Food Standards Agency
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Sirkku Heinimaa
DG Sanco
European Commission

8 July 2013

INITIAL OPINION: **CHIA OIL.**

Dear Sirkku

On 1 November 2012, the UK Competent Authority accepted an application from Functional Products Trading for the use of chia oil as a novel food ingredient, in accordance with Article 4 of regulation (EC) 258/97.

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

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

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

Yours sincerely,
(By e-mail only)

Dr Chris Jones
For the UK Competent Authority

cc Sebastián Romero Melchor (K&L Gates)

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ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON AN APPLICATION UNDER THE NOVEL FOOD REGULATION FOR CHIA SEED OIL

Applicant	**Functional Products Trading**
Responsible Person	**Sebastián Romero Melchor (K&L Gates) on behalf of Functional Products Trading**
EC Classification	**2.1**

1. An application has been submitted by Functional Products Trading SA of Chile for the use of chia seed oil as a novel food ingredient.
2. Chia (*Salvia hispanica* L) is a summer annual herbaceous plant belonging to the Labiatae family. It grows from a seedling to develop lush green foliage before it produces long flowers which are purple or, less commonly, white. These flowers develop into seed pods which ultimately contain the seeds which are the source of the oil. Chia seeds typically contain around 250-390g oil/kg. This is the first application for chia seed oil and follows the authorisation for chia seeds which was originally issued in 2009 and extended in January 2013.
3. In accordance with the novel food regulation chia seed oil has been classified as a complex novel food from non-GM source (Class 2.1).

I Specification of the Novel Ingredient (NI)

Dossier p 7-17

4. A specification of the oil is set out in the attached Annex. The applicant has provided analyses of 7 batches of the oil, each of which complies with the specification (Dossier, Table 2). The applicant has also carried out additional analyses to which further characterise the oil (see Dossier Tables 3 and 4). This includes an extensive fatty acid analysis which indicates that, in addition to the predominant fatty acids detailed in the specification (alpha linolenic acid (ALA) and linoleic acid), a number of other fatty acids are also present at low, but measurable levels. These include palmitic acid, stearic acid and oleic acid (See Dossier, Table 5).
5. The applicant has also carried out a number of analyses to determine whether environmental contaminants (pesticides, heavy metals, hazardous air pollutants, PCBs and dioxins) are present. Where detectable quantities were found these were in compliance with relevant EU food contaminants legislation.

Discussion *The Committee was content with this information (refer to Section II and XIII for a commentary regarding manufacturing method and protein analyses respectively).*

II Effect of the production process applied to the NI

Dossier pp17-18

6. The oil is produced under HACCP conditions by cold pressing the seeds. Cold pressing is a technique that is widely used in the production of edible oils and is regarded to be the 'best' technique to preserve the nutritional value and flavour of oils. The low temperature allows the removal of high molecular weight waxes after which the oil is filtered to remove solid material. The final oil is stored in steel drums and the applicant notes that tocopherols, naturally present in the oil, inhibit oxidation. A detailed diagram of the methods employed is presented in the Dossier (Appendix 9).

Discussion *The Committee was content that the production process did not give cause for concern, but noted that the flowchart in Appendix 9 included additional steps which were not described in the dossier. This flowchart also indicated that tocopherols may also be added as required, implying that the oil may be prone to oxidation.*

In response, the applicant explained that the additional steps that are highlighted in Appendix 9 (e.g. winterising, deodorising) are commonly used in the production of vegetable oils and may be used as required. The applicant noted that the oil is as prone to oxidation as other cold pressed oils with a similar peroxide index value (measured at 7.2 mEqO_2/kg anhydrous fatty acids). In addition the applicant pointed out that the low level presence of copper and iron, which catalyse oxidation reactions, indicates that oxidation will be slow. The Committee was reassured that the oil was comparable to other cold pressed oils in terms of oxidation and manufacturing processes. Members were concerned by the apparent ad hoc approach to the use of additional processing steps, but accepted that this may be because the oil is not yet being produced in commercial quantities for the EU market. The Committee advised that the list of manufacturing steps should be included in the authorisation decision for this novel ingredient, should it be approved.

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

Dossier p19 & Section 5

7. The applicant refers to evidence of chia seeds being consumed for millennia but acknowledges that that their use appears to have been restricted to local markets in rural South America until the 1990s, when increased commercialisation led to exports to North America and, latterly, Australasia and Europe.

8. There has been a marked increase in the availability of chia seeds in a wide range of food products across the world in recent years. The seeds have been authorised as a novel food in the EU for use, at defined levels, in bread and other baked products, breakfast cereals and various seed mixes.[1]

Discussion *Members accepted that there was a history of use of chia seeds and noted that both the original application for chia seeds and the subsequent request to extend the use received favourable risk assessments from the Committee.*

IX Anticipated intake and extent of use of the NI

Dossier p20-22

9. The applicant intends to market chia seed oil in vegetable oils (blended at a maximum level of 10%) and as a food supplement. The proposed levels are consistent with approved reference intake values for omega-3 fatty acids. EU rules require at least 0.3 g alpha-linolenic acid per 100 g (and per 100 kcal) to be present in products that claim to be a source of omega-3 fatty acids and at least 0.6 g alpha-linolenic acid per 100 g to be present in order for a claim that a food is high in omega-3 fatty acids. The proposed use categories and level of incorporation are detailed below. It should be noted that the category 'Non-alcoholic beverages' was deleted by the applicant due to concerns raised by the Committee as seed-allergic individuals would not expect to find seeds in these foods and were unlikely to check the ingredient lists.

Proposed Category	**% Inclusion / Recommended Daily Intake**
Fats and Oils	10%
Food Supplements	2g/day

10. The applicant provided data from the 2002 UK National Diet and Nutrition Survey (NDNS) for UK consumers aged 19-64 years old to estimate the likely consumption of chia seed oil for the proposed range of products. In the light of the applicant's decision to drop the use in beverages the tables in the dossier have been amended as follows:

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:021:0034:0035:EN:PDF
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:294:0014:0015:EN:PDF

Estimated mean and high level (97.5th%ile) intake of chia seed oil as calculated from UK NDNS survey data

Product Category	Age Groups (Mean consumption, g/day)				% Chia seed oil	Chia seed oil g/day	ALA g/day
	19-24	25-34	34.49	50-64			
Fats and Oils	11.4	11.1	10	13.9	10	1.2	0.7

Product Category	Age Groups (97.5th%ile consumption, g/day)				% Chia seed oil	Chia seed oil /day	ALA g/day
	19-24	25-34	34-49	50-64			
Fats and Oils	22.8	22.2	24	27.8	10	2.5	1.5

11. The amended figures indicate that the high level consumption for chia seed oil will be 2.5g per day (containing 1.5g alpha linolenic acid), which equates to consuming 6-7g of the seed, assuming an oil concentration of 30-35%[2]. The applicant does not include intake of chia seed oil from supplements (2g/day) or intake of alpha linolenic acid from other dietary sources in this estimate. EFSA has recognised that recommended intakes of alpha linolenic acid, for nutritional purposes, is of the order of 1% of energy intake, which equates to 2–3 grams/day for the typical diet, but has not identified a tolerable upper intake level.

Discussion *The Committee was content with the projected levels of intake for the oil.*

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

Dossier p23-24

12. The applicant has identified chia seed oil containing products which are on the market in non-EU countries, highlighting products which are similar to those that are the subject of this application. The Mintel Global New Product Database lists over 350 chia seed and chia seed oil products which entered the market worldwide between 2009 and 2011. Although it is not known how widely consumed these products are, the number of newly launched products indicates increasing exposure to chia seed and chia seed oil internationally. The applicant also mentions allergenic potential in this section and this issue is considered in detail in Section XIII below.

[2] The recent application to extend the use of chia seed estimated that the average consumption of chia seeds would be around 13g/day see http://www.food.gov.uk/multimedia/pdfs/chialetop.pdf

Discussion *The Committee noted that products containing chia seed oil were available elsewhere in the world and, following a recent decision authorising the use of chia seeds in a wider range of products, chia seeds were increasingly available in the EU.*

XI Nutritional information on the novel food

Dossier p24-28

13. The applicant provided a basic fatty acid profile which is compared with two other vegetable oils – canola (rapeseed) and flax. The applicant notes that chia seed oil contains around 82% polyunsaturated fatty acids, including around 63% alpha linolenic acid, significantly more than the other oils. A more comprehensive comparison of the oil compared with flax oil is also provided (Dossier, Appendix 8). The applicant also provides an extensive commentary on the function and metabolism of alpha linolenic acid in humans. As alpha linolenic acid is already found in the diet, and the novel ingredient is a new source of this essential fatty acid, this aspect is not discussed in this opinion.

Discussion *The Committee observed that the omega-3 fatty acids in chia seed are mainly in the form of alpha linoleic acid, a nutritionally essential fatty acid that is required for synthesis of important fatty acids and eicosanoids. Alpha linoleic acid therefore has a different function to the long chain omega-3 fatty acids that are found in certain other foods and chia seed oil is not a "like-for-like" substitute for other sources of omega-3 fatty acids, such as fish oils.*

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

XII Microbiological Information

Dossier p31

14. The applicant's chia seed oil is routinely tested for the presence of a range of micro-organisms and mycotoxins. The results of these analyses are tabulated on page 32 of the Dossier and show extremely low levels of microbial contamination.

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

XIII Toxicological information

Dossier p32-37

15. The applicant has carried out a 14 day acute toxicity study in rats, carried out to OECD standards, in which their chia seed oil was administered to 50 rats at doses up to 9000mg/kg body weight. The rats were monitored throughout and at the end of the study. The LD_{50} was determined to be >5000mg/kg; the full study report is attached to the Dossier (Appendix 14).
16. All other studies that are reported in the dossier examined the perceived beneficial effects of consumption of chia in both rats and humans, with the exception of a 30 day dietary exposure study in rats. In this study, carried out using a chia seeds and chia oil of unspecified origin, the authors reported that 5% chia seed oil (and 15% seed) reduced serum triglyceride levels by 60% and increased the levels of HDL cholesterol.
17. The paucity of toxicological studies carried out on chia seed oil is consistent with the previous chia seed dossiers that the Committee reviewed in 2003 and 2011. The first dossier was also reviewed by EFSA[3], who concluded that, although the data were limited, ‘‘experience gained from previous and current use of chia seeds in non-EU countries can be regarded as supportive evidence of the safety of chia seeds.”

Discussion *The Committee noted that it has previously established the safety of chia seeds, when consumed at levels that could result in the consumption of chia seed oil at levels greater than are proposed here. The Committee queried the results of the 30 day feeding study with the applicant, noting that there were small changes in weight gains in the control and test animals but, having reviewed the raw data concluded that this was not a cause for concern.*

Allergenicity and Labelling

18. The applicant does not propose special labelling for products that contain the oil but, in line with EU food labelling requirements, it will appear on ingredient lists as ‘chia seed oil’.
19. In response to a request from the Committee the applicant provided additional information detailing the level of protein present. The Committee regarded the level of protein present (typically 0.5%) to be consistent with other unrefined oils, which would be sufficient to elicit a reaction in any individual who may be allergic to chia seeds.

Discussion *The Committee noted similarities between this application and the recent application to extend the use of chia seeds[4]. The Committee accepted that chia seed oil would be clearly labelled but reiterated its view that IgE-mediated reactions in individuals who are allergic to other seeds and*

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

[4] Paragraphs 20, 21 and conclusion of UK initial opinion http://www.food.gov.uk/multimedia/pdfs/chialetop.pdf

nuts could be possible. The Committee again highlighted the relative absence of studies defining the extent to which seed allergic individuals might react to chia seeds. Such data could be useful in determining whether increasing use of chia seed, and derived products such as the oil, would restrict the choice of seed allergic individuals. The Committee also noted that chia seeds have little history of consumption in the European Union and it was therefore possible that extending the range of uses could, like any novel food containing new proteins, give rise to increased sensitisation in the wider population.

CONCLUSION

20. The Committee considered that the main concern in relation to the use of chia seed oil related to its consumption by individuals with existing seed allergy. Despite evidence of historical use in South America the seeds are effectively new to markets across in the world and the true extent of allergenicity, including cross-reactivity with allergens in other seeds and nuts, is not known. The applicant is aware of this and, following concerns raised by the Committee during this evaluation, deleted one of the proposed food categories (non-alcoholic beverages) because these foods do not typically contain seeds and could lead to inadvertent consumption of chia seed protein by seed and nut allergic individuals.

21. Chia seed is not a known allergen and it is not subject to EU rules on mandatory declaration of allergens in food. The existing authorisations for chia seeds are limited to products that typically contain seeds and require that there is reference to chia seeds on the label, which should also apply to this oil.

22. The Committee accepted that clear labelling would be adequate to address safety concerns in relation to allergic reactions amongst known “at risk” groups and suggested that this should be accompanied by a programme to raise awareness among these individuals. In order that information is widely disseminated the Committee recommended that the applicant should proactively seek to work with consumer groups, allergy support groups and the relevant competent authorities in each Member State when they are seeking to place new products containing chia on the market. It would also be advisable to inform allergy clinics so that they can report any cases of chia allergy to the relevant national authorities.

23.. The Committee remains concerned that the use of chia in a wider range of foods could result in a restriction of choice for people with existing seed allergies. This might be unnecessary if chia seeds do not cause reactions in individuals with allergies to other seeds (so-called cross-reactive allergies). The Committee advised that the uncertainty could be reduced by research into the likelihood of different seed allergic individuals cross-reacting to chia seeds

24. In relation to potential changes in sensitisation across the population the Committee advised that the company should be proactive in reporting

allergic reactions and specifically highlight any that occurred in individuals who had not previously demonstrated any symptoms of allergy to seeds.

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Annex

Product Specification

Description

To produce the oil from Chia (*Salvia hispanica* L) the seeds (99.9% pure) are cold pressed. No solvents are used and, once pressed, the oil is held in decantation tanks and a three-phase filtration process employed to remove impurities. The filtered oil may be subjected to additional processing steps (winterising and deodorising) which are widely used in the production of edible oils. Antioxidants may also be added in conformity with EU food additives legislation.

Parameter	**Limits**	**Test Method**
Acid Value	<2% Oleic Acid	AOCS Ca 5a-40
Peroxide Value	<10 mEq/Kg	NF EN ISO27107
Insoluble Impurities	<0.001%	AOCS Ca 3a-46
Alpha Linolenic Acid	>60%	AOCS Ce 1e-91
Linoleic Acid	>15%	AOCS Ce 1e-91