CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7.3 **CRD28**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FATS AND OILS
Twenty-Seventh Session
Virtual, 18 - 26 October 2021

PART III - AMENDMENT/REVISION TO THE CODEX STANDARD FOR NAMED VEGETABLE OILS (CXS 210-1999) - INCLUSION OF SACHA INCHI OIL

DISCUSSION PAPER

(Comments from Peru)

The Delegation of Peru appreciates the comments made and wishes to provide the following additional notes, as per ALINORM 99/17 - REPORT OF THE SIXTEENTH SESSION OF THE CODEX COMMITTEE ON FATS AND OILS:

- **Scope**: **justification for inclusion within the scope of the standard and proof that the oil will be presented in a satisfactory condition for human consumption:**

The scope of this Project is an international Technical Standard.

Justification of the new work
To elaborate a framework of actions to amend the Standard for Named Vegetable Oils (CODEX STAN 210-1999) and include in Section 2, the product definition of sacha inchi oil, as well as to include the fatty acid profile of this oil in the mentioned standard in order to establish essential compositions, quality factors, purity and food safety criteria for this edible oil, in order to facilitate its commercialization.
Sacha inchi (*Plukenetia* Volubilis L.) is also known as maní del monte, maní estrella (Colombia), maní del inka, supua (Bolivia).
This oil can be consumed in the same food categories and at the same levels of use at which it is currently marketed as flaxseed oil. This includes its use as a dressing, for example, in salads, and its incorporation into a range of foods and food supplements, as well as in light frying (smoke point 255°C).
Sacha inchi oil has been traded internationally and has been characterized as having health benefits, so since it is involved in international trade, it should be included in the standard for specified oils as are other similar oils.

Proof that the oil will be in satisfactory condition for human consumption:
The fat profile of this oilseed was considered equivalent to linseed oil (*Linum usitatissimum* L.) by EFSA (European Food Safety Authority)/Novel Food 2012 and has GRAS (Generally Recognized as Safe, 2014) status by FDA, a safety standard that provides assurance of reasonable safety and evaluation of the product for the proposed use. The recognition of this status is framed in the United States Federal Food, Drug and Cosmetic Act (FFDCA) of 1938; as well as, in the Food Additives Amendment of 1958 (Food Additives Amendment).

- Taxonomic data:

It is the oil obtained from the almonds of sacha inchi (*Plukenetia volubilis* L.) cold pressed. Filtered by mechanical means.

Taxonomy
The range of P. *volubilis* extends from the Lesser Antilles, Suriname and the northwestern sector of the Amazon basin in Venezuela and Colombia to Ecuador, Peru, Bolivia and Brazil (Gillespie, 1999; 1993; Webster & Huft, 1988).

The highest variability within P. *volubilis* is found on the eastern slopes of the Andes in Peru, bordering Brazil (Gillespie, 1993). Collections from the regions of Peru: Cusco, Junín and Pasco, from an altitudinal range

between 1600-2100 m, are also morphologically differentiable and could represent new species or hitherto unknown species from Peru (cf. Rodríguez et al., 2010). Fruit morphology of collections from Mendoza Province, Department of Amazonas, support the existence of at least four different species in that region, of which one was recently reported as a species new to science (Bussmann et al., 2009).

Taxonomic category:
Kingdom: Plantae
Phylum: Tracheaphyta
Class: Magnoliopsida
Order: Malpighiales
Family: Euphorbiaceae
Genus: Plukenetia
Species: *Plukenetia volubilis* L.

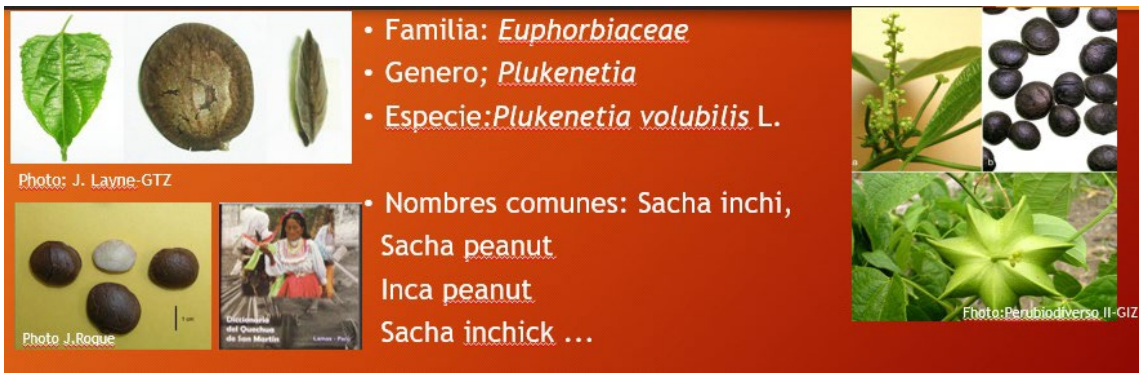

Figure 1 - Taxonomy of *Plukenetia volubilis* L.

- **Level of difference with respect to other oils:**

The results of research related to fatty acids in linseed and sacha inchi oil indicate the former to be higher in palmitic acid, oleic acid and α-linoleic acid with respect to sacha inchi, and lower in linoleic acid; stearic acid presents similar values for both oils[1] [,2] , also Table 1 shows differences in physicochemical characteristics between sacha inchi and linseed oil.

[1] Rallidis LS, Paschos G, Liokos GK, Velissaridou AH, Anastasiadis G, Zampelas A. Dietary α-linolenic acid decreases C-reactive protein, serum amyloid A and interleukin-6 in dyslipiademic patients. Atherosclerosis. 2003; 167: 237-242.

[2] Ruiz A. Manual de Diagnóstico Y Tratamiento de las Dislipidemias. Atha Comunicação e Editora Ltda. Sao

Table 1 - Physicochemical characteristics of sacha inchi oil and flaxseed oil[3]

Característica fisicoquímica	Aceite crudo	
	Sacha inchi	Linaza
Índice de refracción	1,480 ± 0,000	1,478[12]
Densidad a 25 °C (g/mL	0,9269 ± 0,002	0,931[12]
Ácidos grasos libres (% ácido oleico)	0,231 ± 0,003	0,304 ±0,028
Índice de yodo (g de I/ 100g)	194,035 ± 0,381	188,707 ± 0,189
Índice de saponificación (mg KOH/g)	184,748 ± 0,200	197,976 ± 0,480
Valor de peróxido (meq O_2/ kg	0,889 ± 0,143	0,396 ± 0,280
Valor de dienos conjugados (umol/g)	7,282 ± 0,524	8,459 ± 1,457

A comparison of fatty acids of sacha inchi oil and other vegetable oils is shown in Figure 2:

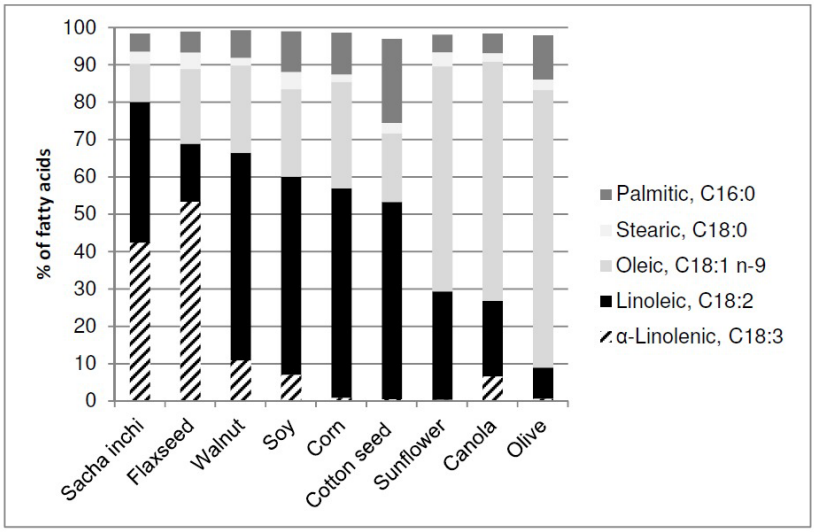

Figure 2 - Fatty acid composition of sacha inchi oil and other edible vegetable oils

- In addition to the above, submissions should include any other relevant information, together with details of the proposed "Essential Composition and Quality Factors".

In Annex A part 3 of this document, the essential composition and quality factors of sacha inchi are presented.
Sacha Inchi oil contains higher levels of omega-3 than omega-6.
The higher levels of omega 3 make Sacha Inchi oil a food with potent health effects.
Sacha Inchi has a high protein content, which proposes it as an important source of amino acids of vegetable origin in the diet.

About the international production of Sacha Inchi oil:

In addition, most supplies come from Peru, but other countries, including Colombia and especially Thailand, are growing competitors of Peruvian producers.

With respect to importing countries, Figure 3 shows that the U.S. between 2015 and 2019 had an absolute growth of USD$147,872, followed by China with USD$69,306, Sweden with USD$29,680, Germany with USD$25,566 and the Netherlands with USD$22,777, while a decrease of USD $18,269.

Sacha Inchi exports from Laos

[3] Paulo Brazil. Available ponlecorazon.com/pdfs/manualdislipidemia.pdf (23-12-09)
Biswas et al. (2001). Average values.

The information below is based on HS code 120799 (Oil seeds and oleaginous fruits - nec in heading 1207, whether or not broken).
The value of exports from Laos was $30.61 thousand, and the export volume was 102.90 thousand metric tons in 2020.

Source: Global trading platform Tridge.

Figure 3 - Export of Sacha Inchi from Laos

Destination markets for Sacha Inchi oil - 2019
According to Promperú, 2021:

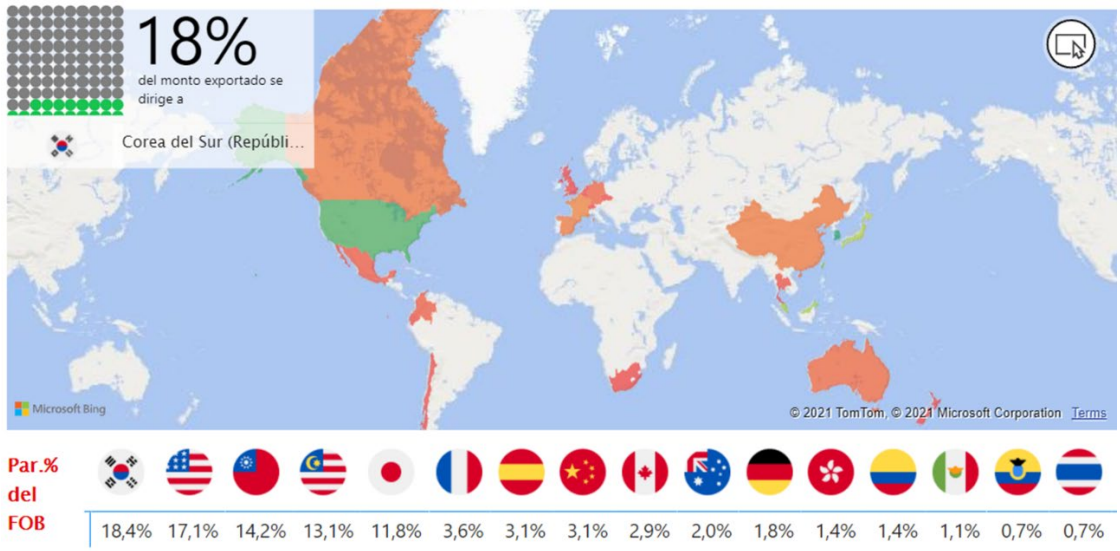

Table 2 - Imports of Sacha Inchi from Peru 2013 – 2018

Año	Pais	$	Peso Neto	C.U. $
2013	Ecuador	$ 30,694.00	14,850.00	2.07
2014	Ecuador	$ 241,315.19	102,930.00	2.34
2015	Colombia	$ 214,453.74	74,840.00	2.87
2015	Ecuador	$ 612,560.45	203,225.00	3.01
2016	Colombia	$ 149,110.69	34,176.00	4.36
2016	Ecuador	$ 491,721.77	130,630.00	3.76
2017	Colombia	$ 416,608.42	129,270.00	3.22
2017	Ecuador	$ 796,735.00	231,030.50	3.45
		$ 2,953,199.26	920,951.50	
	Ecuador	$ 2,173,026.41	682,665.50	
	Colombia	$ 780,172.85	238,286.00	

Año	País	$	KG
2018	Colombia	1,371,403.00	335,345.00
2018	Ecuador	652,726.96	160,995.30
		2,024,129.96	496,340.30

From the data presented there is evidence of international trade in sacha inchi oil.

On the comments of the CCFO Secretariat:

(i) coverage of major consumer protection and trade issues by existing or proposed general standards:

Some studies of sacha inchi oil and its effect on human health are as follows:

Rev Peru Med Exp Salud Publica. 2011;28(4):628-32. ORIGINAL BREVE

EFECTO DEL ACEITE DE SACHA INCHI (*Plukenetia volúbilis L*) SOBRE EL PERFIL LIPÍDICO EN PACIENTES CON HIPERLIPOPROTEINEMIA

Fausto Garmendia[1,2,a], Rosa Pando[1,3,b], Gerardo Ronceros[1,3,c]

- ✓ The intake of the oil produced a drop in the mean values of TC, and AGNE with elevation of c-HDL in both groups.
- ✓ The 10 mL dose was associated with higher insulin levels.
- ✓ Sacha inchi oil seems to have beneficial effects on the lipid profile in patients with dyslipidemia, requiring the evaluation of its efficacy and safety in randomized clinical trials.
- ✓ Open experimental pilot study to determine the effect, effective dose and side effects of sacha inchi oil (*Plukenetia volubilis* L.) on the lipid profile of patients with hypercholesterolemia.
- ✓ 24 patients aged 35 to 75 years, in whom the following were determined:
  - Blood values of total cholesterol (TC), HDL, triglycerides (Tg), glucose, non-esterified fatty acids (NEFA) and insulin.
  - Participants were randomized to receive 5 mL or 10 mL of a suspension containing 2g/5ml of sacha inchi oil for four months.

Toxicology Mechanisms and Methods

http://informahealthcare.com/txm
ISSN: 1537-6516 (print), 1537-6524 (electronic)

Toxicol Mech Methods, Early Online: 1–10
 DOI: 10.3109/15376516.2013.850566

informa healthcare

RESEARCH ARTICLE

Exposure of fatty acids after a single oral administration of sacha inchi (*Plukenetia volubilis* L.) and sunflower oil in human adult subjects

Gustavo F. Gonzales[1,2], Carla Gonzales[1,2], and Leon Villegas[3]

- ✓ The objective was to assess fatty acid exposure after a single oral administration of sacha inchi or sunflower oil in healthy volunteers.
- ✓ 18 healthy adults
- ✓ Blood samples were taken at 0, 0.5, 1, 1, 2, 2, 4, 8 and 24 h after ingestion of 10 or 15 ml of Sacha inchi or sunflower oil.
- ✓ The ratio of ALA (w3)/LA (w6) was 1.37 in sacha inchi and 0.01 sunflower.
- ✓ ALA, lauric acid, linolelaidic acid, cis-8,11,14-eicosatrienoic acid, cis-13,16-docosadienoic acid and cis-4,7,10,13,16,19-docosahexaenoic acid (DHA) changed after sacha inchi intake, but not with sunflower.

These studies, in addition to the compositional characteristics detailed in Annex A, show that sacha inchi oil is a product fit for human consumption, so the establishment of the requirements in the international standard CXS 210 guarantees that this food is healthy and can be marketed as it is being made.

ii) Number of products that would require separate standards, indicating whether they are raw, semi-processed or processed, including information on the justification for such requirements; and

No additional standards will be necessary for sacha inchi oil, it should be indicated that the product is obtained by cold extraction by the traditional method.

iii) Information on work already undertaken by other international organizations in this area and/or suggested by the relevant international intergovernmental body(ies), including an analysis of areas of potential complementarity, gaps, duplication or conflict with the above activities are not provided in the project document, as required in the Criteria for the Establishment of Work Priorities: Criteria for Commodities by the Procedural Manual.

The amendment to the Standard for Specified Vegetable Oils (CODEX STAN 210-1999) is related to the proposed topic, which is why an amendment to this standard is proposed with the inclusion of Sacha Inchi oil in the aforementioned international standard.

At the ISO level, there is no ongoing work on sacha inchi oil for human consumption, so there is no duplication or conflict with the aforementioned activities.

Therefore, there is no duplication or conflict with the standardization activities between the aforementioned international or governmental organizations.

Annex A
DRAFT AMENDMENT TO THE STANDARD FOR SPECIFIED VEGETABLE OILS

1 SCOPE OF APPLICATION
This Standard applies to the edible vegetable oils listed in Section 2.1, presented in a state for human consumption.

2 DESCRIPTION

2.1 Product Definition
Sacha inchi oil is derived from the fruit of sacha inchi kernels (*Plukenetia volubilis* L.).

2.2 Other definitions
Not applicable

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Fatty acid composition ranges determined by Gas Liquid Chromatography (GLC) (expressed as percentages)
Samples falling within the appropriate ranges specified in Table 1 are in compliance with this Standard. Supplementary criteria, for example national geographical and/or climatic variations, may be considered, as necessary, to confirm that a sample is in compliance with the Standard.

Sacha inchi oil must contain not less than 42 % linolenic acid (as a percentage of total fatty acid content) and more than 32 % linoleic acid.

3.2 Slip Point
not applicable

4 FOOD ADDITIVES

No food additives are permitted in virgin or cold pressed oils.

(*Sacha inchi oil is a cold press oil.)*

4.1 Flavorings
The flavourings used in products covered by this standard shall comply with *the Guidelines for the Use of Flavourings* (CXG 66-2008).

4.2 Antioxidants

Sacha inchi oil is a cold press oil so does not permitted the use of antioxidants.

4.3 Antioxidant synergists
Sacha inchi oil does not permitted the use of antioxidant synergists, sacha inchi oil is a cold press oil.

4.4 Antifoaming agents (for oils and frying fats at high temperatures)
Sacha inchi oil does not permitted the use of Antifoaming agents, sacha inchi oil is a cold press oil.

5 CONTAMINANTS
The products covered by this Standard shall comply with the maximum levels of the General Standard for

Contaminants and Toxins in Food and Feed (CXS 193-1995).

The products covered by this Standard shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission.

6 HYGIENE

It is recommended that the products covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the General Principles of Food Hygiene (C (CXC 1-1969), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

The products should comply with any microbiological criteria established in accordance with the Principles and Guidelines for the Establishment and Application of Microbiological Criteria related to Foods (CXC 21-1997).

7 LABELLING

7.1 Name of Food

The product shall be labelled in accordance with the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985). The name of the oil shall conform with the descriptions in Section 2 of this Standard.

Where a product is listed under more than one name in 2.1, the label for that product must include one of those names acceptable in the country of use.

7.2 Labelling of non-retail containers

Information on the above labelling requirements shall be given either on the container or in accompanying documents, except that the name of the food, lot identification and the name and address of the manufacturer or packer shall appear on the container.

However, lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark, provided that such a mark is clearly identifiable with the accompanying documents.

8 METHODS OF ANALYSIS AND SAMPLING

8.1 Determination of Fatty Acid Composition Ranges by GLC

According to AOCS Ce 2-66 and Ce Ie-91 or Ce 1f-96.

TABLE 1 - Fatty acid composition of vegetable oils determined by gas liquid chromatography (GLC) of authentic samples[1] (expressed as percentage of total fatty acids) (see section 3.1 of the standard)

Ácidos grasos	Aceite de Sacha Inchi
C6:0	ND
C8:0	ND
C10:0	ND
C11:0	ND
C12:0	ND
C14:0	ND
C15:0	ND
C16:0	3,6 - 4,5
C16:1	ND - 0,1
C17:0	ND
C17:1	ND
C18:0	2,6 - 3,3
C18:1	8,7 – 10,1
C18:2	34,0 - 37,0
C18:3	44,0 – 49,0
C20:0	ND - 0,10
C20:1	ND - 0,4
C20:2	ND – 0,1
C22:0	ND – 0,1
C22:1	ND – 0,1
C22:2	ND
C24:0	ND
C24:1	-

ND - not detectable, defined as 0,05 %

1 Data for species included in Chapter 2.

APPENDIX

OTHER QUALITY AND COMPOSITION FACTORS

These quality and composition factors are supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet these supplementary factors, may still conform to the standard.

1 QUALITY CHARACTERISTICS

The color, odour and taste of each product shall be characteristic of the designated product. It shall be free from foreign and rancid odour and taste.

	Maximum levels
Matter volatile at 105 °C	0,1 m/m –
Insoluble impurities	0,05 % m/m
Soap content	0,005 % m/m
Iron (Fe):	
Virgin oils	5,0 mg/kg
Copper (Cu):	
Virgin oils	0,4 mg/kg
Acidity index:	
Cold pressed and virgin oils	2,0 mg de KOH/g Oil
Peroxide value:	
Cold-pressed and virgin oils up to	Up to 15 milliequivalents active oxygen/kg oil

2 COMPOSITIONAL CHARACTERISTICS

The tocopherol content for sacha inchi oil should be in the ranges of
641 - 856 mg/kg (Delta - tocopherol) and 1 108 -1 367 mg/kg (Gamma - tocopherol).

3 CHEMICAL AND PHYSICAL CHARACTERISTICS

The chemical and physical characteristics are presented in Table 2.

4 IDENTITY CHARACTERISTICS

The levels of desmethylsterols in vegetable oils specified as a percentage of total sterol content are given in Table 3.

The levels of tocopherols and tocotrienols in the specified vegetable oils are given in Table 4.

5 METHODS OF ANALYSIS AND SAMPLING

Current issues:

Determination of moisture and volatile matter at 105 °C.
According to ISO 662 and AOCS Ca 2b-38.

Determination of insoluble impurities.
According to ISO 663, the AOCS Ca 3a-46 method may also be used.

Determination of soap content.
According to AOCS Cc 17-95.

Determination of copper and iron content
According to ISO 8294, or AOAC 990.05; or AOCS Ca 18b-91.

Determination of relative density
According to: ISO 6883.

Determination of bulk density
According to ISO 6883:2000, with appropriate conversion factor or AOCS Cc 10c-95.

Determination of refractive index
According to ISO 6320 or AOCS Cc 7-25.

Determination of the saponification index (SI).
According to ISO 3657; or AOCS Cd 3-25.

Determination of the iodine value (IY).
Wijs - ISO 3961; or AOAC 993.20; or; or NMKL 39; or AOCS Cd 1 d - 92. AOCS Cd 1b-87; AOAC 920.158.

Determination of unsaponifiable matter
According to ISO 3596; or ISO 18609; or AOCS Ca 6b-53 or AOCS Ca 6a - 40.

Determination of peroxide value (PI)
According to AOCS Cd 8b-90; or ISO 3960 AOCS Cd 8-53

Determination of acidity
According to ISO 660; or AOCS Cd 3d-63

Determination of sterol content
According to ISO 12228; or AOCS Ch 6-91

Determination of tocopherol content
According to ISO 9936; or AOCS Ce 8-89

TABLE 2 - Chemical and Physical Characteristics of Crude Vegetable Oils (see Annex A of the Standard)

	Sacha Inchi Oil
Relative density (x° C wáter at 20 °C)	0,920 - 0,930 X =20 ºC
Refractive index (20 °C)	1,478 - 1,482
Saponification index (mg KOH/g de aceite)	189 - 196
Iodine value	182 - 199
Unsaponifiable matter (g/kg)	≤ 5

*See the following publication: NTP 151.400 SACHA INCHI. Oil for edible use. Requirements

TABLE 3 - Levels of desmethylsterols in crude vegetable oils derived from authentic examples1 as a percentage of total sterol content (see Annex A of the Standard).

	Sacha Inchi

	Oil
Cholesterol	ND - 0,8
Brassicasterol	-
Campesterol	6,6 - 7,3
Stigmasterol	24,2 - 27,0
Beta-sitosterol	51,6 - 53,8
Delta-5-avenasterol	4,3 - 7,0
Delta-7-stigmastenol	(*)
Delta-7-avenasterol	(*)
Other	-
Total sterols (mg/Kg)	2 080 – 2 180

ND - Non-detectable, defined as ≤ 0,05 %.
(*) To be defined

TABLE 4 - Levels of tocopherols and tocotrienols in crude vegetable oils as a percentage of total sterol content (see Annex A of the Standard)[1] (mg/kg)

	Sacha inchi oil
Alpha-tocopherol	6,0 – 7,0
Beta-tocopherol	1,8 – 2,9
Gamma-tocopherol	1 108 – 1 367
Delta-tocopherol	641 – 8 56
Alpha-tocotrienol	ND
Gamma-tocotrienol	ND
Delta-tocotrienol	ND
Total (mg/kg)	1 756 – 2 322

ND - Not detectable.
1 Species data included in Chapter 2.