

SUBSTANTIAL EQUIVALENCE OPINION

Ilex guayusa

The Food Safety Authority of Ireland (FSAI) received an application in February of 2017 from Runa, LLC of the USA for an opinion on the substantial equivalence of aqueous extracts of the dried leaves of *Ilex guayusa*. The novel ingredient is compared to aqueous extracts of *Ilex paraguariensis* which is outside the scope of the novel food as it was on the EU market prior to 1997. *Ilex guayusa*, a close relative of *Ilex paraguariensis*, grows wild and in cultivation in several Amazonian countries in South America. The harvested leaves are kept in an aerated drying area for about 20 hours to reduce moisture content by approximately 40%. They are further dried at 58 °C for 5 hours to reduce the moisture content to less than 8% (w/w) and the milled to a powder form.

The applicant considers the ingredient to be novel and fall within the category of “*food and food ingredients consisting of or isolated from plants*” as set out in Article 1(2) (e) of the novel food Regulation (EC) No. 258/97.

Composition

Batch analysis of *Ilex guayusa* aqueous extract demonstrates that the novel ingredient is similar to the aqueous extract of the comparator *Ilex paraguariensis* in terms of protein, fat, fibre, carbohydrates and total sugars. There is some natural variation in the levels of caffeine and chlorogenic acids both within and between the closely related species.

Parameter (Aqueous extract)	<i>Ilex guayusa</i>	<i>Ilex paraguariensis</i>
Protein	<0.1	<0.3
Fat (g/100mL)	<0.1	<0.1
Carbohydrate (g/100mL)	0.2 – 0.3	0.1 – 0.3
Total sugars (g/100mL)	<0.2	<0.2
Caffeine (mg/100mL)	19.8 – 57.7	8.6 – 14.5
Theobromine (mg/100mL)	0.14 – 2.0	1.5 – 2.4
Chlorogenic acids (mg/100mL)	9.9 – 72.4	22.5 – 43.4

Nutritional Value and Metabolism

The composition of the novel ingredient is similar to the existing comparator in that both contain low to negligible levels of nutritional constituents like protein, fat and carbohydrate. There are some differences in the caffeine content of the novel and comparator extracts which corresponds to natural variation in endogenous caffeine levels found in the leaves which can be due to the location and type of cultivation as well as the development phase of the leaves at harvesting and the extraction process. However, the novel and comparator aqueous extracts are substantially equivalent overall in terms of nutritional value and therefore metabolism.

Intended Uses

The aqueous extracts of *Ilex guayusa* will be used in the same way as the aqueous extracts of the comparator *Ilex paraguariensis* on the EU market which includes use as an infusion and in supplements.

Levels of undesirable substances

Batch analysis demonstrates that heavy metals (lead, arsenic, cadmium, and mercury) are within regulatory limits while the levels of possible microbial contaminants are not a concern due to the nature of the extraction process involving water at high temperature, and this is confirmed by analysis of product batches for yeast, moulds, *E. coli* and *Salmonella*.

Conclusion

The FSAI is satisfied from the information provided by Runa LLC that the aqueous extract of *Ilex guayusa* is substantially equivalent to the aqueous extract of *Ilex paraguariensis* already on the EU market before 1997. The novel ingredient will be subject to relevant specific and general EU food law and will be used in the same way as the comparator which includes use as an infusion and in food supplements.