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Technical Report on the notification of roasted seeds from *Plukenetia volubilis* L. as a traditional food from a third country pursuant to Article 14 of Regulation (EU) 2015/2283

European Food Safety Authority (EFSA)

Abstract

Following a notification from PROMPERU/Agroindustrias Osho SAC/Amazon Health Products SAC/Comercio Alternativo de Productos No Tradicionales y Desarrollo para Latino América Perú – Candela/Shanantina SAC (Peru) submitted to the European Commission under Article 14 of Regulation (EU) 2015/2283 to place on the market roasted seeds from *Plukenetia volubilis* L. as a traditional food from a third country (TF), and in line with Article 15(2) of that Regulation, EFSA was asked by the European Commission whether there are duly reasoned safety objections to the placing on the market of the TF within the European Union. The approach of EFSA for the evaluation of TF notifications is based on the EFSA guidance for stakeholders on notifications for authorisation of TF and on the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. Based on the lack of information on the type and quantity of alkaloids in the TF, EFSA concludes that the TF may pose a risk to human health. Thus, EFSA raises safety objections to the placing on the market within the EU of the TF (i.e. roasted seeds from *Plukenetia volubilis* L.).

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Key words: *Plukenetia volubilis* L., sachá, seeds, traditional food, third country

Requestor: European Commission following a notification from PROMPERU/Agroindustrias Osho SAC/Amazon Health Products SAC/Comercio Alternativo de Productos No Tradicionales y Desarrollo para Latino América Perú – Candela/Shanantina SAC (Peru)

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

On 30 November 2018, PROMPERU/Agroindustrias Osho SAC/Amazon Health Products SAC/Comercio Alternativo de Productos No Tradicionales y Desarrollo para Latino América Perú – Candela/Shanantina SAC (Peru) submitted a notification under Article 14 of the Novel Food Regulation (EU) 2015/2283¹ to place on the market roasted seeds from *Plukenetia volubilis* L. as a traditional food from a third country (TF).

On 8 November 2019, the European Commission forwarded to EFSA the notification on roasted seeds from *Plukenetia volubilis* L. as a TF in accordance with Article 15(1) of Regulation (EU) 2015/2283.

In accordance with Article 15(2) of Regulation (EU) 2015/2283, EFSA may submit to the European Commission duly reasoned safety objections to placing on the market within the European Union (EU) roasted seeds from *Plukenetia volubilis* L. as TF.

2. Data and Methodologies

2.1. Data

The data provided to EFSA concern a notification for roasted seeds from *Plukenetia volubilis* L. as a TF pursuant to Regulation (EU) 2015/2283 and Commission Implementing Regulation (EU) 2017/2468.²

Additional data, which were not included in the notification, were retrieved by performing a literature search (Dibusz and Vejvodova, 2020) and considered by EFSA.

A common and structured format on the presentation of TF notifications is described in the EFSA guidance on the preparation and presentation of TF notifications.³

2.2. Methodologies

The approach of EFSA for the evaluation of TF notifications is based on the EFSA guidance for stakeholders on notifications for authorisations of TF³ and on the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. As indicated in the EFSA guidance on TF, it is the duty of applicants to provide all the available data that are pertinent to the safety of the TF. EFSA may retrieve additional publicly available information in order to perform comprehensive hazard identification and evaluate whether identified hazards may pose a risk to human health.

Based on that evaluation, EFSA may submit to the European Commission duly reasoned safety objections in accordance with Article 15(2) of Regulation (EU) 2015/2283.

3. Assessment

3.1. Introduction

The TF consists of roasted seeds from *Plukenetia volubilis* L. that, according to the applicant, have been consumed for more than 25 years in Peru. Seeds from *Plukenetia volubilis* are consumed after removing the shell, washing and roasting.

¹ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 concerning novel foods. OJ L 327, 11.12.2015, pp. 1–22.

² Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, pp. 55–63.

³ EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck D, Bresson J-L, Burlingame B, Dean T, Fairweather-Tait S, Heinonen M, Hirsch-Ernst KI, Mangelsdorf I, McArdle H, Naska A, Neuhäuser-Berthold M, Nowicka G, Pentieva K, Sanz Y, Siani A, Sjödin A, Stern M, Tome D, Vinceti M, Willatts P, Engel K-H, Marchelli R, Pötting A, Poulsen M, Schlatter J, Gelbmann W, de Sesmaisons-Lecarré A, Verhagen H and van Loveren H, 2016. Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283. EFSA Journal 2016;14(11):4590, 16 pp. doi:10.2903/j.efsa.2016.4590

Roasted seeds from *Plukenetia volubilis* L. are proposed to be marketed as such in the EU and are intended to be consumed as snacks.

A summary of the notification on roasted seeds from *Plukenetia volubilis* L. has been published by the European Commission on its website.⁴

3.2. Identity of the TF

The TF consists of roasted seeds from *Plukenetia volubilis* L. (family: Euphorbiaceae). According to The Plant List⁵ *Plukenetia volubilis* L. is an accepted scientific name. Other synonyms are: *Fragariopsis paxii* Pittier, *Plukenetia macrostyla* Ule, *Plukenetia peruviana* Müll. Arg. and *Sajorium volubile* (L.) Baill. Common names used by the applicant are: sachá inchi seeds and Inca peanuts.

3.3. Production process

Technical Standards on cultivation, harvesting, storage, quality requirements and traceability for roasted sachá inchi seeds have been established by the Standards Division of the National Institute of Quality in Peru. The applicant declared to follow these Technical Standards to produce the TF. EFSA notes that these Technical Standards do not include processing parameters, such as washing conditions or roasting time/temperature.

The prepared seeds (i.e. after shelling and peeling by sieving using mesh) are washed in hot water and then roasted in a roasting machine at temperatures below 120°C. The applicant indicated that under the applied roasting conditions the risk of formation of acrylamide and 5-(hydroxymethyl)furfural is reduced (EFSA CONTAM Panel, 2015). EFSA notes that acrolein may also be formed during the roasting process (Endo et al., 2013). Oxidation processes of acrolein also contributes to the formation of acrylamide (Gertz and Klostermann, 2002; EFSA CONTAM Panel, 2015). Antinutrients concentrations (hydrogen cyanide, tannins, phytates, oxalates, lectins) can be reduced by heating in water (Pusztai and Grant, 1998; Udousoro and Akpan, 2014). However, EFSA notes that heating under dry conditions might not efficiently inactivate antinutrients (e.g. lectins) (Savage, 2003).

EFSA notes that according to the description provided in the notification, the production process of the TF follows conventional agricultural and technological practices.

3.4. Compositional data

The applicant provided compositional data on 5 representative batches of roasted sachá inchi seeds originating from 4 different companies producing the TF. The compositional data of the TF include standard proximate analysis as well as contents of cholesterol, vitamins and minerals. For the proximate analysis of the TF the following ranges were reported: lipids: 47.2–53.7%; protein: 31.5–35.6%; carbohydrates: 7.2–10.4%; dietary fiber: 7.3–9.7%; fiber (crude): 2.8–4.8%; moisture: 1.6–3%; ash: 2.6–2.8%.

The publication by Wang et al. (2018) presents ranges of compositional parameters reported in raw and processed sachá inchi seeds, including proximate composition [lipids: 33.4–54.3%; protein: 24.2–27.0%; carbohydrate (mainly fibers): 13.4–30.9%; moisture: 3.3–8.3%; ash: 2.7–6.4%], fatty acids profile, tocopherols, phytosterols. The reported data (summarized as ranges) were collected from 9 different research articles and included both raw and processed seeds. Therefore, these data are not necessarily applicable to the TF.

The publication by Bueno-Borges et al. (2018) presents the proximate composition of raw and roasted sachá inchi seeds (roasted at a temperature of either 80°C, 120°C or 160°C for 15 minutes). The following ranges were reported for roasted seeds: fat 54.3–54.8 %; protein 28.8–29.0%; total fiber 6.23–6.58%; moisture ranges from 0.80% (at temperature of 160°C) to 5.05% (at temperature of 80°C); ash 2.97–3.02 %; carbohydrates 6.92–7.43%.

⁴ https://ec.europa.eu/food/safety/novel_food/authorisations/summary-applications-and-notifications_en

⁵ <http://www.theplantlist.org/>

Antinutritional substances in the TF

Contents of saponins, alkaloids and lectins were reported in batches of raw/unprocessed (i.e. excluding washing and roasting) and roasted sachu inchi seeds.

Saponins

The applicant reported that the content of saponins is reduced in roasted sachu inchi seeds as compared to the unprocessed (raw) sachu inchi seeds owing to the traditional practice of washing or soaking sachu inchi seeds before roasting (Table 1). For three out of five initially tested batches of the TF, contents of saponins below 0.05 mg/kg were reported. In one of the batches, the saponin content was 2.2 mg/kg; analysis of an extra batch (150719) from this producer resulted in a content of saponins below 0.05 mg/kg.

The applicant proposed a maximum limit for 'total saponins' (< 0.05 mg/kg) in the specifications of the TF (see section 3.5).

Table 1: Saponin content in raw (unprocessed) and roasted sachu inchi seeds

	Shanantina	Shanantina	Agroindustrias Osho	Candela		Amazon Health Products
Raw seeds	Batch	Batch	Batch 394520	Batch	-	Batch 394522
Total	12 mg/kg	11.5 mg/kg	6.3 mg/kg	8.8 mg/kg	-	13.7 mg/kg
Roasted	Batch	Batch	Batch 394520	Batch	Batch	Batch 394522
Total	<0.05 mg/kg	<0.05 mg/kg	<0.05 mg/kg	2.2 mg/kg	<0.05	2.5 mg/kg

Total alkaloids

Concentrations of total alkaloids in raw (unprocessed) sachu inchi seeds ranged from 11 mg/kg to 17 mg/kg (Table 2). For three out of five batches of the TF initially tested contents of total alkaloids below 0.1 mg/kg were reported. For two batches total alkaloid contents of 2.5 and 3.2 mg/kg, respectively, were determined. Therefore, two additional batches (150719 and 19190) of the TF were analysed for total alkaloid contents which resulted in concentrations below 0.1 mg/kg (Table 2). The applicant explained that the level of alkaloids in processed roasted sachu inchi seeds is reduced by the roasting process.

The applicant proposed a maximum limit for 'total alkaloids' (< 0.1 mg/kg) in the specifications of the TF (see section 3.5).

EFSA notes that the analytical methods used by the applicant are insufficiently described and that validation information was not provided. Therefore, EFSA considers that they may not be appropriate to determine quantitatively total alkaloids in the TF in such small amounts. In addition, no information has been provided on the type of alkaloids which may be present in the TF.

Table 2: Total alkaloid content in raw (unprocessed) and roasted sachu inchi seeds

	Shanantina	Shanantina	Agroindustrias Osho	Candela		Amazon Health Products	
Raw seeds	Batch 394518	Batch 394519	Batch 394520	Batch 394521	-	Batch 394522	-
Total alkaloids	15.2 mg/kg	17.3 mg/kg	13.3 mg/kg	11.2 mg/kg	-	12.1 mg/kg	-
Roasted seeds	Batch 394518	Batch 394519	Batch 394520	Batch 394521	Batch 150719	Batch 394522	Batch 19190
Total alkaloids	<0.1 mg/kg	<0.1 mg/kg	<0.1 mg/kg	2.5 mg/kg	<0.1 mg/kg	3.20 mg/kg	<0.1 mg/kg

Lectins

Concentration of lectins in the tested batches of raw and roasted sachu inchi seeds were below the limit of detection (i.e. 0.01% or 100 mg/kg) of the applied analytical method.

The applicant proposed a maximum limit for 'lectins' (< 100 mg/kg) in the specifications of the TF (see section 3.5).

Publications on antinutritional substances in roasted sachu inchi seeds

Srichamnong et al. (2018) reported the amount of saponins, total alkaloids, and lectins in fresh (FS) and roasted (RS) sachu inchi seeds (120 °C for 10 minutes) [total alkaloids in FS 485±35 mg/kg dry weight (DW) and in RS 20±0 mg/kg DW; saponins in FS 27±4 mg/kg DW and in RS 5±0 mg/kg DW; lectins in FS 0.22±0.03 ng/g DW and in RS 0.15±0.02 ng/g DW]. The authors did not report any washing step prior to roasting.

Bueno-Borges et al. (2018) reported the presence of antinutrients (phytic acid, saponins, lectins, trypsin inhibitors) in raw and roasted sachu inchi seeds (at temperature of either 80 °C, 120°C or 160°C for 15 minutes). The authors did not report any washing step prior to roasting. The authors reported a decrease in phytic acid and trypsin inhibitors levels upon increasing of roasting temperature [phytic acid decreased by 34% at 120°C and by 91% at 160°C as compared to raw seeds (59.4±1.0 mg/g seeds); trypsin inhibitor activity decreased by 60% at 120°C and by 94% at 160°C as compared to raw seeds]. The minimal concentration of sample necessary to generate hemagglutination, increased with temperature (from 0.68 µg seed/mL in raw seeds, up to 3.36 µg seed/mL at 120°C and 62.5 µg seed/mL at 160 °C), suggesting inactivation of lectins. Saponins concentration in raw seeds (7.02±0.2 mg/g) increased with the temperature (by 20% at 120 °C and by 54% at 160°C). This apparent increase of the saponin concentration may be explained by increasing loss of water upon roasting at these temperatures.

Publications on composition of raw sachu inchi seeds, pressed-cakes and oil from sachu inchi seeds

Ruiz et al. (2013) reported the contents of saponins and tannins in raw sachu inchi seeds and oilcakes (i.e. residues after oil extraction).

The following two publications were retrieved by EFSA. Rawdkuen et al. (2016) reported the composition of cold pressed oilcakes from sachu inchi seeds, particularly in relation to condensed tannins, saponins, trypsin inhibitors. Fanali et al. (2011) reported the composition of a sachu inchi oil derived from cold pressing of seeds which included triacylglycerols, polyphenols (including phenyl alcohols, coumarins, flavonoids, secoiridoids and lignans), and tocopherols as main components.

Other compounds in the TF

The applicant provided the analysis on heavy metals of five batches of the TF: concentrations of arsenic, lead and mercury were below the limit of quantifications and the concentration of cadmium ranged from 0.03 mg/kg to 0.06 mg/kg.

A total of 5 batches of the TF were also analysed for acrylamide (range: 11–46 µg/kg) and 5-hydroxy methyl furfural content (range: 2–13 mg/kg). The applicant proposed specifications for acrylamide (< 50 µg/kg) and 5-hydroxy methyl furfural (<13 mg/kg) in the TF (see section 3.5).

The applicant provided also analyses on microbiological contamination, pesticides and contaminants (namely mycotoxins, polycyclic aromatic hydrocarbons, dioxins and polychlorinated biphenyls).

Stability of the TF

Based on the accelerated stability tests on 5 samples of the TF, the applicant proposed a shelf life of 18 months.

3.5. Specifications

The applicant proposed a list of specifications for the TF (Table 3).

Table 3: List of specifications of the TF

Component	Unit	Test Method	Range
Proximate Analysis			
Moisture	g/100g	AOAC 925.40:2016 20th Ed.	< 3
Protein	%	AOAC 950.48:2016 20th Ed.	28–35
Carbohydrate	%	Método de Análisis para Etiquetado Nutricional: 1993, pág. 8	7–11
Sugar (Sucrose)	% (g/100g)	AM/C/1014	0.5–2
Fat	g/100g	AOAC 948.22(a) 20th Ed. 2016	46–56
Polyunsaturated fat	g/100g	AOAC 996.06, 20th Ed., 2016, Fat (Total, Saturated and Unsaturated) in Foods. Hydrolytic Extraction Gas Chromatographic Method.	31–38
Saturated Fat	g/100g		3.3–4.4
Cholesterol	mg/100g	AOAC 994.10 20th Ed. 2016/\Cholesterol in Foods	<1.02
Omega 3	g/100g	ISO 5508	17–22
Omega 6	g/100g	AOAC 996.06, 20th Ed., 2016, Fat (Total, Saturated and Unsaturated) in Foods. Hydrolytic Extraction Gas Chromatographic Method	14–16
Omega 9	g/100g		2.5–5.0
Fibre Crude	%	AOAC 962.09, 20th Ed.2016	2.5–5.0
Dietary fibre	%	AOAC 985.29 20th Ed. 2016	7–10
Ash	g/100g	AOAC 950.49(B):2016: 20th	2.5–3
Energy	Kcal/100g	AOAC: 1993	595–650
Peroxide Value	MeqO ₂ /kg	AOAC 965.33 20th Ed.	< 10
Acid value	mgKOH/g	AOCS Cd 3d-63: 2017 7th Ed.	< 4
Odour		ISO 4121 Sensory analysis	Characteristic
Component	Unit	Test Method	Range
Colour		ISO 4121 Sensory analysis	Characteristic
Flavour		ISO 4121 Sensory analysis	Characteristic
Texture		ISO 4121 Sensory analysis	Characteristic
Vitamins			
Vitamin E	ng/100g	DIN EN 12822 HPLC/FI	9–12
Minerals			
Sodium/Salt	mg/kg	DIN EN 15621	50–160
Microbiological Analysis			
Moulds	CFU/g	ICMSF Microorganisms in food	< 10
Yeasts	CFU/g	ICMSF Microorganisms in food	< 10
<i>Escherichia coli</i>	MPN/g	FDA/BAM Online 8 th Ed. A/.1997 Chapter 4	< 3.0
Total Coliforms	MPN/g	FDA/BAM Online 8 th Ed. A/.1997 Chapter 4	< 3.0
<i>Salmonella</i> sp.	In 25 g	FDA/BAM Online 8 th Ed. A/.1999 Chapter 5	Absent

Aerobic mesophiles			
Aerobic plate count	CFU/g	FDA/BAM Online 8 th Ed. A/.1999 Chapter 3 (Estimated Aerobic Plate Count)	<10EAPC
Contaminants			
Hydroxymethylfurfural	mg/kg	J. Agric Food Chem. 1997, 45, 2128-2133	< 13
Acrylamide	µg /kg	FDA Method Acrylamide rev2003	< 50
Polycyclic Aromatic Hydrocarbons			
Benzo(a)anthracene	µg/kg	SOP M 2920, GC/MS	< 0.2
Chrysene	µg /kg	SOP M 2920, GC/MS	< 0.2
Benzo(b)fluoranthene	µg /kg	SOP M 2920, GC/MS	< 0.2
Benzo(a)pyrene	µg /kg	SOP M 2920, GC/MS	< 0.2
Sum PAH 4	µg /kg	Calculated	< 0.2
Anti-Nutritional Factors			
Total Saponins	mg/kg	HPLC-DAD	< 0.05
Total Alkaloids	mg/kg	HPLC-DAD and colorimetric bromocresol assay	< 0.1
Lectins	mg/kg	ELISA	< 100

As indicated in section 3.4, EFSA notes that the analytical methods used by the applicant to determine the concentration of total alkaloids in such small amounts in the TF are not sufficiently described and may not be appropriate.

3.6. Experience of continued food use in a third country

Extent of use of the TF

The applicant indicated that sachachi seeds have been consumed by indigenous groups in Peru, in particular in the San Martín region, with evidence back to pre-Inca times (Rodríguez Cerrón, 2006; Flores, 2010; Rodríguez et al., 2019). In the 1970s, sachachi seeds were subjected to investigations by the Peruvian government in order to promote its use as a crop. At this time Technical Standards on cultivation, harvesting, and traceability of roasted sachachi seeds for sale in Peru and for exports started to be developed.

Several publications provided by the applicant reported the consumption of sachachi seeds roasted or cooked with salt and their use in the preparation of dishes by native population in Peru (Manual de producción de sachachi, undated; de la Vega, 1609; Arevalo, 1989–1992; de Mayolo, 1981; Mori, 1991; Correa and Bernal, 1992; Benavides and Morales, 1994; Duke and Vasquez, 1994; Proyecto Suelos Tropicales/INIA, 1996; Arevalo, 1999; INIA, 1998; Flores, 2010; PPB, 2013; Rodríguez et al., 2019).

The applicant indicated that in 2008, Peruvian companies started exporting sachachi seeds (roasted, oil, flour) to different international markets (e.g. Japan, USA, Canada, Australia) (ITC, 2013).

Characteristics of the population group(s) of consumers

The TF has been consumed by the general population.

Role in the diet

Roasted sachachi seeds have been consumed as such or in foods preparations.

Information on the handling and preparation of the food

No particular information on handling and preparation of the TF has been indicated by the applicant.

Precautions for the preparation and restrictions of use

No particular precautions for the preparation and restrictions of use have been indicated by the applicant.

Human data

The applicant provided a thesis (Lazaro Aguilar, 2015), which reported an allergic reaction to *Plukenetia volubilis* and investigated the potential cross reactivity of proteins from *Plukenetia volubilis* seeds and soy and peanut known allergenic proteins. No cross reactivity was found.

The publication by Bueso et al. (2010) reported occupational allergic rhinoconjunctivitis and bronchial asthma induced by *Plukenetia volubilis* seeds in a cosmetic company. Prick-to-prick test with *Plukenetia volubilis* seed extracts (crushed seeds in saline solution 10 mg/ml) was positive.

The publication by Gonzales et al. (2018) reported no statistically significant differences between allergy to sachá inchi or soy in a skin Prick-test in subjects who consumed either sachá inchi or soybean flour.

3.7. Other information on the TF

Srichamnong et al. (2018) investigated cellular toxicity of extracts (80% ethanol) of fresh and roasted (at 120 °C for 10 minutes) sachá inchi seeds in a variety of non-cancerous mouse and human cell lines. Extracts from fresh seeds displayed mild toxicity observed in hepatic stellate cells (LX-2) with IC₂₀ at 250 µg/mL. In contrast to fresh seeds, extract from roasted seeds did not show *in vitro* toxicity [50% inhibitory concentration > 500 µg/mL, the highest dose tested] in all tested cell types, including hepatic stellate cells (LX-2), implying that heat processing sachá inchi seeds may inactivate or destroy hepatotoxins. The authors concluded that heat processing should be applied before the consumption of sachá inchi seeds in order to reduce phytotoxins and potential health risks.

Srichamnong et al. (2018) investigated also the genotoxicity of different parts of *P. volubilis* using the SMART test in *Drosophila melanogaster*. Powder of fresh and roasted sachá inchi seeds tested at 145 mg/mL and all tested sachá inchi seed samples did not increase the incidence of total mutant spots compared to urethane (positive control) after statistical analysis. Therefore, the authors concluded that this indicates that secondary metabolites including saponins, alkaloids, and lectins detected in sachá inchi seeds are not mutagenic and roasting does not lead to the formation of mutagens.

The applicant provided the publication by Rodeiro et al. (2018) which reported no signs of toxicity in rats and mice after administration of a single dose of 2,000 mg/kg body weight (bw) of sachá inchi powder obtained from seeds after oil extraction and heat treatment (conditions of heat treatment were not specified). No toxicity was observed in rats after daily oral administration of doses of sachá inchi powder up to 500 mg/kg bw for 90 days. A micronucleus test was also conducted in mice with a single oral dose of 2,000 mg/kg bw of sachá inchi powder. A negative and a positive control were included in this experiment. No statistically significant differences were observed between the treated and control groups.

EFSA retrieved the publication by Gorriti et al. (2010) which evaluated the oral toxicity (repeated dose of 0.5 mL/kg bw for 60 days) and determined the lethal dose 50 (LD₅₀) of raw sachá inchi oil in rats and mice. No signs of toxicity on body weight or serum parameters were observed after 60 days of administration. The LD₅₀ was above the highest dose administered of raw sachá inchi oil (i.e. 37 g/kg bw).

The English abstract of a Chinese publication retrieved by EFSA (Huang et al., 2012) reported that the oral LD₅₀ of sachá inchi oil in mice was higher than the dose tested (54 g/kg bw). There was no increase in the number of revertant colonies in an Ames test with sachá inchi oil. Micronucleus rates and sperm abnormality rates at all doses tested of sachá inchi oil were not significantly different from the negative control.

No publications reporting adverse effects in animals fed with sachá inchi seeds have been identified either by the applicant or by EFSA.

3.8. Proposed conditions of use for the EU market

Target population

The target population proposed by the applicant is the general population. However, as with other nuts and seeds, the consumption of the TF in individuals below 2 years of age should be avoided owing to the risk of choking.

Proposed uses and use levels

The TF (roasted sacha inchi seeds) is proposed to be marketed as such in the EU, in packets of 28 g. The TF is intended to be consumed as snacks.

The applicant referred to the UK National Diet and Nutrition Survey which reported a consumption of 16 g per day of nuts and seeds for consumers-only.

EFSA notes that, according to the EFSA Comprehensive European Food Consumption Database⁶, the highest P95 percentile consumption of 'peanuts and similar' among the EU surveys is 100 g/day in the population of consumers-only.

Intended role in the diet

The TF is expected to be an alternative to seed or nut snacks already on the market.

Precautions and restrictions of use

No specific precautions or restrictions of use have been indicated by the applicant. However, considering that one company in the group of applicants processes other nuts, the applicant proposes to include a warning in the labelling that the product may contain nuts.

4. Conclusions

EFSA notes that:

- the analytical methods used by the applicant are insufficiently described and that validation information was not provided. Therefore, EFSA considers that they may not be appropriate to determine quantitatively total alkaloids in the TF in such small amounts;
- no information has been provided on the type of alkaloids which may be present in the TF.

Therefore, EFSA concludes that the TF may pose a safety risk to human health. Thus, EFSA raises safety objections to the placing on the market within the EU of the TF (i.e. roasted seeds from *Plukenetia volubilis* L.).

5. Documentation as provided to EFSA

1. On 8 November 2019, a valid notification on roasted seeds from *Plukenetia volubilis* L. as a TF, which was submitted by PROMPERU/Agroindustrias Osho SAC/Amazon Health Products SAC/Comercio Alternativo de Productos No Tradicionales y Desarrollo para Latino América Perú – Candela/Shanantina SAC (Peru), was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2018/0752).

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⁶ <https://www.efsa.europa.eu/en/food-consumption/comprehensive-database>

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Abbreviations

bw: body weight

DW: dry weight

EU: European Union

FS: fresh sachu inchi seeds

RS: roasted sachu inchi seeds

TF: traditional food from a third country