Letter from: AGES [Austrian Institute for Health and Food Safety]
Food Safety Institute, Vienna
Klaus Riediger

Date: 2 April 2014

To: Mr Wallensteiner
Altaselva GmbH
Pfarrgasse 2b
9900 Lienz
Austria

Our ref.: D 16/14-2 zu AN14026230

Opinion on the application for the notification - pursuant to Article 5 of Regulation (EC) No 258/97 (Novel Foods Regulation) - of Sacha Inchi oil produced by Altaselva GmbH

Please find attached our opinion (AN 14026230), which concludes on the basis of all the information submitted that Sacha Inchi oil (Plukenetia volubilis linneo) produced by Altaselva GmbH is substantially equivalent within the meaning of Article 3(4) of Regulation (EC) No 258/97 to linseed oil (Linum usitatissimum linneo) and the product Inca Inchi virgin oil already authorised by the competent Irish authority (hereinafter: FSAI) under Article 5 of Regulation (EC) No 258/97:


Pursuant to Article 5 of Regulation (EC) No 258/97, you must notify the Commission of the placing on the market of your product, enclosing the relevant information as provided for in Article 3(4).

Contact person at the European Commission:
SIRKKU HEINIMAA
DG Health and Consumers
Unit E 6 Innovation and Sustainability
TEST REPORT

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Order number: 14026230

Date of order: 12.3.2014

Opinion on the application to notify the placing on the market of Sacha Inchi oil by Altaselva GmbH pursuant to Article 5 of the Novel Food Regulation.

Authorised signatory:

Klaus Riediger

- End of test report –
EXPERT OPINION

Comments on the application submitted by Altaselva GmbH for the notification of Sacha Inchi Oil (*Plukenetia volubilis*) pursuant to Article 5 of Regulation (EC) No 258/97 (Novel Food Regulation)

In his letter of 13 June 2013, Mr Kurt Wallensteiner, representing Altaselva GmbH, Pfarrgasse 2b, A-9900 Lienz, applied to the Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH-Institut für Lebensmittelsicherheit Wien (AGES-LSV Vienna), as the competent authority, for an evaluation of the substantial equivalence within the meaning of Article 3(4) of Regulation (EC) No 258/97 of the novel ingredient Sacha Inchi oil (*Plukenetia volubilis*).

The application concerns the substantial equivalence of Altaselva GmbH’s Sacha Inchi oil to linseed oil and the product Inca Inchi virgin oil (*Linum usitatissimum* linneo) made from the same plant, which has been authorised by the FSAI under Article 5 of the Novel Food Regulation.

The applicant submitted information and documentation on the origin and production process, specifications, labelling with anticipated daily intake of the product and microbiological and analytical information on the product [01-07].

Since the aforementioned assessment body categorised the analytical information submitted by the applicant as insufficient, the latter had further testing carried out on a total of three batches at two accredited laboratories (Divisione Oli e Grasse di Innovhub SSI Milano and Eurofins Analytik GmbH Hamburg) and submitted the results to the assessment body in the period October 2013 to beginning of March 2014 [17, 18].

AGES-LSV Vienna comments as follows on the current application:

1. Product specification

*Plukenetia volubilis* L. commonly known as Sacha Inchi (and also Inca Inchi and Inca Peanut) is a perennial, oil-rich plant of the *Euphorbiaceae* family. The plant, which grows up to two metres tall, grows mainly in the tropical areas of the Peruvian jungle at altitudes ranging between 200 and 1 500 m, and has hairy, heart-shaped leaves. The capsule-shaped fruits are green and black-brown when ripe. The seeds they contain are oval, dark brown with a diameter of 2 cm. Sacha Inchi seeds contain around 54% oil and 33% protein. Sacha Inchi oil has a high unsaturated fatty acid content, in particular linoleic acid and alpha-linolenic acid. [01]

1.1 Origin and production process [01, 04, 05, 06, 07]

The applicant indicates that its product Sacha Inchi virgin oil is equivalent to the Inca Inchi virgin oil [08] (authorised by the FSAI in a notification procedure carried out in 2012) in terms of both origin and production process, since its seeds are harvested in the same region as those of Inca Inchi virgin oil and are processed into native oil using the same methods, i.e. cold pressing followed by purification.

Altaselva GmbH works closely with several farmers who are named in the application documentation [01] and whose farmland is located exclusively in the Loreto region,
where the Sacha Inchi plant originates. Giving these farmers a fair deal is a key concern for the applicant.

In order to ensure sustainability and to prevent any disruption to the ecological balance of the region, some Altaselva GmbH specialists (agricultural experts) remain on site to monitor and give advice on the cultivation and harvesting of Sacha Inchi plants. The availability of the plant is of course limited owing to the need for a specific microclimate, which exists only in the tropical area of the Peruvian jungle.

It should nonetheless be possible to make small but steady improvements over time on the basis of the natural laws of supply and demand, as well as ecological efficiency and sustainability. For this reason the applicant anticipates an initial production figure of only 15,000 bottles, each containing 250 ml Sacha Inchi virgin oil.

A detailed overview of the manufacturing process and all quality-assurance measures implemented by the firm is provided in the flow diagram in [04], the declaration of conformity of the equipment: Bracco [05] and also in Chapter F of the application [01], as well as in the HACCP plan of the Italian firm Tosi [07].

The production process for Sacha Inchi virgin oil can be summarised as follows:

In Peru: cultivation without the use of pesticides. The nuts are harvested by hand, cleaned and put into 50 kg sacks and stored off the ground in a storeroom which meets the quality standards.

In Italy: the oil is obtained through cold pressing and purified using a decanter and coarse filter before being poured into 250 ml dark bottles and labelled.

This corresponds to the production process for obtaining native linseed oil [09] and the already authorised Inca Inchi virgin oil [08].

1.2 Composition [01, 03, 17, 18]

The applicant's native Sacha Inchi oil is substantially equivalent to linseed oil [09] and the already authorised Inca Inchi virgin oil [08]* as regards the following parameters:

- refractive index, specific weight
- acid number, iodine number, peroxide number and unsaponifiable content
- water content, insoluble impurities content
- sensory quality: colour, taste
- fatty acid composition
- triglyceride composition
- tocopherol composition
- phytosterol composition

*The data necessary for the evaluation were provided to AGES by our Irish colleagues. [10 – 14]
2. Nutritional value and metabolism [01, 03, 17, 18]

A comparison of one tablespoon of Sacha Inchi oil with the same amount of linseed oil shows that the oils are very similar. They are virtually identical in terms of nutritional value, with Sacha Inchi oil providing 126 kcal and linseed oil 133 kcal.

The fatty acid profiles of the two oils are also similar:

- saturated fats (1 – 1.5 g)
- polyunsaturated fats (9.9 – 11.5 g)
- monounsaturated fats (3 – 1.5 g)

Both oils contain negligible amounts of the following parameters: trans-fatty acids, cholesterol, carbohydrates, calcium, sodium and iron.

Given the high level of unsaturated fatty acids, the digestibility of native Sacha Inchi oil is similar to that of linseed oil (both around 96%).

A comparison of all the analyses [03, 17, 18] demonstrates that Altaselva GmbH's Sacha Inchi oil is the same as Inca Inchi virgin oil, which is already on the European market. Sacha Inchi oil is therefore equivalent to Inca Inchi virgin oil as regards its metabolism and nutritional content.

3. Intended use

Sacha Inchi oil has already been authorised as a food/food ingredient and can be used in the same way as linseed oil. According to the applicant, Sacha Inchi virgin oil, like Inca Inchi virgin oil, should be used in the same quantities as linseed oil, in edible oil (e.g. for dressings), as a food ingredient (e.g. oil mixes) and as a food supplement.

Sacha Inchi virgin oil is filled into 250 ml dark bottles [Translator's note: remainder of sentence appears to be incomplete "and meet the general and specific rules on the use of vegetable oils in the EU" sic].

4. Level of undesirable substances [17, 18]

The applicant mentions a toxicological study (Oral toxicity at 60 days of Sacha Inchi oil (Plukenetia volubilis L.) and linseed (Linum usitatissium L.) and determination of lethal dose 50 in rodents" [15]) which demonstrates that both Sacha Inchi oil and linseed oil can be classified as safe.

The following parameters were tested:

- heavy metals (lead, cadmium, mercury and arsenic), mycotoxins (including aflatoxins B1, B2 and G1), PAHs, plasticisers, pesticides, solvents, erucic acid and, inter alia, (as already mentioned in 2) trans-fatty acids, proteins (no allergens) and iron.

A microbiological test was also carried out: Coliforms 30 °C (< 1/g), E. coli (< 1/g), Salmonella (absent/25g).

A comparison of all analyses [17, 18] revealed that Sacha Inchi oil from Altaselva GmbH is the same as Inca Inchi virgin oil, which is already on the European market. It is therefore equivalent to the already authorised Inca Inchi virgin oil as regards the level of
undesirable substances it contains and from the point of view of its microbiological safety.

By way of clarification, reference was also made to the report "Untersuchung von Pflanzenölen auf Kontamination mit polyzyklischen aromatischen Kohlenwasserstoffen, Weichmachern, Pestiziden, Lösungsmitteln und Schwermetallen 2008" [Testing of vegetable oils for contamination with PAHs, plasticisers, solvents and heavy metals 2008] on the homepage of the Bavarian Office for Health and Food Safety. [16]

The applicant intends to place only Sacha Inchi oil on the market and not the nuts themselves or other foods/food ingredients obtained from the nuts since these are not currently authorised novel foods and may not therefore be placed on the market as novel foods/food ingredients. Consequently, Sacha Inchi nuts may be used only in the production of Sacha Inchi virgin oil. It should be noted that Sacha Inchi oil is also used within the European Union as an ingredient in cosmetics.

The applicant will of course continue to monitor the quality of the oil on an ongoing basis.

Based on all the data provided, Sacha Inchi virgin oil (Plukenetia volubilis linneo) produced by Altaselva GmbH is considered to be substantially equivalent within the meaning of Article 3(4) of Regulation (EC) No 258/97 to linseed oil (Linum usitatissimum linneo) and the product Inca Inchi virgin oil already authorised by the FSAI. [08]

As in the case of linseed oil, which is considered within the EU to be a safe food, general and specific rules on the placing on the market and use of vegetable edible oils in the EU should be applied to Sacha Inchi virgin oil.

It is therefore recommended that the application from Altaselva GmbH for notification under Article 5 of Regulation (EC) No 258/97 be accepted.

**Literature and documentation submitted by the applicant**

[01] Altaselva-Application_signed.Pdf
[02] Annex 1.pdf (Auszug aus dem Unternehmensregister)
[04] Annex 3.pdf (Flussdiagramm des Herstellungsprozesses)
[05] Annex 4.pdf (Konformitätsklärung Ausstattung: Bracco)
[06] Annex 5.pdf (Pflanzengesundheitszeugniss Peru)
[10] INCA INCHI OIL NF application.pdf