

## SUBSTANTIAL EQUIVALENCE OPINION

### Sacha Inchi Virgin Oil

The Food Safety Authority of Ireland (FSAI) received an application in February of 2016 from the company CORPEI in Ecuador for an opinion on the substantial equivalence of Sacha inchi virgin oil produced by RANGUPACORP S.A. of Ecuador, to Inca inchi virgin oil from the same plant that is already on the EU market.

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). Sacha inchi virgin oil (also called Inca inchi oil among other names) 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 is classified by the applicant 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.

Having reviewed the information provided, the FSAI is satisfied that the novel ingredient 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.

#### Composition

Through compositional analysis of the novel ingredient and the comparator vegetable oil, the applicant demonstrates that the oils are almost identical in that they comprise 99.9% fatty acids with negligible levels of protein (<0.5%), carbohydrate (<0.1%) and moisture (<0.1%). The applicant also demonstrates that both oils contain the same profiles in terms of individual fatty acids, phytosterols and tocopherols, while the trans-fatty acids content is negligible (<0.1%).

#### *Production of the novel ingredient*

Small scale farmers in Ecuador produce the seeds of *Plukenetia volubilis linneo* which are dried, shelled and dehulled. The seeds are then cold-pressed to release the available seed oil which is clarified by filtration and polishing prior to storage in

bottles, or larger cylinders depending on the destination. Each production lot is subjected to quality control procedures in line with Codex guidelines and Good Food Production practices.

### **Nutritional Value and Metabolism**

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

### **Intended Uses**

The applicant intends placing the novel oil on the EU market in the same food categories and at the same use levels as the existing Inca inchi virgin oil, including its use as a salad dressing and incorporation into a range of foods and food supplements.

### **Level of Undesirable Substances**

The applicant provides data demonstrating that levels of heavy metals (lead, cadmium, mercury, arsenic, iron and copper), pesticides, dioxins, PAHs and microbiological contaminants such as *E. coli*, *Listeria*, *Salmonella*, *Shigella* and *Clostridium* are within regulatory or guideline limits. Erucic acid is not present while allergenicity is not a concern since protein is not present at any appreciable level.

### **Conclusions**

The FSAI is satisfied from the information provided by the applicant that their Sacha inchi virgin oil produced by RANGUPACORP S.A. of Ecuador 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. The novel Sacha inchi virgin oil 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.