

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

ARRACACHA ROOT (*Arracacia xanthorrhiza*)

Issue

The Spanish Competent Authority (CA) has prepared an initial opinion on an application for the authorisation of Arracacha root (*Arracacia xanthorrhiza*) as a novel food ingredient under the Novel Food Regulation (EC) No. 258/97. The Committee is asked whether it agrees with the conclusions of the Spanish CA and whether it has any further comments or objections to make on the application. The Committee's advice will form the basis for the UK's formal response.

Introduction

1. On 11 August 2009, the European Commission (EC) forwarded the Spanish CA's initial opinion on an application made by Euroandina De Importaciones SL under Article 4(1) of Regulation (EC) 258/97, for the authorisation of yellow precooked IQF* Arracacha root (*Arracacia xanthorrhiza*). Under the time scales set out in the regulation, the UK and other Member States have until 10 October 2009 to provide comments and/or reasoned objections to the initial opinion
2. *Arracacia xanthorrhiza* is a biennial plant grown primarily in Columbia, but also throughout the Andean Highlands of South America: Venezuela, Northern Chile and North Western Argentina. The root of *A. xanthorrhiza* is consumed as an alternative to potatoes, yams etc. and the applicant refers to a number of varieties with different phenotypic characteristics including a number of different colours. However this application is solely for the yellow variety which, according to the applicant, is the most widely consumed. Reference to 'Arracacha' in this paper therefore refers solely to the yellow precooked IQF Arracacha root which is the subject of this application.
3. This application, like the application for Baobab Fruit Pulp that was given a favourable opinion by the ACNFP in 2007 and subsequently authorised in 2008, draws extensively on traditional use, which the applicant considers provides adequate reassurance regarding the safety of the product, thereby reducing the need for conventional safety studies that are normally required for a novel food application.
4. The Spanish Initial Assessment Report is attached as **Annex 1** (restricted). The dossier provided by the applicant is attached as **Annex 2** (restricted).

* Individually Quick Frozen

Background

5. This application is for the use of pre-cooked Arracacha root as a food ingredient. In accordance with Regulation 258/97, CMC falls under Article 1(2)(e): foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals. This corresponds to Class 2.2 under Commission Recommendation 97/618/EC, which sets out the guidelines for novel food applications. The requirements for a submission for this class are as follows:

I	Specification of the NF	X
II	Effect of the production process applied to the NF	X
III	History of the organism used as the source of the NF	X
IV	Effect of the genetic modification on the properties of the host organism	-
V	Genetic stability of the GMO	-
VI	Specificity of expression of novel genetic material	-
VII	Transfer of genetic material from GM micro-organisms	-

VIII	Ability to survive in and colonise the human gut	-
IX	Anticipated intake/extent of use of the NF	X
X		X
XI	Nutritional information on the NF	X
XII	Microbiological information on the NF	X
XIII	Toxicological information on the NF	X

I. Specification of the novel food

Annex 2, p.5-19

6. Arracacha (*Arracacia xanthorrhiza*) is a perennial plant which belongs to the family Umbelliferae (apiaceae). There are a number of names for the root including Arracacha, which is the name used in Columbia, the country where the product has the most extensive use and which is the subject of this application.
7. The application dossier includes information that is not of direct relevance to the specification and Members are directed to pages 17-19 of Annex 2, which concerns the composition of Arracacha. The product, which will be marketed initially in Spain, will be produced in a precooked IQF form including, but not restricted to, chunk and flaked forms. The applicant has provided an analysis of three batches of Arracacha carried out by the Columbian producer (CI Listo Y Fresco LTDA), which is summarised below and can also be seen in Table 3, p18 Annex 2. This indicates that Arracacha predominantly comprises water and starch with smaller quantities of protein fat and fibre, and a number of trace minerals and vitamins. No anti-nutrients are reported in the compositional analysis.

Composition of Arracacha (% or quantities per 100g)

Nutritional Composition			
	Lot 1	Lot 2	Lot 3
Humidity	73%	75%	74%
Calories	103 kcal	105 kcal	104 kcal
Ash	1.2%	1.4%	1.3%
Carbohydrates	28.70%	25.40%	24.70%
Proteins	0.90%	0.11%	0.86%
Fibre	0.75%	0.95%	0.75%
Starch	21.00%	24.51%	22.50%
Lipids or fat	0.20%	0.36%	0.26%
Ascorbic acid or vitamin C	22 mg	24 mg	23 mg
Calcium	34.2 mg	29.2mg	32.1mg
Thiamine or vitamin B1	0.1 mg	0.1 mg	0.1 mg
Niacin	4.35 mg	4.45 mg	4.15 mg
Vitamin A	1.75 mg	1.77 mg	1.76 mg
Phosphorus	45 mg	55 mg	52 mg
Potassium	2.3mg	2.4 mg	2.1mg
Magnesium	64.0mg	64.1mg	62.1mg
Iron	8mg	10 mg	9mg
Microbiological characteristics	Total Coliforms	0/g	
	Faecal Coliforms	0/g	
	E. Coli	0/g	

The Spanish CA considered that the compositional analyses provided by the applicant was adequate and accepted the applicants' view that there were no known anti-nutrient or toxic factors. The Spanish CA also noted that the compositional analysis carried out by the applicant was consistent with published analyses.

The Spanish CA also noted that precooking would limit the activity of certain enzymes that might have a deleterious effect on some vitamins.

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

Annex 2, p23-25

- The applicant provides a detailed overview of the production process and highlights the key procedures that are employed by the producer to ensure that the only best quality roots are used. As the majority of the production process relates to precooking, freezing and distribution aspects, these are not reproduced (see Table 4 on pp21-22 of Annex 2). Of more relevance to the safety of Arracacha is that the producer follows HACCP Guidelines and that the product has been exported to the USA for a number of years.

The Spanish CA noted that the production process and quality control program was standard for precooked, frozen food. At the request of the Spanish CA the applicant

submitted a number of batches of Arracacha for aflatoxin and pesticide residue screening. All batches were reported to be negative [Results not available].

III. History of the source organism

Annex 2, p. 26-48

9. The applicant gives an overview of dietary uses of Arracacha, noting that it can be used like a potato and has a wide range of uses in traditional cuisine. In addition to documenting its uses in a number of South American countries, the applicant highlights use as a baby (presumably weaning) food in Brazil by Nestle-Brazil. They also refer to a UN Food and Agriculture Organisation (FAO) report *Traditional dishes of Latin America* which refers to the traditional use of Arracacha in Columbia. Certain aspects of the information are not relevant in the consideration of the safety of the product (e.g. best growing conditions), but when viewed as a whole this information demonstrates the widespread use of Arracacha in a number of South American countries. This is borne out by Columbian cultivation figures which record a marked increase in the cultivation of *A. xanthorrhiza* in the 20 years to 2006. The applicant has not provided any indication of the level of use prior to 1987 but note that production is generally at a very local level on a large number of small holdings rather than by large farming operations.
10. The applicant also highlights that a number of codes exist for Arracacha which appear in FAO Food Composition Tables. The applicant views the inclusion of Arracacha in the FAO tables as evidence that it is a safe and nutritious food source. The applicant also provides evidence of cultivation in Peru and Ecuador. In Peru there appears to have been a government led enterprise in encouraging the cultivation of Arracacha in poorer areas. In Ecuador consumption is predominantly in two geographical regions and the applicant has provided sales information which appears to indicate that, where Arracacha is most popular, it is consumed at least weekly. The applicant also highlights that Arracacha is recognised by the FAO as being on sale in Bolivia and Brazil.

The Spanish CA reviewed the information provided by the applicant and, although they note that a direct link between cultivation data and level of consumption can not necessarily be made, the fact that the Arracacha is included in FAO Food Composition Tables indicates that its consumption 'as part of the standard diet in the area of origin is well established'.

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

Annex 2, p.55-57

11. The applicant indicates that Arracacha will be marketed in Spain in the first instance and, as they are of similar composition, will be marketed in addition to, or as an alternative to, potato and cassava, yams and carrots.

The Spanish CA accepted that the characteristics of Arracacha would be appropriate for the food uses described.

XI. Nutritional information on the novel food

Annex 2, p.58-67

12. The applicant again presents the compositional information detailed in Section 1 (above) and also indicates that Arracacha is a rich source of niacin (vitamin B3), vitamin A and C, iron and phosphorus. A nutritional comparison of yellow Arracacha with its white and purple counterparts show that the yellow form contains significantly more Vitamin A (190 IU, compared with 10 and 20 IU respectively). The applicant also highlights literature reviews of the composition of Arracacha (a) when grown in across South America, (b) when compared with other root crops (c) amino acid and (d) vitamin content, and none of these appear to detail any significant differences or issue of particular concern.

The Spanish CA conclude that Arracacha would play much the same role in the diet as potatoes and other starchy foods. The Spanish CA also acknowledged that Arracacha contains significant niacin and Vitamin C.

XII. Microbiological information on the novel food

Annex 2, p.67-68

13. The applicant's compositional analysis (See Section 1 above) indicates that Arracacha is tested for and is free from coliform bacteria. The applicant highlights the use of potable water in the washing stage, pre-cooking in direct steam, and freezing as steps which would minimise the likelihood of contamination by pathogenic bacteria. The applicant also details the microbial load at various points during the production process, which indicate the absence of coliform bacteria at each stage.

The Spanish CA was content that the microbiological analysis carried out by the applicant did not highlight any issues of concern.

XIII. Toxicological information on the novel food

Annex 2, p.68-94

14. This applicant highlights that Arracacha is a traditional food widely consumed in South America and that there no are reports of toxicological concern in the scientific literature¹. They contend that, in the absence of such reports and of any anti-nutrients, there is no reason to carry out a detailed toxicological analysis. This is consistent with the approach taken in the 2007 application for the novel food Baobab Fruit Pulp (see para 3 above). The applicant uses the concept of "nutritional equivalence" to demonstrate that Arracacha is broadly similar to cassava and potatoes when consumed in the diet. Given that the three products are taxonomically distinct, however, this information is limited to a compositional

¹ This has been confirmed by safety experts in the Food Standards Agency

comparison and is of limited relevance in the context of toxicological concerns as the presence of toxins or anti-nutrients would be genus (or even species) specific.

The Spanish CA noted that the widespread traditional use of Arracacha (supported by the inclusion in the FAO Compositional Tables), together with the absence of negative reports in the scientific literature were important factors. Noting that Boabab was an appropriate precedent for Arracacha, they agreed with the applicant that there was nothing to indicate that anitnutrients or toxic factors would be present and that no negative effects or allergies are to be expected following consumption of the novel ingredient.

Committee Action Required

15. The Committee is asked whether it agrees with the initial opinion from the Spanish CA that Arracacha meets the criteria for the acceptance of a novel food or whether it has any additional comments on the application.

**Secretariat
September 2009**

Annexes attached:

Annex 1 – Spanish Competent Authority's initial assessment report
(RESTRICTED)

Annex 2 – Application dossier (RESTRICTED)

ACNFP/94/8 Annex 1

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

RESTRICTED

Spanish Competent Authority's Initial Assessment Report

**Secretariat
September 2009**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

RESTRICTED

Application dossier for the approval of yellow precooked IQF Arracacha root
(*Arracacia xanthorrhiza*) as a novel food ingredient

**Secretariat
September 2009**