pesticide and herbicide residues (altogether >100) was carried out on a composite sample from the four consignments of chia seed. An analysis for paraquat residues, however, was not provided by the applicant.

III. History of the organism used as the source of the NF

Chia (*Salvia hispanica* L.) is a summer annual plant belonging to the mint family. Chia seeds are described by the applicant as a core element of the diet of pre-Columbian civilisations, mainly the Aztecs. The species originated in mountainous areas extending from West Central Mexico to Northern Guatemala. These civilisations used this species as a raw material in making several medicinal and nutritional compounds, and even paints. Historically, chia seeds were roasted and ground to form a meal called "pinole", then mixed with water to form 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 ancient grain. Chia is still used in the preparation of a popular beverage called "chia fresca", where the seeds are soaked in water and then flavoured with fruit juice and consumed as a cooling drink.

Chia cultivation has declined since pre-Columbian times. Today chia is grown contractually for the applicant in Argentina and Peru.

IV. Anticipated intake and extent of use of the NF

Estimation of anticipated intakes is needed to evaluate the dietary and nutritional significance of the NF. This assessment will draw upon information on the nature of the NF and its anticipated use as an ingredient of bread.

The proposed use of chia is to include the whole and ground seed as ingredients in multigrain-style bread. Pilot studies carried out by the applicant have suggested that the level of chia seeds and whole ground chia seeds included in the multi-grain bread mix should be 5.0%. On this basis, and based on data on the average bread consumption by adults 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. Although estimates of chia intake for different age groups were not provided, the UK Food Standards Agency additionally provided these estimates based on food consumption data from Diet and Nutrition Surveys of different age groups in Britain. This information is shown in Table 1 (ACNFP, 2004).

	Soft grain bread consumption (g/person/day)		Chia consumption (g/person/day)	
	Mean	97.5 th percentile	Mean	97.5 th percentile
1.5-4.5 years old	22	65	1.1	3.2
4-18 years old	29	86	1.4	4.3
Adults (19-64 years)	43	231	2.1	11.6

Table 1.Estimates of chia intake for different age groups (ACNFP, 2004)

XI. Nutritional information on the NF

According to the applicant, chia seeds contain 21% protein, a level markedly greater than other nutritional grains such as wheat (14%), corn (14%), rice (8.5%), oats (15.3%), barley (9.2%), and amaranth (14.8%). Unlike most cereals chia seeds are not limiting in any amino acids necessary in the adult diet. Chia seeds have an oil content of approximately one third of their weight, about 60% of which is α -linolenic acid, making this ingredient a rich source of n-3 fatty acids. According to the applicant, by including chia in bread products at a level of 5% there is the potential to contribute to an improved daily intake of n-3 fatty acids through a staple food.

According to the applicant, once the oil has been extracted from the seed, the material that remains contains 50-60% fibre. The seed alone possesses about 5% soluble fibre. Chia seeds are also a rich source of vitamins B, calcium, phosphorous, potassium, zinc, and copper. Also, chia seeds contain natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides); and water and methanol extracts of defatted chia seeds have shown a strong *in vitro* antioxidant activity.

Studies on the bioavailability of essential nutrients in chia are not provided.

Human studies provided by the applicant are described in section XIII.

Two 8-week feeding studies with laying hens were carried out. The main objective of these studies was to assess the effects of chia on the composition of egg yolk lipids and egg acceptability compared with administration of other sources of n-3 fatty acids.

In the first study provided, a total of 32 animals received diets with four different α -tocopherol contents containing 14.0% whole chia seed corresponding to a dose of 16.8 g/day.

Control groups of equal size received isoenergetic diets supplemented with 1.5% soya oil or 1.5% fish oil. According to the study report, inclusion of chia seed in the diet reduced the content of C16:0, C18:1 and total n-6 fatty acids in eggs whereas the content of total n-3 fatty acids was increased. There was no adverse effect on egg yolk lipid oxidative stability with any of the dietary treatments. Egg production and daily food intake were recorded; the results, however, were not presented. According to the applicant, the study revealed no adverse effects.

In the second study, a diet with 15% whole chia seeds corresponding to a dose of 18.2 g/day was administered to 32 hens. According to the applicant, chia seed was more effective in modifying egg yolk fatty acid composition compared with the controls receiving diets with whole linseed or linseed oil. There were no differences in egg quality and no adverse effects in the birds. The study report, however, was not provided.

The effects of chia seed on the fatty acid content of breast and thigh muscle of broilers and on sensory attributes of these products were examined. The animals received diets with 10% chia for 28 days. According to the applicant, deposition of linolenic acid was markedly increased in the breast meat of birds fed the chia-supplemented diet compared with control animals. There were no significant differences in performance and no adverse effects. The study report, however, was not provided.

In addition, the summary results of four reports of feeding studies, all from the same team (Ayerza and Coates, 2000; Ayerza and Coates, 2002; Ayerza and Coates, 1999; Ayerza *et al.* 2002), have been found by the Panel for *Salvia hispanica* L. They are described below.

Four hundred and fifty laying hens were fed for 90 days to compare a control diet with diets containing 7, 14, 21, and 28% chia (*Salvia hispanica* L.) seed (Ayerza and Coates, 2000; Ayerza and Coates, 2002). Cholesterol content, total fat content, and fatty acid composition of the yolks were determined. Significantly less cholesterol and total saturated fatty acid content were found as the chia percentage increased and as the trial progressed. Total polyunsaturated fatty acid (PUFA) and omega-3 fatty acid contents were significantly greater for chia diets compared with the control diet (Ayerza and Coates 2000).

It was found that hen weight was not significantly affected by diet; however, manure production was less for the hens fed on chia and some decrease in yolk weight was found (Ayerza and Coates, 2002). No significant differences in egg production were found among treatments for the brown hens. However, with the 28% chia diet, the white hens produced fewer and lighter eggs than did the hens fed on the control diet. On day 90, the yolks produced by the white hens fed on the 7% chia diet were significantly lighter in weight, whereas the brown hens produced significantly heavier yolks, compared with the hens fed on the control diet. Yolk weight as a percentage of egg weight was lower for white hens throughout the trial except on day 58 with the 14% chia diet. Significant differences, however, were detected only with the 7% chia diet on day 90 and with the 21% chia diet on days 58, 72 and 90 (Ayerza and Coates, 2002).

In a 28-day study with 24 laying hens a diet with 30% chia (*Salvia hispanica* L.) seeds was administered. Compared with the control animals there was no statistically significant difference in yolk fat content. The palmitic acid content of yolks was lower with the chia diet and α -linolenic acid content was greater. Egg production was lower than in the controls, however, there was no effect on egg weights (Ayerza and Coates, 1999).

Five thousand four hundred, 1-day-old, male, Ross 308, broiler chicks were fed for 49 days to compare diets containing 10 and 20% chia (*Salvia hispanica* L.) seed to a control diet. Cholesterol content was not significantly different among treatments; however, the 10% chia diet produced a lower fat content in the dark meat than did the control diet. Chia significantly lowered the saturated fatty acid content as well as the saturated:polyunsaturated fatty acid and omega-6:omega-3 ratios of the white and dark meats compared with the control diet. No significant differences in flavour or preference ratings were detected among diets. Body weight and feed conversion were significantly lower with the chia diets than with the control, with weight reductions up to 6.2% recorded with the 20% chia diet. According to the authors, reduced body weights and decreased feed conversion efficiency were also observed in other studies when omega-3 rich sources were added to broiler diets. The effects of chia, however, were less pronounced when compared with other sources, e.g. flaxseed where the effects can be explained by the presence of anti-nutritional factors (Ayerza *et al.* 2002).

XII. Microbiological information on the NF

Chia seeds from four consignments were tested for contamination with microorganisms. Enterobacteriaceae were not detected, total viable count was maximum 4.4×10^4 cfu/g and yeast and moulds were maximum 6.0×10^3 cfu/g.

In its initial assessment, the ACNFP 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 it was agreed by the ACNFP that the proposed HACCP schema described sufficient measures that would control and monitor levels of moisture within the seeds during bulk storage and transport.

XIII. Toxicological information on the NF

Animal studies

Feeding studies with laying hens and broilers, which were carried out to assess the nutritional quality of chia as feed ingredient and its effects on animal performance and egg composition, were provided. The results are summarised in section XI. According to the applicant, there were no adverse effects. In one of the studies, however, reduced body weights and decreased feed conversion efficiency occurred in broilers receiving 10% and 20% chia seed in the diets for 49 days (Ayerza *et al.*, 2002). In a study with white and brown laying hens, administration of a diet with 28% chia seed for 90 days reduced egg production and egg weight in white hens (Ayerza and Coates, 2002). In a study with laying hens receiving a diet with 30% chia seed for 28 days, egg production was reduced (Ayerza and Coates, 1999).

Human studies

In a 4-week placebo-controlled dietary intervention study with 100 male and female subjects (21 to 65 years) the effects of chia seed intake on selected markers of coagulation and immune function were assessed. Chia seed intake in the test groups (n=25) was 2.5, 5.0 or 10.0 g/day; the control group received 4.0 g of sunflower seed/day. Fasting blood samples were taken at baseline and after 4 weeks, and analysed for haematological parameters, plasma lipid levels, and by lymphocyte subset typing. In addition, anthropometric data, a lifestyle and

food questionnaire, and a questionnaire monitoring any possible adverse effects were collected. According to the study report, there were no relevant health-related effects. Analysis of the adverse effects questionnaire revealed a statistically significant effect on tiredness and fatigue in the mid dose group which was considered by the applicant as a single effect and not dose-related.

The applicant has also presented (as a summary, in poster form) the results of a randomised, single-blind crossover trial on subjects with type-2 diabetes. Twenty individuals on a conventional diabetes diet received either *Salvia hispanica alba* seeds (25 g/1000 kcal) or a control supplement for 12 weeks separated by a 4-week washout period. Fasting blood samples and blood pressure measurements were taken at weeks 0 and 12. According to the authors, the *Salvia hispanica alba* diet statistically significantly lowered systolic blood pressure compared with the control diet. The levels of coagulation factors (fibrinogen, factor VIII and von Willebrand factor) and C-reactive protein (CRP), a marker of inflammation, were statistically significantly decreased. There were no differences in blood lipids (HDL and LDL cholesterol and triglycerides), measures of glycaemic control, bleeding time (INR, PT, PTT), liver enzymes (ALT, AST) and parameters of kidney function (urea, creatinine).

Studies on potential allergenicity

No allergenicity of chia seeds has been reported in the literature. Sporadically, allergic crossreactivity of common crops used for food that are taxonomically close to chia has been observed. One case study of a patient reacting to oregano and thyme, belonging to the family of Labiatae to which chia belongs, has been published (Benito *et al.*, 1996).

The applicant has performed studies on cross-reactivity using a panel of 30 sera from food allergic patients. In addition sera from double-blind placebo-controlled food challenge (DBPCFC) proven allergic individuals to peanut and tree nut were used. Sera from peanut allergic individuals gave IgE-binding to proteins from chia. The binding was variable, though specific. In addition, also skin prick testing with chia protein was carried out, and 2 individuals that were sensitive to sesame reacted positively to chia. Proteins reacting were sensitive to proteolysis. The emphasis on peanut and tree nut has rendered the value of the studies limited.

The applicant states that while some binding and reactions occurred, and allergenicity could not be ruled out, the best approach would be to label foods containing chia, indicating that such foods are inappropriate for individuals sensitized to sesame or mustard. However, no binding to mustard specific IgE but IgE-binding to peanut has been shown so far. In addition, no clinically relevant adverse reactions have yet unequivocally been shown.

Cross-reactivity of chia seed with food allergens cannot be ruled out. Indications of cross-reactivity exist, while no reactions to chia have been studied with DBPCFC.

An issue that has not been addressed is the potential sensitizing activity of proteins of chia themselves. Even if the proteins from chia seed seem susceptible to proteolysis, such proteins could be capable of inducing food allergy. Obviously, it is as yet not possible to gain such information from individuals ingesting chia, as the latter is currently not or only very incidentally the case. Animal models exist in which immunogenicity and allergenicity of proteins are discriminated on the basis of the profile of the antibody response induced, and these models could have been used to try to identify potential allergenicity. However, these

models have currently not been validated. Hence, it is not possible to predict, using methodologies available to date, the potential allergenicity of chia. Given the fact that indications for cross-reactivity exist, there is a probability of allergenicity of chia.

DISCUSSION

Specification of the NF

A MS commented that according to the literature, chia is *Salvia potus Epling*, while *Salvia hispanica* L. is "chia blanco" (literally: "white chia"). Therefore, care should be taken to ensure that the name under which *Salvia hispanica* L. is sold describes the novel food/novel food ingredient unambiguously. The Panel agrees that, together with an appropriate characterisation of the NF, the use of the botanical name of chia (*Salvia hispanica* L.) at least as an addition to chia or white chia will ensure an unambiguous identification.

The information on the composition of chia seed is not adequate. The analytical data should be presented according to modern standard, e.g. indicating the natural ranges and methods of analyses. In addition, data on secondary metabolites which typically occur in the plant in question or in related species of the plant family should be included. Of particular interest are compounds of potential concern, e.g. natural toxins and anti-nutritional compounds.

Production process

The production process of the NF as described by the applicant does not raise concern. In any case, it should be ensured that any residues or contaminants derived from apparatus and equipments or from chemical, physical or biological aids used should be controlled. In the event of paraquat being used it would be necessary to control it.

The applicant has provided data in respect of potential microbial contamination of chia seed. According to the ACNFP assessment, the seeds are monitored during transport and storage on the basis of a HACCP plan that describes measures to be put in place to control temperature and humidity during storage and transport. Provided the above monitoring is implemented, the Panel considers it is not likely that the process introduces changes in the food that might have an impact on essential nutritional, toxicological and microbiological parameters of the final product.

History of safe use

Documentation on previous use of the NF source in other parts of the world is important to establish a baseline for assessment (EC, 1997). In the present case, no adverse effects have been reported from the previous human exposure to the NF in pre-Columbian civilisations. The information on the history of use of chia in modern society is not sufficient to establish history of safe use.

Anticipated intake

From the applicant's judgment, the anticipated mean intake of chia could be 2.1 g/person/day, and the 97.5th percentile 11.6 g/person/day. However, these estimates cannot be considered

representative enough for the European population, as the applicant did not present data on bread consumption from European countries other than the UK.

Nutritional information

The nutritional data reported by the applicant does not, in itself, cause a concern to the Panel regarding the use of the NF in multi-grain bread, at total content of up to 5%. The high α -linolenic acid content of chia seeds makes this NF have the potential to contribute to an improved daily intake of n-3 fatty acids through a staple food. However, the application contains insufficient information to undertake a full nutritional assessment. Studies on the bioavailability of key compounds are lacking. The compositional studies are rather limited, and not taking into account effects of storage and other possible treatments. Animal and human studies reported in this application included an appropriate range of doses but animal studies were limited to laying hens and broilers and there is only one, limited, human study in healthy humans.

Allergenicity

Various MS considered that this product's possible allergenic properties should be further investigated prior to market introduction.

In the assessment of the Panel, cross-reactivity of chia seed with common food allergens cannot be ruled out. In addition, an issue that has not been addressed by the applicant is the potential sensitizing activity of proteins of chia themselves. Currently, it is not well possible to predict potential allergenicity of chia.

Toxicological information

According to the applicant, feeding studies in rapidly growing birds (broilers and hens) and short-term dietary studies in humans showed no evidence of adverse effects. However, a large nutritional study in broilers showed an effect of chia seed on body weight and feed conversion (Ayerza *et al.*, 2002). Another study showed an effect on egg weight and egg production (Ayerza and Coates, 2002). The cause of these effects remains unclear.

There are no concerns regarding the analytically identified individual chemical components in chia seed but the compositional studies provided by the applicant are limited. Thus, the presence of unknown constituents which might exert anti-nutritional or toxic effects cannot be excluded.

According to the applicant, no citations can be found in a data base search for toxicologically relevant compounds or metabolites in chia seeds. However, a MS quotes an article showing that "*Salvia hispanica* L. was also used in traditional medicine (Cahill, 2003)", which suggests that it may contain pharmacologically active ingredients.

A subchronic (90-day) study in rats has not been provided and the toxicological information from human studies is also limited.

In summary, adequate toxicological information has not been provided to perform a safety assessment of chia seed. Previous use of chia seed for food purposes and documentation of

the corresponding experience gained is very limited and can not be regarded as sufficient to allow a conclusion on the safety of chia seed and ground whole chia.

CONCLUSIONS AND RECOMMENDATIONS

The compositional data on chia seeds provided by the applicant are not sufficient to perform a full nutritional assessment. From the data provided by the applicant there is no evidence of adverse effects of whole chia seed and whole ground chia seeds. There are uncertainties with regard to the potential allergenicity of chia. The presence in the intended NF ingredient of constituents which might exert anti-nutritional or toxic effects cannot be excluded. Adequate toxicological information on chia seed is not available and the human data provided to the Panel are limited. Therefore the safety of chia cannot be established from the available information and additional studies are required.

DOCUMENTATION PROVIDED TO EFSA

Dossier on whole chia (*Salvia hispanica* L.) seed and ground whole chia as a novel food ingredient in the European Union. Application pursuant to Regulation (EC) 258/97 submitted by R Craig & Sons [M] Ltd.

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ACKNOWLEDGEMENT

The Scientific Panel on Dietetic Products, Nutrition and Allergies wishes to thank Karl-Heinz Engel, Werner Grunow and Annette Pöting for their contributions to the draft opinion.