Chiazaad

Tweede beoordeling van de veiligheid voor de consument, volgens de Europese verordening 258/97 betreffende nieuwe voedingsmiddelen en nieuwe voedselingrediënten

Chia seed

Second opinion regarding consumer safety, in accordance with European Regulation 258/97 concerning novel foods and novel ingredients

Gezondheidsraad:
Commissie Veiligheidsbeoordeling nieuwe voedingsmiddelen (VNV)

Health Council of the Netherlands
Committee on the Safety Assessment of Novel Foods

aan/to

de minister van Volksgezondheid, Welzijn en Sport/
the Minister of Health, Welfare and Sport

de minister van Landbouw, Natuur en Voedselkwaliteit/
the Minister of Agriculture, Nature and Food Quality

Nr 2004/05VNV, Den Haag, 9 september 2004
No. 2004/05VNV, The Hague, September 9, 2004

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The Health Council receives most requests for advice from the Ministers of Health, Welfare & Sport; Housing, Spatial Planning & the Environment; Social Affairs & Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

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Uw kenmerk : VGB/VL2494916
Ons kenmerk : 2004/05VNV, U-1168/MR/CvR/cv/622-DI
Datum : 9 september 2004

Mijnheer de minister,

Dit schrijven dient ter beantwoording van de adviesaanvraag over de veiligheid van nieuwe voedingsmiddelen en nieuwe voedselingrediënten, die door u mede namens de Minister van Landbouw, Natuur en Voedselkwaliteit aan de Gezondheidsraad is voorgelegd. Aan de orde is een zogenoemde tweede beoordeling, conform de Europese verordening 258/97, van hele en tot meel vermalen zaden van chia (*Salvia hispanica L.*), een plant uit de familie der lipbloemigen (Lamiaceae of Labiatae). Deze producten komen niet direct beschikbaar voor de consument, maar zullen in meergranenbrood worden verwerkt. De aanvrager die deze nieuwe voedselingrediënten op de Europese markt wil brengen is de firma R. Craig and Sons [M] Ltd. De beoordeling is verricht door de Commissie 'Veiligheidsbeoordeling nieuwe voedingsmiddelen' van de Gezondheidsraad (Commissie VNV).

De eerste beoordeling van de aanvraag voor markttoelating is verricht door de *Advisory Committee on Novel Foods and Processes* (ACNFP) van het Verenigd Koninkrijk. De ACNFP heeft geen bezwaar tegen markttoelating van chiazaad en chiameel. Wel plaatst de ACNFP de kanttekening dat er nog onduidelijkheid bestaat over potentiële allergene eigenschappen van deze producten. De aanvrager stelt daarom een uitgebreide etikettering voor, die consumptie door personen met een bekende allergie voor andere zaden moet voorkomen. De ACNFP is van mening dat op deze manier de consument geen onacceptabel risico loopt. Zij merkt op dat deze benadering de keuzevrijheid van de consument wellicht onnodig beperkt, maar dit is niet van invloed op haar positieve conclusie van de veiligheidsbeoordeling.

De Commissie VNV maakt bezwaar tegen toelating op de markt van chiazaad en chiameel als voedselingrediënten (hierna aangeduid als chia). Zij baseert haar oordeel op de informatie in het

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dossier (zie Bijlage D voor een samenvatting) en het rapport van de eerste beoordeling door de ACNFP (zie Bijlage E).

De Commissie VNV is het eens met de ACNFP dat de kwaliteit van het productieproces gewaarborgd lijkt. De aanvrager heeft op verzoek van de ACNFP aanvullende informatie verstrekt inzake het beheersen van microbiologische risico's en het garanderen van de kwaliteit tijdens opslag en transport. Volgens de Engelse beoordelaars is de firma in staat om te voldoen aan de algemeen geldende eisen voor voedselveiligheid.

Gezien de bestanddelen (eiwit, olie en vezel) van chia is er vanuit voedingskundig oogpunt geen bezwaar tegen het gebruik hiervan in brood. Een karakteristiek van dit zaad is het relatief hoge gehalte aan α-linoleenzuur, een zogeheten n-3 meervoudig onverzadigd vetzuur.

De aanvrager stelt voor om chia tot een totaalgehalte van 5% in meergranenbrood te verwerken. Bij de voorgestelde toepassing schat de aanvrager de gemiddelde inneming van dit nieuwe voedselingrediënt door volwassenen in de Engelse bevolking op 2,1 gram per dag (97,5 percentiel: 11,6 g). De Commissie VNV tekent aan dat de voor deze schatting gebruikte consumptiegegevens voor brood niet meer dan een globale indicatie geven. Ook is het onbekend in hoeverre deze inneming representatief is voor de Europese bevolking. Zo wordt er in Nederland in vergelijking met het Verenigd Koningrijk meer brood gegeten (Hul98).

Eén van de belangrijkste punten van kritiek van de Commissie VNV op het dossier is dat resultaten van toxicologisch proefdieronderzoek, die noodzakelijk zijn voor de veiligheidsbeoordeling, geheel ontbreken. De commissie vindt dit, in tegenstelling tot de ACNFP, onacceptabel. Er zijn wel voederproeven bij legkippen en braadkuikens uitgevoerd, maar dergelijke proeven zijn geen substituut voor gestandaardiseerd toxicologisch onderzoek. Ook concludeert de commissie dat het dossier onvoldoende resultaten van mensgebonden onderzoek bevat. Gegevens over eerdere consumptie in Latijns-Amerika zijn slechts anekdotisch en daardoor niet van waarde voor de veiligheidsbeoordeling.

De Commissie VNV heeft ook kritiek op het onderzoek naar eventuele allergene eigenschappen van chia. De aanvrager heeft zich hiervoor geconcentreerd op mogelijke kruisreacties tussen chia en bepaalde andere zaden, te weten pinda's en noten. Allergische reacties tegen chia of tegen zaden van verwante planten zijn niet bekend uit de wetenschappelijke literatuur. Bij het testen van patiëntensera met reactiviteit tegen pinda of noten, reageerden er enkele met eiwitten uit chia. Twaalf personen, die waren geselecteerd op basis van overgevoeligheid voor pinda of noten, ondergingen een huidtest met een extract van chia. Bij twee van hen, die eveneens gevoelig waren voor sesamzaad, werden positieve reacties waargenomen.

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Gezondheidsraad **Vice-voorzitter**
Health Council of the Netherlands

Hun sera reageerden met een 15 kD-eiwit uit chia. Hierop vroeg de ACNFP om aanvullend onderzoek naar mogelijke kruisreacties bij patiënten met een allergie voor zaden, zoals mosterd of sesamzaad. De aanvrager is hierop niet ingegaan, maar kwam met het voorstel om producten met chia te etiketteren als ongeschikt voor mensen met een allergie tegen zaden[1]. Volgens de ACNFP zou dit weliswaar de keuzemogelijkheden voor allergische individuen verder beperken, maar is het wel een afdoende maatregel om de veiligheid van het product te garanderen. Zij meent dat patiëntenorganisaties en allergieklinieken op de hoogte moeten worden gesteld van een eventuele introductie van dit nieuwe product.

De Commissie VNV is van mening dat de mogelijke allergene eigenschappen van dit product nader zouden moeten worden onderzocht vóór marktintroductie. De commissie meent ook dat er op dit moment nog onvoldoende wetenschappelijke basis bestaat voor de etikettering zoals nu door de firma voorgesteld.

Samenvattend is de Commissie VNV het niet eens met de conclusie van de eerste beoordeling door de ACNFP. Zij is van mening dat chia voorlopig niet op de markt zou moeten worden toegelaten, in afwachting van nader onderzoek naar mogelijke toxische en allergene eigenschappen van dit product.

Ik onderschrijf de conclusies en aanbevelingen van de Commissie VNV.

Hoogachtend,

Prof. dr JGAJ Hautvast

[1] Uit de beschikbare documentatie is niet duidelijk of de voorgestelde etikettering alleen gericht zou zijn op patiënten met allergie tegen sesamzaad of mosterd, of tevens andere zaden zou betreffen.

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Letter to the Dutch Minister of Health, Welfare and Sport

On September 9, professor JGAJ Hautvast, Vice-president of the Health Council of the Netherlands wrote as follows to the Minister of Health, Welfare and Sport:

This letter has been prepared in reply to your request for advice regarding the safety of novel foods and food ingredients, also made on behalf of the Minister of Agriculture, Nature and Food Quality. The subject in question is a second opinion, in accordance with European Regulation 258/97, concerning whole Chia seeds (Salvia hispanica L.), and Chia seeds that have been milled to flour. Chia is a member of the Mint family (Lamiaceae or Labiatae). These products will not be directly available to consumers, but will be incorporated into multigrain bread. The applicant who wishes to introduce these novel food ingredients to the European market is R. Craig and Sons [M] Ltd. This assessment was carried out by the Health Council Committee on the Safety Assessment of Novel Foods (VNV Committee).

The initial assessment of the application for marketing authorisation was carried out by the Advisory Committee on Novel Foods and Processes (ACNFP), in the United Kingdom. The ACNFP has no objection to Chia seed and Chia flour being admitted to the market. However, the ACNFP has commented that there is still some doubt about the extent of the allergenic potential of these products. The applicant therefore proposes the use of extensive labelling, in order to prevent individuals with a known allergy to other seeds from consuming these products. The ACNFP takes the view that, in this way, consumers will not run undue risk. It points out that while this approach may restrict con-

sumers' freedom of choice, this has no bearing on its favourable conclusions with regard to the safety assessment.

The VNV Committee is against admitting Chia seed and Chia flour to the market as food ingredients (referred to hereinafter as Chia). It bases its views on the information contained in the dossier (see Appendix D for the summary) and on the report of the initial assessment by the ACNFP (see Appendix E).

The VNV Committee concurs with the ACNFP that, in terms of quality, the production process appears to incorporate the necessary safeguards. At the ACNFP's request, the applicant provided supplementary information on the management of microbiological risks, and on guaranteeing quality during storage and transport. The British assessors feel that the company is able to meet the generally accepted food safety requirements.

In view of Chia's ingredients (protein, oil, and fibre), from the nutritional point of view, there is no objection to its use in bread. One characteristic of this seed is that it contains relatively large amounts of alpha-linolenic acid, an n-3 polyunsaturated fatty acid. The applicant proposes that Chia be incorporated into multigrain bread, at total content of up to 5%. In the proposed application, the applicant estimates that the average intake of this novel food ingredient by adults in the population of Britain will be 2.1 grams per day (97.5 percentile: 11.6 g). The VNV Committee notes that the consumption data for bread, which were used for this estimate, provide nothing more than a rough indication. Furthermore, it is not known to what extent this intake is representative of the population of Europe as a whole. For instance, in comparative terms, more bread is consumed in the Netherlands than in the United Kingdom (Hul98).

One of the VNV Committee's main criticisms of the dossier is that it contains no data whatsoever from toxicological studies in experimental animals, which are essential to the safety assessment. Unlike the ACNFP, the Committee feels that this is unacceptable. While feeding trials were carried out in laying hens and broiler chickens, such tests are no substitute for a standardised toxicological study. The Committee also concludes that the dossier contains too few results from research involving human subjects. Data on past consumption in Latin America is purely anecdotal, so it is of no value in terms of the safety assessment.

The VNV Committee is also critical of the research conducted into Chia's possible allergenic properties. In this context, the applicant has focused on possible cross-reactions between Chia and certain other seeds, namely peanuts and nuts. The scientific literature contains no information concerning allergic reactions to Chia or to the seeds of related plants. Of various patient sera with reactivity to peanuts or nuts, some reacted to Chia proteins. Twelve individuals, selected on the basis of hypersensitivity to peanuts or nuts, underwent a skin prick test using a Chia extract. Positive reactions were observed in two of these individuals, who were also sensitive to sesame seed. Their sera reacted against a 15 kD protein from Chia. In response to this, the ACNFP requested that fol-

low-up studies of possible cross-reactions be carried out in patients with allergic reactions to seeds, such as mustard or sesame seed. The applicant did not fall in with this suggestion, but instead proposed that all products containing Chia should be labelled as being unsuitable for individuals with seed allergies*. According to the ACNFP, while this would further restrict the choices available to allergic individuals, it is nevertheless an adequate means of guaranteeing the product's safety. It takes the view that patient support groups and allergy clinics should be informed about the possible introduction of this novel product.

The VNV Committee feels that this product's possible allergenic properties should be further investigated prior to market introduction. The Committee believes that the scientific basis for the labelling, proposed by the applicant, is presently inadequate.

In summary, the VNV Committee cannot concur with the conclusion of the initial assessment by the ACNFP. It believes that Chia should not be admitted to the market for the time being, pending further research into this product's possible toxic and allergenic properties.

I endorse the conclusions and the recommendations of the VNV Committee.

(signed) professor JGAJ Hautvast

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* On the basis of the available documentation, it is not clear whether the proposed labelling would focus purely on patients with an allergy to sesame seed or mustard, or whether it would also make mention of allergies to other seeds.

Literatuur/Literature

EG97 Verordening (EG) nr. 258/97 van het Europees Parlement en de Raad van 27 januari 1997 betreffende nieuwe voedingsmiddelen en nieuwe voedselingrediënten. Publikatieblad van de Europese Gemeenschappen 1997; L43: 1-6
(Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Official Journal of the European Communities 1997; L43: 1-6).

EG97a Aanbeveling (EG) nr. 97/618/EG van de Commissie van 29 juli 1997 betreffende de wetenschappelijke aspecten en de presentatie van de informatie die nodig is om aanvragen voor het in de handel brengen van nieuwe voedingsmiddelen en nieuwe voedselingrediënten te ondersteunen alsmede het opstellen van de verslagen van de eerste beoordeling uit hoofde van Verordening (EG) nr. 258/97 van het Europees Parlement en de Raad. Publikatieblad van de Europese Gemeenschappen 1997; L253: 1-36
(97/618/EC: Commission Recommendation 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) No 258/97 of the European Parliament of the Council. Official Journal of the European Communities 1997; L253: 1-36).

EG03 Verordening (EG) nr. 1829/2003 van het Europees Parlement en de Raad van 22 september 2003 inzake genetisch gemodificeerde levensmiddelen en diervoeders. Publicatieblad van de Europese Unie 2003; L268: 1-23.
(Regulation (EC) nr. 1829/2003 of the European Parliament and of the Council of 22 September 2003 concerning genetically modified food and feed. Official Journal of the European Union 2003; L268: 1-23.)

FAO96 Biotechnology and Food Safety. Report of a joint FAO/WHO Consultation. Rome, FAO 1996.

GR92 Commissie Toxicologische aspecten van biotechnologisch bereide producten. Productveiligheid bij nieuwe biotechnologie. Den Haag, Gezondheidsraad 1992, publicatienummer 1992/03.

GR02 Commissie Veiligheidsbeoordeling nieuwe voedingsmiddelen. Veiligheidsbeoordeling van nieuwe voedingsmiddelen. Den Haag, Gezondheidsraad 2002, publicatienummer 2002/05VNV.
Committee on the Safety Assessment of Novel Foods. Safety assessment of novel foods. The Hague, Health Council 2002, publication number 2002/05VNV.

Hul98 Hulshof KFAM, Kistemaker C, Bouman M. De consumptie van groepen voedingsmiddelen door de Nederlandse bevolkingsgroepen – Voedselconsumptiepeiling 1997–1998. TNO-rapport V98.804, Zeist, 1998

OECD93 Safety evaluation of foods derived by modern biotechnology. Concepts and principles. Paris, OECD 1993.

OECD96 OECD Workshop on Food Safety Evaluation. Paris, OECD 1996.

WHO91 Strategies for assessing the safety of foods produced by biotechnology. Report of a joint FAO/WHO Consultation. Geneva, WHO 1991.

A	De adviesaanvraag/Request for advice
B	De commissie/The committee
C	EU-procedure/EU-procedure
D	Samenvatting van het dossier/Executive summary of the dossier
E	Eerste beoordeling/First assessment

Bijlagen/Annexes

Bijlage **A**

De Adviesaanvraag/Request for advice

Op 18 augustus 1999 schreef de Minister van Volksgezondheid, Welzijn en Sport aan de Voorzitter van de Gezondheidsraad (brief kenmerk GZB/VVB 993428):

Sinds mei 1997 is in de Europese Unie de Verordening (EG) 258/97 van kracht inzake nieuwe voedingsmiddelen en nieuwe voedselingrediënten. Daarmee werd de veiligheidsbeoordeling onderdeel van een communautaire procedure.

Met u is reeds de mogelijkheid besproken de beoordeling door de Gezondheidsraad te laten uitvoeren. Ik verzoek u dan ook mede namens de Staatssecretaris van Landbouw, Natuurbeheer en Visserij, in deze eerste fase van uitvoering van de Europese Verordening (EG) 258/97 gedurende een aantal jaren, de veiligheidsbeoordeling gestalte te geven. Voor het onderbrengen bij de Gezondheidsraad pleit het experimentele karakter dat de beoordeling de eerste jaren zal hebben. Dit experimentele karakter komt voort uit het feit dat het een nieuw soort beoordeling betreft van deels nieuwe categorieën van voedingsmiddelen of voedselingrediënten. Het is namelijk een veiligheidsbeoordeling vóór het op de markt brengen van met name voedingsmiddelen van een genetisch gemodificeerde oorsprong en zogenaamd functional foods (nutriceutica). Daarnaast ga ik ervan uit dat de onafhankelijke wetenschappelijke advisering door de Gezondheidsraad het vertrouwen van de Europese Commissie en de andere lidstaten in het Nederlandse oordeel nog versterkt.

Mijn beleid is erop gericht een zo groot mogelijke openheid en transparantie te realiseren van de gevolgde procedure en de beoordeling om de consument vertrouwen te geven in de veiligheid van de

nieuwe voedingsmiddelen. Ik verzoek de Gezondheidsraad hieraan bij te dragen door bijvoorbeeld inzage te geven in de dossiers waarvoor een aanvraag wordt ingediend, waarbij uiteraard bedrijfsvertrouwelijke gegevens worden beschermd en door de criteria, waarop de veiligheid zal worden beoordeeld, te publiceren.

De Minister van Volksgezondheid, Welzijn en Sport,
w.g. dr E Borst-Eilers

English translation

On 18 August 1999, the Minister of Health, Welfare and Sport wrote as follows to the President of the Health Council of the Netherlands (under reference GZB/VVB 993428):

Since May 1997, Regulation (EC) 258/97 concerning novel foods and novel food ingredients has been in force in the European Union. Under the Regulation, the safety of novel foods has to be assessed as part of a community procedure.

Following discussions regarding the possibility of the Health Council making such assessments, the State Secretary for Agriculture, Nature Management and Fisheries and I wish the Council to take responsibility for safety assessment for a period of several years during the fist phase of implementation of European Regulation (EC) 258/97. It is considered appropriate that the Health Council should initially take on this role because the assessment activities will be of an experimental nature, involving both a new form of assessment (i.e. pre-marketing assessment) and, in many cases, new categories of foodstuff (primarily foodstuffs with a genetically modified basis and functional foods or nutraceuticals). We also feel that if assessments are made by a body with the Council's independent scientific status, this will support the validity of the Netherlands' opinion in the eyes of the European Committee and other member states.

My wish is to make the procedure and the assessment as open and transparent as possible, so as to enhance consumer trust in the safety of novel foods. I would like the Health Council to support this objective by, for example, allowing perusal of the application dossier (insofar as consistent with the need to protect the confidentiality of commercially sensitive information) and publishing the criteria upon which safety assessments are made.

The Minister of Health, Welfare and Sport,
(signed) dr E Borst-Eilers

Bijlage **B**

De commissie/The committee

- Prof. dr EG Schouten, *voorzitter/chairman*
  hoogleraar epidemiologie; Wageningen Universiteit and Researchcentrum
  professor of epidemiology; Wageningen University and Research centre
- Prof. dr CAFM Bruijnzeel-Koomen
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  professor of dermatology/allergology; Academic Hospital Utrecht
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- Dr ir JMA van Raaij
  voedingsfysioloog; Wageningen Universiteit and Researchcentrum/
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- Prof. dr ir G Schaafsma
  hoogleraar voeding; TNO Voeding, Zeist/
  professor of nutrition; TNO Nutrition and Food Research, Zeist
- Dr GJA Speijers
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  Ministry of Health, Welfare and Sport; The Hague
- Prof. dr WM de Vos
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  professor of microbiology; Wageningen University and Research centre
- Dr RA Woutersen
  toxicoloog, toxicologisch patholoog; TNO Voeding, Zeist/
  toxicologist, toxicologic pathologist; TNO Nutrition and Food Research, Zeist
- Dr ir F van der Wilk, *adviseur/advisor*
  COGEM, Bilthoven/
  Committee on Genetic Modification, Bilthoven
- Dr CMA van Rossum, *secretaris/scientific staff member*
  Gezondheidsraad, Den Haag/
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Bijlage **C**

EU-procedure/EU-procedure

Als een fabrikant een nieuw voedingsmiddel op de markt brengt, dient de veiligheid voor de consument gewaarborgd te zijn. In 1997 werd de Europese verordening van kracht waarin de procedure is geregeld voor de goedkeuring voor marktintroductie van een nieuw voedingsmiddel (EG97). Bij deze procedure zijn verschillende actoren betrokken. De aanvrager moet beoordelen of het product werkelijk 'nieuw' is, dat wil zeggen dat het nog niet eerder in de Europese Unie in substantiële mate voor menselijke voeding is gebruikt en ook niet wezenlijk gelijkwaardig is aan een bestaand product. (Voor een wezenlijk gelijkwaardig product kan worden volstaan met een kennisgeving van de marktintroductie.) Ook moet het niet gaan om een levensmiddelenadditief, aroma of extractiemiddel, omdat deze producten op een andere wijze worden beoordeeld. Voor een nieuw voedingsmiddel in de zin van de Europese verordening moet de aanvrager een veiligheidsdossier overleggen volgens aanbevelingen van de Europese Commissie (EG97a). Deze aanbevelingen zijn gebaseerd op rapporten van verschillende instanties die zich met het onderwerp nieuwe voedingsmiddelen bezighouden, te weten de OECD (OECD93, OECD96) en de WHO/FAO (FAO96, WHO91). Ook de Gezondheidsraad heeft zich al eerder over dit onderwerp gebogen (GR92). Sinds het verschijnen van de aanbevelingen van de EU wordt in internationaal verband gewerkt aan explicitering en aanpassing aan de stand van de wetenschap (GR02).

De fabrikant levert het volgens de richtlijnen samengestelde dossier in bij het land waar het product het eerst op de markt zal komen. Daarop komt de nationale veiligheids-beoordelingsautoriteit in actie. In Nederland is dat de Minister van Volksgezondheid, Welzijn en Sport. Zij heeft de Gezondheidsraad verzocht haar van advies te dienen. De

Voorzitter van de Gezondheidsraad heeft hiertoe de commissie Veiligheidsbeoordeling nieuwe voedingsmiddelen (commissie VNV) ingesteld.

De commissie beoordeelt op basis van de huidige stand van de wetenschap of de door de fabrikant geleverde gegevens juist en volledig zijn en of zij het eens is met diens conclusies. Zij maakt een verslag van haar bevindingen — ook volgens de Europese aanbevelingen (EG97a, deel III) — en biedt dat de minister aan. De minister formuleert het Nederlandse oordeel over een voedingsmiddel en brengt dat in bij het Europese overleg in het Permanent Comité voor de voedselketen en de diergezondheid. Alle Europese lidstaten worden uitgenodigd hun oordeel (de zogeheten tweede beoordeling) te geven over het dossier en over de eerste beoordeling alvorens genoemd Comité een eindoordeel velt. Als een dossier veel vragen oproept, gaat er een adviesvraag van de Europese Commissie naar de Europese Autoriteit voor voedselveiligheid (EAV). Komt men dan nog niet tot overeenstemming dan beslist de Europese Ministerraad. Sinds 18 april 2004 moeten veiligheidsdossiers van voedingsmiddelen van genetisch gemodificeerde oorsprong rechtstreeks ingediend worden bij de EAV (EG03).

English translation

When manufacturers bring novel foodstuffs onto the market, consumer safety has to be ensured. In 1997, a European Regulation (EG97) came into force, laying down the procedure for approving the market introduction of novel foodstuffs. The procedure recognizes various actors. The applicant must decide whether a product is a novel foodstuff, i.e. a substance that has not previously been available for human consumption to any substantial extent within the European Union and is not substantially equivalent to any existing product. (If a foodstuff is substantially equivalent to any existing product, it is sufficient to inform the authorities of its market introduction). Food additives, aromas and extracts are excluded from the provisions of the directive, since they fall within the scope of an established assessment regime. Before marketing a novel foodstuff, the applicant must compile a safety dossier that complies with the Recommendations of the European Commission (EG97a). These Recommendations are based on reports by a number of bodies that have studied the issue of novel foodstuffs, in particular the OECD (OECD93, OECD96) and the WHO/FAO (FAO96, WHO91). The Health Council of the Netherlands has also considered the question earlier (GR92). Since publication of the EU recommendations, international efforts have been made to clarify and adapt the latest scientific knowledge in the field (GR02).

Having compiled a dossier in line with the guidelines, the manufacturer has to submit it to the competent authority in the country where the product is to be marketed first. This dossier is assessed by the national safety assessment authority. In the Netherlands, this is the Minister of Health, Welfare and Sport, who is advised by the Health Council.

The President of the Health Council has created a Committee on the Safety Assessment of Novel Foods (VNV Committee) to advise the minister on behalf of the Council.

On the basis of the scientific state of the art, the committee has to decide whether the information provided by the manufacturer is accurate and complete and whether the manufacturer's conclusions are sound. The committee then draws up a report on its findings for the minister; this report must also comply with the European Recommendation (EG97a, part III). After considering the report, the minister formulates the Netherlands' opinion regarding the foodstuff in question, which is discussed at European level in the Standing Committee on the Food Chain and Animal Health. All other European member states are invited to express a 'second opinion' regarding the dossier and the first opinion. The Standing Committee then arrives at a final judgement. If a dossier is particularly contentious, the European Commission calls upon the European Food Safety Authority (EFSA) for advice. If consensus still cannot be reached, the issue is referred to the European Council of Ministers. From April 18th 2004 safety dossiers of food from genetically modified origin have to be submitted to EFSA directly (EC03).

Bijlage **D**

Samenvatting van het dossier/ Executive summary of the dossier

R Craig & Sons [M] Ltd

APPLICATION FOR APPROVAL OF WHOLE CHIA SEED AND GROUND WHOLE CHIA AS NOVEL FOOD INGREDIENTS

SUMMARY

Chia – seed and flour Novel Food application Summary

Contents

1. Administrative Data

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2. Application

This application seeks approval under Regulation (EC) No 258/97 of the European Parliament and of the Council of 27th January 1997 concerning novel foods and novel food ingredients for Chia (Salvia hispanica L) seed and flour. Chia has historically been consumed in South America but has not hitherto been used for human consumption to a significant degree within the European Community and so general approval, as a Novel Food Ingredient is required.

3. Identification of Relevant Submission Requirements

The structured scheme (Table II, Part I under EC Regulation No. 258/97) has been followed to determine which of schemes I-X are essential to provide data permitting a safety and nutritional evaluation of the Novel Food Ingredient.

Chia may be classified as a complex novel food from a non-GM source (2.2). Relevant requirements for submission to this class are as follows:

I	Specification of the Novel Food
II	Effect of the production process applied to the Novel Food
III	History of the organism used as the source of the Novel Food
IX	Anticipated intake/extent of use of the Novel Food
XI	Nutritional information on the Novel Food
XII	Microbiological information on the Novel Food
XIII	Toxicological information on the Novel Food

This information has been provided in full in our application dossier, ' Application for Approval of Chia (Salvia hispanica L) seed and flour as a Novel Food Ingredient'.

4. Summary

Nutritionists now recommend that not only should the number of calories that are obtained from fat in our diet be decreased, but that we increase our intake of n-3 fatty acids. As a result, consumers are becoming increasingly aware of the nutritional content of the foods they purchase and the importance of increasing dietary levels of n-3 fatty acids in the ongoing battle against coronary heart disease. Introduction of whole Chia seeds and ground whole Chia as food ingredients in bread within Europe would broaden the number of dietary sources of n-3 fatty acids with terrestrial origins.

Chia (*Salvia hispanica L*) is a summer annual herbaceous plant belonging to the mint family. Chia seeds are high in oil, and in particular the n-3 fatty acid α-linolenic acid (C18:3, n-3). Chia was a major food crop of the Aztecs, which was 'rediscovered' and is now grown contractually for R Craig & Sons [M] Ltd in sub-tropical conditions in Argentina and Peru.

Chia seeds contain 33% oil, 57% of which is the n-3 fatty acid α-linolenic acid. In addition, Chia seeds are an abundant source of protein (21%), fibre (28%) and contain a wide range of vitamins and minerals.

Chia seeds are not processed in any way prior to their use a as a food ingredient. Seeds are not chemically treated prior to sowing, however they do receive chemical treatments by way of herbicides and fertilizers. As Chia is grown contractually for R Craig & Sons [M] Ltd, chemical treatments shall comply with current EU legislation. The seed is generally allowed to ripen naturally and is mechanically harvested. Post-harvest, the seeds are cleaned mechanically. In production of ground whole Chia, the seeds are simply passed through a hammer mill.

Anticipated intake was calculated using the National Diet Survey figures (2002) for soft grain bread consumption. Pilot studies indicate that Chia shall be included in these types of bread at a level no greater than 5%. As a result mean anticipated intake is calculated to be 2.1g/person/day.

Safety of the Novel Food has been assessed by microbiological and toxicological means. In addition large scale human allergenicity studies have determined that there are no adverse effects from consumption of whole Chia seeds at relatively high levels and although there was moderate IgE binding to protein in the allergenicity trial, this protein was shown to be susceptible to peptic digestion and therefore probably does not represent a food allergy hazard.

Bijlage **E**

Eerste beoordeling/First assessment

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

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

Applicant **Robert Craig and Sons**

Responsible Person **David Armstrong**

EC Classification **2.2**

Introduction

1. An application was submitted by R Craig & Sons [M] Ltd. to the UK Competent Authority for authorisation of whole Chia (*Salvia hispanica* L) seed and ground whole Chia as a novel food ingredient in soft grain bread.

2. Chia (*Salvia hispanica* L) is a summer annual herbaceous plant belonging to the mint family (Labiatae). The seed of the Chia plant has a long history of consumption in South America and was a major part of the diet in pre-Columbian civilisations, mainly in the Aztec population. If approved in Europe, Chia seeds would provide consumers with an alternative source of the n-3 polyunsaturated fatty acid, alpha-linolenic acid. A number of studies carried out by one South American company suggest that incorporating Chia seeds into hens' diets results in eggs with an increased content of n-3 fatty acids, thereby providing another potential source of these fatty acids in the diet.

3. The applicant will import whole Chia seeds that are mechanically harvested from conventionally-grown crops in two locations: Peru and Argentina. The whole ground Chia to be marketed in the EU will be produced in the UK by milling the imported whole seeds.

I. Specification of the novel food

pp 5 – 9 of the application dossier

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

5. Detailed compositional analyses of Chia seed are given in the application dossier for these analyses the applicant has tested four samples from four consignments of Chia from Peru, for proximate analysis, fatty acid composition and heavy metal content. Whilst details of the methods employed in the proximate analysis and heavy metal analysis are not given, fatty acid profiling was carried out to accredited procedures. Mineral, vitamin and carbohydrate analyses were also carried out on seed in Argentina. Although details of the methods of analysis are

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

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

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

pp 10 – 11 of the application dossier

6. Whole Chia seeds are not processed in any way prior to their use as a food ingredient. The seeds are grown in Argentina and Peru under contract for the applicant who states that agronomic practices will be carried out to fully comply with EC legislation. Details of the cultivation conditions are given in the application.

7. Post-harvest, the seed is cleaned mechanically and not subjected to any chemical treatments. The seed is stored in sacks within a fully enclosed warehouse facility in preparation for shipment. Although the information on the storage and transport conditions is limited, following a request from the Committee concerning proposed conditions of handling, storage and shipment, the applicant submitted a proposed HACCP procedure the use of which would minimise batch to batch variation. The seeds are monitored during transport and storage whilst the proposed HACCP plan describes measures to be put in place to control temperature and humidity during storage and transport. The applicant has also provided data in respect of potential microbial contamination of Chia seed.

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

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

pp 12 – 13 of the application dossier

8. Chia (*Salvia hispanica* L) seeds have a history of use as a food and a medicine, mainly by the Aztecs up until colonisation by the Europeans. Historically, Chia seeds were roasted and ground to form a meal called ‘pinole’, then mixed with water to form a porridge or made into cakes. Although grown only on a very small scale, and with rudimentary technological methods, Mexican Indian descendants are still producing this grain. Chia seeds are also used in a Mexican beverage ‘chia fresca’ in which the seeds are soaked in water and then flavoured with fruit juice and consumed as a drink.

9. An extensive research and development programme on Chia has been undertaken in South America to determine the feasibility of growing this crop on a commercial scale. This has resulted in the development of new production areas

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

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

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

pp 14 – 16 of the application dossier

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

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

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

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

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

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

X. Nutritional information on the novel food

pp 17 – 19 of the application dossier

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

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

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

15. Alpha-linolenic acid is a significant contributor to the intake of n-3 polyunsaturated fatty acids (PUFA) and can be elongated and desaturated *in vivo* to its long-chain derivatives, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). However, in man the extent and regulation of this conversion is unclear[1].

16. Chia seed contains natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides) which confer a distinct technological advantage over alternative alpha-linolenic acid sources such as flaxseed, in terms of product stability and flavour quality.

17. Since Chia is intended to be used as a nutritional ingredient, any claims made on the food due to the inclusion of the seed or milled whole seed must comply with the general criteria for making nutrient content claims. Final products will need to be labelled with the ingredient name and the prescribed nutritional labelling according to Directive (79/112/EEC as amended).

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

XII. Microbiological information on the novel food

p 20 of the application dossier

18. Samples were taken from four consignments of Chia seeds for microbiological analysis. No pathogenic organisms were detected. No substances inhibitory to BHK21 (C-13) cells were detected in a cytotoxicity assay.

19. No mycotoxins were detected in the screen carried out on a composite sample from the four Chia consignments (the applicant describes this analysis under scheme XIII).

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

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

XIII. Toxicological information on the novel food

pp 21-27 of the application dossier

20. A number of human clinical studies were carried out to assess the safety of this product, including an allergenicity study, a 4-week dietary intervention study and a 12-week randomised, single blind crossover feeding trial.

21. The applicant has also provided details of two 8-week trials in laying hens and one 28-day study in broiler chickens which investigated the effects of Chia on hens' egg yolk composition and chicken breast and thigh muscle.

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

Allergenicity

p 21 - 22 of the application dossier

22. An investigation into potential allergenicity of Chia was carried out at BIBRA International Ltd., Surrey, Southampton University and King's College London. The study described in the report was carried out to internationally accepted standards of Good Laboratory Practice but was not subject to any Quality Assurance inspection programme. The study is summarised below and more detailed information can be found in the application dossier.

23. No allergy-associated properties of Chia seed have been reported in the literature to date and no verifiable cases of patients with allergies to common UK food plants with any botanical relationship to Chia have been found. Chia belongs to the Labiatae, or Laminiaceae, family. The plants of this family include mint, sage, thyme, basil, pennyroyal, lavender, lemon balm, bergamot, oregano and savory. An allergic response to oregano and thyme is cited in the report, however this is related to the leaf of the plant rather than the seed. Consequently the investigation was targeted at the peanut and tree nut allergens as the most likely source of cross-reactivity.

24. An initial IgE binding screen was carried out against a panel of 30 individuals by Multiple Allergy Screening Test (MAST), selected on the basis of their reactivity to peanut. Sera from peanut allergic subjects showed low levels of serological binding to Chia protein in immunoblots, although this binding varied considerably between different serum samples. Inhibition studies indicated that IgE binding to Chia was specific. However, it was considered that the binding of IgE to Chia protein did not necessarily imply that there would be coincidental clinical reaction to Chia.

25. IgE binding of Chia was further analysed using sera from five double-blind placebo-controlled food challenge (DBPCFC) peanut sensitive individuals. None of these individuals were reported to have allergy to sesame seeds although one had sensitivity to mustard. Immunoblotting demonstrated some IgE binding in these sera, however this was concluded to be non-specific in nature. Furthermore

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

26. Resistance to proteolytic digestion was investigated in Chia protein extracts using methodology based upon the recommendations of the 2001 Joint FAO/WHO expert consultation on foods derived from biotechnology. Immunoblot analysis demonstrated that all the Chia proteins were sensitive to peptic digestion with the exception of a 14kD band and protein bands below 6kD. The investigator suggests the 14kD band is non-specific cross-reactivity since this band was detected in the negative control serum.

27. Skin prick tests (SPT) were carried out on 12 individuals, selected because of sensitivity to peanut and tree nuts, to determine the clinical relevance of IgE binding activity observed in immunoblotting experiments. Two subjects gave positive SPT responses to Chia which were below the level of the histamine positive control challenge and therefore were considered of doubtful clinical significance. Both subjects were at the most broadly allergic end of the spectrum of sensitivities and both demonstrated sensitisation to sesame. Subsequent immunoblotting revealed a band that could represent an authentic IgE binding protein. This protein was shown to be susceptible to proteolytic digestion. The investigator speculates that this protein is related to sesame and its molecular weight could indicate it to be a profilin, a group of proteins associated with clinical food allergy.

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

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

Human clinical trials

pp 22-24 of the application dossier

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

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

29. Dose response effects of Chia were statistically analysed. Differences between groups were compared using one-way ANOVA, and differences within groups were compared using the paired t-test. According to the investigator, no significant health-related effects associated with consumption of high levels (10g) of Chia seed were detected. However, analysis of the adverse effects questionnaire revealed a significant effect of consumption of 5g per day on tiredness and fatigue. The study investigators concluded this to be an anomalous result since it was a single effect that was not dose-related. Consequently, no significant adverse effects on human health or well-being were seen after consumption of Chia, even at levels exceeding the anticipated mean daily intake.

30. The applicant also describes a human feeding trial carried out at the University of Toronto, Canada, on subjects with type-2 diabetes, investigating the effects of Chia on measures of glycaemic control and traditional and non-traditional risk factors of cardiovascular disease. A randomised single blind crossover trial using 20 subjects with type-2 diabetes was carried out for 12 weeks with individuals consuming 25g Chia/1000kcals. Fasting blood samples and blood pressure measurements were taken at 0 and 12 weeks.

31. The results suggested that when used as a food supplement, the consumption of Chia significantly lowered systolic blood pressure compared to controls and favourably altered coagulation factors. No adverse effects were reported including no change in bleeding times, liver function or kidney parameters and no adverse effects on glycaemic control.

Laying hen and broiler chicken trials

pp 24 – 27 of the application dossier

32. The applicant presents three studies carried out at Queens University, Belfast, in laying hens and broilers, to assess the nutritional and compositional effects on foods produced from animals fed a diet enriched with Chia. These tests do not examine toxicological endpoints.

33. Two laying hen trials investigated the effects of Chia on hens' egg yolk composition by manipulating the feed. The main aim of the first study was to alter the fatty acid composition of the egg yolk by manipulating the hen's diet. The diets were carefully formulated to be isoenergetic and were supplemented with either 1.5% soya oil, 1.5% fish oil or 14% whole Chia seed. No adverse effects were observed, but again no specific toxicity tests were carried out.

Evaluation of n-3 enriched eggs in humans

p25 of the application dossier

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

Additional information relevant to the application

p28 of the application dossier

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

Overall Discussion

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

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

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

Conclusion

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

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

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

April 2004