Committee paper for discussion ACNFP/140/01

Advisory Committee on Novel Foods and Processes

Roasted sacha inchi seeds – Traditional food notification NF2018/752

Issue

1. A notification for roasted sacha inchi seeds, a traditional food from a third country, has been received under Regulation (EU) No 2015/2283.

2. The Committee is asked whether there are safety concerns with the proposed use of this traditional food in the EU market. The information from the Committee will provide the basis for any safety objections raised at EU level and for risk management decisions made by the UK.

Background

3. On the 30 November 2019 the European Commission received a notification from PROMPERU for authorisation of roasted sacha inchi seeds. The applicant intends to market the product within the food categories: Legumes, Oilseeds and Spices, to be consumed as a snack.

4. Member States have four months until 30 March 2020 to submit reasoned objections to the notification. If authorised, the authorisation will be open to any company subject to the specification and conditions of use detailed in the dossier.

5. The notification dossier is attached as **Annex A**. Relevant supporting information is attached as **Annex B.** Both contain confidential information. **Annex C** lists all the documents provided by the applicant.

This application

Identification

6. The applicant describes the product as the seed of the Amazon-native oleaginous plant *Plukenetia volubilis* Linnaeus. Other common names for it are sacha inchic, sacha peanut, mountain peanut and Inca peanut. The seed is intended to be consumed whole after removing the shell and roasting.

7. They indicate the seeds are a source of oil with high omega-3 content and that it has been used traditionally by numerous Amazonian ethnic groups in Peru. The oil of sacha inchi was authorised as a novel food under the substantial equivalence process of 258/97 EC due to its similarity to linseed oil.

Production Process

8. The applicant states that the production of seeds follows the Peruvian Technical Standards, which include good practice guidelines for cultivation, traceability, postharvest management, storage, roasting and requirements for the final roasted sacha inchi seeds product.

9. They describe how the seeds are washed in hot water and then roasted in a roasting machine at a temperature not higher than 120°C for no more than 30 minutes.

Composition

10. The application references data from five different batches, providing information on proximate analysis (**Table 1**)

Parameter	Method	Unit	Result	Result	Result	Result	Result	Limit of Quantification
Carbohydrates	Methods of Analysis for Nutrition Labelling 1993, Page 8	%	7.20	10	10.37	7.38	9.48	0.10
Ash	AOAC 950.49(B):2016; 20th Ed Ash of Nuts and Nuts Products Method II	g/100g	2.87	2.63	2.65	2.77	2.62	-
Energy	Methods of Analysis for Nutrition Labelling-AOAC 1993	Kcal/100g	639	599	602	638	597	-
Fibre (Crude)	AOAC 962.09:2012 20th Ed Fiber (Crude) in Animal Feed and Pet Food Ceramic Fiber Filter Method	%	2.88	4.78	4.63	2.78	4.09	0.10
Dietary Fibre	AOAC 985.29:2012; 20th Ed. 2016 Total Dietary Fiber in Foods Enzimatic Gravimetric Method	%	7.5	9.7	9.5	7.3	9.5	1.0
Fat	AOAC 948.22 (a):2012, 20th Ed 2016 (Crude) in nuts	g/100g	53.75	47.22	47.85	53.41	47.17	-
Moisture	AOAC 925.40:2016, 20th Ed Moisture in Nuts and Nuts Products	g/100g	1.79	1.82	2.14	1.64	2.96	-
Protein (N x 6.25)	AOAC 950.48:2016, 20th Ed Protein (Crude) in Nuts and Nuts Products	%	31.51	35.55	32.36	32.02	33.68	0.30

Table 1 Results of proximate analysis of roasted sacha inchi seeds

11. The applicant claims that the product can be considered as high protein, since more than 20% of the energy content comes from proteins. Similarly, they consider the product as high in fibre, with a fibre content of more than 6g/100g. The average vitamin E content is 10mg/100g, which, in a single serve pack of 28g, would exceed 1.8mg, and hence the food could be labelled as a source of vitamin E.

12. The seeds of sacha inchi are described as containing antinutritional factors in the form of saponins, alkaloids and lectins. The applicant provided analytical data and evidence from the scientific literature supporting the liable nature of these phytotoxins and their reduction in concentration from the raw form of the seed to the washed and roasted final product. Lectins were found at concentrations below the detection limit of 0.01% (100mg/kg). Original test results were provided by the applicant.

13. Data on microbial analysis was also provided in the laboratorial reports.

Contaminants

14. The applicant provided data on laboratory analysis of 5 batches of the product for mycotoxins, pesticides, heavy metals, PAHs , dioxins and PCBs. The original lab results were provided by the applicant. They also provided a rationale for levels above the limit of detection and a comparison with EFSA reference levels whenever possible.

Stability

15. Based on a test of accelerated shelf life, the applicant estimates the shelf life of the product to be 1.5 years, when stored at 25^{o}C and factoring in the peroxide index, moisture, and microbiological levels. The original test was provided and can be found in **Annex B**.

Specifications

16. The application presents three specification tables for physical and chemical properties, microbes and mycotoxins, presented below. The applicant refers to the specifications of the Peruvian Technical Standards as the best reference for roasted sacha inchi seeds.

Requirement	**Range**
Moisture	No greater than 3g/100g
Acid Value (expressed as oleic acid)	No greater than 2g/100g
Fat	No less than 43g/100g
Protein	No less than 26g/100g

Table 2 Physical and chemical properties of sacha inchi seeds

	Maximum Level
Aflatoxin B_1	5µg/kg
Sum of Aflatoxins (B_1, B_2, G_1, G_2)	20µg/kg

Table 3 Microtoxin properties of sacha inchi seeds

Micro-organism	**Category**	**Class**	**n**	**c**	**Limit per Gram (m)**	**Limit per Gram (M)**
Moulds (CFU/g)	3	3	5	1	10^2	10^3
Yeasts (CFU/g)	3	3	5	1	10^2	10^3
Escherichia coli (MPN/g)	5	3	5	2	10	10^2
Total Coliforms (MPN/g)	5	3	5	2	10	10^2
Salmonella sp.	10	2	5	0	Absent/25g	--------
Aerobic mesophiles (CFU/g)	2	3	5	2	10^4	10^5

Table 4 Microbial properties of sacha inchi seeds

Where:

n = Number of samples tested
C = Maximum number of rejected samples allowed
m = Values less than or equal to m are acceptable. Values greater than m are acceptable up to the limit of M
M = Values greater than M are acceptable and present a health risk.

History of Continued Use/Traditional Use

Literature review

17. The applicant performed a literature review by accessing the database compiled by the Technical Board of Sacha Inchi and the BioTrade Research Group (GIB), as well as databases accessible through the National Council for Science, Technology and Technological Innovation (CONCYTEC). The search focused on published scientific research on toxins in *Plukenetia volubilis* seeds, history of use of the seed in Peru, grey literature relating to consumption and data on chemical analysis. The search terms used were not specified. They included scientific publications on botanical, physico-chemical, biological and microbiological characterization of the species, belonging to a peer-reviewed database. The list of references cited were provided by the applicant.

Extent of use

18. The review describes the consumption practices of sacha inchi seeds going back to the pre-Inca period, between 3,000 and 5,000 years ago. If remained a common practice amongst native ethnic groups in Peru until the late 70's when the discovery of the seed's oil as a source of omega-3 fatty acids increased the product's demand, becoming more widely available in the country.

19. In 2008 efforts started to export the product internationally and develop the Peruvian Technical Standards for the production of sacha inchi seeds. Data presented from 2015 shows 2,377ha of land dedicated to the production of the seed, with a total yield of 4,393 tonnes of sacha inchi. For that same year, international exports constituted more than $320,000, which in 2017 grew to $4,055,927.

20. The application recognises a lack of data regarding the consumption of roasted sacha inchi as snacks, but shows several recipes containing the toasted seed in quantities that go from 25g to 80g of roasted sacha inchi per person. References were provided by the applicant.

Consumers and role in the diet

21. A description of the location and quantification of the ethnic groups known to consume sacha inchi across different Peruvian regions was provided. These populations go from groups of 82 to larger populations of more than 3,000 individuals. The seed is said to be consumed daily in different dishes and also stored and conserved for times of shortages. It is recognised that there is no data on frequency of consumption of sacha inchi snacks, but that it is an ingredient used in different recipes an consumed all year round, with reports of the snack being popular in Japan, South Korea and Canada, and the seed being cultivated in Thailand, China and Laos.

Preparation and precautions

22. According to the applicant, sacha inchi seeds as a snack require no precautions or restrictions of use, provided that they are produced according to the Peruvian Technical Standard, with which the companies working with the applicant are said to be compliant. No reports on allergic reactions to the seed were identified by the applicant in the literature search.

Safety data

23. A toxicological study in rats cited in the application, showed an estimated median single lethal oral dose of roasted sacha inchi was greater than 5,000mg/kg. Another study was cited, performed on a powdered form of sacha inchi obtained from processed press cake. No toxicity concerns were identified in the data presented for oral doses up to 500 mg/kg during 90 days of daily feeding. References were provided by the applicant.

Conditions of Use in the EU market

24. The applicant intends for the product to be sold as a snack in 28g packets targeting the general population other than children under 2. This group is excluded on the basis of the snacks could represent a choking hazard in very young children.

25. They cite the NDNS calculation of daily nut consumption for men and women at 16g and 12g respectively. They argue that in the case of a complete substitution of other seeds and nuts for sacha inchi there would be an increase in the total intake of protein, fat and omega-3 fatty acids.

26. The product is not expected to replace a major food group according to the applicant. It is stated that sacha inchi seeds processed under the Peruvian Technical Standards require no precautions or restrictions of use. However, since some companies process other nuts like brazil nuts in their factories, the applicant recommends including “may contain nuts” in the label of the product.

Committee Action Required

- Members are asked whether there are safety concerns that need to be managed with this traditional food from third countries.
- The Committee’s advice will form the basis for the UK’s formal response to the Commission and whether reasoned safety objections are submitted.

Secretariat
January 2019

Annexes Attached

Annex A – Dossier
Annex B – Selected application annexes.
Annex C – List of all available documents and annexes within the application.