COMMITTEE PAPER FOR DISCUSSION **ACNFP/139/01**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

HERBAL INFUSION MADE FROM COFFEE LEAVES - TRADITIONAL FOOD NOTIFICATION NF 2019/0740

Issue

A notification has been received under the traditional food authorisation process for an herbal infusion made from coffee leaves under Regulation (EU) No 2015/2283.

The Committee is asked whether there are safety concerns with the proposed use of this traditional food in the EU market. The information from the Committee will provide the basis for any safety objections raised at EU level.

Background

1. On 11th September 2019 the European Commission forwarded the notification from 1A Food Consulting on behalf of AM Breweries IVS for an herbal extract from coffee leaves from *Coffea arabica* and/or *Coffea canephora.*

2. Member States have four months, until 11th January 2020 to submit any reasoned safety objections to the notification. If authorised, the authorisation will be open to any company to use, subject to the specification and conditions of use detailed the authorisation.

3. The notification dossier is attached as **Annex A** and the key appendices to the dossier are attached as **Annex B**, both of which contain protected commercial information. The Secretariat has prepared a list of all the appendices to the dossier in **Annex C**, these are available to members, on request.

Identification

4. The product is an herbal infusion made from coffee leaves of *Coffea arabica* and/or *Coffea canephoroa* species*.* While beverages made from coffee beans have been consumed in the EU, drinks from the leaves are considered novel foods.

5. Herbal infusions from the leaves have been consumed in Ethiopia, South Sudan, Liberia, Indonesia and Jamaica as a traditional beverage. It is intended to be consumed in the same way as tea, by adding water to the fresh, dried or roasted coffee leaves. Sometimes, spices, herbs and milk are added to the drink.

6. It is not easily discernible from the application, but it suggests the application is for pasteurised herbal infusion sold as a beverage/ready to drink product or used in beverages that normally could contain coffee and/or tea (e.g. iced tea, drinks etc.). However, that applicant states in the production process that it can be added to a product directly from the production line.

7. Specification details are provided by the applicant in the form of a specification document provided below:

Specification: **Herbal infusion from coffee leaves (20 g/litre)** **(*Coffea arabica* L. and/or *Coffea canephora* Pierre ex A.Froehner).**		
Test	**Criteria**	**Method**
Visual	Brown green liquid	Visual evaluation
Odour and Taste	Characteristic	Organoleptic evaluation
Assay	**Chlorogenic acid < 100 ppm**	HPLC
	Caffeine < 80 ppm	HPLC
MICROBIOLOGY	Complies with 2073/2005/EC	Complies with EU Reg. 852/2004
Total Plate count	< 500 cfu/g	AOAC
Total Yeast and mould count	< 100 cfu/g	AOAC
Total coliforms	< 100 cfu/g	AOAC
Escherichia coli	Absent in 1g	AOAC
Salmonella	Absent in 25 g	AOAC
HEAVY METALS	Complies with 1881/2006/EC	Complies with EU Reg. 333/2007
Lead (Pb)	< 3,0 ppm	AA
Arsenic (As)	< 2,0 ppm	AA
Cadmium (Cd)	< 1,0 ppm	AA
Mercury (Hg)	< 0,1 ppm	AA
Pesticide residue	Complies with 396/2005/EC	GC-MS
Aflatoxins	Complies with 1881/2006/EC	IAC-LC
The following are tested on the leaves periodically, based on the risk for irradiation and GMO material.		
Irradiation	NON-Irradiated	Thermoluminescence analysis
GMO	NON-GMO	

Composition

8. Compositional analysis is based on fives batches of herbal infusion, selected after production. Samples were tested by accredited laboratories, for a range of parameters detailed below:

(All analyses were made right after production of the herbal infusion of coffee leaves.)

Batch	1A – Ren te (1)	2A – Ren te (2)	3A – Ren te (3)	4A – Ren te (4)	5A – Ren te (5)
Ash (%)	< 0,05 (LOQ)	< 0,05 (LOQ)	< 0,05 (LOQ)	< 0,05 (LOQ)	< 0,05 (LOQ)
Dry Matter (%)	< 0,05 (LOQ)	< 0,05 (LOQ)	< 0,05 (LOQ)	< 0,05 (LOQ)	< 0,05 (LOQ)
Protein (%)	< 0,1 (LOQ)	< 0,1 (LOQ)	< 0,1 (LOQ)	< 0,1 (LOQ)	< 0,1 (LOQ)
Fat (%)	< 0,4 (LOD)	< 0,4 (LOD)	< 0,4 (LOD)	< 0,4 (LOD)	< 0,4 (LOD)
Caffeine (ppm)	10,4	10,3	10,3	10,3	10,8
Chlorogenic acid (3-CQA) (ppm)	7,6	8,0	7,4	7,3	8,3
Arsenic (ppm)	< 0,1	< 0,1	< 0,1	< 0,1	< 0,1
Cadmium (ppm)	< 0,01	< 0,01	< 0,01	< 0,01	< 0,01
Mercury (ppm)	< 0,005	< 0,005	< 0,005	< 0,005	< 0,005
Lead (ppm)	< 0,05	< 0,05	< 0,05	< 0,05	0,064
Pesticides	N.D.	N.D.	N.D.	N.D.	N.D.
Thermotolerant Coliforms (cfu/ml)[1]	< 1	< 1	< 1	< 1	< 1
Salmonella (in 25 g)	Neg.	Neg.	Neg.	Neg.	Neg.
Moulds (cfu/g)[2]	< 10	< 10	< 10	< 10	< 10
Yeast (cfu/g)[2]	< 10	< 10	< 10	< 10	< 10
Total Aerobic count (cfu/g)[3]	90	< 100	< 100	< 100	90
Coliforms (in 1 g)[4]	Neg.	Neg.	Neg.	Neg.	Neg.

LOQ – Limit of Quantification. LOD – Limit of Detection. N.D. – Not Detected. Neg. – Negative. [1]This is comparable to "Total coliforms" in the specification for the herbal infusion of coffee leaves. [2]These two summed are comparable to the "Total yeast and mould count" of the specification. [3]This is comparable to "Total Plate count" of the specification. [4]This is comparable to "Escherichia coli" of the specification.

9. The applicant indicates that the herbal infusion does not contain significant amounts of macro or micro nutrients, but contains phenolic compounds. Tests were conducted on milled leaves and two drinkable products. 11 polyphenols were found including caffeoylquinic acids, phenolic acids, flavonols and Mangiferin. The phenolic content has been analysed and a safety summary has been made by the applicant. Chlorogenic acids is the main polyphenol found in the product and it is proposed limits for this component are included in the specification for the product.

10. The herbal infusion has also been tested for the content of aflatoxins (B1, B2, G1 and G2) on 5 batches by accredited laboratories and the results found to be negligible. Testing has also been undertaken by the applicant on the Copper content which was also found to be negligible. The reason for testing for Copper is that Copper-based fungicides are often used to control coffee berry disease.

11. The applicant draws attention to the amount of fat, carbohydrates and protein being low in the infusion. Their contents will be lower in tea, the product as consumed when water is added.

12. The applicant considers two compounds as benefiting from monitoring as part of the specification, these are caffeine and chlorogenic acid. This because it can be considered caffeine product and the applicant draws attention to potential effects of high caffeine consumption in pregnant women.

13. The level of caffeine found in this product is consistent with the level of caffeine in the literature (8-12mg/g). Chlorogenic Acid was selected as it was the most prominent polyphenol. The actual content in the five production batches for both Caffeine and chlorogenic acids were much lower than the limits of the specification.

Stability

14. The applicant does not provide a stability study but suggests a 1-year shelf life for the infusion before preparation. This is based on the product not having a significant amount of macro-nutrients that could breakdown during storage.

15. The applicant suggests this novel food is intended to be drunk or used as one ingredient among other ingredients in a finished beverage immediately after brewing.

Production Process

The applicant has detailed their production process in the follow chart below.

Flow chart of the process from harvest to herbal infusion:

Processes	QA
Harvest of leaves	No leaves with rust, sickness or dirt are picked. Visual inspection.
Drying of leaves (2 days)	Leaves are sorted. Leaves are dry. Visual inspection.
Packing in airtight sacks	Sacks are made of approved food-contact material.
Transport	Transported by NTG (Approved food transporter)
Washing with pure tap water	Leaves sorted. Washed till clean. Visual inspection.
Brewing herbal infusion	Brewing is controlled by computerized system. (Ratio, temperature and time)
Pasteurization	Pasteurization is controlled by computerized system. (Standard process)
Immediate use in in another product	Further processing in fully automated closed system.

16. The leaves come from coffee trees/bushes grown from plantations in Ethiopia. They grow 2m apart in semi shadows of taller trees e.g. avocado trees. Vegetation is controlled by macheting. The trees are primarily cultivated for coffee beans

17. While for the traditional use, the leaves are pricked fresh from the tree. The applicant indicates that for the use in herbal infusion, the leaves are picked before the coffee bean harvest in September and March. The picking is done by hand, with only health leaves harvested to maintain quality.

18. The leaves are sorted, and then are dried on drying beds made of mesh nets or wooden planks, 1m off the ground. The leaves are dried 1 day in the sun and one day in shadows with air. Temperatures range were suggested to range from 20-28^{o}C.

19. After drying they are packed in sacks and stored in dark and dry storage until they are transported by tuck to the sea port or airport. The sacks are layered: Standard sack Kraft paper/ laminated paper and metalized polyester / aluminium foil to protect the leaves.

20. In Denmark, the leaves are sorted and washed using clean tap water before being used for brewing. This herbal infusion of coffee leaves is prepared by using 20g of coffee leaves per litre of water in fully automated brewing facilities at 55°C for 3 minutes. This process is computer controlled by the automated equipment.

21. After pasteurization the herbal infusion is used immediately as an ingredient in other beverages straight from the pasteurisation tank in a closed system thus keeping the aseptic conditions intact.

History of Continued Use/Traditional Use

22. The applicant states that the herbal infusion beverage has been consumed by millions of people in Ethiopia, South Sudan, Liberia, Indonesia and Jamaica through many decades. The consumes have been the general public and include children, adults and the elderly. They state the pregnant women have also consumed this the traditional product. Further details to understand how the product has been used traditionally were not provided.

Proposed use for the EU market

23. The applicant suggests the expected level of consumption as being 0,5 to 1 litre (3-7 teacups) of herbal infusion from coffee leaves (using 20 g of coffee leaves in 1 litre water for brewing) or equivalent beverage per day.

24. This is a bit less than the estimated use in Ethiopia which corresponds to 0,6 to 1,5 litre herbal infusion per day.

25. The applicant intends that the herbal infusion from coffee leaves will replace ordinary coffee or tea in the diet of consumers. In terms of maximum use level these were predicted to 5 litres herbal infusion from coffee leaves or equivalent beverage per day, using 20 g of coffee leaves in 1 litre water for brewing as per the international standards.

26. No formal exposure assessment was provided in the application.

Committee Action Required

- Members are asked whether there are safety concerns that need to be managed with this traditional food from third countries.
- The Committee's advice will form the basis for the UK's formal response to the Commission and whether reasoned safety objections are submitted.

Secretariat
October 2019

Annexes Attached

Annex A – The notification

Annex B – The Reference list

Annex C - Quality Analysis Report / raw analytical data

Annex D – Supporting Documents to the dossier