COMMITTEE PAPER FOR DISCUSSION **ACNFP/137/05**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

CACAO FRUIT PULP (THEOBROMA CACAO L) – TRADITIONAL FOOD NOTIFICATION NF 2019/866

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 22 May 2019 the European Commission forwarded the notification from Nestec York Ltd. for authorisation of cacao fruit pulp and products thereof. The applicant intends to market the product within the food categories: Frozen fruit, Fruit and vegetable preparations, Jam jellies and marmalades, Confectionery and Fruit juices.

4. Member States have four months, until 22 September 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 in the dossier.

5. The notification dossier is attached as **Annex A**. Analytical data and other relevant supporting information are attached as **Annex B.** Both contain confidential information. **Annex C** lists all the documents provided by the applicant.

This application

Identification

6. The applicant explains that the product is derived from Theobroma cacao L., traditionally consumed in Brazil. 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. The applicant describes that the pulp is obtained by splitting cocoa pods, separating the pulp from husks and beans and then pasteurised and frozen. The pulp is proposed to be used as an additional fruit pulp source for direct consumption or further processing.

Production Process

8. The applicant describes how cocoa plants destined to obtain cocoa pulp are cultivated under the same conditions as those for production of cocoa, following recommendations by the Federation of Cocoa Commerce. The applicant states that pesticides are used, complying with Maximum Residue Limits as set out in Regulation (EC) No 396/2005. According to the applicant, only ripened pods are harvested, avoiding harvesting of over-ripened pods due to potential Ochratoxin A contamination.

9. The applicant describes the mechanical separation of cocoa pulp as a traditional process in which, immediately after splitting the pods, 20-100% of the pulp is removed, then pasteurised and frozen. Operational parameters and flow charts were provided by the applicant in the notification dossier in Annex A.

10. For the production of cocoa juice, the applicant describes the process of pressing the pulp, removing fibres and using further pasteurisation. They also point to the potential processing of the juice into a dehydrated/powdered form and the various uses of the processed juice as an ingredient in different foods. More details on the production process are provided by the applicant in the notification dossier in Annex A .

11. The applicant states that the production processes described are not expected to affect the bioavailability or nutritional value of cocoa pulp. According to the applicant, biological hazards are controlled via pasteurisation and freezing, chemical hazards are controlled along with best practices for the manufacture of cocoa, and contaminants are managed via HACCP.

Composition

12. The applicant states that the compositional data was obtained based on a literature search, which is described in the “Data from experience of continued use” section. References used for values can be found in the “References” document. The original papers were not provided by the applicant, but the summary composition tables for the original papers can be found in “Annex B – Part 3: Annexes to the Dossier”, from page 2 onward. Tables for the composition values chosen by the applicant of cocoa pulp and cocoa pulp juice can be found in tables 2 and 3, respectively, in section 2.4 “compositional data” of the dossier, in Annex A.

Table 2 Compositional data of cocoa pulp.

Parameter	Range as reported in the literature
pH	3.2 - 4.8
Total soluble solids (° Brix)	12.1 – 20.5
Moisture (%)	83 – 90

Ash (g / 100 g)	0.22 - 0.24
Fat (g / 100 g)	0.45 *
Carbohydrates (g / 100 g)	15.2
Protein (g / 100 g)	0.64 – 0.74 *
Sugars (g/ 1 00 g)	11.15 - 17.4
Fructose (g / 100 g)	3.8 – 6.2
Glucose (g / 100 g)	3.0 – 5.1
Sucrose (g / 100 g)	2.1 – 4.3
Ethanol (% w/w)	0.01 – 0.5
Pectin (g / 100)	0.57 - 1.08
Citric acid (mg / g)	3 – 24
Acetic acid (mg / g)	0.2 – 0.4
Lactic acid (mg / g)	0.1 – 0.3
Biotin ((µg / 100 g)	10 **
Calcium (mg / 100 g)	46 ** –316
Copper (mg / 100 g)	2
Cyanocobalamin (µg / 100 g)	5 **
Folic acid (µg / 100 g)	15 **
Iron (mg / 100 mg)	2.4 – 3.7 **
Magnesium (mg / 100 g)	12 ** – 151
Manganese (mg / 100 g)	0.01 ** – 0.95
Niacin (mg / 100 g)	
Nickel (mg / 100 g)	
Pantothenate (mg / 100 g)	0.4 **
Potassium (mg / 100 g)	180 ** – 842
Pyridoxin (mg / 100 g)	0.6 **
Riboflavin (mg / 100 g)	41 **
Sodium (mg / 100 g)	48.4 – 103.3 ***
Thiamine ((µg / 100 g)	36 **
Vitamin C (mg / 100 g)	49 **
Zinc (mg / 100 g)	0.2 – 3,2

* fat content values, 15.85 – 29.27 g / 100 g, from Escalante et al 2013 were excluded as they do not match, or are compatible with,, data in other articles also on juice (e.g. Santos et al, 2014; Pettipher, 1986) and in reviews (Schwan and Wheals, 2004). For similar reasons values for protein were excluded.. ** recalculated to wet weight assuming average dry weight of 16.3 %. *** values from Pettipher, 1986 (0.6 – 1 mg / 100 g fresh weight) for sodium were considered outliers and are not listed.

Table 3 Composition of cocoa pulp juice.

Parameter	Range as reported in the literature
pH	3.3 – 3.75
Total soluble solids (° Brix)	11.5 – 16.7
Moisture (%)	83.2 – 85.3
Ash	0.26 – 3.76
Fat (g / 100 g)	0.25 *
Carbohydrates (g / 100 g)	15.2
Fibre (g / 100 g)	0.0 – 0.2
Protein (g / 100 g)	1.11
Glucose (g / L)	215.24
Sucrose (g / 100 g)	21.31
Pectin (g / 100)	0.078
Citric acid (g / L)	9.14
Malic acid (g / L)	3.6
Acetic acid (g / L)	2.28
Oxalic acid (g / L)	1.27
Lactic acid (g / L)	1.23
Fumaric acid (mg / L)	0.2
Calcium (mg / 100 g)	171
Magnesium (mg / 100 g)	20.8 - 82.5
Phosphorus (mg / L)	62.47
Potassium (g / 100 g)	1.11
Sodium (mg / L)	30.5
Vitamin C (mg/L)	18.3
Catechin (mg / L)	13.6
Ferulic acid (mg / L)	9.5
Protocatechuic acid (mg / L)	6.9
Syringic acid (mg / L)	6.2
Trans-cinnamic acid (mg / L)	2.3
Gallic acid (mg / L)	2.2

* fat content values, 3.54 ± 0.2 g / 100 g, from Anvoh et al 2009 were excluded as they do not match, or are compatible with the composition of fruit and more recent data (Santos et al, 2014).

13. Theobromine levels were not provided by the applicant as part of the composition analysis. A separate document outlines the intended product specifications for product when produced by this applicant.

Contaminants

14. The applicant provides a table (Table 1), showing the levels of contaminants tested in two batches of their product. Pesticides were analysed via GC-ECD/GC-NPD/GC-MS/LC-MS or by LC-MS/MS, ochratoxin A via IAC-LC-MS/MS and metals via IC-MPS. Tests can be found in the document titled “Annex B - Annex 32”. The applicant describes levels of Cadmium, Aluminium, Nickel and Copper as being within regulation limits. No microbiological information other than ochratoxin A levels was provided by the applicant in this section.

Table 1 Data on contaminants obtained by the applicant on two lots of dehydrated cocoa pulp.

Parameter	Lot RD50796	Lot RD52012
Pesticides	ND*	ND*
Ochratoxin A	ND*	ND*
Arsenic	ND*	NQ*
Lead	0.05 mg / kg	0.016 mg / kg
Cadmium	0.063 mg / kg	0.030 mg / kg
Aluminium	6.3 mg / kg	26 mg / kg
Nickel	1.4 mg / kg	2.3 mg / kg
Copper	5.0 mg / kg	3.3 mg / kg

* ND = Not Detected or NQ = Not Quantified, with a LOQ of 0.100 mg / kg (dithiocarbamates), of 0.0250 mg / kg (ETU), of 0.010 mg / kg (phosphane and phosphide salts), of 0.025 mg / kg (PTU), of 0.100 mg / kg (methyl bromide), 0.5 µg/kg (ochratoxin A), 0.125 mg / kg (arsenic)

Stability

15. The applicant explains that cocoa pulp may be stored as a frozen product, pasteurised juice, dehydrated or powered juice, pasteurised fruit preparation or as a jam. They also state that freezing and pasteurisation are expected to prevent instability risks.

16. The applicant describes that no specific degradation products are expected, and that there are no compounds specific to cocoa pulp that would warrant stability testing. That, together with the familiarity of the food industry with similar products, lead the applicant to believe that no specific data is required, and give an estimation of 24 months of storage time for frozen cocoa pulp. Dates and evidence for other forms of the product were not provided by the applicant.

Specifications

17. The applicant provides a specification table with what they consider to be the relevant parameters for cocoa from a safety point of view. This can be found below in Table 4 (labelled Table 1 by the applicant in the document). Further specifications can be found in the confidential section of the dossier. Theobromine maximum levels were not provided as part of the specifications. The rationale for this is provided by the applicant at the end of section 2.6 of the dossier.

Table 4

Parameter	Limits	Method
Description/definition	The traditional food is the pulp of *Theobroma cacao* L. (genus: Theobroma family: Malvaceae). Cocoa pulp is obtained by splitting cocoa pods followed by separation from husks and beans; the pulp is then subject to pasteurisation and freezing. The frozen or dried cocoa pulp is used as a fruit ingredient of juices, confectionery, edible ices, fruit preparations and jams.	
Compositional data of pulp from *Theobroma cacao*	Minimum Brix Level (° Brix) 14 (AOAC 985.26) Minimum pH 3.4 Sugars, total: > 11,0 g/100 g	
Pesticides	Complies with levels set by Regulation (EC) No 396/2005 for "0640000" "Cocoa beans / scientific name: *Theobroma cacao*"	As defined in EU law
Cadmium	0.60 (mg / kg wet weight) (dehydrated cocoa pulp when sold to the final consumer)	As defined in EU law
Aerobic colony count	5,000 cfu / g (dry powder only)	ISO 4833 *
Enterobacteriaceae	10 cfu / g (dry powder only)	ISO 21528-2 *
Salmonella	Absence in 25 g	EN/ISO 6579 *

* or alternative analytical method validated against the reference method listed in the table.

History of Continued Use/Traditional Use

Literature review

18. The applicant describes that a comprehensive literature review was performed. The search was run on Scopus with "cocoa pulp" as the sole search term with no limits set. In order to identify grey literature, the applicant searched for "cocoa pulp" on Google Scholar with no limits set and translating the term into other languages.

Extent of use

19. The applicant describes that cocoa pulp has been a relevant component of cocoa production for a long time and that it is already part of the fermentation process needed in the production of cocoa powder and butter. The pulp is suitable for immediate consumption but is susceptible to quick microbial growth. Cocoa pulp and its derivatives have been reported and used for decades in places like Brazil

and Indonesia, with references to “cocoa honey”, jellies, soft drinks and cocoa wine. References were provided by the applicant.

20. According to the applicant, in Brazil, the heat-treated juice from the cocoa pulp has been used together with compote-like preparations (“geleia”) since the last half of the 19th Century. Industrial production of geleia is described to have started in the 1970s, although the cocoa pulp juice as such was not introduced as a semi-industrialised product until the 1980s. The applicant provides several references of production trends in Brazil from the 1900s to the present day, and mentions the presence of products in supermarket shelves that are made of, or with, cocoa pulp, such as shelf-stable juice, frozen cocoa pulp juice and geleia. No intake estimates based on food consumption surveys or other estimates were available to the applicant. References were provided.

21. The applicant mentions evidence of the use of cocoa pulp products in Africa, including jam and a different type of “cocoa honey” to the one consumed in Brazil. They also mention several research projects in Ghana looking at introduction of products based on cocoa pulp such as cakes and biscuits. In Indonesia and Malaysia, “nata de kako” has reports of being produced since the early 1990s, and is based on the fermentation of the cocoa pulp with *Acetobacter xylinum*, imitating the Philippine equivalent “nata de coco” (cream of coconut). References were provided by the applicant.

Consumers and role in the diet

22. The applicant describes that there is no reason to suspect that consumption has been limited to any specific subpopulation historically, following the general trend for all food products that relate to the ones the applicant is looking to authorise. Estimates of yearly consumption in the State of Bahia in Brazil are estimated between 100,000 and 1,000,000 consumers. The role in the diet is expected to be the same as that of other juices, to be consumed as a snack or during breakfast rather than as a main dish. Contribution to the overall macro- and micronutrient intake of the population is not expected to be significant.

Preparation and precautions

23. The applicant describes the importance of using the right method for separating the pulp from the cocoa beans in order to prevent extensive and uncontrolled fermentation. They state how a traditional method of separation based on pressing the beans and letting the pulp juice drip is not proposed for this notification. Instead, the Brazilian method is recommended by the applicant, using mechanical de-pulpers for quick removal of the pulp, therefore separating the de-pulping and fermentation processes. The applicant also cites a reference saying how the juice must be processed within 10 hours after pulp separation.

24. The applicant outlines they are not aware of any prohibition or restrictions imposed for cocoa pulp and its derivatives, and that the literature search and examination of regulations have not identified any information which may indicate the need for precautions or restrictions of use.

Safety data

25. The literature review conducted by the applicant looking for relevant human data provided no evidence on toxicity, case reports, illness or other effects on humans. The applicant reports only one article reporting positive skin prick tests to cocoa in Iranian children, and concludes that as an integral part of fermented cocoa beans, any specific allergenicity would have been revealed through the historic consumption of cocoa products. Four search strategies in two different databases are described by the applicant, who provided further information on the nature of the articles retrieved.

26. The applicant also provides a section based on information from the EFSA chemical hazard database looking at potentially hazardous components of cocoa pulp and the conclusions of EFSA on the toxic levels for these components, comparing them to those of cocoa pulp. These include synaptic acid, ferulic acid, gallic acid, protocatechuic acid, syringic acid, trans-cinnamic acid, caffeine and theobromine.

Conditions of Use in the EU market

27. The applicant looks for the food to be used in a consistent way with the history of safe use in Brazil, with the target population being the general population, without any age or gender restriction. Table 5 (labelled as Table 1 by the applicant), contains a summary of the food categories and form of uses for the traditional food:

Food category	Form of use	Proposed maximum levels
Frozen fruit	As fruit pulp	Whole food
Fruit and vegetable preparations, including compotes, fillings	As pulp or pure or compote or other preparation or as ingredient	As for other fruit
Jam, jellies and marmalades and similar products	As ingredient (cocoa pulp)	As for other fruit and in compliance with applicable legislation
Confectionery, including chocolate products and other confectionery	As an ingredient (cocoa pulp preparation)	As for other fruit-based ingredients
Fruit juice, including concentrated and dehydrated juice, fruit nectars and flavored drinks	As an ingredient (pulp)	As for other fruit and in compliance with applicable legislation
Edible ices	As an ingredient (pulp)	As for other fruit and in compliance with applicable legislation

28. The applicant proposes daily intakes to be consistent with intake of fruit pulp within the EU and proposes no precautions and restrictions related to handling, preparation or consumption of the traditional food. They suggest that the food is intended to provide an additional source of fruit pulp and juice, and that it is not intended to replace another food.

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
June 2019

Annexes Attached

Annex A – Dossier

Annex B – Laboratory tests. Supporting information.

Annex C – List of all available documents and annexes within the application.