

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

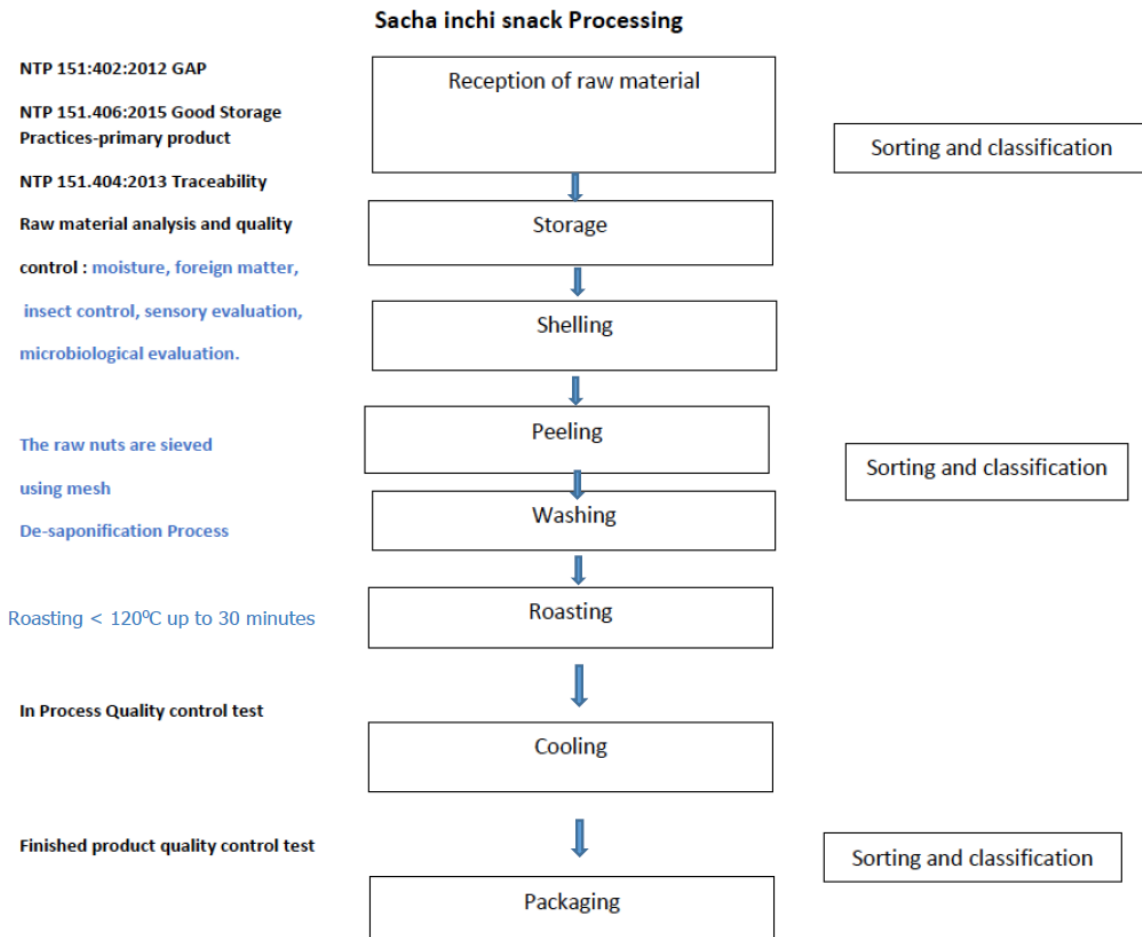
3. On the 30 November 2019 the European Commission received a notification from PROMPERU for authorisation of roasted sacha inchi seeds. The applicant intends to market the product within the food categories: Legumes, Oilseeds and Spices, to be consumed as a snack.
4. Member States have four months until 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 inchi, 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 sachu 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. The applicant provided a flow chart:



Composition

10. The application references data from five different batches, providing information on proximate analysis (**Table 3**), vitamin (**Table 4**) and mineral (**Table 5**) content, as well as an amino acid profile (**Table 6**).

Parameter	Method	Lab	Unit	Result					Limit of quantification
				180839168 Figo - São	180839169 Chanarina	180839170 Chanarina	180838171 Sanda	180839172 Amazon PP	
	Method								
* Carbohydrates	Methods of Analysis for Nutrition Labeling 1993, pag 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 Labeling -AOAC: 1993		Kcal/100g	639	599	602	638	597	-
* Fiber (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 fiber	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
* Odor	ISO 4121:2003 Sensory analysis. Guidelines for the use of quantitative response scales			Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	-
* Color	ISO 4121:2003 Sensory analysis. Guidelines for the use of quantitative response scales			Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	-
* Flavor	ISO 4121:2003 Sensory analysis. Guidelines for the use of quantitative response scales			Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	-
* Peroxide index	AOAC 965.33, 2016; 20Th Ed.2016 Peroxide Value of Oils and Fats		meq O2/Kg	2.2	1.9	1.7	2.6	3.7	1
* Value Acid	AOCS Cd 3d-63: 2017; 7th Ed. Acid Value		mgKOH/g	<1	<0.3	<0.3	< 1	<0.3	0.3
Mass balance	Calculation			100.00	102.00	100.00	100.00	100.00	

Table 3 Results of proximate analysis of roasted sacha inchi seeds

Parameter	Method	Lab	Unit	Result				
				180839168	180839169	180839170	180838171	180839172
Vitamins:								
Vitamin A *calculated*	DIN EN 12823-1, HPLC/FI	B2	IU/g	0.000	0.000	0.000	0.000	0.000
Vitamin A (Retinol)	DIN EN 12823-1, HPLC/FI	B2	µg/100 g	< 0.500	< 0.500	< 0.500	< 0.500	< 0.500
Niacin	AOAC 944.13, Microbiology	B2	mg/100 g	0.846	0.556	0.542	0.506	0.497
Vitamin D2	SOP M 2885, LC-MS/MS	B2	µg/100 g	< 0.050	< 0.050	< 0.050	< 0.050	< 0.050
Vitamin D3	SOP M 2885, LC-MS/MS	B2	µg/100 g	< 0.050	< 0.050	< 0.050	< 0.050	< 0.050
Vitamin E "Calculation based on the assumption that native Tocopherols/Tocotrienol are present."	DIN EN 12822 HPLC/FI	B2	mg/100 g	11.6	10.8	9.89	9.33	9.7
Alpha - Tocopherol	DIN EN 12822 HPLC/FI	B2	mg/100 g	0.474	0.478	0.437	0.432	0.411
Beta - Tocopherol	DIN EN 12822 HPLC/FI	B2	mg/100 g	0.052	0.049	0.047	0.035	0.042
Gamma - Tocopherol	DIN EN 12822 HPLC/FI	B2	mg/100 g	44.2	40.6	37.4	35.3	36.9
Delta - Tocopherol	DIN EN 12822 HPLC/FI	B2	mg/100 g	7.61	7.14	7.18	6.86	7.02
Alpha - Tocotrienol	DIN EN 12822 HPLC/FI	B2	mg/100 g	0.011	< 0.010	0.011	< 0.010	< 0.010

Table 4 Analysis of vitamin content in roasted sacha inchi seeds

Parameter	Method	Lab	Unit	Result					Limit of quantification	Requirements
				180839168	180839169	180903767	180838171	180839172		
Minerals/metals:										
Sodium	DIN EN 15621, mod.	HH	mg/kg	100	53.3	97.6	89.5	153	2.0	5mg/day Adult
Calcium	DIN EN 15621, mod.	HH	mg/kg	2280	2351	2927	2644	2642	2.0	
Potassium	DIN EN 15621, mod.	HH	mg/kg	5161	4272	4662	3752	3592	5.0	
Iron	DIN EN 15763, mod.	HH	mg/kg	27.6	25.3	28.3	22.2	22.1	0.50	
Copper	DIN EN 15763, mod.	HH	mg/kg	8.46	9.21	9.04	9.77	10.2	0.20	
Selenium	DIN EN 15763, mod.	HH	mg/kg	0.24	< 0.20	< 0.20	< 0.20	< 0.20	0.20	
Manganese	DIN EN 15763, mod.	HH	mg/kg	7.07	8.49	7.39	7.48	8.21	0.05	
Molybdenum	DIN EN 15763, mod.	HH	mg/kg	2.32	3.01	3.04	0.87	0.80	0.05	
Cobalt	DIN EN 15763, mod.	HH	mg/kg	0.10	0.06	0.05	0.07	0.07	0.05	

Table 5 Analysis of minerals in roasted sacha inchi seeds

Parameter	Result					Limit of quantification
	180839168	180839169	180839170	180838171	180839172	
Amino acids (total):						
Aspartic acid	3.06	3.25	3.17	3.33	3.32	0.05
Threonine	1.20	1.27	1.27	1.27	1.22	0.05
Serine	1.59	1.69	1.71	1.73	1.67	0.05
Glutamic acid	3.50	3.71	3.67	3.89	3.76	0.05
Proline	1.11	1.16	1.17	1.19	1.20	0.05
Glycine	3.01	3.07	3.04	3.16	3.10	0.05
Alanine	1.06	1.09	1.07	1.10	1.11	0.05
Valine	1.61	1.70	1.61	1.71	1.75	0.05
Methionine	0.18	0.27	0.27	0.22	0.13	0.05
Isoleucine	1.36	1.42	1.34	1.43	1.50	0.05
Leucine	1.98	2.12	2.01	2.08	2.12	0.05
Tyrosine	1.53	1.57	1.57	1.60	1.58	0.05
Phenylalanine	0.70	0.74	0.72	0.75	0.78	0.05
Ornithine	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	0.05
gamma Aminobutyric acid	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	0.05
Lysine	1.11	1.28	1.23	1.31	1.30	0.05
Histidine	0.50	0.52	0.51	0.55	0.56	0.05
Arginine	2.92	3.04	2.87	3.18	3.23	0.05
Taurine	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	0.05
Hydroxyproline	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	0.05
Cystine	0.50	0.46	0.58	0.45	0.49	0.05
Hydroxylysine	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	0.05
Sum amino acids (without ammonium)	26.92	28.36	27.81	28.95	28.82	0.05
Tryptophan	0.71	0.70	0.73	0.71	0.62	0.05
Total Amino Acids	54.55	57.42	56.35	58.61	58.26	
Total Essential Amino Acids	9.35	10.02	9.69	10.03	9.98	

Table 6 Results of analysis of amino acids 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. Analysis of saponins and alkaloids can be found in **Table 7** and **Table 8**, respectively. Lectins were found at concentrations below the detection limit of 0.01% (100mg/kg). Original test results were provided by the applicant.

Raw Seeds	Batch 394518	Batch 394519	Batch 394520	Batch 394521	Batch 394522
Total Saponins %	0.0012	0.00115	0.00063	0.00088	0.00137
Total Saponins mg/kg	12mg/kg	11.5mg/kg	6.3mg/kg	8.8mg/kg	13.7mg/kg
Roasted Seeds	Batch 394518	Batch 394519	Batch 394520	Batch 394521	Batch 394522
Total Saponins %	< 0.000005	< 0.000005	< 0.000005	0.00022	0.00025
Total Saponins mg/kg	<0.05mg/kg	<0.05mg/kg	<0.05mg/kg	2.2mg/kg	2.5mg/kg

Table 7 Results of saponin analysis of raw and roasted sacha inchi seeds

Raw Sacha Inchi Seeds	Lot 394518	Lot 394519	Lot 394520	Lot 394521	Lot 394522
Total Alkaloids mg/kg	15.2	17.3	13.3	11.2	12.1
Roasted Sacha Inchi Seeds	Lot 394518	Lot 394519	Lot 394520	Lot 394521	Lot 394522
Total Alkaloids mg/kg	< 0.1	< 0.1	< 0.1	2.5 mg/kg	3.20 mg/kg

Table 8 Results of analysis of alkaloid content of raw and roasted sacha inchi seeds

13. Data on microbial analysis was also provided (**Table 9**) as well as the laboratorial reports.

Parameter	Unit	Result				
		180839168	180839169	180839170	180838171	180839172
Yeasts	CFU/g	<10	<10	<10	<10	<10
Aerobic Plate Count	CFU/g	<10EAPC	<10.0 APC	<10.0 APC	<10EAPC	<10EAPC
Numeration of Moulds	CFU/g	<10	<10	<10	<10	<10
Enumeration of Total coliforms	MPN/g	<3.0	<3.0	<3.0	<3.0	<3.0
Numeration of Escherichia coli	MPN/g	<3.0	<3.0	<3.0	<3.0	<3.0
Detection of Salmonella	in 25g	Absence	Absence	Absence	Absence	Absence

Table 9 Results of microbiological analysis of roasted sacha inchi seeds

Contaminants

14. The applicant provided data on laboratory analysis of 5 batches of the product for mycotoxins (**Table 10**), pesticides, heavy metals (**Table 12**), PAHs (**Table 14**), dioxins (**Table 15**) and PCBs (**Table 16**). 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.

Parameter	Method	Lab	Unit	Result						Limit of quantification
				180839168	180839169	180839170	180903767	180838171	180839172	
Mycotoxins:										
Aflatoxin B1	ASU L 00.00-50a(EG)	HH	µg/kg	< 0.2	< 0.2	< 0.2		< 0.2	< 0.2	0.2
Aflatoxin B2	ASU L 00.00-50a(EG)	HH	µg/kg	< 0.2	< 0.2	< 0.2		< 0.2	< 0.2	0.2
Aflatoxin G1	ASU L 00.00-50a(EG)	HH	µg/kg	< 0.2	< 0.2	< 0.2		< 0.2	< 0.2	0.2
Aflatoxin G2	ASU L 00.00-50a(EG)	HH	µg/kg	< 0.2	< 0.2	< 0.2		< 0.2	< 0.2	0.2
Sum of Aflatoxins B/G	calculated	HH	µg/kg	< 0.2	< 0.2	< 0.2		< 0.2	< 0.2	
Ochratoxin A	ASU L 00.00-50a(EG)	HH	µg/kg	< 0.5	< 0.5	< 0.5		< 0.5	< 0.5	0.5
Fumonisin B1	SOP M 2919, LC-MS/MS	HH	µg/kg	< 50	< 50	< 50		< 50	< 50	50
Fumonisin B2	SOP M 2919, LC-MS/MS	HH	µg/kg	< 50	< 50	< 50		< 50	< 50	50
Sum fumonisins B1 and B2	calculated	HH	µg/kg	< 50	< 50	< 50		< 50	< 50	

Table 10 Results of mycotoxin analysis of roasted sacha inchi seeds

Parameter	Method	Lab	Unit	Result					Limit of quantification
				180839168	180839169	180903767	180838171	180839172	
Heavy Metals									
Lead	DIN EN 15763, mod.	HH	mg/kg	< 0.015	< 0.015	< 0.015	< 0.015	< 0.015	0.015
Cadmium	DIN EN 15763, mod.	HH	mg/kg	0.04	0.04	0.03	0.06	0.05	0.01
Mercury	SOP M 2567, direct mercury analyser	HH	mg/kg	< 0.005	< 0.005	< 0.005	< 0.005	< 0.005	0.005
Arsenic	DIN EN 15763, mod.	HH	mg/kg	< 0.04	< 0.04	< 0.04	< 0.04	< 0.04	0.04

Table 12 Results of analysis of heavy metal content of roasted sachu inchi seeds

Parameter	Method	Lab	Unit	Result					Limit of quantification
				180839168	180839169	180839170	180838171	180839172	
PAH									
Benzo(a)anthracene	SOP M 2920, GC/MS	HH	µg/kg	< 0.2	< 0.2	< 0.2	< 0.2	< 0.2	0.2
Chrysene	SOP M 2920, GC/MS	HH	µg/kg	< 0.2	< 0.2	< 0.2	< 0.2	< 0.2	0.2
Benzo(b)fluoranthene	SOP M 2920, GC/MS	HH	µg/kg	< 0.2	< 0.2	< 0.2	< 0.2	< 0.2	0.2
Benzo(a)pyrene	SOP M 2920, GC/MS	HH	µg/kg	< 0.2	< 0.2	< 0.2	< 0.2	< 0.2	0.2
Sum PAH 4 (Benzo(a)anthracene, Benzo(a)pyrene, Benzo(b)fluoranthene, Chrysene)	calculated	HH	µg/kg	< 0.2	< 0.2	< 0.2	< 0.2	< 0.2	

Table 14 Results of analysis of polycyclic aromatic hydrocarbons in roasted sachu inchi seeds

Parameter	Method	Lab	Unit	Result					Limit of quantification
				180839168	180839169	180839170	180838171	180839172	
Dioxins/Furans:									
2,3,7,8-TCDD	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
1,2,3,7,8-PeCDD	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
1,2,3,4,7,8-HxCDD	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
1,2,3,6,7,8-HxCDD	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
1,2,3,7,8,9-HxCDD	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
1,2,3,4,6,7,8-HpCDD	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.500	< 0.500	< 0.500	< 0.500	< 0.500	0.5
OCDD	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 1.00	< 1.00	< 1.00	< 1.00	< 1.00	1.000
2,3,7,8-TCDF	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
1,2,3,7,8-PeCDF	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
2,3,4,7,8-PeCDF	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
1,2,3,4,7,8-HxCDF	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
1,2,3,6,7,8-HxCDF	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
1,2,3,7,8,9-HxCDF	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
2,3,4,6,7,8-HxCDF	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.100	< 0.100	< 0.100	< 0.100	< 0.100	0.1
1,2,3,4,6,7,8-HpCDF	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.300	< 0.300	< 0.300	< 0.300	< 0.300	0.3
1,2,3,4,7,8,9-HpCDF	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 0.300	< 0.300	< 0.300	< 0.300	< 0.300	0.3
OCDF	Reg. (EU) 2017/644 ⁽¹⁾	ZfD	ng/kg	< 1.00	< 1.00	< 1.00	< 1.00	< 1.00	1.000
Sum PCDD	calculated ⁽¹⁾	ZfD	ng/kg	2.00	2.00	2.00	2.00	2.00	
Sum PCDF	calculated ⁽¹⁾	ZfD	ng/kg	2.30	2.30	2.30	2.30	2.30	
Sum PCDD/PCDF	calculated ⁽¹⁾	ZfD	ng/kg	4.30	4.30	4.30	4.30	4.30	
			ng/kg=pg/g						

Table 15 Results of analysis of Dioxins in roasted sacha inchi seeds

Parameter	Method	Lab	Unit	Result					Limit of quantification
				180839168	180839169	180839170	180838171	180839172	
mono-ortho PCBs:									
PCB 118	ASU L00.00-34	B2	mg/kg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.001
PCDDs/PCDFs/dioxin-like PCBs:									
Sum PCDD/PCDF	calculated as WHO-TEQ (2005) fat(1) \leq	ZfD	ng/kg	0.32460	0.32460	0.32460	0.32460	0.32460	
non-dioxinlike PCBs:									
PCB 28	ASU L00.00-34	B2	mg/kg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.001
PCB 52	ASU L00.00-34	B2	mg/kg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.001
PCB 101	ASU L00.00-34	B2	mg/kg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.001
PCB 138	ASU L00.00-34	B2	mg/kg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.001
PCB 153	ASU L00.00-34	B2	mg/kg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.001
PCB 180	ASU L00.00-34	B2	mg/kg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.001

Table 16 Results of analysis of PCBs in roasted sachu inchi seeds

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°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 sachu inchi seeds.

REQUIREMENT	RANGE	TEST METHOD
Moisture	No greater than 3g/100g	AOCS Ba 2a-38
Acid Value (expressed as oleic acid)	No greater than 2g/100g	AOCS Cd 3d-63
Fat	No less than 43g/100g	AOAC 963.15 AOCS 996.06
Protein	No less than 26g/100 g	AOAC 992.23 AOAC 2001.11 AOCS Ba 4d-90 ISO 16634-1

	Maximum level	Method
Aflatoxin B ₁	5µg/kg	AOAC 2005.08
		AOAC 970.45
		ASTA 24.2
		IRAM 14803
Sum of Aflatoxins (B ₁ ,B ₂ ,G ₁ ,G ₂)	20µg/kg	AOAC 2005.08
		AOAC 970.45
		IRAM 14803
		ASTA 24.2

Micro-organism	Category	Class	n	c	LIMIT per Gram		TEST METHOD
					m	M	
Moulds (CFU/ g)	3	3	5	1	10 ²	10 ³	ISO 4833-1 ISO 4833-2 ISO 21527-2 FDA/BAM
Yeasts (CFU/ g)	3	3	5	1	10 ²	10 ³	ISO 4833-1 ISO 4833-2 ISO 21527-2 FDA/BAM
<i>Escherichia coli</i> (MPN/ g)	5	3	5	2	10	10 ²	ISO 7251 ISO 16649-3 FDA/BAM
Total Coliforms (MPN/ g)	5	3	5	2	10	10 ²	ISO 4832 FDA/BAM
<i>Salmonella sp.</i>	10	2	5	0	Absent/ 25g	----	ISO 6579 FDA/BAM
<i>Aerobic mesophiles</i> (CFU/ g)	2	3	5	2	10 ⁴	10 ⁵	ISO 4833-1 ISO 4833-2 ISO 7251 FDA/BAM

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 unacceptable 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. It 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 and 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.