

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

GUAYUSA LEAF (*ILEX GUAYUSA*) FROM IKIAM UNIVERSITY GUAYUSA CONSORTIUM

Issue

The Committee is asked to consider information provided by Ikiam University Consortium, who have requested the opinion of the UK Competent Authority. An opinion is sought on whether their Guayusa leaf (*Ilex guayusa* Loes.) should be considered substantially equivalent with Yerba mate leaf (*Ilex paraguariensis* A. St. Hil.) already on the EU market. The Committee is asked if it agrees that substantial equivalence has been demonstrated.

Background

1. Guayusa (*Ilex guayusa* Loes.) is a tropical tree native to the Northwestern Amazon region across Ecuador, Colombia, and Peru. *Ilex guayusa* is a species of holly, as are all species of the *Ilex* genus within the *Aquifoliaceae* family. Consumption is widespread across many South American countries, in addition to also have been historically for thousands of years. The species to which equivalence is being sought is *Ilex paraguariensis*, known as Yerba mate leaf. *Ilex paraguariensis* has a history of consumption in the EU prior 15 May 1997 and is not a novel food.
2. Regulation (EC) 258/97 makes provision for novel foods or ingredients that are substantially equivalent to an existing product to be placed on the market once the applicant has notified the Commission. In most cases, the Commission requires that the applicant first obtain an opinion on equivalence from a Member State. Ikiam University Consortium is requesting such an opinion from the UK Competent Authority.
1. According to Article 3(4) of (EC) 258/97, the notification procedures applies to “foods or food ingredients...which on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the

competent bodies...are substantially equivalent to existing foods or food ingredients as regards to their:

- Composition
- Nutritional value
- Metabolism
- Intended use, and
- Level of undesirable substances contained therein.”

2. Ikiam University Consortium has provided information to support the claim that their Guayusa leaf (*Ilex guayusa* Loes.) is substantially equivalent to Yerba mate leaf (*Ilex paraguariensis* A. St. Hil.). Ikiam University Consortium seeks equivalence to use Guayusa leaf in tea as is currently on the market for Yerba mate leaf tea. The novel food will be market as dried tea to be consumed at home in the same way as other teas and coffee. The dossier is currently under public consultation and the results will be presented at the next meeting in September. The application dossier is attached as **Annex A** and appendices are attached at **Annex B1 and Annex B2**.

Evaluation

a) Composition

The dossier states that Yerba mate leaves and Guayusa leaves have an equivalent production process chain. Farmers reproduce Guayusa by placing small plant cuttings into the earth. Mechanical weed control is carried out when necessary. Only plants that have matured and grown to the correct standard are harvested and sent for processing. At the processing plant, an inspection to check compliance with the quality characteristics is carried out and the highest quality leaves harvested are kept for further processing.

3. Leaf material is then dried using covens/dehydrators and then minced and ground to a uniform size in a clean commercial plant tissue grinder. The final products are sent for analytical testing including microbiology, nutrients, heavy

metals and pesticides. A representative sample of all batches is kept for traceability.

In all of the analyses, the applicant's data have been compared with both the dry leaf and the product consumed by the public. The applicant has also calculated the percentage difference, between their Guayusa leaves and the comparator Yerba mate leaf, to show how small the differences between the two foods are. This pragmatic approach is in line with a realistic opinion on equivalence between the two products. The applicant in each analysis had compared three batches of Guayusa leaf to one batch Yerba mate leaf.

4. The applicant has compared the nutritional content of their Guayusa leaf to Yerba mate leaf. This is summarised in the table below:

Nutritional Content(g/ 100g)	Guayusa leaf (Dried)	Yerba Mate (Dried)	Guayusa leaf (Tea)	Yerba Mate (Tea)
Protein	14.7 - 15.1	14.1	<0.11	<0.11
Fat	7.8 - 8.3	2.7	<0.06	<0.02
Fibre	34.3 - 38.8	36.5	<0.28	<0.27
Ash	7.2 - 9.5	6.4	<0.06	<0.05
Sugar	3.4 - 5.3	4	<0.04	<0.03
Total Carbohydrate	61.1-65.1	71.7	<0.48	<0.53

5. The applicant has compared the mineral content of their Guayusa leaf to Yerba mate leaf. This is summarised in the table below.

Minerals (µg/g)	Guayusa leaf (Dried)	Yerba Mate leaf (Dried)	Guayusa leaf (Tea)	Yerba Mate leaf (Tea)
Sodium	24.1 - 34.5	19.7	24.1- 34.5	19.7
Potassium	15800-16800	15300	15800 - 16800	15300

Copper	8.74 - 9.18	9.44	8.74 - 9.18	9.44
Iron	29.5 - 32.1	184	29.5 - 32.1	184
Phosphorus	3110 - 3340	1370	3110 - 3340	1370
Magnesium	5800 - 6140	6580	5800 - 6140	6580

6. The applicant has compared the caffeine content of their Guayusa leaf to Yerba mate leaf. This is summarised in the table below.

Caffeine Content	Guayusa leaf (Dried) (mg/100g)	Yerba Mate leaf (Dried) (mg/100g)	Guayusa leaf (Tea) (mg/100ml)	Yerba Mate leaf (Tea) (mg/100ml)
	1860 < 1940	1540	14.27	11.55

7. The applicant has also compared the Amino acid content (Table 3a/b of **Annex A**) and pesticide analysis (Table 1& 2 of **Annex A**).

8. Small variations can be seen in the levels of Fat and some minerals (Sodium, Iron and Phosphorus) notably in the dry leaf comparison but the applicant does not regard these to be significant. The applicant highlights the difference is very small and in each instance less than 1% difference.

b) Nutritional Value and Metabolism

9. The applicant's explains that the commercial interest in both Guayusa and Yerba mate teas is due to the stimulant effect of caffeine and other methylxanthines in the leaves. The applicant highlights that the caffeine content of Guayusa and Yerba mate (as dry leaves) are both substantially below 200mg single dose upper limit determined by the European Food Safety Authority.

10. The applicant's dossier studies relating to Guayusa concluded that there were no safety concerns at dosages of Guayusa leaf extract containing up to 200mg caffeine. The study found no differences between the effects on heart rate or blood pressure due to the Guayusa compared with a synthetic caffeine control.

No significant difference was noted for absorption of caffeine between Guayusa and the synthetic control.

c) Intended Use

11. The applicant intends to market Guayusa leaf for use by consumers, in exactly the same way that the very common green, white, or black teas (*Camellia sinensis*), or herbal teas such as yerba mate (*Ilex paraguariensis*) are marketed. Products for sale in will take the form of Loose-leaf tea and Leaf tea within 1.5 – 2.0g tea bags.

d) Level of undesirable substances

Chemical and Microbial Content

Chemical Contamination

12. The applicant provided results of heavy metals analyses (arsenic, cadmium and lead) for three separate batches of its Guayusa leaves seeds and has compared these with data obtained for a Yerba Mate product on the market (Table of 5 **Annex A**). The applicant also provided data relating to mycotoxins (Aflatoxin B1, B2, G1, G2 and Ochratoxin A) for three separate batches of Guayusa leaf. All results are comparable to those obtained for a Yerba Mate leaf product.

Microbial Contamination

13. The applicant presented a summary microbiological data in Table 6 of **Annex A** and provided analyses of three separate batches of its Guayusa leaf compared these to relevant data for a Yerba Mate leaf product. Data relating to yeasts and moulds, *E.coli*, *Salmonella*, coagulase positive Staphylococci, *Bacillus cereus*, Coliforms and Enterobacteriaceae were presented. No concerns were identified and Ikiam University Consortium's guayusa leaf results are comparable to those obtained by a Yerba Mate product.

Committee Action Required

- The Committee is asked whether it agrees that substantial equivalence has been established between Ikiam University Consortium's Guayusa leaf and an existing

product on the market, Yerba mate (*Ilex paraguariensis*) in accordance with Article 3(4) of Regulation (EC) 258/97.

- If so, the Secretariat proposes to draft an opinion incorporating the ACNFP's comments on this application which will be presented along with the results of the public consultation at the next meeting in September.
- If not, the Committee is asked what additional information the applicant should supply in order to demonstrate equivalence.

Secretariat

June 2017

Annexes attached:

Annex A - Application Dossier

Annex B1 - Certificates of analysis

Annex B2 – Certificates of analysis