

## SUBSTANTIAL EQUIVALENCE OPINION

### Inca Inchi Virgin Oil

#### SUMMARY

The Food Safety Authority of Ireland (FSAI) received an application in May of 2012 from Perles de Gascogne Sarl (France) and Agroindustrias Amazonicas (Peru) for an opinion on the substantial equivalence of vegetable oil derived from the seeds of *Plukenetia volubilis linneo* (Inca Inchi virgin oil) to a vegetable oil similarly extracted from the seeds of *Linum usitatissimum linneo* (flaxseed or linseed oil). Having reviewed the information provided, along with subsequent clarifications from the applicant, the FSAI is satisfied that the novel ingredient is substantially equivalent to linseed oil in terms of composition, nutritional value, metabolism, intended use and the level of undesirable substances as set out in *Article 3.4* of the novel food Regulation EC No 258/97.

#### Introduction

Inca Inchi virgin oil is a vegetable oil mechanically derived from the seeds of *Plukenetia volubilis linneo* in a process similar to that for virgin linseed oil (*Linum usitatissimum linneo*), and does not involve any refinement. The applicant considers the ingredient to be novel and fall 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.

#### Composition

The applicant provided data on the composition of Inca Inchi virgin oil which is 100% vegetable oil with no protein or carbohydrate present, and with general characteristics

conforming to Codex standards for edible oils. The composition of the novel ingredient compares favourably with that of linseed oil based on data which was obtained by the applicant from French sources. The characteristics for both virgin oils are very similar in terms of visual perception, taste, flavour and odour. Both ingredients are also compositionally equivalent in terms of water and volatiles, impurities insoluble in hexane and trans-fatty acid content. Both oils are predominantly made up of polyunsaturated fatty acids (>90%) and to a lesser extent saturated fatty acids (<10%) and very low levels of trans-fatty acids (<0.5%). The total phytosterol and triglyceride content in both ingredients are also very similar. Inca Inchi virgin oil has higher levels of total tocopherols than linseed oil which the applicant notes can help to maintain oxidative stability.

#### *Production of the novel ingredient*

The novel ingredient is produced by standard procedures used in the production of virgin vegetable oils, including linseed oil, and the quality is controlled by Codex and GPP standards. Dehulled seeds of non-GM *Plukenetia volubilis linneo* are cold-pressed to release approximately 80% of the available seed oil. The crude oil is clarified by static sedimentation and press-filtering to yield clear and transparent oil which is stored in bulk tanks under liquid nitrogen to minimise oxidative degradation.

#### **Nutritional Value and Metabolism**

Inca Inchi virgin oil possesses the same energy value as linseed oil. Both vegetable oils are a rich source of mono- and poly-unsaturated fatty acids, particularly alpha linoleic acid, with relatively low levels of saturated fatty acids. The novel ingredient is equivalent to linseed oil in terms of its content of total cholesterol and trans-fatty acids, but contains slightly higher levels of vitamin E. The applicant demonstrates that Inca Inchi oil is as stable as linseed oil, aided by the natural presence of tocopherols that serve to maintain oxidative stability. The compositional and nutritional similarity of the novel ingredient to linseed oil suggests that its metabolism will be equivalent. However, the applicant provides some evidence that digestibility and bioavailability of the novel ingredient are equivalent to those for linseed oil.

#### **Intended Uses**

The applicant intends placing the novel ingredient on the EU market in the same food categories and at the same use levels at which linseed oil is currently marketed. This will include its use as a dressing, for example on salads, and its incorporation into a range of foods and food supplements.

### **Level of Undesirable Substances**

The applicant provides data which demonstrates that levels of heavy metals, pesticides, dioxins, PAHs or microbiological contaminants are within regulatory or guideline limits. Erucic acid is not present while allergenicity is not a concern since protein is not detectable in the novel ingredient.

### **Conclusions**

The FSAI is satisfied that the information provided by the applicant, along with subsequent clarifications, demonstrates that Inca Inchi virgin oil is substantially equivalent to linseed oil in terms of its composition, nutritional value, metabolism, intended use and level of undesirable substances. Linseed oil has a history of safe consumption within the EU and the novel ingredient (Inca Inchi virgin oil) would be subject to the same conditions of general and specific legislation governing the marketing and use of vegetable oils in the EU.