European Food Safety Authority

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SCIENTIFIC OPINION

Opinion on the safety of 'Chia seeds (*Salvia hispanica* L.) and ground whole Chia seeds' as a food ingredient[1]

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-008)

Adopted on 13 March 2009

PANEL MEMBERS

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SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver a scientific opinion on the safety of 'Chia seed (*Salvia hispanica*) and ground whole Chia' as a food ingredient.

The Panel has been requested 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 concerns of a scientific nature raised by various Members States. On 5 October 2005 the "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.*) seeds and ground whole Chia seeds as a novel food ingredient intended for use in bread" was adopted. On the basis of the available data the safety of Chia could not be established and additional studies were required.

In 2006 the 'Columbus Paradigm Institute S.A.' became responsible for this application and submitted an amended file in order to provide the information necessary to establish the safety of Chia.

From the compositional data on Chia seeds, its nutritional characteristics and the proposed use, the Panel considers that there is no reason to consider this novel food ingredient nutritionally disadvantageous to the consumer under the proposed conditions of use.

There is no evidence of adverse effects of whole Chia seeds and whole ground Chia seeds, while there are still uncertainties with regard to the potential allergenicity of Chia. However, the Panel recognises the difficulty of predicting, using methodologies available to date, the potential allergenicity of this NF, noted the provided complementary information showing no

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indication of allergenicity and considers that concerns on this issue could be reasonably addressed by appropriate management measures.

The toxicological information on Chia seeds from animal and controlled human studies is limited. However, experience gained from previous and current use of Chia seeds for food purposes in non-EU countries can be regarded as supportive evidence to allow a positive conclusion on the safety of Chia seeds and ground whole Chia seeds under the proposed conditions of use.

Based on the available data, the Panel concludes that it is unlikely that the use of Chia seeds in bread at a maximum of 5 % would have an adverse effect on public health.

Key words: Chia seeds, ground whole Chia, *Salvia hispanica*, novel food, ingredient.

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BACKGROUND AS PROVIDED BY THE COMMISSION

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

On 7 May 2004, the competent authorities of the UK forwarded to the Commission their initial assessment report of the product concerned 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 Commission forwarded the initial assessment report to Member States on 16 July 2004. Member States submitted their comments and/or presented reasoned objections within the 60 day period provided for in the authorisation procedure.

The main concerns/suggestions raised by the competent authorities of the MS are on the following aspects:

Insufficient information on:

- analytical data and methodology;
- intake estimate which is based on UK data would not be representative for other European countries;
- toxicology and allergenicity.

In consequence, a Community Decision was required and beforehand, it appeared necessary to request a scientific opinion of the Authority.

On 5 October 2005 the "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.) seeds and ground whole Chia seeds as a novel food ingredient intended for use in bread" was adopted. On the basis of the available data the safety of Chia could not be established and additional studies were required (EFSA, 2005).

In 2006 the Columbus Paradigm Institute S.A. became responsible for this application and submitted additional information with the intention to provide the information necessary to establish the safety of Chia.

TERMS OF REFERENCE AS PROVIDED BY THE COMMISSION

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 seeds and ground whole Chia as a novel food ingredient in the context of Regulation (EC) No. 258/97.

The Authority is asked to specify whether the authorisation of Chia as a food ingredient to 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 Member States to the Initial Assessment Report.

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Pagona Lagiou, Bevan Moseley, Andreu Palou, Annette Pöting, Seppo Salminen, Hendrik Van Loveren and Hans Verhagen.

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 by the application belongs to Class 2 which comprises complex NF derived from sources which have not been genetically modified. Intact plants, animals and micro-organisms 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.

An 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.) seeds and ground whole Chia seeds as a novel food ingredient intended for use in bread was previously adopted in October 2005 (EFSA, 2005). In particular, at that time the Panel was asked to address the question whether the safety of Chia may be established without additional toxicological studies. The opinion of the Panel was mainly summarized as follows: "From the data provided by the applicant there is no evidence of adverse effects of whole Chia seeds 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 seeds 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. In addition, it was also indicated that "the compositional data on Chia seeds provided by the applicant are not sufficient to perform a full nutritional assessment".

The Panel undertakes the assessment based on the dossier received in 2005 and the additional information received in 2008 submitted by the applicant and forwarded by the European Commission to EFSA.

I. Specification of the novel food (NF)

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

A Member State 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 original data on the composition of Chia seeds were based on the results of the analyses of 4 consignments from Peru (EFSA, 2005).

The new petitioner Columbus Paradigm Institute S.A., indicated that all his sources are located in Bolivia, and thus provided analytical data from several batches from harvests from this country over the years 2005 – 2008. In addition, a few compositional data were provided also on Chia seeds from Australia showing little variety to Chia seeds sourced from the South American countries.

Samples have been analysed for proximate parameters (dry matter, protein, oil, crude fibre and ash) and fatty acids (Table 1). Further analyses were carried out on the content of minerals and vitamins (Table 2 and 3), on carbohydrates, the amino acid profile and the fatty acid profile, showing that approximately 60 % of the fatty acids are α-linolenic acid (Appendix Table 1, 2, 3).

Table 1. **Composition of Chia seeds**

Nutrient	**Result** % Mean (range)	**Samples origin/date**	**Method/Laboratory**
Dry matter	96.0	Australia, Oct. 2007	AOAC 934.06 & 964.22
	93.2	Bolivia, Santa Cruz, Dec. 2008	SGS Chile, accreditated internal method
	92.2 (91.7 – 92.7)	4 consignments from Peru	3.5 g sample dried at 100° C over night; residual weighted
Protein	21.1 (15 - 25)	Bolivia, Santa Cruz, harvests 2005 - 2008	AOAC 990.03, 2006
	21.1	Bolivia, Santa Cruz, Dec. 2008	SGS Chile, non-accreditated internal method
	21.1 (20.8 – 21.3)	4 consignments from Peru	Dumas procedure (using LECO FP 2000 analyser)
Fat	32.8 (30 - 35)	Bolivia, Santa Cruz, harvests 2005 - 2008	AOAC 920.39 (A), 2006
	31.5	Bolivia, Santa Cruz, Dec. 2008	SGS Chile, accreditated internal method
	32.3 (31.5 – 32.6)	4 consignments from Peru	Tecator Manual 1987-09-28; AN 92/87
Carbo-hydrate	37.5 (26 – 41)	Bolivia, Santa Cruz, harvests 2005 - 2008	Difference (100-Prot./Ash/Fat/Moisture) (Moisture fixed at 4%)
Crude* Fibre	24.0 (18.0 - 30.0)	Bolivia, Santa Cruz, harvests 2005 - 2008	AOAC 978.10, 2006
	19.4	Bolivia, Santa Cruz, Dec. 2008	SGS Chile, non-accreditated internal method
	27.8 (24.9 – 30.0)	4 consignments from Peru	Tecator Manual 1987-03-15; AN 01/78
Ash	4.6 (4 - 6)	Bolivia, Santa Cruz, harvests 2005 - 2008	AOAC 942.05, 2006
	5.2	Australia, Oct. 2007	AOAC 923.03 & 900.02
	4.6	Bolivia, Santa Cruz, Dec. 2008	SGS Chile, accreditated internal method
	4.8 (4.6 – 5.0)	4 consignments from Peru	3.5 g sample was placed into a mule overnight at 550° C; residual weighted

* Crude fibre (as the part of fibre made mainly of indigestible cellulose, pentosans, lignin) gives indication on dietary fibre content (AOAC 978.10, 2006), but usually underestimates it considerably (Table 3, Carbohydrates in Chia seeds. Appendix A)

Table 2. **Mineral content of Chia seed**

Mineral	Result mg/100g Mean (range)	Samples origin/date	Methods
Sodium	0.94 (< 5)	Bolivia, Santa Cruz, harvests 2005 to 2008	AOAC 956.01
	12.15	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Potassium	667 (>500)	Bolivia, Santa Cruz, harvests 2005 to 2008	AOAC 956.01
	660	Peru, harvest 2006	Unknown
	809.15	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Calcium	557 (>500)	Bolivia, Santa Cruz, harvests 2005 to 2008	Atomic Absorption Spectroscopy
	770	Peru, harvest 2006	Unknown
	679.8	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Iron	6.3 (> 5)	Bolivia, Santa Cruz, harvests 2005 to 2008	Atomic Absorption Spectroscopy
	7.9	Peru, harvest 2006	Unknown
	9.9	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Magnesium	390	Bolivia, Santa Cruz, harvest 2005	Unknown
	380	Peru, harvest 2006	Unknown
	326	Bolivia, Santa Cruz, harvest 2007	AOAC 985.35 (2000)
	325	Bolivia, Santa Cruz, harvest 2008	AOAC 985.35 (2000)
	380	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Phosphorus	751 (>600)	Bolivia, Santa Cruz, harvests 2005 to 2008	AOAC 966.01
	780	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Zinc	< 0.1	Australia, Oct. 2007	US EPA 3050B
	3.7	Bolivia, Santa Cruz, harvest 2005	Unknown
	4.95	Bolivia, Santa Cruz, harvest 2007	AOAC 999.11 (2000)
	4.46	Bolivia, Santa Cruz, harvest 2008	AOAC 999.11 (2000)
	4.40	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Copper	1.2	Australia, Oct. 2007	US EPA 3050B
	0.2	Bolivia, Santa Cruz, harvest 2005	Unknown
	1.83	Bolivia, Santa Cruz, harvest 2007	Manual ISP (1998) – SGS Chile
	1.94	Bolivia, Santa Cruz, harvest 2008	Manual ISP (1998) – SGS Chile
	1.70	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Selenium	0.006	Bolivia, Santa Cruz, harvest 2007	AOAC 986.15 (2000)

	< 0.005	Bolivia, Santa Cruz, harvest 2008	AOAC 986.15 (2000)
	1.00	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Chromium	< 0.1	Australia, Oct. 2007	US EPA 3050B
	< 0.03	Bolivia, Santa Cruz, harvest 2007	SGS Chile
	< 0.03	Bolivia, Santa Cruz, harvest 2008	SGS Chile
	0.50	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Cobalt	< 0.05	Bolivia, Santa Cruz, harvest 2007	Atomic Absorption
	< 0.05	Bolivia, Santa Cruz, harvest 2008	Atomic Absorption
	0.25	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Molybdene	0.2 (mean)	Bolivia, Santa Cruz, harvest 2005	Unknown
	< 0.1	Bolivia, Santa Cruz, harvest 2007	Atomic Absorption
	< 0.1	Bolivia, Santa Cruz, harvest 2008	Atomic Absorption
	0.25	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Nickel	< 0.02	Bolivia, Santa Cruz, harvest 2007	Manual ISP (1998) – SGS Chile
	< 0.02	Bolivia, Santa Cruz, harvest 2008	Manual ISP (1998) – SGS Chile
	0.25	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina
Sulphur	290	4 consignments from Peru	Lab: Food Control S.A., Buenos Aires, Argentina

Table 3. **Vitamins in Chia seeds**

Vitamin	**Result** mg/100 g* Mean (range)	**Samples origin/date**	**Methods**
Vitamin A	44 (> 10) IU	Bolivia, Santa Cruz, harvests 2005 to 2008	Standard Methods of Vitamin Assay (1985), 4th, Ed. John Wiley & Sons (in an ISO 17025 lab)
Vitamin C	< 3.0	Bolivia, Santa Cruz, harvest 2008	HPLC
	5.4	4 consignments from Peru, one sample	Standard Methods of Vitamin Assay (1985), 4th, Ed. John Wiley & Sons
Vitamin E	0.74	Bolivia, Santa Cruz, harvest 2008	HPLC
Thiamine	0.18 (> 0.1)	Bolivia, Santa Cruz, harvests 2005 to 2008	Standard Methods of Vitamin Assay (1985), 4th, Ed. John Wiley & Sons (in an ISO 17025 lab)
	0.7	4 consignments from Peru, one sample	Standard Methods of Vitamin Assay (1985), 4th, Ed. John Wiley & Sons
Riboflavine	0.04 (> 0.01)	Bolivia, Santa Cruz, harvests 2005 to 2008	Standard Methods of Vitamin Assay (1985), 4th, Ed. John Wiley & Sons (in an ISO 17025 lab)

	0.2	4 consignments from Peru, one sample	Standard Methods of Vitamin Assay (1985), 4th, Ed. John Wiley & Sons
Niacine	6.13 (> 5)	Bolivia, Santa Cruz, harvests 2005 to 2008	Standard Methods of Vitamin Assay (1985), 4th, Ed. John Wiley & Sons (in an ISO 17025 lab)
	7.2	4 consignments from Peru, one sample	Standard Methods of Vitamin Assay (1985), 4th, Ed. John Wiley & Sons
Vitamin B6	0.1	4 consignments from Peru, one sample	Standard Methods of Vitamin Assay (1985), 4th, Ed. John Wiley & Sons

* (except for vitamin A)

Two batches of Chia seeds from the applicant's sources from Bolivia 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 were 0.102 mg/kg and <0.01 mg/kg, respectively.

Table 4 provides an overview on the analytical information on heavy metals on samples from Peru and Bolivia provided by the applicant.

Table 4. **Analytical data on heavy metals in Chia seeds**

Heavy metals	Result (ppm)	Samples origin/date	Methods
Arsenic	< 0.1	Australia, Oct. 2007	US EPA 3050B
	< 0.2	Santa Cruz, Bolivia, Dec. 2007	Atomic Absorption
	0.102	4 consignments from Peru	Lab.: Dept of Agriculture and Rural Affairs, Northern Ireland
Cadmium	< 0.1	Australia, Oct. 2007	US EPA 3050B
	< 0.2	Santa Cruz, Bolivia, Dec. 2007	Atomic Absorption
	0.018	4 consignments from Peru	Lab.: Dept of Agriculture and Rural Affairs, Northern Ireland
Mercury	<0.03 (< 0.1)	Bolivia, Santa Cruz, harvests 2005 to 2008	Absorption Atomic Spectrometry
	< 0.02	Australia, Oct. 2007	US EPA 3050B
	< 0.03	Bolivia, Santa Cruz, 07/3/2008	NCh 2667 2001 (SGS Chile)
	< 0.03	Santa Cruz, Bolivia, Dec. 2007	Atomic Absorption
	< 0.01	Santa Cruz, Bolivia, Apr. 2008	SGS Belgium
	< 0.01	4 consignments from Peru	Lab.: Dept of Agriculture and Rural Affairs, Northern Ireland
Lead	< 0.07 (< 0.1)	Bolivia, Santa Cruz, harvests 2005 to 2008	Atomic Absorption Spectroscopy
	< 0.12	Bolivia, Santa Cruz, 07/3/2008	NCh 2751 2003 (SGS Chile)
	< 0.07	Santa Cruz, Bolivia, Dec. 2007	Atomic Absorption
	< 0.1	Santa Cruz, Bolivia, Apr. 2008	SGS Belgium
	< 0.004	Bolivia, Santa Cruz, harvest 2007	Manual ISP (1998) – SGS Chile
	< 0.004	Bolivia, Santa Cruz, harvest 2008	Manual ISP (1998) – SGS Chile
	< 0.020	4 consignments from Peru, analysed in 2 composite samples	Lab.: Dept of Agriculture and Rural Affairs, Northern Ireland

In a mycotoxin screen of a composite sample from four consignments of Chia seeds from Peru and from harvests from Bolivia from 2005 and 2008, respectively, 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.

The method used for samples from Peru did 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.

The applicant provided additional analyses on mycotoxins in 3 additional lots of Chia seeds sourced from Bolivia. Table 5 provides an overview on the analytical data on microbial contamination.

Table 5. **Analytical data on mycotoxins and microbiological contaminants in Chia seeds**

Myco-toxines	Result (ppb)	Samples origin/date	Methods
Ochratoxine A	n.d. [(a)] DL[(b)]: 3	Bolivia, Santa Cruz, harvest 2005	Lab: CER Hormonologie, Belgium
	n.d. DL: 5	4 consignments from Peru	UKAS accredited lab, non-accredited method
Aflatoxine B1	n.d. DL: 2	Bolivia, Santa Cruz, harvest 2005	Lab: CER Hormonologie, Belgium
	< 0.5 (DL)	Bolivia, Santa Cruz Apr. 2008	SGS Belgium, 0008-LC
Aflatoxine B2	n.d. DL: 4	Bolivia, Santa Cruz, harvest 2005	Lab: CER Hormonologie, Belgium
	< 0.5 (DL)	Bolivia, Santa Cruz Apr. 2008	SGS Belgium, 0008-LC
Aflatoxine G1	n.d. DL: 2	Bolivia, Santa Cruz, harvest 2005	Lab: CER Hormonologie, Belgium
	< 0.5 (DL)	Bolivia, Santa Cruz Apr. 2008	SGS Belgium, 0008-LC
Aflatoxine G2	n.d. DL: 4	Bolivia, Santa Cruz, harvest 2005	Lab: CER Hormonologie, Belgium
	< 0.5 (DL)	Bolivia, Santa Cruz Apr. 2008	SGS Belgium, 0008-LC
Sum of afl. B1B2G1G2	n.d. DL: 2	4 consignments from Peru	UKAS accredited lab, non-accredited method
Toxine T-2	n.d. DL: 20	Bolivia, Santa Cruz, harvest 2005	Lab: CER Hormonologie, Belgium
	n.d. DL: 50	4 consignments from Peru	UKAS accredited lab, non-accredited method
Toxine HT-2	n.d. DL: 300	Bolivia, Santa Cruz, harvest 2005	Lab: CER Hormonologie, Belgium
Fumonisine B1	n.d. DL: 100	Bolivia, Santa Cruz, harvest 2005	Lab: CER Hormonologie, Belgium
Fumonisine B2	n.d. DL: 100	Bolivia, Santa Cruz, harvest 2005	Lab: CER Hormonologie, Belgium
Deoxy-nivalenol	n.d. DL: 200	4 consignments from Peru	UKAS accredited lab, non-accredited method
	< 70 (DL)	Bolivia, Santa Cruz Apr. 2008	SGS Belgium, HPLC method
Zearalenone	n.d. DL: 75	Bolivia, Santa Cruz, harvest 2005	Lab: CER Hormonologie, Belgium
	n.d. Detection limit: 50	4 consignments from Peru	UKAS accredited lab, non-accredited method

Bacterial contamination	Result	Samples origin/date	Methods
Total aerobe count (37°C)/g	< 10	Bolivia, Santa Cruz Apr. 2008	ISO 4833 modified, ISO 17025 accredited
Total aerobe count (30°C)/g	2000 240	4 consignments from Peru analysed in 2 composite samples	Lab: Anser Lab. Ltd, N-Ireland
Yeasts and moulds (25°C)/g	< 10	Bolivia, Santa Cruz Apr. 2008	ISO 7954 modified, ISO 17025 accredited
	1100 120	4 consignments from Peru analysed in 2 composite samples	Lab: Anser Lab. Ltd, N-Ireland
Staph. Aureus (37°C)/g	< 100	Bolivia, Santa Cruz Apr. 2008	ISO 6888-1 modified, ISO 17025 accredited
Bacillus cereus (30°C)/g	< 100	Bolivia, Santa Cruz Apr. 2008	ISO 7932 modified, ISO 17025 accredited
Entero-bacteriaceae (37°C)/g	< 10	Bolivia, Santa Cruz Apr. 2008	ISO 21528-2 modified, ISO 17025 accredited
Salmonella (37°C)/25 g	absent	Bolivia, Santa Cruz Apr. 2008	ISO 21528-2 modified, ISO 17025 accredited

[(a)] n. d. = not detected
[(b)] DL. = Detection Limit

In a new study of 3 lots of Chia grains from Bolivia, it has been reported that after milling, the seeds present an odour and a flavour close to linseed (Angenot, 2007). The microscopic checking reveals the presence of oil globules, of transparent cells containing mucilage, of sclerous cells, of rectangular and plane cells (like linseed) and of aleurone grains.

In compositional analyses of secondary metabolites conducted on these 3 lots, total polyphenols were detected at 0.38 %, tannins 0.25 %, rosmarinic acid at 0.11 %. Thuyone was not detected.

Concerning storage, the applicant used some samples of lots dating from 2005 for compositional data / nutritional assessment and performed a study demonstrating that storage of 18 months of goods in closed tissue material bags protected from heavy light, and at temperatures from 5 to 35° C and relative humidity from 40 to 85 % did not affect the product.

II. Effect 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 seeds are sown mechanically at a seeding rate of 3 to 5 kg/hectare. The seeds are not treated chemically in any way prior to sowing, but a herbicide called Trifluralin [CAS No. 75635-23-3; 2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)aniline] 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 seeds are mechanically harvested.

Post-harvest, the seeds are 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 was present a 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 certified analysis submitted by the applicant on one composite sample from a Chia harvest 2008 from Santa Cruz area, Bolivia, for more than 50 organchlorides and organophosphatides, respectively, provided values below the given limit of detection. The limit of detection for these substances ranged between 0.01 and 0.05 mg/kg. In addition, the applicant stated that his source in Bolivia is certified GLOBAL-GAP (Global Good Agricultural Practices), which ensured that the Chia fields were granted pesticides use free. A copy of this certificate however was not provided. The cleaning of the lands was ensured by manual labour.

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.

IX. Anticipated intake/extent of use of the NF

Estimation of anticipated intakes is needed to evaluate the dietary and nutritional significance of the NF. The initial assessment by the UK Advisory Committee for Novel Food and Processes (ACNFP) is draw upon information on its anticipated uses as an ingredient of soft grain bread and on consumption data.

The proposed use of Chia is to include the whole and ground seeds as ingredients in bread with no limitation as to the kind of bread (white, wholemeal, soft grain, etc). 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 (UK NDNS) of Adults Aged 19-64 years (Henderson et al., 2002), the applicant has estimated the amount of the novel ingredient that will be consumed (Table 6).

Table 6: **Bread Consumption Figures (g/person/day) - Adults (19 – 64 years)**

	95%ile	97.5%ile	Average	% of	Average

			consumers	consumers	population
Bread - White	176.6	210.7	72.9	90.6	66.1
Bread – Wholemeal	116.6	142.2	42.9	36.3	15.6
Soft Grain Bread	166.4	231.3	42.5	2.5	1.1
Other Bread	99.6	125.6	32.0	51.7	18.1
Total Bread	**204.9**	**232.5**	**102.3**	**98.5**	**100.9**

Five % of the mean daily intake of 102.3 g of the average consumer and 232.5 g/d for the 97.5 % percentile would provide 5.1 g/d and 11.6 g/d, respectively if all soft grain bread in the United Kingdom (UK) would contain 5 % Chia, which is a very conservative approach.

In its initial assessment report, the UK Food Standards Agency (FSA) provided an additional intake estimate for soft bread consumption based on food consumption data from Diet and Nutrition Surveys for children and young adults in Britain. This information is shown in Table 7 (ACNFP, 2004).

Table 7: **Estimates of Chia intake for different age groups (ACNFP, 2004)**

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

Based on the data provided in Table 7, the applicant concluded, the anticipated mean intake of Chia could be 2.1 g/person/day, and the 97.5th percentile 11.6 g/person/day.

A member state and EFSA commented previously that these intake estimates based on UK bread consumption data could not be considered sufficiently representative for the European population (EFSA, 2005).

In its resubmission the applicant provided additional data on 17 European Member States and estimating that the average consumption for bread in Europe is 66 kg/person/year, with the highest consumption figure presented for Bulgaria (110 kg/year), Czech Republic (89 kg/year) and Germany (80 kg/year). Compared to the average bread consumption in the UK based on the UK NDNS (102.3g/d), the figure from the Association Internationale de la Boulangerie Industrielle were about 40 % higher (140 g/d). The applicant did not provide an intake estimate for European consumers with average or high (95 or 97.5 %ile) consumption.

Table 8: **Average bread consumption in 17 Member States***

Country	Population	Consumption * kg//person/year	Consumption g//person/day	Chia intake g//person/day (if 5 % Chia in bread)
Austria	8.1	69	189	9.5
Belgium	10.3	61	167	8.4
Bulgaria	7.4	110	301	15.1
Cyprus	0.8	64	175	8.8
Czech Republic	10.2	89	244	12.2
Denmark	5.4	70	192	9.6
Finland	5.2	52	142	7.1
France	60.6	58	159	8.0
Germany	82.4	80	219	11.0
Greece	10.0	58	159	8.0
Italy	58.1	55	151	7.6
Norway	4.5	54	148	7.4
Poland	38.5	73	200	10
Spain	40.4	58	159	8.0
Sweden	8.5	56	153	7.6
The Netherlands	16.4	61	167	8.4
United Kingdom	60.4	51	140	7.0
MEAN		**65.8**	**180.3**	**9.0**

* data issued from XXIX Association Internationale de la Boulangerie Industrielle - Congress Barcelona 6th – 29th May 2005.

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

In the EFSA's previous assessment on safety of Chia (*Salvia hispanica L.*) seeds and ground whole Chia seeds, the NDA Panel referred to the Recommendation of the Scientific Committee for Food (SCF) concerning the assessment of novel foods (EC, 1997) and that the documentation on previous use of the NF source in other parts of the world is important to establish a baseline for assessment (EFSA, 2005). It was considered that the information on the history of use of Chia in modern society was not sufficient to establish a history of safe use (EFSA, 2005).

In a response to the EFSA Opinion of 2005, the applicant claims that *Salvia hispanica L.* is commonly consumed in several countries, including the USA, Canada and Australia. According to the applicant these countries would now have a "history of safe use" regarding *Salvia hispanica L.*, and "the data from these countries would be typical of a modern society".

The applicant claims that a "history of safe use" is based on the absence of records of adverse effects, including allergenicity, anti-nutritional or toxic effects for Chia seeds and ground whole Chia intake in the listed countries. In addition, the applicant provided detailed data on products including Chia as summarised in Table 9.

The Panel considers the response from the applicant and the additional information provided on the history of use, being supportive for the safety assessment.

Table 9. **"Worldwide overview: Examples of products including Chia seeds or oil as provided by the applicant"**

Company Name	Web Site	Monthly Consumption	History	Applications
1. USA and CANADA				
Nutraceuticals Holding LLC	www.omega3Chia.com www.researchedproducts.com	1MT*/month	Since 2007	Nutritional Supplement Industry: Chia seeds and Chia oil soft gel caps
Valensa International LLC	www.valensa.com	10MT/month	Since 2002	Nutritional Supplement Industry: Chia seeds Food Industry : Chia oil (Tresalbio™)
Greensplus	www.greensplus.com	17 MT/month	Since 2007	Nutritional Supplement Industry: Chia seeds Food Industry : Chia Bars
Nature's Path	www.naturespath.com	1MT/month	Since 2007	Food Industry: Chia Bars; Dr. Weil™ Chia Razz™ Pure Fruit and Nut Bar INGREDIENTS: including organic Chia seeds
Ruth's Hempfood	http://www.ruthshempfoods.com/Chia.html	1,5 MT/Month	Since 2006	Food Industry: Cereal Breakfast
Salba	http://www.sourcesalba.com/products.php	300 MT / Year	Since 2002	Food Industry: cookies, cereal bars, chips, and seeds. (all white Chia seed)
2. MEXICO				
Fuentenatura, Mexico	www.fuentenatura.cl	500 kg/ month	Since 2006	Nutritional Supplement Industry: Chia seeds and Chia oil
3. CHILE				
FPT SA, Chile	www.benexia.com	2 MT/month for its final product (Chia seeds growers, 850 MT this year, for Food Industry)	Since 2005	Nutritional Supplement Industry: Chia seeds and Chia oil soft gel caps
Empresas Carozzi SA, Chile	www.carozzi.cl	3 MT/month	Since December 2007	Pastas (Chia Oil) Cereals Breakfast (Chia Seeds)
Others, Chile	www.Chiachile.cl www.supernatural.cl	500 kg/month	Since 2006	Nutritional Supplement Industry: Chia seeds
4. AUSTRALIA AND NEW ZEALAND				
Dovedale Bread, NZ	http://www.dovedalebread.co.nz/index.html	2MT/month	Since 2005	Bakery Industry : Bread with Chia

The Chia Company, AU	www.theChiaco.com.au	MT / Month for its final product (Chia Growers, 1000 MT this year, for Food Industry)	Since 2000	Nutritional Supplement Industry : Chia seeds Food Industry in General
5. ASIA				
Latina Inc., Japon	http://www.latina-inc.com	2MT/month	Since 2005	Nutritional Supplement
K-Squares, Korea	http://www.ksquares.com	500 kg / month	Since 2006	Nutritional Supplement
6. EUROPEAN UNION				
Naturkost Übelhör GmbH & Co. KG, DE	http://www.saChia.de/home.htm http://www.shop.saChia.de	not available	Since 2005	Nutritional Supplement Industry

* MT (metric ton = 1000 kg)

XI. Nutritional information on the Novel Food

According to the information provided by the applicant, Chia seeds contain about 21 % protein, a level greater than other nutritional grains such as wheat (14 %), corn (14 %), rice (8.5 %), oats (15.3 %), barley (9.2 %), and amaranth (14.8 %). Chia seeds have an oil content of approximately one third of its weight, about 60 % of which is α-linolenic acid, making this ingredient a source of n-3 fatty acids.

According to the applicant, once the oil has been extracted from the seeds, the material that remains contains 50 - 60 % fibre. The seeds alone possess about 5 % soluble fibre. Chia seeds are also a source of vitamins B, calcium, phosphorous, potassium, zinc, and copper, and contain natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides).

Various animal studies have been performed or carried out in laying hens or broiler chickens as follows:

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 seeds 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 seeds 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 seeds were more effective in modifying egg yolk fatty acid composition compared with the controls receiving diets with whole linseeds 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 seeds 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), were 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 to diets containing 7, 14, 21, and 28 % Chia (*Salvia hispanica* L.) seeds (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).

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 4-week study with 24 laying hens, a diet with 30 % Chia (*Salvia hispanica* L.) seeds were fed. Compared with the control animals there was no statistically significant difference in yolk fat content. Saturated palmitic fatty acid content of yolks was less with the Chia diet and polyunsaturated omega-3 α-linolenic fatty 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.) seeds 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 to 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).

Studies on the bio-availability of essential nutrients in Chia have not been provided.

Based on the compositional data, animal studies and the history of use, the Panel considers that Chia seeds are unlikely to be nutritionally disadvantageous to the consumer under the proposed conditions of use.

XII. Microbiological information on the NF

In its initial assessment, the ACNFP requested further information on the control of storage and transport, which would minimise the potential for food-borne 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.

Table 5 provides analytical data on the microbiological analyses provided by the applicant.

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 a feed ingredient and its effects on animal performance and egg composition, were provided. The results were 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 seeds 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 seeds 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 seeds for four weeks, egg production was reduced (Ayerza and Coates, 1999).

Human studies

In a four-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 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

In 2005, Member States considered that the possible allergenic properties of Chia seeds should be further investigated prior to market introduction. In its first opinion on Chia seeds, EFSA addressed the uncertainties related to the potential allergenicity of Chia seeds (EFSA, 2005):

No allergenicity of Chia seeds has been reported in the literature. Sporadically, allergic cross-reactivity 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 also 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 a double-blind placebo-controlled food challenge (DBPCFC) of 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, 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 seeds 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 seeds seem rather 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 and 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 (EFSA, 2005).

Since then, the applicant has not conducted any additional clinical studies. In 2008, the applicant described his bibliographic search for information on specific allergic response to the consumption of Chia seeds focusing on the countries where Chia seeds are consumed such as the USA, Canada, Australia, South America. According to the applicant, no evidence for an allergic or cross-allergenic response was found

Thus, the applicant concluded that on the allergenic risk it is very low but should be under control and, for this reason proposed that *Salvia hispanica* L. should be labelled with a warning concerning allergens.

The Panel notes the cross-reactivity of sera from patients known to be allergic against peanuts and sesame and reiterates its previous opinion that it is not possible to predict the potential allergenicity of Chia using methodologies available to date.

DISCUSSION

In its resubmission the applicant has provided significant additional analytical data on the composition of Chia seeds, including satisfactory data on nutrients, contaminants and some data on secondary metabolites.

The production process of the NF as described by the applicant does not raise concern. It should be ensured that any residues or contaminants derived from apparatus and equipment or

from chemical, physical or biological aids are controlled. 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 would induce changes in the food that might have an impact on essential nutritional, toxicological and microbiological parameters of the final product.

In its resubmission the applicant presents consumption data for 17 European countries and estimates that the average consumption of bread is 66 kg/person/year. This can result in an average intake of Chia seeds of 9 g/person/day if all bread consumed contained 5 % Chia seeds.

Seeds from *Salvia hispanica L.* are commonly consumed in several countries, with the USA, Canada and Australia now having a history of up to eight years of use.

The applicant has provided appropriate data on the nutritional composition of Chia seeds. On the basis of the provided compositional data, animal studies and the history of use, the Panel considers that Chia seeds as are unlikely to be nutritionally disadvantageous to the consumer under the proposed conditions of use.

According to the applicant, feeding studies in rapidly growing birds and short-term dietary studies in humans showed no evidence of adverse effects related to the consumption of Chia seeds. However, a large nutritional study in broilers showed an effect of Chia seeds on body weight and feed conversion (Ayerza et al., 2002). Another study showed a ngenative effect on egg weight and egg production (Ayerza and Coates, 2002).

A subchronic (90-day) study in rats has not been provided.

Various Member States considered that this product's possible allergenic properties should be further investigated prior to market introduction. In addition, an issue that has not been addressed by the applicant is the potential sensitising activity of proteins of Chia themselves. Since EFSA's first assessment on Chia seeds, the applicant has not conducted any additional clinical studies. In 2008, the applicant described his bibliographic search for information on specific allergic response to the consumption of Chia seeds focusing on the countries where Chia seeds are consumed such as the USA, Canada, Australia, and South America. The Panel notes the cross-reactivity of sera from patients known to be allergic against peanuts and sesame and reiterates its previous opinion that it is not possible to predict the potential allergenicity of Chia using methodologies available to date.

The toxicological information on Chia seeds from animal and controlled human studies is limited. However, experience gained from previous and current use of Chia seeds for food purposes in non-EU countries can be regarded as supportive evidence of the safety of Chia seeds and ground whole Chia seeds.

CONCLUSIONS

Based on the data available, taking into account the additional data on composition, consumption and the history of use, the Panel concludes that it is unlikely that the use of Chia seeds and ground whole Chia seeds in bread products at a maximum of 5 % would have an adverse effect on public health.

DOCUMENTATION PROVIDED TO EFSA

1) Letter from the European Commission to the Chairman of the European Food Safety Authority with the request for an opinion on the safety of 'Chia seed (*Salvia hispanica*) and ground whole Chia'. SANCO E4/Ak/mm (2008) D/540002

2) Original dossier received on 08 April 2005 which was the basis for the first EFSA Opinion on the Safety of Chia seed (Salvia Hispanica) and ground whole Chia (EFSA-Q-2005-059). Submitted by R Craig & Sons [M] Ltd. http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620765844.htm

3) Updated Dossier on whole Chia (*Salvia hispanica* L.) seeds and ground whole Chia as a novel food ingredient in the European Union, received by EFSA on 25 Jan 2008. Application pursuant to Regulation (EC) 258/97. Resubmitted by Columbus Paradigm Institute S.A in 2007.

4) Initial assessment report by the Advisory committee of the United Kingdom competent Authority concerning the 'Opinion on an application under the Novel Food regulation for Chia (*Salvia hispanica* L)", April 2004, on the original submission.

5) Letters from Member States with comments (2004) on the initial assessment report 'Opinion on an application under the Novel Food regulation for Chia (*Salvia hispanica* L)" of the Advisory committee of the United Kingdom competent.

6) Response of the applicant to Member States' comments on the UK Initial Assessment Report.

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Commission Directive 2002/26/EC laying down the sampling methods and the methods of analysis for the official control of the levels of ochratoxin A in foodstuffs. *Off. J. Eur. Communities*, 16.3.02, L 75/38.

Commission Regulation 466/2001/EC setting maximum levels for certain contaminants in foodstuffs. *Off. J. Eur. Communities*, 16.03.2001, L 77/1.

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EC (European Commission), 1997. Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) N° 258/97 of the European Parliament and of the Council. *Off. J. Eur. Communities*, 16.9.97, L 253/1.

EFSA (European Food Safety Authority), 2005. 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). *The EFSA Journal* 278: 1-12.

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Appendix

Table 1. **Carbohydrates in Chia seeds**

Fraction	**Result** % Mean (range)	**Samples origin/date**	**Method/Laboratory**
Carbo-hydrate [(a)]	37.5 (26 – 41)	Bolivia, Santa Cruz, harvests 2005 - 2008	Difference (100-Prot./Ash/Fat/Moisture) (Moisture fixed at 4 %)
	37.45	4 consignments from Peru	Lab.: Food Control S.A., Buenos Aires, Argentina [(b)]
Dietary fibre [(a)]	41.2 (35 - 43)	Bolivia, Santa Cruz, harvests 2005 - 2008	AOAC 985.29, 2006
	33.91	4 consignments from Peru	Lab.: Food Control S.A., Buenos Aires, Argentina
Soluble	5.3 (3 - 7)	Bolivia, Santa Cruz, harvests 2005 - 2008	AOAC 991.43
	5.3	Bolivia, Santa Cruz, Sept. 2006	Eurofins France AA011
	3.07	4 consignments from Peru	Lab.: Food Control S.A., Buenos Aires, Argentina

Insoluble	35.8 (30 - 38)	Bolivia, Santa Cruz, harvests 2005 - 2008	AOAC 991.43
	35.9	Bolivia, Santa Cruz, Sept. 2006	Eurofins France AA012
	30.43	4 consignments from Peru	Lab.: Food Control S.A., Buenos Aires, Argentina

[(a)] Calculated carbohydrates value is lower than dietary fibre analysis result. These analytical results can be explained by the deviation possibly due to the theoretical calculation of carbohydrates and to the analysis method of dietary fibre.

[(b)] Food Control SA are members of the Union of International Independent Laboratories and are also approved by the UK Grain and Feed Trade Association (GAFTA)

Table 2. **Amino acid profile of Chia seed protein fraction**

Amino acid	**Result** % of protein	**Samples origin/date**	**Methods**
Aspartic acid	9.47	4 consignments from Peru	Unknown
	7.64	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	7.36	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Threonine	4.25	4 consignments from Peru	Unknown
	3.43	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	3.23	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Serine	6.02	4 consignments from Peru	Unknown
	4.86	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	4.43	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Glutamic acid	15.37	4 consignments from Peru	Unknown
	12.40	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	13.65	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Glycine	5.23	4 consignments from Peru	Unknown
	4.22	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	4.03	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Alanine	5.34	4 consignments from Peru	Unknown
	4.31	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	4.41	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Valine	6.32	4 consignments from Peru	Unknown
	5.10	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	5.32	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Cystine	1.82	4 consignments from Peru	Unknown

	1.47	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	1.04	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Methionine	0.45	4 consignments from Peru	Unknown
	0.36	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	0.36	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Isoleucine	3.98	4 consignments from Peru	Unknown
	3.21	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	3.35	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Leucine	7.30	4 consignments from Peru	Unknown
	5.89	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	5.99	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Tyrosine	3.41	4 consignments from Peru	Unknown
	2.75	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	2.75	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Phenyl-alanine	5.86	4 consignments from Peru	Unknown
	4.73	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	4.77	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Lysine	5.50	4 consignments from Peru	Unknown
	4.44	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	3.60	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Histidine	3.19	4 consignments from Peru	Unknown
	2.57	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	2.45	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Arginine	11.03	4 consignments from Peru	Unknown
	8.90	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	8.63	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted
Proline	5.45	4 consignments from Peru	Unknown
	4.40	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Solvent extracted
	3.92	Unknown	Office of Arid Lands Studies, The University of Arizona, 31/7/01, Press extracted

Table 3**. Lipid profile of Chia seeds**

Fatty Acid		Results for Sample (% of total fatty acids)			
		Bolivia, Santa Cruz, harvests 2005 – 2008[a]	Bolivia, Santa Cruz, March 2006[b]	Bolivia, Santa Cruz, May 2008[c]	4 consignments from Peru[d]
C06:0	**Caproic**	<0.01	n. t. [d]	n. t.	n. t.
C08:0	**Caprilic**	<0.01	n. t.	n. t.	n. t.
C11:0	**Undecanoic**	<0.01	n. t.	n. t.	n. t.
C12:0	**Lauric**	<0.01	n. t.	n. t.	n. t.
C13:0	**Tridecanoic**	<0.01	n. t.	n. t.	n. t.
C14:0	**Myristic**	0.10	<0.1	n. t.	0.10
C15:0	**Pentadecanoic**	<0.01	n. t.	n. t.	n. t.
C16:0	**Palmitic**	6.64	6.73	n. t.	6.7
C17:0	**Heptadecanoic**	0.29	n. t.	n. t.	0.2
C18:0	**Stearic**	3.24	2.93	n. t.	3.0
C20:0	**Arachidic**	<0.01	0.23	n. t.	0.3
C21:0	**Heneicosanoic**	<0.01	n. t.	n. t.	n. t.
C22:0	**Docosanoic**	<0.01	n. t.	n. t.	0.1
C23:0	**Tricosanoic**	<0.01	n. t.	n. t.	n. t.
C14:1	**Miristoleic**	<0.01	n. t.	n. t.	n. t.
C16:1	**Palmitoleic**	0.15	n. t.	n. t.	0.1
C17:1	**Heptadecanoic**	<0.01	n. t.	n. t.	0.1
C18:1w9	**Oleic**	7.51	6.60	n. t.	6.9
C20:1w9	**Eicosaenoic**	<0.01	<0.1	n. t.	0.1
C22:1w9	**Erucic**	<0.01	<0.1	n. t.	n. t.
C16:2w4	**Hexadecadienoic**	<0.01	n. t.	n. t.	n. t.
C16:3w4	**Hexadecatrienoic**	<0.01	n. t.	n. t.	n. t.
C18:2w6	**Linoleic**	18.64	19.6	n. t.	18.8
C18:3w3	**Linolenic**	62.94	63.8	60.9	58.7
C18:3w6	**Linolenic**	n.t.	n.t.	<0.1	0.1
C18:4w3	**Octadecatetraenoic**	<0.01	n. t.	n. t.	n. t.
C20:2w6	**Eicosadienoic**	<0.01	n. t.	n. t.	0.1
C20:3w3	**Eicosatrienoic**	n.t.	n.t.	n.t.	0.1
C20:4w6	**Eicosatetraenoic**	<0.01	n. t.	n. t.	n. t.
C20:5w3	**Eicosapentaenoic**	<0.01	n. t.	n. t.	n. t.
C22:4	**Docosatetraenoic**	n.t.	n.t.	n.t.	0.1
C22:5w3	**Docosapentaenoic**	<0.01	<0.1	n. t.	n. t.
C22:6w3	**Docosahexaenoic**	<0.01	n. t.	n. t.	n. t.
C24	**Lignoceric**	n.t.	<0.1	n. t.	0.2

[a] AOAC Official Method 996.06

[b] Sample from Santa Cruz, Bolivia taken on February 2006; method of detection: GC-FID; laboratory: Proanalisis S.A., Argentina, 10/3/2006, accredited ISO/IEC 17025-IRAM 301

[c] Sample from Santa Cruz, Bolivia; method of detection: ISO 5508:1995, ISO 5509:2000; laboratory: SGS Agrilab-Agro Food Services, Belgium, 13/5/2008, accredited BELAC ISO 17025 n°005-TEST

[d] Method: Perkins-Elmer 300 chromatograph with a Unisole 3000-Unipor C80/100 column, using ISO methods 5508/1990 and 5509/1978

[d] n. t. = not tested