

## SUBSTANTIAL EQUIVALENCE OPINION

### Sacha Inchi Oil

#### SUMMARY

The Food Safety Authority of Ireland (FSAI) received an application in October of 2013 from four Peruvian companies for an opinion on the substantial equivalence of their Sacha inchi virgin oils (derived from the seeds of *Plukenetia volubilis linneo*) to Inca inchi virgin oil derived from the same plant and already on the EU market.

Having reviewed the information provided by the individual companies (Agroindustrias OSHO SAC; Amazon Health Products SAC; RODA Selva SAC and Olivos del Sur SAC), the FSAI is satisfied that the novel ingredient from the four sources is substantially equivalent to Inca inchi virgin oil already on the EU market in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances as set out in *Article 3.4* of the novel food Regulation EC No 258/97.

#### Introduction

In November of 2012, the FSAI concluded that Inca inchi virgin oil produced by Perles de Gascogne Sarl (France) and Agroindustrias Amazonicas (Peru) was substantially equivalent to a vegetable oil extracted by a similar process from the seeds of *Linum usitatissimum linneo* (flaxseed or linseed oil). Virgin Sacha inchi oil (also called Inca inchi oil) is a vegetable oil derived from the seeds of *Plukenetia volubilis linneo* by a mechanical process that does not involve any refinement. The vegetable oil is novel and falls within the category of “foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use”, as set out in *Article 1.2(e)* of the novel food Regulation EC No. 258/97. The four Peruvian companies that produce the Sacha inchi virgin oil submitted a joint application to the FSAI for an opinion on the substantial equivalence of their vegetable oils with the same vegetable oil (Inca inchi oil) already on the EU market.

## **Composition**

The novel Sacha inchi virgin oil is comprised of >99% vegetable oil, with very low levels of moisture or insoluble materials and general characteristics conforming to Codex standards for edible oils. In order to enable sufficient comparison of the novel oil with the existing comparator, the applicants carried out certain compositional analysis on the Inca inchi oil as well as their own oils. The fatty acid profiles for the four novel oils were comparable with the existing comparator, being predominantly made up of polyunsaturated fatty acids (>80%), monounsaturated fatty acids (≤10%) and to a lesser extent saturated fatty acids (<10%). The phytosterol and tocopherol content were also very similar to the comparator while trans-fatty acids (<0.1%) and protein (<0.1%) constituted negligible components.

### *Production of the novel ingredient*

The novel ingredient is produced by extraction procedures that are standard in the production of virgin vegetable oils, while the quality is controlled by Codex and GMP standards. Dehulled seeds of *Plukenetia volubilis linneo* are cold-pressed to release the available seed oil. The crude oil is clarified by filtration to yield oil which is stored in bottles for the local market or in drums flushed with nitrogen to minimise oxidative degradation.

## **Nutritional Value and Metabolism**

As the novel Sacha inchi virgin oil is compositionally very similar to the comparator Inca inchi oil, it is reasonable to conclude that they will also be similar in terms of nutritional value and metabolism. These vegetable oils are a rich source of mono- and poly-unsaturated fatty acids, particularly linoleic and linolenic fatty acids, with relatively low levels of saturated fatty acids. The novel oils are also equivalent to the comparator oil in terms of the cholesterol and tocopherol content with very low levels of trans-fatty acids (<0.1%).

## **Intended Uses**

The applicants intend placing the novel oil on the EU market in the same food categories and at the same use levels as the existing Inca inchi oil which will include use as a salad dressing as well as incorporation into a range of foods and food supplements.

### **Level of Undesirable Substances**

The applicants provide data which demonstrates that levels of heavy metals, pesticides, dioxins, PAHs and microbiological contaminants are within regulatory or guideline limits. Erucic acid is not present while allergenicity is not a concern since protein is not present at any significant level.

### **Conclusions**

The FSAI is satisfied from the information provided by the four applicants that their Sacha inchi virgin oils are substantially equivalent to Inca inchi virgin oil already on the EU market in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances. The novel Sacha inchi virgin oils will be subject to the same general and specific EU food legislation that currently governs the marketing and use of vegetable oils on the EU market.