

SCIENTIFIC OPINION

Scientific Opinion on the safety of *Arracacia xanthorrhiza* as a novel food¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

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ABSTRACT

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on the safety of “*Arracacia xanthorrhiza*”. This novel food (NF) comprises pre-cooked and individually quick-frozen slices, chunks and “*other formats*” of the roots of *Arracacia xanthorrhiza* Bancroft (arracacha roots). *Arracacia xanthorrhiza* var. *xanthorrhiza* (cultivated) is one of three varieties of this species. In the original application the analytical methods employed for the batch testing of these three lots from 2008 had not been described and certificates regarding the accreditation of the laboratory had been missing. No data on secondary plant metabolites were provided. The applicant provided data on cultivation, production tonnage and human consumption, including information on the preparation and recipes for arracacha used in South American countries. According to the applicant, arracacha is consumed in the same way as other crops such as potato, cassava, yam or carrot. The NF is intended for human consumption in dishes such as “sudados”, soups and stews. EFSA requested the applicant to provide information on potential “*other formats*” of the NF intended by the applicant, compositional data on a current lot of the NF covering all analyses contained in the specifications of the NF as proposed in the original application and analysed by a certified laboratory and analytical data on the presence of secondary metabolites, in particular of coumarin and monoterpene derivatives. EFSA also asked for details on the two-step steam heating process, in particular time – temperature conditions. As the applicant did not respond to the request by EFSA, the Panel cannot conclude on the safety of the NF.

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KEY WORDS

Arracacia xanthorrhiza, novel food, arracacha

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SUMMARY

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on the safety of “*Arracacia xanthorrhiza*” as a novel food.

This novel food (NF) comprises pre-cooked and individually quick-frozen slices, chunks and “*other formats*” of the roots of *Arracacia xanthorrhiza* Bancroft (arracacha roots). *Arracacia xanthorrhiza* var. *xanthorrhiza* (cultivated) is one of three varieties of this species. In the original application the analytical methods employed for the batch testing of these three lots from 2008 had not been described and certificates regarding the accreditation of the laboratory had been missing. No data on secondary plant metabolites were provided. The applicant provided information on the cultivation and the subsequent processing of the root. The growing practices are usual for root vegetables grown for consumption. The manufacturing process is standard for cut and frozen vegetables and includes selection of raw material, washing, abrasion peeling, dry cutting, steam pre-cooking in two stages, cooling, individual quick freezing, packaging, metal detection and frozen storage.

The applicant stated that arracacha is considered one of the oldest domestic plants in the Americas, and that the earliest documents concerning the arrival of Europeans on that continent contain references to its consumption by the native population. Documents published by the FAO (1992) suggest that, although its domestication may well predate that of the potato, the fact that it can only grow under certain conditions has prevented it from spreading around the world. In the regions of origin, arracacha is sold fresh. The root is eaten boiled or fried in various preparations, such as salads, soups, purées, cakes, etc., in much the same way as other crops, e.g. potato or cassava. The product has been the subject of various studies conducted by the International Centre for Tropical Agriculture and the International Potato Centre.

According to the applicant, arracacha is consumed in the same way as other crops such as potato, cassava, yam or carrot. The NF is intended for human consumption in dishes such as “*sudados*”, soups and stews. People of South American origin living in Spain are the primary target group of the NF. Arracacha is included in the FAO Food Composition Table for use in Latin America and in the Composition Table of the most consumed foods in various Andean countries. The applicant provided information on the estimated annual marketed volumes of arracacha and on the cultivated areas in various South American countries. The main producer of arracacha is Colombia, with a production of approximately 111 000 metric tons per year. Other producing countries are Venezuela, Ecuador and Peru. For three locations in Ecuador, annual per capita purchases of arracacha roots (5–10 kg) have been reported.

No toxicological data and no information on the potential allergenicity of the NF have been provided.

EFSA requested the applicant to provide information on potential “*other formats*” of the NF intended by the applicant, compositional data on a current lot of the NF covering all analyses contained in the specifications of the NF as proposed in the original application and analysed by a certified laboratory and analytical data on the presence of secondary metabolites, in particular of coumarin and monoterpene derivatives. EFSA also asked for details on the two-step steam heating process, in particular time–temperature conditions. As the applicant did not respond to the request by EFSA, the Panel cannot conclude on the safety of the NF.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

On 05 February 2009, the company Euroandina de Importaciones S.L (Madrid, Spain) submitted a request under Article 4 of the Novel Food Regulation (EC) N° 258/97 to place on the market '*Arracacia xanthorrhiza*' as a novel food.

On 01 June 2009, the competent authorities of Spain forwarded to the Commission their initial assessment report, which came to the conclusion that '*Arracacia xanthorrhiza*' meets the criteria for acceptance as a novel food.

On 11 August 2009, the Commission forwarded the initial assessment report to the other Member States. Several of the Member States submitted comments or raised objections.

The concerns of a scientific nature raised by the Member States can be summarized as follows:

- The applicant did not provide detailed compositional analysis for the novel food. Furthermore, the application documents do not show whether the test body holds an internationally recognised accreditation for the analysis in question.
- The specification should state which *Arracacia* species is to be used for the product in question.
- The arracacha belongs to the *Apiaceae* family, which is characterised by the presence of secretory ducts, found mainly in the roots, containing toxic aromatic compounds such as terpenes or coumarins. As the aromatic terpenes and coumarins are easily steam-distilled, they are likely to be eliminated by traditional cooking and preparation methods. However, the applicant has not provided evidence that his heating process effectively eliminates these potentially toxic compounds. The applicant should provide analytical data relating to the terpene and coumarin compounds in the product offered to consumers.
- The declared vitamin A content is particularly high (1 700–1 900 mg/100g); this should be checked again and the nature of the vitamin A present in the food should be specified.
- The applicant did not present any analytical data to confirm the absence of potential antinutrients/toxicants/contaminants in *Arracacia xanthorrhiza*, and in related species within the family of *Apiaceae*. In the initial test, AESAN had tests for plant protection agent residues and aflatoxins carried out by the *Centro Nacional de Alimentacion*, which it stated were negative. No reports of these analyses are available.
- There is no reference on the potential allergenicity, though *Arracacia xanthorrhiza* belongs to a family (*Apiaceae*) which includes members with allergenic properties such as celery (*Apium graveolens*). Special concern raised was cross reactivity and adverse reactions to celeriac amongst birch pollen allergic individuals possibly reacting in a similar manner to arracacha root.
- Recommendations should be made on shelf life and suitable storage conditions, as well as on traditional use and usual methods of preparation.
- The roots are said to keep for only a few days. The applicant did not go into this specific aspect when describing the manufacturing process. Further information, especially with regard to the timetable for harvesting the novel food and the quality assurance measures, should be requested.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Food Safety Authority is asked to carry out the additional assessment for '*Arracacia xanthorrhiza*' as novel food in the context of Regulation (EC) N° 258/97.

EFSA is asked to carry out the additional assessment and to consider the elements of scientific nature in the comments raised by the other Member States.

ASSESSMENT

In accordance with the Recommendation 97/618/EC “*Arracacia xanthorrhiza*” is allocated to class 2.2, “Complex NF from non-GM source; the source of the NF has no history of food use in the Community”. The assessment of the safety of this novel food is based on data supplied in the original application, the initial assessment by the competent authority of Spain, the concerns and objections of the other Member States (MSs) and the applicant’s response to MSs’ comments. The data are required to comply with the information required for novel foods of class 2.2, i.e. structured schemes I, II, III, IX, X, XI, XII and XIII. This assessment concerns only risk that might be associated with consumption and is not an assessment of the efficacy of “*Arracacia xanthorrhiza*” with regard to any claimed effects.

1. Specification of the novel food (NF)

The NF comprises pre-cooked and quick-frozen slices, chunks and “other formats” of the roots of *Arracacia xanthorrhiza* (arracacha roots). The final product is marketed in polyethylene/polyester packages of 250, 500, 1 000 and 2 000 g.

EFSA asked the applicant to provide information on potential “other formats”, but the applicant did not respond to EFSA’s question.

Arracacia xanthorrhiza is a perennial plant that belongs to the family of *Umbelliferae* (*Apiaceae*). According to the applicant, 12 species of the genus *Arracacia* have been identified along the Andean Cordillera in South America. The source of the NF is the root of the species *Arracacia xanthorrhiza* Bancroft. *Arracacia xanthorrhiza* var. *xanthorrhiza* (cultivated) is one of the three varieties of this species. Based on the colour of the root flesh (white, yellow and purple), three morphotypes of the variety are differentiated. In the response to the MSs’ comments, the applicant specified that the novel food will be produced from *Arracacia xanthorrhiza* var. *xanthorrhiza* (cultivated) yellow morphotype.

The applicant provided literature data on the composition of fresh yellow *Arracacia xanthorrhiza* roots (Table 1).

Table 1: Compositional data on fresh yellow *Arracacia xanthorrhiza* roots

	Colombian Family Welfare Institute (1992)	Peruvian Network of Nourishment and Nutrition (1993)
Water (%)	72.8	75.1
Carbohydrates (%)	24.0	22.9
Protein (%)	0.9	0.7
Fat (%)	0.1	0.3
Fibre (%)	1.0	1.1
Ash (%)	1.2	1.0
Vitamin A (i.u.) ^(a)	190	—
Thiamine (mg/100 g)	0.06	0.09
Riboflavin (mg/100 g)	0.04	0.08
Niacin (mg/100 g)	2.8	2.8
Ascorbic acid (mg/100 g)	20	27.1
Energy (kcal/100 g)	100	97

(a): Calculated from the beta-carotene content.

The applicant presented compositional data on three individual lots of the NF produced in 2008 and proposed the specification shown in Table 2.

Table 2: Compositional data on individual lots of the NF and specification as proposed by the applicant

	Lot 1	Lot 2	Lot 3	Specification
Water (%)	73	75	74	64–82
Carbohydrates (%)	28.7	25.4	24.7	19–30
Starch (%)	21.0	24.5	22.5	16–22
Fibre (%)	0.75	0.95	0.75	0.6–1.25
Protein (%)	0.9	0.11	0.9	0.–1.85
Lipids (%)	0.20	0.36	0.26	0.2–0.35
Ash (%)	1.2	1.4	1.3	1.05–1.40
Ascorbic acid (mg/100 g)	22	24	23	20–27
Thiamine (mg/100 g)	0.07	0.09	0.08	0.06–0.10
Niacin (mg/100 g)	4.4	4.5	4.2	2.8–4.5
Calcium (mg/100 g)	34.3	29.2	32.1	26–35
Phosphorus (mg/100 g)	45	55	52	45–60
Potassium (mg/100 g)	2.3	2.4	2.1	2.0–2.5
Magnesium (mg/100 g)	64.0	64.1	62.1	60–65
Iron (mg/100 g)	8.4	9.5	9.0	9–10
Total coliforms (per g)	0	0	0	< 3
Faecal coliforms (per g)	0	0	0	< 3
<i>E. coli</i> (per g)	0	0	0	< 3
Energy (kcal/100 g)	103	105	104	96–126

In the original application, the analytical methods employed for the batch testing of these three lots from 2008 had not been described and certificates regarding the accreditation of the laboratory had been missing. In response to the MSs' comments, the applicant provided an additional set of compositional data and two certificates of accreditation for the laboratory which performed the analysis. However, the Panel notes that (i) the list of parameters was different from the set forming the basis of the specifications proposed in the original application; (ii) it remained unclear whether or not the new analyses have been performed by the same laboratory as the original data; and (iii) the descriptions of the analytical methods provided were not sufficiently detailed.

EFSA therefore asked the applicant to provide compositional data (i) on a current lot of the Novel Food, (ii) elaborated by the certified laboratory and (iii) covering all analyses contained in the specification of the NF as proposed in the original application. The applicant did not respond to EFSA's question.

The MSs pointed out that the pro-vitamin A content of the product declared in the original application was particularly high (1 700–1 900 mg/100 g) and that the nature of the pro-vitamin A present in the food should be specified. The applicant responded that an error was made regarding the vitamin A content and presented a new value of 21.92 IU/100 g (calculated from the content of beta-carotene) for the final product (only one sample tested).

EFSA asked the applicant (i) to provide data on the methodology employed, (ii) to provide new data on the pro-vitamin A content in at least three lots of the NF and (iii) to propose a range for the specification. The applicant did not respond to EFSA's questions.

Arracacia xanthorrhiza belongs to the family *Umbelliferae* (*Apiaceae*). Several members of this botanical family have been described to contain secondary plant metabolites, such as phthalides, coumarins, terpenoids and flavonoids. In studies on the related species *Arracacia vaginata* and *Arracacia nelsonii* the presence of pyranocoumarins, phenylpropanoids and monoterpenoids has been reported (Calderon and Rios, 1975; Delgado and Garduno, 1987). The extract of air-dried aerial parts of *Arracacia toluensis* var. *multifada* has also been described to contain several coumarins, e.g. 8-methoxypsoralen and 5-methoxypsoralen (Figueroa et al., 2007). No data on the presence of these secondary metabolites in the NF have been provided.

EFSA asked the applicant to provide analytical data on the presence of these metabolites, in particular of coumarin and monoterpene derivatives in the NF. The applicant did not respond to EFSA's question.

2. Effect of the production process applied to the NF

The applicant provided information on the method of both the cultivation and the subsequent processing of the root. The growing practices are the usual ones for root vegetables grown for consumption. The applicant described these practices and listed the pests and diseases that normally affect this species. The manufacturing process is standard for cut and frozen vegetables and includes selection of raw material, washing, abrasion peeling, dry cutting, steam pre-cooking in two stages, cooling, individual quick freezing (−34 °C, 17 minutes), packaging, metal detection and frozen storage.

The final product is “precooked individual quick frozen arracacha in the form of flakes and/or chunks”.

For the stability of the product, the applicant presented a study carried out for one batch of arracacha, between February 2009 and March 2010. This study analysed the microbiological, physico-chemical and organoleptic characteristics. The results obtained indicated that there were no variations in this period of time, and the organoleptic properties were maintained.

According to the applicant, the firm that carries out the production process applies a quality control programme at all stages and has a HACCP (Hazard Analysis and Critical Control Points) certificate. It holds BASC certification issued by the World BASC Organization Inc. (system for the management and administration of security and control of company activities), and Health Registration (RSAV0512506) issued by the Instituto Nacional de Vigilancia de Medicamentos y Alimentos de Colombia (INVIMA, Colombian National Medicine and Food Surveillance Institute), which authorises the production and sales of pre-cooked and frozen vegetable products.

EFSA asked the applicant to provide conditions of the two-step steam heating process. In addition, the applicant was asked to provide the HACCP certificate for the manufacturing process. The applicant did not respond to EFSA's questions.

3. History of the organism used as a source

The applicant stated that arracacha is considered one of the oldest domestic plants in the Americas, and that the earliest documents concerning the arrival of Europeans on that continent contain references to its consumption by the native population. Documents published by the FAO (1992) suggest that, although its domestication may well predate that of the potato, the fact that it can grow only under certain conditions has prevented it from spreading around the world.

In the regions of origin, arracacha is sold fresh. The root is eaten boiled or fried in various preparations, such as salads, soups, purées, cakes, etc., in much the same way as other crops, e.g. potato or cassava.

The product has been the subject of various studies conducted by the International Centre for Tropical Agriculture (CIAT, Centro Internacional de Agricultura Tropical) and the International Potato Centre (CIP, Centro Internacional de la Papa).

The applicant claims that arracacha is included in the diets of babies and young children and convalescing patients (Pérez et al., 1999; Rodríguez Borray et al., 2000; Rodríguez et al., 2005).

The applicant provided information on traditional recipes from different countries using both the fresh root and the flour made from it.

4. Anticipated intake/extent of the use of the NF

According to the applicant, arracacha is consumed in the same way as other crops such as potato, cassava, yam or carrot. The NF is intended for human consumption in dishes such as “sudados”, soups and stews.

According to the applicant, people of South American origin living in Spain are the primary target group of the NF.

5. Information from previous exposure to the NF or its source

Arracacha is known under several different names in South America. It is included in the FAO Food Composition Table for use in Latin America and in the Composition Table of the most consumed foods in various Andean countries.

The applicant provided information on the estimated annual marketed volumes of arracacha and on the cultivated areas in various South American countries. The main producers of arracacha are Colombia, with a production of approximately 111 000 metric tons and a cultivation area of approximately 10 000 ha), and Brazil with 90 000 metric tonnes a year (CCI, 2006). Other producing countries are Venezuela, Ecuador and Peru.

The applicant indicated that current production is intended almost exclusively for human consumption. However, no actual data on human consumption have been provided. For three locations in Ecuador, annual per capita purchases of arracacha roots and tubers (5–10 kg) have been reported.

6. Nutritional information on the NF

The applicant presented nutritional composition tables taken from the literature and the analysis values of three batches produced (section 1).

7. Microbiological information on the NF

The applicant provided results of microbiological testing at various stages of the production process (section 1).

8. Toxicological information on the NF

No toxicological information has been provided. The applicant emphasised that arracacha has a long history of use and consumption in Latin America and that no negative effects have been reported.

Some MSs pointed out in their comments that there is no reference on the potential allergenicity, although *Arracacia xanthorrhiza* belongs to a family (*Apiaceae*) which includes members with allergenic properties, such as celery (*Apium graveolens*). No information has been provided on allergenicity of the NF.

DISCUSSION

EFSA requested the applicant to provide information on potential “*other formats*” of the NF intended by the applicant, compositional data on a current lot of the NF covering all analyses contained in the specifications of the NF as proposed in the original application and analysed by a certified laboratory and analytical data on the presence of secondary metabolites, in particular of coumarin and monoterpene derivatives. EFSA also asked for details on the two-step steam heating process, in particular time–temperature conditions. As the applicant did not respond to the requests by EFSA, the Panel cannot conclude on the safety of the NF.

CONCLUSIONS

The Panel concludes that the data provided by the applicant are not sufficient to establish the safety of ‘*Arracacia xanthorrhiza*’ as a novel food.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier on “Yellow precooked IQF-frozen Arracacha (*Arracacia xanthorrhiza*) as a novel food for human consumption”, submitted by Euroandina de Importaciones S.L. (Madrid, Spain), received on 6 September 2011.
2. Letter from the European Commission to the European Food Safety Authority with the request for an opinion on the safety of *Arracacia xanthorrhiza* as a novel food. Ref. Ares (2011)944570—06/09/2011.
3. Initial assessment report carried out by the competent authority of Spain, “Pre-cooked and frozen arracacha (*Arracacia xanthorrhiza*), pursuant to Regulation (EC) No 258/97 concerning novel foods and novel food ingredients”.
4. Member States’ comments and objections.
5. Response by the applicant to the initial assessment report and the Member States’ comments and objections.

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ABBREVIATION

NF novel food