

## ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

CACAO FRUIT PULP (THEOBROMA CACAO L) – TRADITIONAL FOOD  
NOTIFICATION NF 2019/1014**Issue**

1. A notification for Cacao Fruit Pulp a traditional food from third country has been received under Regulation (EU) No 2015/2283.
2. 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**

3. On the 20 June 2019 the European Commission forwarded the notification from CABOSSE Naturals NV for authorisation of cacao fruit pulp, including juice made from the pulp. The applicant intends to market the product as a fruit juice, to be consumed as such (juice and pulp), with added water (juice, concentrate, pulp) or as ingredient in foods (mainly concentrate).
4. Member States have four months, until 20 October to submit reasoned objections to the notification. If authorised, the authorisation will be open to any company subject to the specification and conditions of use detailed the dossier.
5. The notification dossier is attached as **Annex A**. Analytical data on composition is attached as **Annex B** and the further annexes to the dossier are provided as **Annex C**. All three contain confidential information. **Annex D** lists all the documents provided by the applicant.

**This application***Identification*

6. The applicant explains that the product is derived from the Theobroma cacao L. plant a member of the Sterculiaceae used to produce chocolate. Cacao pulp is the juicy, off-white mucilaginous flesh that surrounds the beans found inside the cocoa pod. The applicant indicates that the pulp is high in sugars, contains citric acids and is stated to have a sweet and delicate taste that can be eaten straight after opening the pod.
7. During cocoa bean processing, the pulp is fermented through enzymic action producing a run-off liquid called 'Cocoa Sweatings'. This can be collected and used. However, the pulp can be extracted mechanically to produce a highly viscous

liquid also known as ‘cocoa pulp’. This can be further processed to produce ‘cocoa juice’. This is a liquid product produced in an industrial setting, using enzymes. Both, sweatings and the juice can be used to make a cocoa ‘jelly’, a spreadable cocoa product.

### Specifications

- The applicant provides a table of all the analysis completed, organised in an excel table (Annex B). It contains all the results for the individual samples, of the cacao fruit juice (5 samples) and cacao fruit juice concentrate (5 samples), cacao pulp (5 samples) and cacao sweatings (3 samples), detailing on the microbiology, nutritional, heavy metals, anti-nutritional factors and contaminants.

### Composition

- In the dossier, the applicant provides the average of the physico-chemical and nutritional composition see below. The applicant also provides the raw data for individual samples taken for the nutritional analysis, with standard deviations, which have been omitted in the summary table presented here.

	Sample	Juice Average	Concentrate Average	Pulp Average	Sweatings average
Parameter	Unit				
<b><u>Physico-chemical</u></b>					
Ash 500-550 °C	% (m/m)	0.5	1.2	0.5	0.4
Moisture, vacuum	% (m/m)	78.7	38.4	79.4	81.0
<b><u>Energy</u></b>					
Energy value (kcal)	kcal/100 g	83.0	242.0	79.2	73.0
Energy kJ (calculated)	kJ/100 g	348.0	1000.0	332.0	306.7
<b><u>Macronutrients</u></b>					
Protein (Nx6,25)	% (m/m)	0.6	1.4	0.7	<0.5
Carbohydrates Calculated	% (m/m)	19.5	57.9	18.1	17.6
Total sugar as Glucose	% (m/m)	18.0	51.4	16.5	16.2
Total fat, Soxhlet	% (m/m)	<0.2	<0.2	<0.2	<0.2
Insoluble High Molar Weight Dietary Fibre	% (m/m)	0.6	0.4	0.7	0.0
Soluble High Molar Weight Dietary Fibre	% (m/m)	0.6	0.9	0.7	1.0
Total dietary fibre	% (m/m)	0.8	1.2	1.1	1.0
<b><u>Minerals</u></b>					
Calcium	mg/kg	73	208	54	
Phosphorus (P)	mg/kg	123	352	140	
Iron (Fe)	mg/kg	2.6	7.1	2.9	35.7
Potassium (K)	mg/kg	2020	5860	1700	
Copper (Cu)	mg/kg	0.7	1.8	0.7	0.5
Magnesium (Mg)	mg/kg	220	632	200	
Sodium	mg/kg	11	24	6	7

<b>Zinc (Zn)</b>	mg/kg	2.0	5.7	1.9	0.9
<b>Manganese (Mn)</b>	mg/kg	0.6	1.6	0.5	1.0
<b><u>Vitamins</u></b>					
<b>beta-Carotene</b>	µg/100 g	< 0.1	< 0.1	0.0	
<b>Vitamin B12 (cyanocobalamin)</b>	µg/100 g	<5 LOQ	<5 LOQ	<5 LOQ	
<b>Riboflavin (vitamin B2)</b>	mg/100 g	0.00	0.00	0.02	
<b>Niacin (vitamin B3)</b>	mg/100 g	0.00	0.00	0.00	
<b>Pantothenic acid (vitamin B5)</b>	mg/100 g	0.51	1.63	0.61	
<b>Pyridoxine (vitamin B6)</b>	mg/100 g	0.04	0.14	0.04	
<b>Biotin (vitamin B8)</b>	mg/kg	0.04	0.11	0.05	
<b>Ascorbic acid (vitamin C)</b>	mg/100 g	0.01	0.51	0.00	
<b>Ergocalciferol (vitamin D2)</b>	µg/100 g	<0.5 LOQ	7.0	16.1	
<b>alpha-Tocopherol (vitamin E)</b>	mg/100 g	<0.25 LOQ	<0.25 LOQ	<0.25 LOQ	
<b>beta-Tocopherol (vitamin E)</b>	mg/100 g	<0.08 LOQ	<0.08 LOQ	<0.08 LOQ	
<b>delta-Tocopherol (vitamin E)</b>	mg/100 g	<0.5 LOQ	<0.5 LOQ	<0.5 LOQ	
<b>gamma-Tocopherol (vitamin E)</b>	mg/100 g	<0.5 LOQ	<0.5 LOQ	<0.5 LOQ	
<b>Sum of tocopherols</b>	mg/100 g	<0.5 LOQ	<0.5 LOQ	<0.5 LOQ	
<b><u>Phytochemicals</u></b>					
<b>Theobromine</b>	% (w/w)	0.00055	0.00173	0.00065	0.00132
<b>Theophylline</b>	% (w/w)	ND	ND	ND	ND
<b>Caffeine</b>	% (w/w)	ND	ND	ND	ND
<b>Polyphenols calculated as gallic acid equivalent</b>	mg/kg	619	1604	1065	554

LoQ = Limit of quantification ND =Not detected.

## Heavy Metals

10. The applicant provides analysis of heavy metals in the product, linking these metal concentrations to the limits set in EU regulations outlined in the dossier. The applicant draws attention to cadmium results stating the level is below the cadmium limit level set for cocoa. The applicant states that for the other heavy metals no limits are defined for cocoa, however the levels found are below that specified for similar food products.

	<b>Sample</b>	<b>Juice Average</b>	<b>Concentrate Average</b>	<b>Pulp Average</b>	<b>Sweatings average</b>
<b>Parameter</b>	<b>Unit</b>				
<b>Aluminium (Al)</b>	mg/kg	<0.2	<0.2	0.8	6.0
<b>Arsenic (As)</b>	mg/kg	<0.01	0.02	0.02	<0.01
<b>Cadmium (Cd)</b>	mg/kg	0.026	0.075	0.032	0.024
<b>Chromium (Cr)</b>	mg/kg	0.07	0.06	0.06	0.04
<b>Copper (Cu)</b>	mg/kg	0.65	1.78	0.73	0.57
<b>Lead (Pb)</b>	mg/kg	<0.01	<0.01	<0.01	0.06
<b>Molybdenum (Mo)</b>	mg/kg	0.028	0.076	0.020	0.037
<b>Mercury (Hg)</b>	µg/kg	<0.5	<0.5	0.7	<0.5
<b>Nickel (Ni)</b>	mg/kg	0.37	0.99	0.33	0.21

## Microbiology

11. The applicant draws attention to the high sugar content of the pulp, stating its susceptibility for microbiological contamination. The applicant suggests that their pasteurization step reduces the microbiological risk. The applicant also comments on the naturally low PH of the product stating that it prevents the growth of microorganisms.
12. The applicant highlights that positive results that were found for yeast contamination and provides an explanation for where this positive result arises from, stating likely contamination between sampling locally and arrival as the explanation. Within the dossier the applicant provides analytical results for all batches assessing the level of mycotoxins (**Annex B**), Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, Aflatoxin G2 and Ochratoxine A (OTA)). All values were below the Limit of Quantification (LoQ).

## Pesticides

13. The applicant provides information on screening of samples of the product for pesticide residues. All batches tested negative for residues of a panel of pesticides commonly employed in cacao farming, except two of the samples. One of the samples of sweatings showed presence of residues of terbutryn. Terbutryn is a pesticide not commonly used on cacao as per the ICCO Pesticide use in cocoa manual (ICCO, 2015). One sample of the concentrate showed presence of biphenyl below the EU MRL for cacao currently set at 0.05ppm and therefore it is not considered an issue.

## *Stability*

14. The applicant explains that the proposed storage conditions for the juice, pulp and concentrate are 200L barrels lined with 2-MDPE, or 23kg plastic buckets (concentrate only), and that product should be stored frozen or at 4°C and used directly after opening. They propose a shelf-life of one year, stating there is literature data to support this conclusion (Matta et al 1999).
15. The applicant also states that they carried analysis of cacao juice samples in November 2017, after applied pasteurization and food no microbiological risks of concern.

<b>Salmonella</b>	<b>/25 g</b>	<b>Not Detected</b>
<b>Aerobic Plate Count 30°C</b>	cfu/g	<10
<b>Coliforms 30°C</b>	cfu/g	<10
<b>Enterobacteriaceae</b>	cfu/g	<10
<b>Escherichia coli</b>	cfu/g	<10
<b>Yeast 25°C</b>	cfu/g	<10

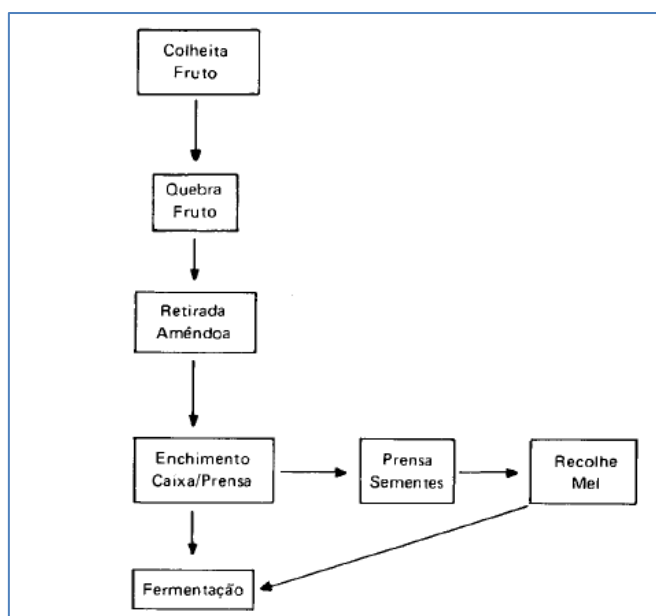
Moulds 25°C	cfu/g	20
pH (acidity)		3.28

### *Production Process*

16. The applicant provides a series of production diagrams in the dossier outlining the industrial process for cocoa and the traditional sweatings process for comparison. Comparisons are also made between traditional collection of the material and the process proposed by the applicant.
17. The applicant explains that the traditional food is produced from the cacao pods that are transported to the production facility where they are cleaned and opened. Undesirable pieces are removed and the wet beans are depulped. The pulp is then cooled and pasteurised if it is direct for further use in food applications. When the pulp is used for further juice and concentrated juice production, then it directly undergoes an enzymatic treatment, a filtration step and centrifugation and finally a pasteurisation. For transport and storage and certain applications a further concentration step takes place. The final juice and juice concentrate are frozen or refrigerated for storage and transport.

### *History of Continued Use/Traditional Use*

18. The applicant provides evidence to support Cocoa Pulp use for beverages in 1400-1100 B.C. They suggest the pulp has been used domestically in Brazil for decades, and was commercialised in the 1970's.
19. The applicant references a CEPLAC 1982 report covering cacao fruit juice production over 1975-77. It describes making a cocoa honey (juice) by pressing and by cocoa pod breaking methods to collecting the honey (juice); outline below.



Portuguese	Translation
Colheita Fructo	Harvest of the fruit
Quebra Fructo	Breaking of the fruit
Retirada Améndoa	Removal of the pod
Enchimento Caixa/Prensa	Collection Box/Press
Prensa Sementes	Pressing of the seeds
Recolhe Mel	Collection of the Honey
Fermentação	Fermentation

20. The report explains that there were 5 juice manufactures at the time of the report in 1979, approximately producing 20,000 litres of cacao fruit juice. 3kg of Cocoa is needed to make 1L of juice using the method available at the time. With the capacity for juice production estimated in the report as 82 million litres, of which 2.15 was used to produce jelly. The report states Jelly production occur(s) in 3 facilities with output of 27.3 tons (1976) and 38.6 tons (1978).
21. The applicant provides additional references to evidence the consumption of the juice including Figueira et al., 1993 on production information and evaluation of industrial de-pulping machine capabilities outlined below

**Quadro 16 - Classificação dos clientes das indústrias - 1978.**

Categoria	% de vendas das fábricas (gelêia)		
	A	B	C
Consumidores	-	5	-
Varejistas	70	70	50
Supermercado	30	25	50

*Classification of the clients of the cacao honey/juice/jelly- 1978. (Consumidores – consumers; Varejistas – retailers; Supermercado – supermarkets).*

22. The applicant provides a series of testimonials, references, products and recipes derived from cocoa pulp, juice and concentrate products including; Brasfrut, Demarchi, Frutamil, Ricaeli, Fruttine, Carbonari, Mashpi, and tropi Juilce, which are a range of frozen and liquid cocoa juice products, jellies and lollies.

23. The applicant also provides a series of testimonials from Professors and members of the cocoa industry who details on the consumption of cocoa pulp products, heavily referencing the use of cocoa pulp products used to make ice lollies.

24. The applicant also provides information on international use of cocoa pulp products, which are produced in other regions where cocoa is produced.

**Conditions of Use in the EU market**

25. The applicant intends the product to be used as a fruit juice, to be consumed as such (juice and pulp), with added water (juice, concentrate, pulp) or as ingredient in foods (mainly concentrate), with primary use as a beverage – with water added to the pulp to produce the beverage.

26. The cacao fruit juice concentrate is intended to be reconstituted as a drink with the addition of water or to be applied at levels of max 40% (w/w) as replacement for traditional sugar in foods like bakery foods, confectionary, smoothies, cereal bars and other health food products.

27. The applicant states that cacao fruit juice and cacao pulp concentrate will not introduce changes in the dietary pattern.

28. The applicant applied the FAIM model for calculating dietary exposure indicating a maximum consumption of cocoa soft drinks and fruit juices in adults accounts for 1.48 litre per day for high level consumers across dietary surveys. For adolescents, the intake is 1.21 litre and for children, this amounts to 1.2 litre.

29. For the concentrate, if used in all proposed uses at maximum use level this would result in intakes of 136 g of concentrate (corresponding roughly to 340 ml of juice) for adults and adolescents at highest level consumption and 142 g for children.

30. The applicant also provides a table for the intended use of cocoa concentrate in products.

FCS Name (level 2)	Food category	Specific conditions of use	
14.1	Beverages (fruit juices, flavoured drinks, fruit nectars, non-alcoholic beverages, dairy alternatives, smoothies)	Concentrate: max 8% Juice: max 100% Pulp: max 15%	The designation of the novel food on the labelling of the foodstuffs containing it shall be for the pulp, 'cacao pulp' and for the juice (concentrate) 'cacao fruit juice (concentrate)' or 'cacao pulp juice (concentrate)'

7.2	Fine bakery wares	Concentrate: max 10%	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'cacao fruit juice concentrate' or 'cacao pulp juice concentrate'
5.1	Cocoa & Chocolate products as defined in Directive 2000/36/EC	Concentrate: max 40%	
5.2			
3.	Candy & Confectionery products	Concentrate: max 25%	
1.23	Edible Ices (ice cream and sorbet)	Concentrate: max 10% (max 45% in sorbet)	
15.1	Yoghurt & yoghurt drinks	Concentrate: max 5%	
11.2			
15.1	Cereal bars / Cereal-, potato- flour- or starch based snacks	Concentrate: max 15%	
12.7	Jam & Jellies in accordance with Directive 2001/113/EC	Concentrate: max 25% in a marmalade. (max 30% in mousse spreads)	
	Nutrition bars		
	Plant based spreads (incl. fat-based spreads)	Concentrate: max 25%	
		Concentrate: max 30% use.	

### Other information supplied by the applicant

31. The applicant also assesses the samples for substance of concern including, Erucic Acid, MOSH, CDD, CDF, 3-MCPD, 2-MCPD, Cyanide and Acrylamide. The applicant states that levels detected are below the limit of quantification (LoQ) for the test.

32. The applicant states that all samples tested negative for peanut protein, and states there are no reports of allergy to Cocoa pulp.

### 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.



**Annexes Attached**

**Annex A** – The Dossier

**Annex B**– Quality Analysis Report / raw analytical data (As the report contains all the analytical data, the separate certificates of analysis have been omitted and are available on request)

**Annex C** – Supporting Documents to the dossier