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June 1, 2020

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Subject: GRAS Notification for the Use of Cacao Pulp, Juice and Concentrate in Select Foods
Project No: 1900235.000

Dear Sir/Madam:

In accordance with 21 CFR part 170, subpart E, CABOSSE Naturals NV, hereby provides a notice of a claim that the food ingredient described in the enclosed notification document is excluded from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because the notifier has concluded such use to be generally recognized as safe (GRAS), based on scientific procedures.

One copy of the notification is provided as required; we also have provided a copy of the notification on the enclosed CD-ROM. If you have any questions or require additional information, please do not hesitate to contact me at 202-772-4953 or mmurphy@exponent.com.

Sincerely,

Mary M. Murphy, MS, RD
Senior Managing Scientist

1900235.000 - 7674

GRAS Conclusion for the Use of Cacao Pulp, Juice and Concentrate in Select Foods

SUBMITTED BY:

CABOSSE Naturals NV
Brusselsesteenweg 450
1500 HALLE
Belgium

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
5001 Campus Drive
College Park, MD 20740

CONTACT FOR TECHNICAL OR OTHER INFORMATION:

Exponent, Inc.
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

June 1, 2020

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List of Acronyms

AI	Adequate Intake
BRIX	1 gram of sucrose in 100 gram of solution
CDRR	chronic disease risk reduction
CEPLAC	Comissão Executiva do Plano da Lavoura Cacaueira
CFR	Code of Federal Regulations
CFU	colony forming unit
cGMP	current good manufacturing practice
CRIG	Cocoa Research Institute of Ghana
CVD	cardiovascular disease
DHHS	US Department of Health and Human Services
DM	dry matter
EC	European Commission
EDI	estimated daily intake
EFSA	European Food Safety Authority
EU	European Union
FARE	Foods Analysis and Residues Evaluation Program
FD&C	U.S. Federal Food, Drug, and Cosmetic Act
FDA	U.S. Food and Drug Administration
FNDDS	Food and Nutrient Database for Dietary Studies
FSANZ	Food Standards Australia New Zealand
g	gram
GAE	gallic acid equivalents
GRAS	Generally Recognized As Safe
GRN	GRAS Notification
GSE	grape seed extract
h	hour
HPLC	high performance liquid chromatography
ICCO	International Cocoa Organization
IOM	Institute of Medicine
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kcal	kilocalorie
kg	kilogram
kJ	kilojoule
L	Liter
LOD	limit of detection
LOQ	limit of quantification
m	meter

mg	milligram
mL	milliliter
NASEM	U.S. National Academy of Sciences, Engineering and Medicine
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
NOAEL	no observed adverse effect level
PCB	polychlorinated biphenyl
PCDD	polychlorinated dibenzo-p-dioxins
pH	potential hydrogen
RDA	Recommended Dietary Allowance
TAB	thermophilic acidophilic bact`eria
TCA	tricarboxylic acid cycle
US	United States
UL	Tolerable Upper Intake Level
USDA	United States Department of Agriculture
WWEIA	What We Eat in America

Part 1. Signed Statements and Certification

CABOSSE Naturals NV (Belgium), a subsidiary of Barry Callebaut Belgium NV (Barry Callebaut), submits to the U.S. Food and Drug Administration (FDA) this generally recognized as safe (GRAS) notice in accordance with 21 CFR part 170, subpart E.

Name and Address of Notifier

CABOSSE Naturals NV
Brusselsesteenweg 450
1500 HALLE
Belgium

Name of GRAS Substance

The substance that is the subject of this GRAS notice is cacao pulp as such and the cacao fruit juice and cacao fruit juice concentrate that are made from the pulp.

Intended Use and Consumer Exposure

The cacao ingredients that are the subject of this dossier are intended for use in a variety of foods. Cacao pulp and cacao fruit juice concentrate are intended for use in beverages at the maximum concentrations of 20% by weight, while cacao fruit juice may also be consumed as such. Cacao fruit juice concentrate is also intended for use in bakery products, candy and confections (non-chocolate), cereal bars and chips/crackers, cocoa and chocolate products, edible ices - ice cream type, edible ices - sorbet type, gelatin/fruit mousse spreads, jams/jellies/fruit syrups and toppings, nutrition bars, plant-based spreads, and yogurt/yogurt drinks at maximum use levels ranging from 10 to 65% by weight. Cacao pulp also is intended for use in bakery products, candy and confections (non-chocolate), jams/jellies/fruit syrups and toppings, plant-based spreads, and yogurt/yogurt drinks at maximum concentrations ranging from 15 to 50% by weight. Only one type of cacao ingredient (pulp, fruit juice, or fruit juice concentrate) would be used in any specific use category at a time.

Basis for Conclusion of GRAS Status

CABOSSE Naturals NV's conclusion of GRAS status for the intended use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate in select foods is based on scientific procedures in accord with 21 CFR §170.30(a) and (b).

Pre-Market Approval Exclusion Claim

The intended use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate in select foods is not subject to the pre-market approval requirements of the Federal Food, Drug, and Cosmetic

Act because CABOSSE Naturals NV has concluded that such use is GRAS through scientific procedures.

Availability of Information

The data and information that serve as the basis for this GRAS conclusion, as well as the information that has become available since the GRAS conclusion, will be sent to the FDA upon request, or are available for the FDA's review and copying during customary business hours at the office of Exponent, Inc. located at:

1150 Connecticut Ave, NW
Washington, DC 20036

Exemptions from Disclosure

It is our view that none of the data and information in Parts 2 through 7 of the GRAS notice are exempt from disclosure under the Freedom of Information Act (FOIA).

Certification Statement

On behalf of CABOSSE Naturals NV, I hereby certify that, to the best of my knowledge, this GRAS notice is a complete, representative, and balanced submission that includes unfavorable, as well as favorable information, known to me and pertinent to the evaluation of the safety and GRAS status of the use of the substance.

HERWIG BERNAERT

Name: [redacted]

30/04/2020

Date:

Part 2. Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

Common or Usual Name

The substance that is the subject of this GRAS notice is cacao pulp as such and the cacao fruit juice and cacao fruit juice concentrate that are made from the pulp.

Cacao pulp is from the fruit of the cacao plant, *Theobroma cacao* L. The fruit of the cacao plant consists of a pod containing the seeds (cacao beans) and a mucilaginous flesh, rich in juice, that surrounds the beans. Cacao pulp is the semi-solid fruit flesh found in the form of a wet mucilaginous layer surrounding the unfermented cacao bean.

Throughout this notification, *Theobroma cacao* will be referred to as 'cacao'. The term 'cacao' is usually used in describing the pods, beans and ground-up contents of the beans, whereas the term 'cocoa' is used to describe the powder left after pressing the cocoa butter fat out of the ground beans.

Identity

Cacao Pulp

The source of the cacao pulp is the cacao plant, *Theobroma cacao* L. *Theobroma cacao* L. belongs to the Malvaceae family and Byttnerioideae subfamily, with *Sterculiaceae* identified as an alternate family. In 2019, the U.S. National Plant Germplasm System identified 49 species of genus *Theobroma* (USDA, 2019). The Criollo and Forastero varieties are the two main varieties of *Theobroma cacao,* with a third hybrid variety named Trinitario developed through cross-pollination between Criollo and Forastero (Dugo et al., 2018).

The fruit of *Theobroma cacao L.* is composed of pericarp, the tissue that arises from the ripened ovary wall of a fruit, and the ovary. The external tissue, also known as the pod and consisting of thick and hard organic material, can be removed when the fruit is ripe and can be used as compost, animal feed, and as a source of potash. The ovary contains numerous seeds embedded in an aqueous, mucilaginous pulp. Figure 1 shows an opened cacao pod with seeds embedded in a mucilaginous layer (white pulp).

Figure 1. Opened cacao pod with seeds embedded in a mucilage

The collection of pulp is part of the traditional method of preparing the beans for chocolate production (Aprotosoaie et al., 2016). In the traditional method, pulp around the beans is removed through fermentation and hydrolysis by microbial pectolytic enzymes. Hydrolyzed pulp is known as "sweatings." In this process, reducing sugars are critically involved in the development of typical chocolate flavor and color by reacting with amino acids during roasting through the Maillard reaction.

Although pulp is necessary for fermentation, more pulp is present in the pod than is needed. Approximately 40 liters of pulp can be obtained from 800 kg of wet seeds. Excess pulp is therefore a valuable by-product that can be used as such or for the production of juice.

Cacao and Mucilage-Derived Products

Several terms are used to describe products derived from cacao and the mucilaginous component within the cacao pod:

- '**Cacao beans**' refers to the seeds that are used for cocoa and chocolate production. During this process, the pods are opened, the beans are removed and typically a natural fermentation process takes place using accepted cacao fermentation practices. This fermentation is essential for the production of flavor precursors for the chocolate. During this process, part of the mucilage is liquefied by microbial enzymatic action, and the liquid is lost in the form of sweatings that drain off from the bean.
- '**Cacao pulp**' refers to the semi-liquid and highly viscous liquid from the white and mucilaginous part that surrounds the seeds. It is a non-fermented and non-diluted product, as defined by the Brazilian legislation (Normative Instruction No 01 of January 7, 2000), which defines the standards for quality and identity of the product. The pulp is commercialized as such after pasteurization, though traditionally the pulp is consumed directly without pasteurization. The pulp is also used for juice production by the addition of water in the same manner as is done for other fruits that do not contain liquid juice (e.g., apricot juice).
- '**Cacao sweatings**' (also referred to as '**cacao honey**'), refers to the product naturally obtained during processing of the cacao beans whereby the pulp surrounding the beans is removed by fermentation and hydrolyzed by microbial enzymes. This hydrolysis removes

pectin and liquefies the pulp. Originally this process of liquefaction of the pulp by fermentation was a naturally-occurring process done via microorganisms present in the environment. Cacao sweatings, therefore, represent the breakdown product of the mucilage (Balladares et al., 2016).

- '**Cacao juice**' (also referred to as '**cacao fruit juice**' or '**cacao pulp juice**') is similar to sweatings and honey but is used in this notification to indicate the product that is industrially produced starting from the cacao pod that is opened and depulped. The pulp is then treated with enzymes (pectinases) to mimic the fermentation step, prefiltered, centrifuged and pasteurized followed by another filtration step. This process is equivalent to the traditional process to obtain cacao sweatings but enables processing at industrial scale and under hygienic conditions appropriate for food. The result is a liquid cacao fruit/pulp juice of variable viscosity. The cacao juice can be further concentrated by evaporation of water for easier transport and storage. This process increases the density of the product to a syrup-type density.
- **'Cacao jelly'** (also referred to as '**cacao nectar**') refers to the ready-to-use jam-type product that is made with cacao juice or cacao sweatings by the addition of sugar until it reaches the concentration of soluble solids of a jelly.

Overall, the main difference between the cacao pulp, fruit juice and sweatings (or honey) lies in processing, as the compositions of these products are similar.

Composition of Cacao Pulp and Juice

Cacao pulp and cacao fruit juice are mixtures of water, macronutrients, micronutrients, and small amounts of other dietary components as reported in the published literature (e.g., Pettipher, 1986). Analyses of multiple batches of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate were completed to quantify the concentration of macronutrients, micronutrients, and potential contaminants in the substances that are the subject of this review. Analytical data are also presented for cacao sweatings, which were obtained by natural draining of the cacao honey during the fermentation process of the cacao beans for comparison. These data demonstrate that the cacao juice is substantially similar to the cacao sweatings.

Macronutrients

As documented in the published literature, cacao pulp and the related juice products consist primarily of water and carbohydrates in the form of sugars. Pettipher (1986) collected samples of cacao pulp from Amelonado cacao pods harvested in the Ivory Coast, Nigeria, and Malaysia and documented results of a detailed compositional analysis of these samples. The samples were taken from three to five pods at each geographic location, typically within five days of harvest, and frozen until analysis.

Cacao pulp collected from the three regions was reported to contain on average 83-86% water, 11-13% sugars, 1.5-2.8% fiber, 0.3-1.3% citrate, 0.7% protein, 0.4-0.8% fat, and approximately 0.2-0.3% ash (Pettipher, 1986). Perez-Mora and colleagues reported a protein content of 25.1

mg per g dry weight in *Theobroma cacao* pulp, and using proteomic analysis identified proteins involved in the processing of genetic information and energy metabolism. Two of the samples contained trace amounts of alcohol (0.1 or 0.2%), presumably as a result of fermentation following harvest of the pods. Other investigators also have reported that cacao pulp contains primarily water, sugars, pectin, and citric acid, as well as trace amounts of starch (Anvoh et al., 2009; Biehl et al., 1989; Dias et al., 2007; Meersman et al., 2017; Perez-Mora et al., 2018; Puerari et al, 2012). Changes in the relative proportions of these constituents may occur during ripening and post-harvest storage (e.g., Biehl et al., 1989).

The typical macronutrient composition of the cacao products that are the subject of this notification are summarized in Table 1. The samples analyzed for cacao pulp did not undergo the pasteurization process as they were used for production of juice and concentrate which were in turn subjected to pasteurization. Consistent with data in the published literature, the cacao pulp and juice consist primarily of water and sugar as glucose. Cacao pulp and juice also contain fiber, predominantly present as soluble fiber, a low concentration of protein (<1%), and trace amounts of fat; a low concentration of starch (<0.3%) was measured in the concentrate. The concentration of macronutrients is comparable in pulp and juice. With a mean moisture content in cacao pulp and cacao fruit juice of 79% and a mean moisture content in cacao fruit juice concentrate of 38%, the concentration of solids (i.e., non-water components) in these components is 21% and 62%, respectively (Table 1), thus the concentration of solids in the cacao fruit juice concentrate is 3 times the concentration present in pulp or juice. Because of the longer processing at higher temperature, further hydrolysis of polysaccharides occurs resulting in a slightly higher concentration of sugars and a lower concentration of fibers.

Table 1. Typical energy and macronutrient composition of cacao pulp, cacao fruit juice, cacao fruit juice concentrate, and cacao sweatings

Parameter	Pettipher, 1986			CABOSSE Naturals NV			
	Ivorian	Nigerian	Malay-sian	Cacao Pulp	Cacao Fruit Juice	Cacao Fruit Juice Concen-trate	Sweat-ings
	% (m/m)						
Energy value, kcal/100 g	-	-	-	79	83	242	73
Moisture, vacuum	82.6	82.5	85.9	79.4	78.7	38.4	81.0
Protein (N x 6.25)	0.74	0.64	0.65	0.7	0.6	1.4	<0.5
Total fat	0.45	0.75	0.35	<0.2	<0.2	<0.2	<0.2
Carbohydrates, calculated[a]	-	-	-	18.1	19.5	57.9	17.6
Total sugar as Glucose	11.15	13.05	11.06	16.5	18.0	51.4	16.2
Total dietary fiber	2.81	ND	1.48	1.1	0.8	1.2	1.0
Insoluble HMW dietary Fiber	-	-	-	0.7	0.6 (*)	0.4	<0.2
Soluble HMW dietary Fiber	-	-	-	0.7	0.6	0.9	1.0
Ash	0.29[b]	0.27[b]	ND	0.5	0.5	1.2	0.4
Organic acids [d]	1.31	0.79	0.29	1.0	1.0	3.5	-
Recovery, %	99.4	98.1[c]	99.9[c]				

Values for Pettipher (1986) represent mean of 3-5 samples. Values for CABOOSE Naturals NV pulp, juice and concentrate represent the mean of five samples unless noted as (*), which indicates value was calculated from one or two samples; values for sweating represent the mean of three samples. Values set at ½ the LOQ to calculate averages.
[a] Carbohydrate calculated as: 100 - fat% - protein% - dietary fiber% - ash% - moisture%.
[b] Sum of concentration of metals and vitamins (composite sample for Ivorian and Nigerian sources).
[c] Recovery % includes 0.1% and 0.2% ethanol in Nigerian and Malaysian samples, respectively.
[d] Primarily citrate; other organic acids (malic, tartaric, and oxalic) measured at concentrations <1% by Pettipher; other organic acids (acetic, succinic, butyric, lactic, formic, oxalic, propionic, pyruvic) measured at concentrations <1% by CABOSSE Naturals NV. Values for CABOSSE Naturals NV samples represent averages of 3 to 7 values.
Abbreviations: HMW – high molar weight; LOQ – limit of quantification; ND – not determined.

The concentrations of individual sugars in cacao pulp as reported in the literature and from analysis of cacao pulp are presented in Table 2. Sugars in the cacao pulp include sucrose, glucose, and fructose. On a dry weight basis, cacao pulp was reported to contain concentrations of 35, 69, and 72 mg sucrose, glucose, and fructose, respectively, per gram pulp (Perez-Mora et al., 2018). Fiber in cacao pulp consists primarily of cellulose, pectin, hemicellulose, and a smaller proportion of lignin as reported by Pettipher (1986) (Table 3).

Table 2. Sugars in cacao pulp

Parameter	Pettipher, 1986			CABOSSE Naturals NV
	Ivorian	Nigerian	Malaysian	Pulp
	g per 100 g			
Sucrose	4.35	1.92	1.35	3.74
Glucose	3.00	5.06	4.90	5.99
Fructose	3.80	6.07	5.35	6.54
Total sugars	11.15	13.05	11.06	16.27
Values for represent mean of 3-5 samples from Pettipher (1986); 1 sample from CABOSSE Naturals NV.				

Table 3. Dietary fiber fractions in cacao pulp

Parameter	Pettipher, 1986		
	Ivorian	Nigerian	Malaysian
	g per 100 g [a]		
Cellulose	0.90	ND	0.67
Hemicellulose	0.50	ND	0.22
Pectin	1.15	1.03	0.53
Lignin	0.26	ND	0.07
Total fiber	2.81	ND	1.48
Values for represent mean of 3-5 samples. [a] Concentration of individual fibers calculated from dry matter concentrations; sum of individual fibers may not equal total due to rounding. Abbreviations: ND – not determined.			

Organic Acids

Cacao pulp is reported to contain organic acids including citric acid and potentially other acids. In samples of cacao pulp from the Ivory Coast, Nigeria, and Malaysia, only citrate was reported in a measurable quantity at 0.3-1.3% in pulp (Pettipher, 1986); other organic acids including malic, tartaric, and oxalic acid were detected at concentrations less than 0.1% for each acid. On a dry weight basis, pulp juice from *T. cacao* was reported to contain 7.8 g citric acid per 100 g DM, 3.1 g malic acid per 100 g DM, and 0.15 g oxalic acid per 100 g DM (Perez-Mora et al., 2018). In another study, cacao pulp juice collected immediately after opening pods was reported to contain 9.14 mg/L citric acid, 3.6 mg/L malic acid, 2.28 mg/L acetic acid, and approximately 1 mg/L or less each of oxalic acid, lactic acid, and fumaric acid (Anvoh et al., 2009). Due to the relatively high concentration of citric acid, cacao pulp is acidic with a mean pH reported in the range of 3.2 to 4.0 (Afoakwa et al., 2013; Anvoh et al., 2009; Biehl et al., 1989; Dias et al., 2007; Perez-Mora et al., 2018; Puerari et al, 2012).

Consistent with the published literature, analysis of representative samples of cacao pulp show the presence of organic acids in cacao pulp that is the subject of this notification (Table 1).

Analytical data demonstrate that the predominate organic acid in the cacao pulp is citric acid, which was present at an average concentration of 1.0 g citric acid per 100 g juice or cacao pulp in representative samples, and 3.5 g citric acid per 100 g cacao fruit juice concentrate. Cacao pulp and juice samples also contained 0.04-0.1 g succinic acid, 0.02-0.03 g lactic acid, and not more than approximately 0.01 g each of other organic acids including acetic, pyruvic, oxalic, formic, butyric, and propionic acids per 100 g sample.

Minerals and Vitamins

Minerals

The composition of cacao pulp has been examined for minerals typically found in fruit juice. Cacao pulp samples collected in the Ivory Coast and Nigeria were analyzed for minerals and reported to contain an average of 201 mg potassium per 100 g pulp as consumed, 13 mg magnesium, 10 mg calcium, 3 mg iron, 1 mg sodium and trace amounts of other minerals (Pettipher, 1986). The typical mineral composition of the cacao products that are the subject of this notification are summarized in Table 4 along with data for commonly consumed fruit juices. The data demonstrate that the mineral profile of cacao juice (and also cacao pulp, which is similar in composition to cacao juice) is similar to that of many common fruit juices. Consistent with data in the published literature, the cacao pulp and juice are a relatively concentrated source of potassium, a modest source of magnesium and lower concentrations of other typical minerals in juice.

Table 4. Typical mineral composition of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate

	CABOSSE Naturals NV			USDA			
Minerals	**Cacao Pulp**	**Cacao Fruit Juice**	**Cacao Fruit Juice Concentrate**	**Coconut water (14090)**	**Orange juice (9509)**	**Apple juice (9016)**	**Grape juice (9135)**
	mg per 100 g						
Calcium	5.4 (*)	7.3	20.8	7	11	8	11
Copper	0.07	0.07	0.18	0.01	0.04	0.01	0.02
Iron	0.29	0.26	0.71	0.03	0.13	0.12	0.25
Magnesium	20 (*)	22	632	6	11	5	10
Manganese	0.05	0.06	0.16	0.22	0.02	0.07	0.24
Phosphorus	14 (*)	12	35	5	17	7	14
Potassium	170 (*)	202	586	165	178	101	104
Sodium	1	1	2	26	2	4	5
Zinc	0.19 (*)	0.20	0.57	0.02	0.07	0.02	0.07

Values for CABOOSE Naturals NV pulp, juice and concentrate represent the mean of five samples unless noted as (*), which indicates value was calculated from one or two samples.
Data source for fruit juices: USDA FoodData Central; https://ndb.nal.usda.gov/ndb/.

Vitamins

Cacao pulp samples collected in the Ivory Coast and Nigeria and freeze-dried were analyzed for vitamins. Overall, vitamin concentrations were low with average values per 100 g pulp of 52 mg vitamin C, 0.7 mg vitamin B6, 0.5 mg niacin, 0.4 mg pantothenate, 0.04 mg each for riboflavin and thiamin, and trace amounts of vitamin B12, folic acid, and biotin (Pettipher, 1986).

The typical vitamin composition of the cacao products that are the subject of this notification are summarized in Table 5. Consistent with data in the published literature, the cacao pulp products contain low concentrations of vitamins. Vitamin C is the vitamin present in the highest concentration followed by niacin. The concentrations of several vitamins were largely below the limit of quantification, including vitamin E (individual alpha, beta, delta, gamma or the sum of all tocopherols; (<0.5 mg/100g), vitamin B12 (<5 µg/100 g); beta-carotene (<5 µg/100 g), and vitamin D (<0.25 µg/100 g).

Table 5. Typical vitamin composition of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate

Parameter	Cacao Pulp	Cacao Fruit Juice	Cacao Fruit Juice Concentrate
	mg/100 g		
Riboflavin (vitamin B2)	<0.01 (LOQ)	-	-
Niacin (vitamin B3)	0.61 (*)	0.51	1.63
Pantothenic acid (vitamin B5)	0.04 (*)	0.04	0.14
Pyridoxine (vitamin B6)	0.05 (*)	0.04	0.11
Biotin	<0.01 (LOQ)	0.01(*)	0.51
Ascorbic acid (vitamin C)	16.10 (*)	<0.5 (LOQ)	7.02
Values for CABOOSE Naturals NV pulp, juice and concentrate represent the mean of five samples unless noted as (*), which indicates value was calculated from one or two samples. Abbreviations: LOQ = limit of quantification. -, not measured			

Polyphenols

Cocoa and chocolate made from cocoa are a recognized source of polyphenols, primarily in the form of flavan-3-ols (epicatechin, catechin), anthocyanins, and proanthocyanidins. In cocoa and chocolate, a typical distribution of flavonoids is 37% flavan-3-ols ((-)-epicatechin and (+)-catechin), 58% proanthocyanidins, and 4% anthocyanins (Dugo et al., 2018).

Analytical data in the published literature indicate that cacao pulp is a source of phenolics (Table 6). The total concentration of phenolics in cacao pulp has typically been reported in units of gallic acid equivalents (GAE) based on the nonspecific, colorimetric Folin-Ciocalteu method that determines the amount of all reducing agents (including reducing sugars). Based on this method, cacao pulp was reported to contain concentrations of 16-104 mg GAE per 100 g. In another study reporting use of spectrophotometry, concentrations of 130-150 mg phenolics per 100 g pulp were reported (Dias et al., 2007).

The Folin–Ciocalteu method is often used to measure "total" phenolics, although it is recognized that the test does not measure exclusively phenolic compounds and in fact detects the reducing capacity from non-phenolic compounds (Ma et al., 2019). As reported by Everette and colleagues (2010), many compounds including vitamins (in particular ascorbic acid), amino acids including cysteine, tryptophan, and tyrosine, thiols, nucleotide bases, substituted salicylic acids, and metal complexes are quantified as polyphenols with the Folin–Ciocalteu method (Everette et al., 2010). Consequently, results from the Folin–Ciocalteu method may overestimate the concentration of polyphenols in a substance.

Concentrations of individual phenolic/flavonoid species in cacao juice were identified in one study identified in the literature; the product contained 8 mg epicatechin, 43 mg catechins, 23 mg flavanols, and 12 mg proanthocyanidins based on high performance liquid chromatography (HPLC) methods and 153 mg GAE per 330 mL based on the non-specific Folin-Denis method (Morgan et al., 2018). Assuming 1 g per mL of juice, the concentrations of polyphenols in the test product used by Morgan and colleagues reported as mg per 330 mL are equivalent to 47 mg GAE, 2 mg epicatechin, 13 mg catechins, 7 mg flavanols, and 4 mg proanthocyanidins per 100 g of cacao pulp. Cacao pulp collected in Malaysia was reported to have a concentration of 1.36 mg catechin per 100 mL and concentrations of less than 1 mg per 100 mL of ferulic acid, protocatechuic acid, syringic acid, trans-cinnamic acid, and gallic acid. For comparison, 100 g of unsweetened dry cocoa powder is reported to contain 56.6-196.43 mg (-)-epicatechin, 36.71-64.82 mg (+)-catechin, and 3.37-10.0 mg flavonol as quercetin (Bhagwat and Haytowitz, 2015), indicating that relative to cocoa powder, cacao pulp is a small source of these flavonoids.

Table 6. Polyphenols in cacao pulp as reported in the literature

Cacao Product	Value	Reported Method	Reference
Unpasteurized pulp	103.76 mg GAE (total phenolics) per 100 g	Folin–Ciocalteu	Endraiyani et al., 2016
Single pasteurized pulp	77.88 mg GAE (total phenolics) per 100 g	Folin–Ciocalteu	Endraiyani et al., 2016
Double pasteurized pulp	64.21 mg GAE (total phenolics) per 100 g	Folin–Ciocalteu	Endraiyani et al., 2016
Frozen pulp	16.15 mg GAE (total phenolics) per 100 g	Folin–Ciocalteu	Zielinski et al., 2014
Pulp	16.33 per GAE (total phenolics) 100 mL	Folin–Ciocalteu	Zabidah et al., 2011
Mature pulp	170 mg per 100 g, phenolics soluble in water	Spectrophotometry	Dias et al., 2007
Mature pulp	150 mg per 100 g, phenolics soluble in methanol	Spectrophotometry	Dias et al., 2007
Mature pulp	130 mg per 100 g, phenolics soluble in 50% methanol	Spectrophotometry	Dias et al., 2007
Frozen pulp	10.58 mg CTE (total flavonoids) per 100 g	Aluminum chloride colorimetery	Zielinski et al., 2014
Pulp	340 mcg/g DW, as tannic acid	Folin–Ciocalteu	Perez-Mora et al., 2018
Ecuadorian cacao mucilage juice	153 mg polyphenols per 330 mL	Folin-Denis (modified)	Morgan et al., 2018

Cacao Product	Value	Reported Method	Reference
Ecuadorian cacao mucilage juice	8 mg epicatechin per 330 mL	HPLC	Morgan et al., 2018
Ecuadorian cacao mucilage juice	43 mg catechins per 330 mL	HPLC	Morgan et al., 2018
Ecuadorian cacao mucilage juice	23 mg flavanols per 330 mL	HPLC	Morgan et al., 2018
Ecuadorian cacao mucilage juice	12 mg proanthocyanidins per 330 mL	HPLC	Morgan et al., 2018
Pulp	1.36 mg catechin per 100 mL	HPLC	Zabidah et al., 2011
Abbreviations: CTE – catechin equivalents; DW – dry weight; GAE – Gallic acid equivalents; HPLC – high performance liquid chromatography.			

The average concentration of polyphenols, calculated as GAE, in cacao pulp, cacao juice and cacao juice concentrate that are the subject of this notification are 106.5, 61.9 and 160.4 mg per 100 g, respectively. The concentration of polyphenols in the cacao pulp is therefore similar to values reported in the published literature. Additional analyses (using HPLC methods) for the specific flavan-3-ols typically present in cocoa and chocolate including monomeric catechin and epicatechin and the B2 dimer and C1 trimer procyanidins indicate that these flavanols were not detected or largely not quantifiable other than the procyanidin B2 fraction which was detected at concentrations in the range of 1.1-1.6 mg per 100 in three of a total of six pulp and juice samples (Table 7). Collectively, the analytical data on the cacao pulp that is the subject of this review and data in the published literature on cacao pulp indicate that the primary flavonoids present in cacao products may be present in cacao juice, albeit at much lower concentrations.

Table 7. Typical concentration of total phenolics in cacao pulp, cacao fruit juice, and cacao fruit juice concentrate from composition analysis

Parameter	Cacao Pulp	Cacao Fruit Juice	Cacao Fruit Juice Concentrate
	mg/100 g		
Polyphenols (GAE)	106.5	61.9	160.4
Catechin (LOD = 0.5 mg/100 g)	ND (n=3)	ND (n=3)	-
Epicatechin (LOD = 0.6 mg/100 g)	<1.7 (n=3)	<1.7 (n=3)	-
Procyanidin B2 (LOD = 0.3 mg/100 g)	1.1 1.6 <0.9	<0.9 (n=2) 1.1	-
Procyanidin C1 (LOD = 0.8 mg/100 g)	<2.4 (n=3)	<2.4 (n=3)	-
Polyphenol values for juice, concentrate and pulp reported as GAE represent the mean of five samples. Abbreviations: GAE – gallic acid equivalent; LOD – limit of detection; ND – not detected; "-"not tested.			

Purine Alkaloids-Methylxanthines

Purine alkaloids including theophylline, theobromine, and caffeine are recognized methylxanthines found in cocoa and chocolate, with theobromine (3, 7-dimethylxantine) the primary methylxanthine in these foods. Cocoa powder contains 2057 mg theobromine and 230 mg caffeine per 100 g (USDA, 2019). An analysis of theophylline, theobromine, and caffeine

concentrations in the developing cacao fruit indicates that concentrations of theobromine and caffeine are highest in the cotyledon. Theobromine is formed in the cotyledons and young pericarp. Relative to the concentrations of theobromine and caffeine in the cotyledon of mature cacao fruit of 21,894 ± 465 and 4,860 ± 565 nmol/g for theobromine and caffeine, respectively, the concentrations of theobromine and caffeine in the placenta (or pulp) are substantially lower at 237±72.9 and 86.5±41.3 nmol/g, respectively (Zheng et al., 2004).

Analytical data show that the mean concentration of theobromine in the cacao products that are the subject of this notification are 0.55-0.65 mg/100 g for cacao pulp and juice, and 1.7 mg/100 g in cacao juice concentrate (Table 8). The level of theophylline in the samples was below the limit of detection, and the level of caffeine was below the limit of detection in all samples of juice and the majority of samples of pulp and concentrate.

Table 8. Typical theobromine, theophylline, and caffeine concentration in cacao pulp, cacao fruit juice, and cacao fruit juice concentrate

Parameter	Cacao Pulp	Cacao Fruit Juice	Cacao Fruit Juice Concentrate
	mg per 100 g		
Theobromine	0.649	0.554	1.7326
Theophylline	ND	ND	ND
Caffeine	ND [a] (3 of 5)	ND	ND (4 of 5)

Values for pulp, juice and concentrate represent the mean of five samples.
Abbreviations: ND = not detected.

Production Process

Manufacture of the Products

Cacao pulp, cacao fruit juice, and cacao fruit juice concentrate are manufactured under conditions of cGMP as detailed below. The production process takes place in a production facility that is FSSC certified and meets appropriate hygiene requirements. A declaration of quality assurance measures is presented in Appendix A as part of the company Statement on Contaminants. The manufacturing process does not give rise to by-products, impurities or contaminants.

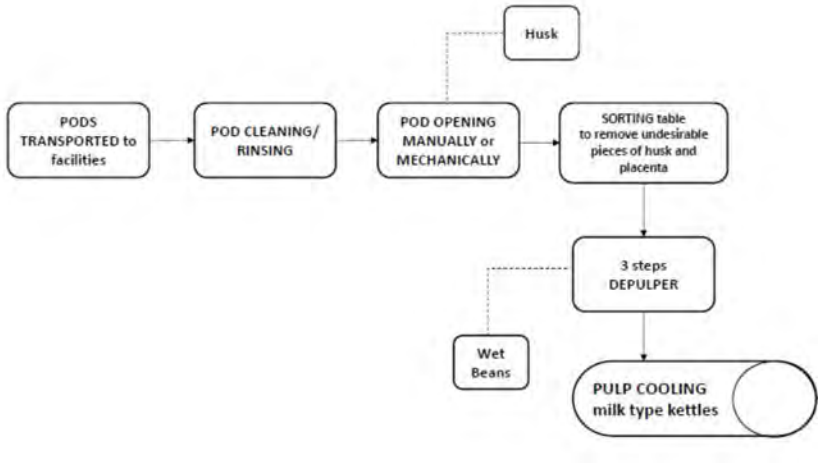
Starting Material

The starting raw material used to make the products is the fruit of the cacao plant, *Theobroma cacao* L produced from *Theobroma cacao* L trees grown in Latin America. Cacao pulp is the semi-solid fruit flesh found in the form of a wet mucilaginous layer surrounding the unfermented cacao bean.

Processing Steps

The industrial collection of cacao pulp is done as part of the initial processing of the cacao bean after pod opening and prior to fermentation of the cacao bean. The collection of cacao pulp is illustrated in Figure 2 and outlined below.

Figure 2. Flow diagram of the collection of cacao pulp



The key steps in the collection of cacao pulp are as follows:

- The pods are transported to the production facility.
- The pods are cleaned.
- The pods are opened, either manually or mechanically.
    - In the manual process, the pods are cut in half and the pulp and the beans are removed by hand from the pods.
    - In the mechanical process, the pods are placed on a conveyor belt that carries the pods over a knife which cuts the pods in half. The pods then enter a rotating drum that forces the beans and pulp to fall from the pods. The beans and pulp fall through holes in the walls of the rotating drum and are collected below.
- The wet beans then pass a sorting stage to remove undesirable pieces of husk and placenta.
- The beans are depulped in a depulper:
    - The depulper consists of rotating drums in a horizontal cascade. This process allows gentle depulping without bean breaking which would induce nibs and shell contamination of the pulp.
    - The outer wall of each drum acts as a sieve. Each drum wall contains holes that are large enough to allow the pulp and juice to drip out of the drum while the beans remain inside.
    - The combination of the rotating drums and the gentle feeding of the wet beans forces the beans to fall from one drum to the next.

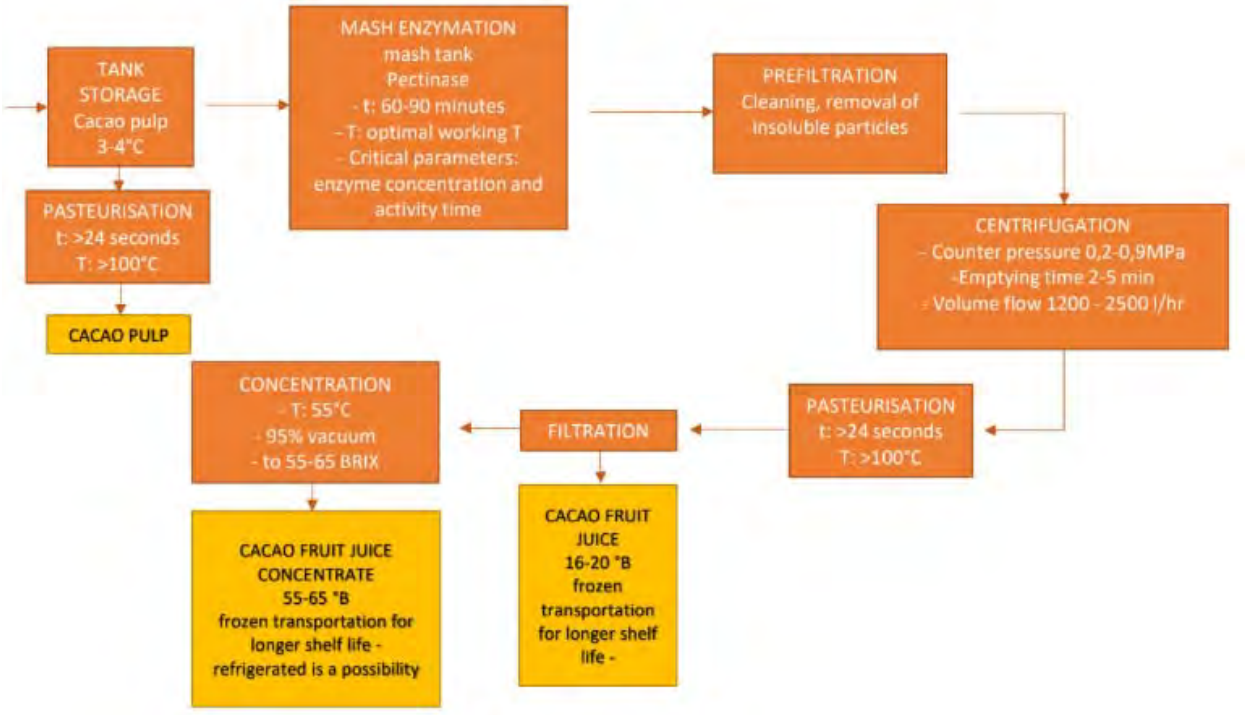
- The depulped beans are removed centrally at the bottom of the depulper while liquid pulp is collected from each drum.
- The pulp solids are separated from the juice by centrifugation and subsequent ultrafiltration.
- The pulp is cooled and stored in a cooling tank.
- The beans are used for further processing into cocoa and chocolate. The husk is used for other purposes.

The subsequent steps of the industrial process are summarized below and shown in Figure 3:

- Fermentation to degrade the pectin: commercially available food-grade enzymes (pectinases) are added to the pulp mass and enzymatic breakdown of pectin and cellulose is allowed to proceed for a controlled time period at fixed conditions.
- Filtration to remove insoluble particles.
- Centrifugation to clear the liquid.
- Pasteurization.
- Filtration to obtain juice for use as such.
- Concentration through evaporation to obtain concentrate for transport and storage.

This processing mimics the natural enzymatic processes under hygienic conditions required for food production and via subsequent removal of insoluble particles, pasteurization and concentration, the whole process is accelerated, increasing yield while still limiting both contamination and fermentation into ethanol without significantly affecting the composition of the juice. The techniques used are standard techniques applied to fruit juice production and no additives or other ingredients are added during the processing.

Figure 3. Flow chart of production of cacao fruit juice from pulp



The final products (cacao fruit juice and cacao fruit juice concentrate) are frozen or refrigerated for storage and transport. As compared to the cacao fruit juice, the heat treatment to produce concentrate gives rise to a slightly higher sugar content from further hydrolysis of the polysaccharides present. In the production process, both the cacao pulp (for direct use) and cacao juice undergo pasteurization to ensure the microbial safety of the product. The pasteurization inactivates the enzymes and destroys the microorganisms capable of growing in the juice during its shelf life. Following the pasteurization, the microbiological load declines to below detectable levels and remains so following concentration. The low pH of the products, pH 3 to 3.3 for cacao pulp and cacao fruit juice, and pH 2.9 to 3.4 for concentrated cacao fruit juice, prevents growth and survival of typically pathogenic microorganisms.

Processing Aids

No processing aids other than enzymes are used in the production of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate. The enzyme preparations contain pectinases (polygalacturonase and pectin lyase [CAS no. 90322-75-1]) made from the production organisms *Aspergillus niger* and *Aspergillus aculeatus*, both of which are recognized as materials that may be used as a source of enzymatic activity to facilitate separation of juice from fruit in the treatment of wine and juice (27 CFR 24.246). The enzymes are used in minimal concentrations and pasteurization will deactivate any remaining activity. All enzymes used in the production

process are food-grade and comply with purity specifications for food-grade enzymes as specified by JECFA and FCC.

Specifications

Product specifications and analytical test methods for cacao pulp, cacao fruit juice, and cacao fruit juice concentrate are presented in Table 9. These physico-chemical parameters, microbiological criteria, and potential heavy metal contaminants and their limits have been established to ensure consistent safety and quality of the products. The specifications are based on analytical results, and, as the cacao pulp products are natural products, provide for a margin to account for natural and processing variability. The methods of analysis used to determine compliance with product specifications are validated for their intended use. Analytical data on non-consecutive batches of cacao pulp, cacao fruit juice, cacao fruit juice concentrate manufactured according to the methods of production described above demonstrate that the products meet the established specifications (Tables 10, 11 and 12, respectively).

Table 9. Product Specifications for cacao pulp, cacao fruit juice, and cacao fruit juice concentrate

Parameter	Cacao fruit juice or cacao pulp	Cacao fruit juice concentrate	Method of Analysis[a]
Physico-chemical properties			
BRIX	16-20	55-65	ISO 2173 – Refractometer
Microbiological limits			
TPC (aerobic) (cfu/g)	<1000	<1000	ISO 4833-1
Molds (cfu/g)	<50	<50	ISO 21527-2
Yeasts (cfu/g)	<50	<50	ISO 21527-2
Enterobacteriaceae (cfu/g)	<10	<10	ISO 21528-2
Salmonella spp. (/25g)	Absent	Absent	ISO 6579-1
TAB (/10g)	Absent	Absent	IFU 12
Heavy metals			
Arsenic	≤0.05 mg/kg	≤0.05mg/kg	ASU L 00.00-135
Mercury	≤0.005 mg/kg	≤0.005 mg/kg	ASU L 00.00-135
Lead	≤0.02 mg/kg	≤0.02mg/kg	ASU L 00.00-135
Cadmium	≤0.02 mg/kg	≤0.2 mg/kg	ASU L 00.00-135

[a] Or a comparable validated method.
Abbreviations: cfu – colony forming units; TAB – Thermophilic Acidophilic Bacteria; TPC - Total Plate Count.

Table 10. Batch data from non-consecutive batches of cacao pulp

Parameter	Specification	1921501011 _ ifp19-49764-002-01	1922201011 _ ifp19-49764-002-02	1931301011 _ ifp20-05169-001
Physico-chemical properties				
BRIX	16-20	17.9	17.9	18.5
Microbiological limits				
TPC (aerobic) (cfu/g)	<1000	<10	<10	<10
Molds (cfu/g)	<50	<10	<10	<10
Yeasts (cfu/g)	<50	<10	<10	<10
Enterobacteriaceae (cfu/g)	<10	<10	<10	<10
Salmonella spp. (/25g)	Absent	Absent	Absent	Absent
TAB (/10g)	Absent	Absent	Absent	Absent
Heavy metals				
Arsenic	≤0.05 mg/kg	<0.05	<0.05	<0.05
Mercury	≤0.005 mg/kg	<0.005	<0.005	<0.005
Lead	≤0.02 mg/kg	<0.02	<0.02	<0.02
Cadmium	≤0.02 mg/kg	<0.02	<0.02	<0.02

See Appendix B for COAs.
Abbreviations: cfu – colony forming units; TAB – Thermophilic Acidophilic Bacteria; TPC - Total Plate Count.

Table 11. Batch data from non-consecutive batches of cacao fruit juice

Parameter	Specification	1924301011 _ ifp19-49764-001-02	1925001011 _ ifp19-49764-001-01	1926401011 _ ifp19-45730-001
Physico-chemical properties				
BRIX	16-20	16.9	16.9	16.6
Microbiological limits				
TPC (aerobic) (cfu/g)	<1000	<10	<10	10
Molds (cfu/g)	<50	<10	<10	<10
Yeasts (cfu/g)	<50	<10	<10	<10
Enterobacteriaceae (cfu/g)	<10	<10	<10	<10
Salmonella spp. (/25g)	Absent	Absent	Absent	Absent
TAB (/10g)	Absent	Absent	Absent	Absent
Heavy metals				
Arsenic	≤0.05 mg/kg	<0.05	<0.05	<0.05
Mercury	≤0.005 mg/kg	<0.005	<0.005	<0.005
Lead	≤0.02 mg/kg	<0.02	<0.02	<0.02
Cadmium	≤0.02 mg/kg	<0.02	<0.02	<0.02

See Appendix B for COAs.
Abbreviations: cfu – colony forming units; TAB – Thermophilic Acidophilic Bacteria; TPC - Total Plate Count.

Table 12. Batch data from non-consecutive batches of cacao fruit juice concentrate

Parameter	Specification	1920301011 _ ifp19-36550-005	1926701011 _ ifp19-47882-001	1929901011 _ ifp19-49966-002
Physico-chemical properties				
BRIX	55-65	60.0	61.4	59.5
Microbiological limits				
TPC (aerobic) (cfu/g)	<1000	<10	<10	<1
Molds (cfu/g)	<50	<10	<10	<1
Yeasts (cfu/g)	<50	<10	<10	<1
Enterobacteriaceae (cfu/g)	<10	<10	<10	<1
Salmonella spp. (/25g)	Absent	Absent	Absent	Absent
TAB (/10g)	Absent	Absent	Absent	Absent
Heavy metals				
Arsenic	≤0.05 mg/kg	<0.05	<0.05	<0.05
Mercury	≤0.005 mg/kg	<0.005	<0.005	<0.005
Lead	≤0.02 mg/kg	<0.02	<0.02	<0.02
Cadmium	≤0.20 mg/kg	0.053	0.051	0.073

See Appendix B for COAs.
Abbreviations: cfu – colony forming units; TAB – Thermophilic Acidophilic Bacteria; TPC - Total Plate Count.

Monitoring of Potential Contaminants

As a component of its current good manufacturing practice (cGMP), CABOSSE Naturals NV routinely tests the cacao products for potential contaminants including mycotoxins, PAHs, polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins (PCDDs), and pesticide residues to ensure high quality and suitable food ingredients. Analytical data demonstrating that all tested compounds were either not detected or detected only within ranges confirming the safety of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate are provided in Appendix C.

Stability

Cacao pulp and cacao fruit juice are liquid or semi-liquid products intended to be added to foods or consumed as such, with or without the addition of water. The products (pulp, juice, and concentrate) are packed in open-head metallic drums or HDPE open-head plastic pails and aseptic bags. The products are pasteurized to ensure microbiological stability and storage is at 4^{O} C or in frozen condition, shielded from light. The products are recommended to be stored in frozen condition and used directly after opening. No physico-chemical or biochemical changes or degradation products have been identified in the literature that are expected over the shelf life of the product that could be of concern to human health.

Analysis of a cacao juice sample frozen -18°C in November 2017 and defrosted after 15 months showed no microbiological risk and a pH value within specifications (pH = 3.28), confirming the stability of the product under the conditions of storage proposed (frozen storage).

In addition to testing of cacao juice, stability testing of cacao fruit juice concentrate at 3 storage temperatures (-18°C, 4°C, and 20°C) was initiated, with monthly testing of microbiological (TPC, enterobacteria, yeasts, molds, salmonella, coliforms, E. coli. counts), physico-chemical (pH, water activity), color (with and without exposure to light and oxygen), and a taste analysis difference sensory test). All samples stored at 20°C showed a nearly identical shift in color, indicating that there is no impact of light or oxygen. When considering samples that have been shielded from oxygen and light, a better color stability was seen for samples that have been stored at lower temperatures (4°C and -18°C) when compared to samples stored at ambient conditions (20°C). At 20°C, a fast color change is observed for all parameters L, a, and b. For samples stored at 4°C, only a minor color change has been observed after 1 month, while the color of the samples that have been stored at -18°C is stable. The results from the microbial analyses on the cacao fruit juice that was stored for 15 months at -18°C and cacao fruit juice concentrate stored for 4 months at -18°C, 4°C, and 20°C are presented in the Table 13.

Table 13. Results from a 15-month stability study on frozen cacao juice and 4-month observations of cacao juice concentrate

			Stability Specification						
			TPC	**Entero-bacteria**	**Yeast**	**Mold**	**Salmonella**	**Coliforms**	**E. coli**
Product	**Storage Temper-ature**	**Month**	**Max 5000/ g**	**Max 10/ g**	**Max 50/ g**	**Max 50/ g**	**Absent/ 25 g**	**Max10/ g**	**Absent /g**
Juice	-18°C	15	<10	<10	<10	20	ND	<10	<10
Juice Conc.	-18°C	0	<10	<10	<10	<10	Absent	/	Absent
		1	<10	<10	<10	<10	Absent	<10	Absent
		2	<10	<10	<10	10	Absent	<10	Absent
		3	<10	<10	<10	<10	Absent	<10	Absent
		4	<10	<10	<10	<10	Absent	<10	Absent
	4°C	0	<10	<10	<10	<10	Absent	/	Absent
		1	<10	<10	<10	<10	Absent	<10	Absent
		2	<10	<10	<10	<10	Absent	<10	Absent
		3	10	<10	66000	<10	Absent	<10	Absent
		4	<10	<10	>5000	<10	absent	<10	Absent
	20°C	0	<10	<10	<10	<10	Absent	/	Absent
		1	<10	<10	<10	<10	Absent	<10	Absent
		2	<10	<10	<10	<10	Absent	<10	Absent
		3	<10	<10	700	<10	Absent	<10	Absent
		4	<10	<10	>5000	<10	Absent	<10	Absent

Abbreviations: ND – not detected; TPC – total plate count.

The microbial data demonstrate that the products remain within specifications when stored at -18°C for 15 months. When stored at 4°C or at 20°C, the products remain within the specifications for 2 months of storage.

The proposed shelf life under the specified processing and recommended storage conditions is one year. Because of compositional similarities among the juice, juice concentrate, and pulp, it is reasonable to assume that the stability of juice concentrate and pulp will be comparable to that of juice when maintained at similar storage conditions. Additionally, the pH of all three products is less than 4.6, the recognized level at which growth of disease-causing bacteria is not supported.

Part 3. Dietary Exposure

Proposed Use and Level

The cacao ingredients that are the subject of this dossier are intended for use in select foods. Cacao pulp and cacao juice concentrate are intended for use in beverages at the maximum concentrations of 20% by weight, while cacao juice may be consumed as such. Cacao concentrate is also intended for use in bakery products, candy and confections (non-chocolate), cereal bars and chips/crackers, cocoa and chocolate products, edible ices - ice cream type, edible ices - sorbet type, gelatin/fruit mousse spreads, jams/jellies/fruit syrups and toppings, nutrition bars, plant-based spreads, and yogurt/yogurt drinks at maximum use levels ranging from 10 to 65% by weight. Cacao pulp is also intended for use in bakery products, candy and confections (non-chocolate), jams/jellies/fruit syrups and toppings, plant-based spreads, and yogurt/yogurt drinks at maximum concentrations ranging from 15 to 50% by weight. Only one type of cacao ingredient (pulp, juice, or concentrate) would be used in any specific use category at a time. The intended use levels and food categories to which cacao juice, pulp, and concentrate will be added are summarized in Table 14.

The maximum intended uses of cacao fruit juice concentrate are the same or higher than the intended uses of cacao pulp in all categories other than the categories of jams, jellies, fruit syrups and toppings and yogurt/yogurt drinks; in these two categories, the maximum intended use of cacao pulp is no more than 2.5 times the maximum intended use of the cacao fruit juice concentrate. As previously noted, the concentration of solids (i.e., non-water components) in the cacao fruit juice concentrate is 3 times the concentration present in pulp or juice due the removal of water in the production of the concentrate. Given the 3-fold higher concentration of solids in the cacao fruit juice concentrate compared to the cacao pulp, the maximum intended use of cacao fruit juice concentrate therefore provides an upper bound on the intended use of cacao pulp or cacao fruit juice concentrate in all food categories. For example, the proposed use of juice concentrate in yogurt/yogurt drinks is 10%, or 10 g cacao fruit juice concentrate per 100 g of yogurt/yogurt drinks. Given that the concentration of solids in cacao fruit juice concentrate is 3 times the concentration in cacao pulp, 10 g of cacao fruit juice concentrate will deliver an amount of non-water constituents equivalent to the amount provided in 30 g of cacao pulp, which is greater than the maximum intended use of cacao pulp in yogurt/yogurt drinks of 25 g pulp per 100 g of product. Estimates of dietary exposure based on the maximum intended use of juice concentrate therefore provide a conservatively high estimate of the maximum exposure to all products that may contain pulp, juice, or juice concentrate. Selected fruit juices were identified for the 100% use level of cacao fruit juice to provide representative intakes for the intended use of cacao fruit juice as such.

Table 14. Intended uses of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate

	Maximum Intended Use of Cacao by Form (weight %)			
Food Category	**Pulp**	**Juice**	**Juice Conc.**	**Description of foods in the category** [a]
Bakery Products	15		50	Cakes, pies, cookies, brownies, doughnuts, sweet rolls, pastries, biscuits, muffins, quick breads, pancakes, waffles
Beverages	20	100	20	Sweetened non-alcoholic beverages including: energy/sport drinks, fruit drinks, nectar, smoothies/grain based drinks, sweetened coffee, sweetened milks and milk alternatives, sweetened tea, sweetened waters
Candy and confections (non-chocolate)	25		65	Candy confections not containing chocolate
Cereal bars and chips/crackers			15	Cereal bars; potato chips; tortilla, corn, other chips; pretzels/snack mix; crackers
Cocoa and Chocolate Products			50	Chocolate, cocoa powder, chocolate candy, chocolate fudge
Edible Ices - ice cream type			30	Ice cream, frozen yogurt, milk shakes
Edible Ices - sorbet type			50	Ices, sherbets, sorbets
Gelatin/fruit mousse spreads			30	Gelatin desserts with fruit or other topping
Jams, jellies, fruit syrups, and toppings	50		25	Jam, jelly, marmalade, fruit-based syrups, fruit toppings, fruit pie filling
Nutrition bars			50	Nutritional bars
Plant-based spreads	20		25	Mayonnaise, salad dressing, hummus, dips, nut butters
Yogurt/yogurt drinks	25		10	Yogurt (including Greek, non-Greek, non-dairy), drinking yogurt, buttermilk, kefir

[a]Intended uses exclude sugar-free and non-calorically sweetened products.

Estimated Daily Intakes

Food Consumption Data

Food consumption records collected in the What We Eat in America (WWEIA) component of National Health and Nutrition Examination Survey (NHANES) conducted in 2013-2014 and 2015-2016 (NHANES 2013-2016) were used to estimate intake of the foods and beverages to which the cacao ingredients are intended to be added. This continuous survey uses a complex

multistage probability sample designed to be representative of the civilian U.S. population (CDC 2016, 2018). The NHANES datasets provide nationally representative nutrition and health data and prevalence estimates for nutrition and health status measures in the United States. Statistical weights are provided by the National Center for Health Statistics (NCHS) to adjust for the differential probabilities of selection.

As part of the examination, trained dietary interviewers collected detailed information on all foods and beverages consumed by respondents in the previous 24-hour time period (midnight to midnight). A second dietary recall was administered by telephone three-to-ten days after the first dietary interview, but not on the same day of the week as the first interview. The dietary component of the survey is conducted as a partnership between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). DHHS is responsible for the sample design and data collection, and USDA is responsible for the survey's dietary data collection methodology, maintenance of the databases used to code and process the data, and data review and processing. A total of 13,600 individuals age two years and older in the survey period 2013-2016 provided 2 complete days of dietary recalls.

Selection of Representative Foods

Exponent reviewed all foods reported consumed in NHANES 2013-2016 and identified NHANES food codes representative of the foods in each intended use category listed in Table 16. NHANES food codes representative of the intended uses were identified based on their WWEIA food category, name, and food description. The Food and Nutrient Database for Dietary Studies (FNDDS) "recipes" were used to identify the proportion of cocoa and chocolate products; jam, jellies, marmalades; yogurt; and plant-based spreads present as components in food mixtures corresponding to the intended use of the cacao pulp-derived products identified in this dossier. In all categories, foods selected as representative of the proposed uses are calorically-sweetened products. Food and beverage codes that were sugar-free or contained a low calorie sweetener were excluded from the analysis as the cacao pulp-derived ingredients are a source of sugars. Use levels of the cacao pulp products in beverage powders were adjusted to correspond to the intended use level on an as-consumed basis assuming a serving size of 250 mL based on the typical serving size of beverage powder as reported in FNDDS. Food and beverages selected for inclusion in the assessment are listed in Appendix D.

Analysis

Using the NHANES consumption data, Exponent estimated 2-day average intakes of cacao juice, pulp, and concentrates from proposed uses for the U.S. population ages 2 years and older, 2-5 years of age, 2-18 years, and 19 years and older on a per capita and per user basis. In the 2-day average consumption analysis, per capita estimates refer to the consumption based on the entire population of interest whereas per user estimates refer to those who reported consuming any of the foods in a given food category on either of the survey days. Thus, if a participant reported consuming the food on day 1 but not on day 2, they would be considered a "user" and their 2-day average consumption is the amount they reported consumed on day 1 divided by two.

The analysis was limited to individuals who provided two complete and reliable dietary recalls as determined by NCHS. The 2-day average intakes by each individual were estimated using Exponent's Foods Analysis and Residues Evaluation Program (FARE® version 13.03) software. Exponent uses the statistically weighted values from the survey in its analyses. The statistical weights compensate for variable probabilities of selection, adjust for non-response, and provide intake estimates that are representative of the U.S. population.

Results

Estimates of intake of the cacao pulp-derived products as represented by cacao concentrate are presented in Table 15. Per user intake of cacao concentrate is estimated at 85 g/day at the mean and 176 g/day at the 90th percentile of intake among the U.S. population ages 2 years and older. Among children 2-5 years of age, per user intake of cacao concentrate is estimated at 72 g/day at the mean and 143 g/day at the 90th percentile of intake.

Table 15. Estimated daily intake of cacao pulp-derived products as cacao concentrate from proposed uses by the US population and subpopulations, NHANES/WWEIA 2013-16

Population	Users (n)[a]	% Users	Per Capita		Per User	
			Mean	90th Percentile	Mean	90th Percentile
			g/day			
Children 2-5 years	1074	100	72	143	72	143
Children 2-18 years	4653	99	93	183	94	183
Adults ≥19 years	8636	98	80	170	82	173
Total population ≥2 years	13289	98	83	174	85	176

[a] Unweighted number of users; %user, *per capita* and *per user* estimates were based on NHANES and derived using the statistical weights provided by the NCHS.

It is important to note that the EDIs presented in this analysis represent conservatively high estimates of intake. In calculating the estimates of intake, all foods in each proposed use category were assumed to contain the maximum intended use of cacao juice concentrate. In reality, not all consumers may select products with cacao juice concentrate at all eating occasions.

Part 4. Self-Limiting Levels of Use

Cacao pulp, cacao fruit juice, and cacao fruit juice concentrate are intended for use as an ingredient in select foods. We are not aware of technological or palatability issues associated with the proposed use levels. Self-limiting levels of use are not applicable to this notice.

Part 5. Experience Based on Common Use in Food before 1958

The conclusion of GRAS status of the use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate as ingredients in select foods is based upon scientific procedures.

Part 6. Narrative

Approach for Assessing Safety

The safety of the intended uses in specified foods of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate derived from the pulp are the subject of this GRAS determination. The cacao products are derived from the cacao pod pulp, which is the source of cacao beans used to produce chocolate. Cacao pulp is the semi-solid fruit flesh found in the form of a wet mucilaginous layer surrounding the unfermented cacao bean.

Chocolate is a widely consumed food with a long history of consumption and considered safe. As previously reviewed, compositional data demonstrate that these cacao pulp-derived products consist primarily of water and sugar as glucose. The products also contain fiber, predominantly present as soluble fiber, a low concentration of protein (<1%), trace amounts of fat (<0.2%), organic acids, macro- and micronutrients primarily as the minerals potassium and a lower concentration of magnesium, polyphenols, and methylxanthines in the form of theobromine. These constituents are well known components in the diet overall and are found in other foods.

The safety of cacao pulp, cacao fruit juice and cacao fruit juice concentrate was evaluated based on a review of available data and information on the constituents in cacao and cacao pulp and an assessment of potential intake of the constituents from the intended use. A series of literature searches was conducted between March and July 2019 (and updated in February 2020) to identify information pertinent to the safety review and included searches of PubMed, Toxline, the U.S. Food and Drug Administration (FDA), European Food Safety Authority (EFSA), JECFA, Codex, and general searches of the Internet. Search terms used in the searches included terms for the cacao product (cacao, cocoa) and components in cacao pulp, including polyphenols (polyphenol, flavanol, flavan-3-ol, flavonoid, catechin, epicatechin, anthocyanins, proanthocyanidins), theobromine, and organic acids. A summary of the PubMed search strings is provided in Appendix E.

Cacao Pulp, Cacao Fruit Juice, and Cacao Fruit Juice Concentrate

History of Consumption

While cacao pulp is commonly viewed as a byproduct of chocolate consumption (Adams et al., 1982; Afolabi et al., 2015; Balladares et al., 2016; Vasquez et al., 2019), there is a long history of consumption of cacao pulp. Evidence suggests that consumption of cacao pulp in Mesoamerica dates back to 1000 BC where it was consumed as a fermented beverage and potentially preceded consumption of cocoa beverages (Henderson et al., 2007).

More recently, cacao pulp is identified as a food with traditional use in Brazil over the last decades. There is evidence that cacao pulp was used for the production of juice in Brazil in the

late 1970s and production commercialized on an industrial scale since the 1980s, mainly as a result of technological advances (e.g. refrigeration/freezing) that enabled longer transport and storage of this seasonal product (Adams et al., 1982; CEPLAC, 1982; Matta et al., 1999).

Evidence of interest in use of cacao fruit juice was also reported in other regions of the world including Africa. Research work conducted by the Cocoa Research Institute of Ghana (CRIG) from 1970 to 1983 demonstrated that sweatings or "bean fruit juice" could be processed into commercially useful by-products such as alcohol, pectin, jelly, soft drinks, wine, and vinegar. Based on these findings, an ICCO/CFC/CRIG project on "Pilot Plants to Process Cocoa By-products in Ghana" was implemented from September 1993 to July 2003 to carry out pilot-scale production and commercialization (Adomako, 2006). As reviewed by Buamah and colleagues (1997), sweatings also were recognized to be suitable for the production of alcoholic drinks such as wine, and some food items such as jams, marmalades and syrup.

Regulated Uses

Cacao pulp or puree from the edible part of cacao (*Theobroma cacao*) currently is a product defined by the Brazilian legislation (Normative Instruction No 01 of January 7, 2000) and therefore recognized as a food that is safe for human consumption. The Codex General Standard for fruit juices and nectars (CODEX STAN 247-2005) includes specifications for a variety of juices including *Theobroma cacao* L. (cacao pulp), thus indicating that cacao pulp is a recognized source of juice. The standards specify a minimum Brix Level of 14.0 for reconstituted cacao pulp juice and a minimum level of 50% cacao pulp juice and/or puree in fruit nectars.

Cacao fruit (*Theobroma cacao*) frozen puree was evaluated by Food Standards Australia New Zealand (FSANZ) and was recognized as a non-traditional food (i.e., not a novel food) with a history of use in South America and no indication of safety concerns (FSANZ, 2019). More recently, the European Union (EU) recognized pulp from *Theobroma cacao* L. as a traditional food on the list of authorized novel foods (EC, 2020; EFSA, 2019; EFSA, 2019).

Cacao pulp and juice are not regulated under 21 CFR (i.e., there is no Standard of Identity for these products), though a variety of cacao products are regulated with appropriate standards of identity, including cacao nibs, chocolate liquor, breakfast cocoa, cocoa, low-fat cocoa, cocoa with dioctyl sodium sulfosuccinate for manufacturing, sweet chocolate, white chocolate, milk chocolate, buttermilk chocolate, skim milk chocolate, mixed dairy product chocolates, sweet cocoa and vegetable fat coating, sweet chocolate and vegetable fat coating, and milk chocolate and vegetable fat coating (21 CFR §163).

Clinical Evidence

Limited information was found in the published literature on clinical studies of using cacao pulp and/or juice as a test product, as only one clinical study of cacao mucilage was identified (Morgan et al., 2018). The efficacy of cacao mucilage juice for muscle recovery after strenuous exercise was investigated in a randomized, double-blind, cross-over trial (Morgan et al., 2018).

Ten healthy, recreationally active males (mean age 22.8 ± 3.3 years) consumed 330 mL Ecuadorian cacao mucilage juice (ZumoCacao) or a carbohydrate and energy matched control for 10 days. The total polyphenol content of the juice beverage was 154 mg as measured with a modified Folin-Denis reagent method. Based on HPLC methods, the product provided 8 mg epicatechin, 43 mg catechin, and 12 mg proanthocyanidins; the control beverage provided no polyphenols. On day eight of the study, participants completed a warm-up and series of leg strength exercises. Muscle damage and recovery were measured 24 and 48 hours after the exercise bout. Consumption of the cacao beverage improved muscle recovery but not muscle strength immediately following exercise and 24 and 48 hours post exercise. Participants were asked to report adverse effects daily with consumption of the cacao beverage; no adverse effects were summarized in the paper. The investigators reported no observed differences in serum markers of muscle damage (creatinine kinase), oxidative damage (protein carbonyls), or inflammation (C-reactive protein and interleukin 6) before and through 48 hours post-exercise.

Components in Cacao Pulp, Cacao Fruit Juice, and Cacao Fruit Juice Concentrate

As demonstrated by analytical data on cacao pulp and cacao fruit juice, water and common sugars (glucose, fructose, sucrose) account for approximately 96-97% percent by weight of the products, with the balance comprised of low levels of the macronutrients fat and protein, dietary fiber, micronutrients primarily as minerals, organic acids, polyphenols, and a low concentration of theobromine. Estimates of intake of each component from the intended use of cacao fruit juice concentrate are presented below and pertinent safety information is reviewed.

Macronutrients and Dietary Fiber

The cacao pulp and juice products consist primarily of macronutrients present as carbohydrates, with less than 1% protein and trace amounts of fat (<0.2%) (Table 1).

The estimated intake of carbohydrate from the intended uses of cacao pulp products (as concentrate) is 102 g/day based on the 90th percentile intake of 176 g cacao juice concentrate and a typical concentration of 57.9 g carbohydrate per 100 g cacao juice concentrate (Table 1). The intake of carbohydrate from the intended use of the cacao pulp, cacao fruit juice, and cacao fruit juice concentrate can reasonably be assumed to replace other sources of carbohydrate in the diet. The estimated intake of dietary fiber from the intended uses of cacao pulp products (as concentrate) is 2.1 g/day based on the 90th percentile intake of 176 g cacao juice concentrate and a typical concentration of 1.2 g dietary fiber per 100 g cacao juice concentrate (Table 1).

Carbohydrates, which include sugars and starches, provide energy to cells in the body. The brain is dependent on glucose for energy, and carbohydrates are the largest contributing macronutrient to dietary energy intake in the typical diet. Dietary recommendations for carbohydrate identify 45-65% of energy from carbohydrate as an acceptable range of intake (IOM, 2005; USDA 2018). Carbohydrates in cacao pulp are present primarily as the sugars glucose, sucrose, and fructose and thus are a potential source of energy for the body.

In general, dietary fiber is the edible plant material resistant to digestion in the small intestine of humans (IOM, 2005). Dietary fiber is present in plants for support and as structural elements of the plant cell wall (celluloses, pectins and lignin), as plant gums and mucilage (hemicellulose), and as non-starch reserve carbohydrates (glucans, galactomannans) (Fuller et al., 2016).

The main constituents of dietary fiber in the common diet are cellulose and hemicelluloses, which are insoluble and both soluble and insoluble, respectively, and pectin which is a soluble fiber (Fuller et al., 2016). These common components of dietary fiber are high molecular weight dietary fiber and low molecular weight dietary fibers, include oligosaccharides such as fructans and galacto-oligosaccharides. Cellulose accounts for approximately one-third of the fiber of vegetables and nuts and 25% of the fiber in fruits and grains. Hemicellulose is found in cereal grains and lignin is found in foods with a "woody" component such as celery or the outer layer of cereal grains. Pectins are particularly concentrated in fruits, while pectin accounts for an estimated 15-20% of the fiber in vegetables, legumes, and nuts.

The total dietary fiber, soluble and insoluble fiber contents of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate were determined, results of which are shown in Table 1. As the key constituents of dietary fiber, cellulose and pectin account for the majority of the fiber fraction in cacao pulp followed by hemicellulose and lignin (Table 3; Pettipher, 1986). The relative fraction of pectin in the cacao juice and juice concentrate can be assumed to be lower than levels found in the pulp given the use of pectinase in the production of juice.

The Adequate Intake (AI) for dietary fiber ranges from 19 g/day for children ages 1-3 years to 38 g/day for males ages 14-50 years (IOM, 2005). There is not a Tolerable Upper Intake Level (UL) established for fiber because there is no evidence of safety concerns from higher intakes and higher intakes tend to be self-limiting. Based on data from the 2015-2016 NHANES, the average daily dietary fiber intake from foods is 14.8 g for males ages 2-19 years, and 13.3 g for females aged 2-19 years. Among adults ages 20 years and over, the average dietary fiber intake from foods is 18.9 g for men and 15.7 g for women (USDA ARS, 2018). Given the low intake of fiber in the typical U.S. diet relative to dietary guidance, fiber has been identified as a nutrient of concern for the US population (USDA/DHHS 2015).

Organic Acids

The estimated intake of citric acid from the intended uses of cacao pulp products (as concentrate) is 6.2 g/day based on the 90th percentile intake of 176 g cacao fruit juice concentrate and a mean concentration of 3.5 g citric acid per 100 g cacao fruit juice concentrate. The estimated intake of succinic acid from the intended uses of cacao pulp products (as concentrate) is 0.5 g/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 0.1 g succinic acid per 100 g pulp and adjusted for moisture in the concentrate.

Organic acids are natural constituents in commonly consumed foods such as fruits. Along with sugars, they contribute to tartness and flavor. Citric acid is the principle organic acid in cacao pulp and juice at a mean concentration of approximately 1 g per 100 g, followed by succinic acid which was measured at a concentration of approximately 0.1 g per 100 g (Pettipher, 1986). For

comparison, the concentrations of citric and succinic acids in fruit juices are summarized in Table 16.

Table 16. Levels of organic acids (citric and succinic) in fruit juices

Product	Additional Description	Citric Acid (g/100 g)	Succinic Acid (g/100 g)	Reference
Apple juice	Average of 4 samples	0.07	0.002	Restuccia et al., 2017
Blueberry juice	Average of 4 samples	1.36	0.006	Restuccia et al., 2017
Grapefruit juice	Florida's Ruby Red	2.50	-	Penniston et al. 2008
Grapefruit juice	Average of 4 varieties	2.17	0.039	Kelebek et al., 2010
Lemon juice	Yellow lemons, mean of 3 storage times	6.80	0.108	Sun et al., 2019
Lemon juice	Fresh from fruit	4.80	-	Penniston et al. 2008
Lemonade	Average of RTD and mix	0.47	-	Penniston et al. 2008
Lime juice	Fresh from fruit	4.58	-	Penniston et al. 2008
Orange juice	From fruit	0.91	-	Penniston et al. 2008
Peach juice	Average of 4 samples	0.07	0.002	Restuccia et al., 2017
Pear juice	Average of 4 samples	0.19	ND	Restuccia et al., 2017
Red orange juice	Average of 4 samples	0.71	0.019	Restuccia et al., 2017

Assumed 1 mL of juice = 1 g.
Abbreviations: "-" – no data; ND – not detected; RTD – ready to drink.

Organic acids have well-established roles as intermediate metabolites in the tricarboxylic acid cycle (TCA), also referred to as the citric acid or Krebs cycle. Therefore, citric acid and other organic acids including succinic acid are normal metabolites in the body and are considered to present no safety concerns.

Citric acid is affirmed as GRAS for use as an ingredient in food (21 CFR §184.1033) with no limitations other than current good manufacturing practice. Several citric acid salts also are recognized as GRAS for use in foods, including calcium citrate (21 CFR §184.1195), ferric ammonium citrate (21 CFR §184.1296), ferric citrate (21 CFR §184.1298), ferrous citrate (21 CFR §184.1307c), and manganese citrate (21 CFR §184.1449).

JECFA evaluated the potential toxicity of citric acid and its calcium, potassium, sodium, and ammonium salts for its use as an acidulant, sequestrant, antioxidant synergist, and flavoring agent and established an ADI "not limited/specified" (JECFA, 1969). Like other organic acids, citric acid is a permitted food additive that may be added directly to food intended for human consumption without any limitation. Citric acid intake from natural and additive sources in the diet has been estimated at approximately 40 mg/kg/day for women, 130 mg/kg for infants and 400 mg/kg for individuals on slimming diets, while the maximum daily intake of citric acid is reported to reach levels of 500 mg/kg/day (OECD – SIDS, 2012). Therefore, for a 60 kg

woman, daily intake of citric acid is approximately 2.4 g/day while maximum daily intake may be up to 30 g/day assuming a typical body weight of 60 kg.

Succinic acid is recognized as GRAS for use as a flavor enhancer and pH control agent, and may be used in food at levels not to exceed good manufacturing practice as specified in 21 CFR §184.1091; as served, maximum concentrations of succinic acid in condiments and relishes (21 CFR §170.3(n)(8)) and meat products (21 CFR §170.3(n)(29)) are 0.084% and 0.0061%, respectively. Succinic acid also is recognized as a food additive in the EU (E 363); an ADI was not established. Use of succinic acid in the EU is permitted in flavored fermented milk products including heat-treated products at a concentration up to 6,000 mg/kg (0.6 g per 100 g), in soups and broths at a concentration up to 5,000 mg/kg (0.5 g per 100 g), in powders for home preparation of flavored drinks at a concentration up to 3,000 mg/L (0.3 g per 100 g), and desserts at a concentration up to 6,000 mg/kg (0.6 g per 100 g). Succinic acid was evaluated at the 29th meeting of the Joint FAO/WHO Committee on Food Additives and Contaminants and an ADI of "not specified" was established for the succinate moiety (JECFA, 1987).

Elements

The cacao pulp and cacao juice are a source of elements including minerals and appropriately low concentrations of heavy metals. As previously reviewed (Table 4), the cacao pulp, cacao fruit juice, and cacao fruit juice concentrate are relatively concentrated sources of potassium and to a lesser extent magnesium while levels of other minerals and vitamins are low.

Potassium

Potassium is an essential nutrient of the diet involved in physiological processes to maintain cellular osmotic homeostasis, pH balance, and electrochemical signal transduction in nerve and muscle cells. The estimated intake of potassium from the intended uses of cacao pulp products (as concentrate) is 1,030 mg/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 586 mg potassium per 100 g cacao juice concentrate.

In 2019, the U.S. National Academy of Sciences, Engineering and Medicine (NASEM) released dietary reference intakes for potassium to update reference intakes released in 2005 (IOM, 2005; NASEM, 2019) (Note: the NASEM was previously known as the Institute of Medicine (IOM)). In the 2019 review, NASEM again determined that there was insufficient evidence to set an Estimated Average Requirement (EAR) and in turn a Recommended Dietary Allowance (RDA) for potassium; however, they did establish an AI level for potassium. The AI released in 2019 corresponds to the median intake by the U.S. population while the AI from 2005 was based on evidence of potassium supplementation trials. Dietary reference intakes for potassium intake by populations age 1 year and older are summarized in Table 17. As part of the 2019 review, the NASEM considered development of a Chronic Disease Risk Reduction Intake (CDRR) for potassium though a value was not established due to “insufficient strength of evidence for causality and intake-response” (NASEM, 2019).

Table 17. Dietary Reference Intakes for Potassium

	Potassium Dietary Reference Intakes				
	Adequate Intake (mg/day)				Tolerable Upper Intake Levels (UL)
	NASEM, 2019		IOM, 2005	EFSA, 2016	IOM, 2005; NASEM, 2019; EFSA, 2016
Age Group	**Male**	**Female** [a]	**Male/Female**	**Male/Female** [a]	**Male/Female**
1-3 years	2,000	2,000	3,000	800	-
4-8 years	2,300	2,300	3,800	1,100 – 1,800	-
9-13 years	2,500	2,300	4,500	1,800 – 2,700	-
14-18 years	3,000	2,300 (2,600/2,500)	4,700	2,700 – 3,500 (3,500/4,000)	-
≥19 years	3,400	2,600 (2,900/2,800)	4,700	3,500 (3,500/4,000)	-

[a] Values in parentheses are for pregnant and lactating women, respectively.

Excess dietary potassium is excreted in the urine and is a concern only among populations with impaired kidney function (i.e., chronic kidney disease, end-stage renal disease, diabetes, severe heart failure, and adrenal insufficiency) or populations taking ACE inhibitors or angiotensin receptor blockers. Potential adverse effects of excessive potassium intake related to gastrointestinal discomfort and arrhythmia were evaluated by the IOM and no evidence of adverse effects from high levels of potassium from food was identified and thus a UL was not established (IOM, 2005). In 2019, the NASEM evaluated the toxicity effects of potassium on blood lipids and catecholamines, and general adverse effects of high potassium intake as noted in case reports. Intake of 2,500 mg/day from short-term potassium supplementation was noted to be safe among the general population, but the NASEM again concluded that the available data did not allow for the establishment of a UL for daily potassium intake due to a "lack of toxicological indicator specific to excessive potassium intake" (NASEM, 2019). High intake of potassium via dietary supplements is discouraged among populations with or at risk for impaired kidney function though no such restrictions are provided for the general population.

As shown in Table 17, recommended intakes of potassium by the EFSA are generally within the range of intakes recommended by IOM and NASEM. EFSA drew the same conclusion that "data are insufficient" to establish a UL for potassium (EFSA, 2005 as cited in EFSA, 2016) and reported that the chronic intake of 3,000 mg potassium as a supplement plus intake from foods, and intake from food at levels up to 5,000-6,000 mg/day, was associated with low risk of adverse effects. Gastrointestinal effects from potassium supplementation have been observed with intake of 1,000-5,000 mg/day, but the incidence and severity of symptoms vary widely (EFSA, 2005 as cited in EFSA, 2016).

Based on data from the 2015-2016 NHANES, the average daily potassium intake from foods is 2,227 mg for males ages 2-19 years and 1,943 mg for females ages 2-19 years. Among adults

ages 20 years and over, the average daily potassium intake from foods is 2,967 mg for men and 2,323 mg for women.

Magnesium

Cacao products are also a source of magnesium. The estimated intake of magnesium from the intended uses of cacao pulp products (as concentrate) is 39 mg/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 22 mg potassium per 100 g cacao juice concentrate.

Magnesium is an essential micronutrient of the diet and cofactor for many enzymes responsible for physiological reactions including protein synthesis, nerve and muscle function, glycemic control, blood pressure homeostasis, cellular transport, and energy production (ODS, 2019).

In 1997, the IOM established the RDA for magnesium at 80-410 and 80-360 mg/day for males and females ages 1-19 years, respectively, and 400-420 and 310-320 mg/day for adult males and females, respectively (IOM, 1997). There are no documented adverse effects from intake of magnesium from dietary sources (IOM, 1997). However, excess intake of magnesium from supplemental magnesium (i.e., magnesium salts) for pharmacological purposes can lead to adverse health effects and was, therefore, the basis of the UL. EFSA also concluded that adverse effects of excess magnesium intake (i.e., diarrhea) are applicable only when consumed from supplemental sources (EFSA, 2015).

Based on data from the 2015-2016 NHANES, the average daily magnesium intake from foods is 248 mg for males ages 2-19 years and 214 mg for females ages 2-19 years. Among adults ages 20 years and over, the average daily magnesium intake from foods is 345 mg for men and 272 mg for women.

Polyphenols

Intake from the Intended Use of Cacao

The estimated intake of polyphenols from the intended uses of cacao pulp products (as concentrate) is 282 mg GAE/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 160.4 mg phenols per 100 g cacao juice concentrate as GAE as determined by the nonspecific colorimetric Folin-Ciocalteu method (Table 7). As previously noted, further analysis of the cacao pulp and juice indicates that with the exception of the procyanidin B2 fraction, the flavan-3-ols typically present in cocoa and chocolate including catechin, epicatechin and the B2 dimer and C1 trimer procyanidins were not detected or largely not quantifiable in the cacao pulp products. The procyanidin B2 fraction was detected at concentrations in the range of 1.1-1.6 mg per 100 g product in three of a total of six pulp and juice samples while in the remaining three cacao samples, the measured level of procyanidin B2 was below the LOQ of <0.9 mg per 100 g. Collectively, analytical data on the cacao pulp that is the subject of this review and data in the published literature on cacao pulp

indicate that the primary flavan-3-ols present in cocoa products may be present in cacao juice, albeit at much lower concentrations than concentrations in cocoa products such as chocolate.

Using the analytical data from the analysis of specific flavon-3-ols in the cacao juice and pulp and assuming the concentration of each measured flavon-3-ol is equal to half the LOD/LOQ, the total concentration of these polyphenols is 2 to 3 mg per 100 g cacao juice or pulp. Assuming a 3-fold concentration of juice in concentrate and a 90th percentile intake of 176 g cacao juice concentrate, the intake of these polyphenols from the intended uses is estimated at 11 to 16 mg per day (Table 7).

Dietary Sources and Intake

Many foods in a typical diet are naturally rich in polyphenols and consequently dietary polyphenols have generally been recognized as safe (Erdman et al., 2007). Accurate determination of polyphenol intake has been greatly hindered by differences in dietary assessment methods and lack of comprehensive food composition databases, though more recently, databases have been developed to support improved quantification of concentrations of these components in foods (Erdman et al., 2007; Del Bo et al., 2019).

In 2019, Del Bo and colleagues completed a systematic review of the literature and summarized total polyphenol and polyphenol subclass intakes as reported in a total of 91 prospective cohort and case-control studies, which thus provides recent estimates of polyphenol intakes (Del Bo et al., 2019). As reported by the authors, mean intake of total polyphenols was estimated at approximately 900 mg per person per day while total polyphenol intakes varied among the populations captured in the systematic review. The highest intakes were estimated for adults in Poland at a mean of 1,741 ± 630 mg/day (Grosso et al., 2014) and adults in Japan with a mean intake of 1,492 ± 665 mg/day (Taguchi et al., 2015) based on food frequency questionnaires (FFQs). For the U.S. population, total polyphenol intake was estimated at 1,370 ± 1,069 mg/day among coffee consumers and 541 ± 368 mg/day among individuals not consuming coffee based on FFQs reported by 77,441 adults in the Adventist Health Study-2 cohort (Burkholder-Cooley et al., 2016). In another study among a population in the U.S., total polyphenol intake was estimated at 717 ± 646 mg/day based on food intake reported in an FFQ and 402 ± 345 mg/day based on 24-hour dietary recall data (Burkholder-Cooley et al., 2017). The main foods contributing to total polyphenol intakes include tea, coffee, red wine, fruit, and vegetables (Del Bo et al., 2019). In several of these studies (e.g., the study by Burkholder-Cooley et al., 2017), a database of values from chromatographic analysis of polyphenol concentrations in foods (Phenol Explorer) was used to develop the estimates of intake, thus the values are potentially more representative of true polyphenol concentrations in foods as compared to older estimates.

Authoritative Bodies

Several GRAS notifications for ingredients that are concentrated sources of polyphenols have been reviewed by FDA and in each case, the FDA responded with a letter of no questions (Table 18; e.g., GRNs 124, 125, 446, 497, 772, 796, 805). Intake of the polyphenols that were the subjects of the GRNs at the 90th percentile of intake ranged from approximately 100 mg to 2,600

mg daily. These GRAS notifications therefore establish recognition of the safe consumption of a variety of polyphenols added to foods.

Table 18. GRAS Notifications (GRNs) for polyphenol-rich ingredients with a FDA Letter of "No Questions"

Ingredient	Uses	Amount	EDI
Mega-Natural™ Grape seed extract (GSE) (GRN 124)	Beverages and beverage bases, breakfast cereals, fats and oils, frozen dairy desserts and mixes, grain products, milk (whole and skim), milk products, processed fruits and fruit juices	0.01 to 0.08%	Mean: 150 mg/p/d 90th percentile: 300 mg/p/d
Mega-Natural™ Grape seed extract (GSE) and grape pomace extract (GPE) (GRN 125)	Fruit juices, fruit flavored beverages, fruit flavored beverage mixes and carbonated fruit flavored beverages	Up to 210 ppm (mg/kg) or 50 mg/8 oz serving	Mean: 70 mg/p/d 90th percentile: 130 mg/p/d
Red grape pomace extract (RGPE) (GRN 446)	Fruit juices, fruit flavored beverages, fruit flavored beverage mixes and carbonated fruit flavored beverages	Up to 210 ppm (mg/kg)	Mean: 70 mg/p/d 90th percentile: 130 mg/p/d (references EDI in GRN 125)
Polyphenols from the fruit of *Litchi chinensis* Sonn. (lychee) and from the leaves of *Camellia sinensis* (L.) Kuntze (green tea) or "PLC" (GRN 497)	Various food categories excluding meat and poultry products and infant formula	0.01 - 0.10%	Monomeric flavan-3-ols 90th percentile: 65.9 mg/p/d Procyanidins 90th percentile: 288.4 mg/p/d
Palmitoylated green tea catechins (PGTC) (GRN 772)	Baked goods and baking mixes; breakfast cereals; cheeses; confections and frostings; dairy product analogs; fats and oils; grain products and pastas; herbs, seeds, spices, seasonings, blends, extracts, and flavorings; nut and nut products; snack foods; and soft candies	Up to 0.28%	Green tea catechins Mean: 63 mg/p/d 90th percentile: 126 mg/p/d
Orange extract (GRN 796)	Flavored milk and imitation milk drinks; dry powdered milk mixtures; yogurts; coconut beverages; cookies; cereals; cereal, granola, and nutrition bars; fruit, fruit-flavored, and vegetable juices and drinks; table fats and vegetable oils; chocolate and dietetic candies; teas; carbonated soft drinks; "fortified" waters; nutrition	500 mg/serving	Hesperidin 90th percentile: 2,608 mg/p/d (intended use + diet)

Ingredient	Uses	Amount	EDI
	drinks; nutrition powders; "energy" drinks; and "sport" drinks		
Apple peel powder (GRN 805)	Fruits and fruit juices, vegetable juices, milk and milk products, bakery products, dairy products and substitutes, ready-to-eat cereals, sauces, dips, gravies, and condiments	0.1 – 20%	Polyphenols (mainly flavonoids and anthocyanins) Mean: 252 mg/person/day 90th percentile: 501 mg/p/d (assume 3% of product is polyphenols based on compositional data)
Abbreviations: d - day; EDI - estimated daily intake; p – person.			

EFSA recognizes health claims for select polyphenols and thus identifies a specified level of polyphenol intake that is considered safe. In 2012, EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA) recognized a cause-and-effect relationship in accordance with Article 19 of Regulation (EC) No 1924/2006 between cocoa flavanols and maintenance of endothelium-dependent vasodilation (Article 13(5)) from consumption of cacao flavanols from cocoa beverages (with cocoa powder) and dark chocolate and the claim was subsequently expanded to include consumption of cocoa flavanols from high-flavanol cocoa extract consumed as a capsule, tablet or other food, including beverages (EFSA, 2012; EFSA, 2014). The claim states that "cocoa flavanols help maintain endothelium-dependent vasodilation, which contributes to normal blood flow" with consumption of 200 mg cocoa flavanols per day.

Clinical Studies

Numerous clinical studies have been conducted with polyphenols, primarily for the purpose of evaluating efficacy of the substance (Del Bo et al., 2019; Raman et al., 2018), while a limited number of studies have been conducted specifically with the intent of collecting data to evaluate safety of consumption.

Ottaviani and colleagues conducted a clinical study for the purpose of evaluating safety and efficacy of cocoa flavanols in humans (2015). Generally healthy adults considered to be at low risk of cardiovascular disease (CVD), with inclusion criteria including body mass index ≤ 30 kg/m^2 and blood pressure ≤140/90 mm Hg, and no history of CVD or stroke were recruited for the study. The study was conducted in two parts: an open-label dose escalation study for 6-weeks in part 1 and a randomized, parallel-arm, double-blind, controlled intervention for 12 weeks in part 2.

In part 1, participants consumed 1,000 mg, 1,500 mg, and 2,000 mg cocoa flavanols per day over consecutive 2-week periods followed by a 2-week washout period. The cocoa flavanols were consumed in capsules containing 500 mg cocoa flavanols delivered as 62 mg flavanol monomers

and 438 mg procyanidins (dimers to decamers). Blood samples were collected and BP was measured on days 15, 29, and 43 of the intervention and after the 2-week washout period at the end of the intervention. Blood samples were analyzed for platelet function, metabolic variables, and blood concentrations of cocoa flavanols and methylxanthine metabolites.

In part 2, participants were randomized to consume the cocoa flavanol-containing capsules or cocoa-flavanol free capsules twice daily throughout the 12-week intervention. During week 1, participants in the cocoa flavanol arm consumed 2 capsules daily which provided 1,000 mg cocoa flavanols; during week 2, participants consumed 3 capsules daily which provided 1,500 mg cocoa flavanols; and during weeks 3-through-12 participants consumed 4 capsules daily which provided 2,000 mg cocoa flavanols. A 2-week washout period followed the 12-week intervention. During study visits at baseline and on days 43 and 85 of the intervention and after the 2-week washout period at the end of the intervention, participants provided blood samples for assessment of platelet function, metabolic variables, and blood concentrations of cocoa flavanols and methylxanthine metabolites. Blood pressure was measured at each of the study visits and participants completed 24-hour ambulatory measures at study day 1 and study day 85. Study participants also were actively monitored for the occurrence of adverse events via completion of a questionnaire during regularly scheduled interviews in each part of the study and self-reporting of adverse events at any time. Study participants maintained their normal diet, activities, and routine throughout the study.

The study results showed no effect of daily intake of cocoa flavanols at any dose on blood pressure (systolic or diastolic), platelet function (measured by clotting time), or clinically relevant changes in the metabolic variables in part 1 or part 2 of the intervention. Additionally, there was no difference between the cocoa flavanols and control groups in number and type of adverse events. Adverse events were not associated with the amount of cocoa flavanols consumed. With the exception of one serious event (headaches), all other adverse events were mild in nature. Based on these findings, the study authors concluded “that the consumption of up to 2000 mg [cocoa flavanols] daily is well tolerated by healthy men and women”.

While many other studies have been conducted with cocoa flavanols (Del Bo et al., 2019; Raman et al., 2018), their primary objectives have largely been to examine efficacy. The efficacy studies nonetheless provide corroborative support for safe consumption of intakes up to 1200 mg per day and studies spanning up to 18 weeks as reported by Reid et al., 2017. Raman and colleagues identified 52 clinical studies of chocolate and report an average flavan-3-ol intake of 618.68 mg per study (range 2.70 - 8301.81 mg) from the test products.

Overall, the estimated intake of polyphenols from the intended uses of cacao pulp products (as concentrate) is 282 mg GAE which is likely an overestimate of true polyphenol intake. Based on testing of flavanols typically found in cocoa, intake of polyphenols from the intended uses of cacao pulp products is in the range of 11-16 mg per day of flavan-3-ols.

Theobromine

Theobromine (CAS # 83-67-0) is a xanthine alkaloid that occurs naturally in cacao beans and can be found in tea, coffee, and cola nuts. Exposure to theobromine in humans can occur from an oral dose of caffeine, whereby ~11% of the caffeine is metabolized within the body to theobromine (EFSA, 2017). Theobromine is also recognized as a flavoring agent by FDA and has FEMA (Flavor Extract Manufacturers Association) #3591- for use in baked goods (1050 PPM), confectionery/frostings (4000 ppm), gelatin/pudding (795 ppm), milk products (990 ppm), soft candy (4020 ppm), and sweet sauces (3300 ppm).

There are several studies on the pharmacokinetics (absorption, distribution, metabolism, and excretion) of theobromine in man (Cornish and Christman, 1957; Drouillard *et al.,* 1978; Miners *et al.,* 1982; Tarka *et al.,* 1983; Lelo *et al.,* 1986).

A literature search in PubMed was conducted to identify studies pertinent to the safety of theobromine, with a special emphasis on reproductive toxicity. The search string "dart [subset] AND theobromine" without restrictions was applied and returned 229 results, which were evaluated for relevant data pertaining to reproductive toxicity. Additional databases searched included European Food Safety Authority (EFSA), U.S. Food and Drug Administration (FDA), the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA), and the National Toxicology Program (NTP).

Relevant studies were reviewed and summarized in tabular format (Appendix F). Studies of the reproductive toxicity of theobromine include studies with multiple dose groups and oral route of administration (diet or gavage) performed in the rat (Appendix F, Table 1) and studies in the dog, rabbit, mice and hamsters (Appendix F, Table 2). In the majority of these studies, a NOAEL was not reported by the study authors. However, in cases where a NOAEL could be derived based on the reported data, these NOAELs are noted. For the purpose of being comprehensive, single dose group studies in rats and mice theobromine via the diet or oral gavage are listed in Appendix F, Table 3. Additionally, Appendix F, Table 4 summarizes data from a single ex vivo reproductive toxicity study.

In a published EFSA Scientific Opinion from 2008, the EFSA Panel on Contaminants in the Food Chain evaluated the risks for animal and public health to theobromine in animal feed and determined the NOAEL for testicular toxicity to be 150 mg/kg bw/day. The Panel derived the NOAEL from studies conducted by Tarka et al. (1981) (Appendix F, Table 1) and Gans et al. (1980) (Appendix F, Table 2). Specifically, Tarka et al. (1981) reported irreversible testicular toxicity at the two highest doses in a 49-day exposure/49-day recovery rat study. The EFSA Panel did not report specific dose conversions for the Tarka et al. (1981) study; however, the EFSA Panel concluded that doses above 300 mg/kg bw/day caused irreversible testicular toxicity. Moreover, the EFSA Panel selected a NOAEL of 150 mg/kg bw/day based on the Gans et al. (1980) 1-year dog study that did not report any testicular toxicity up to the highest tested dose (i.e., 150 mg/kg bw/day). The overall conclusion from the EFSA Panel was that the target reproductive organ of theobromine toxicity are the testes (namely, Sertoli cells) in rodents.

Based on the collective multiple dose group studies in rats (Appendix F, Table 1), the GLP/FDA guideline, three-generation reproductive study (Hostetler et al., 1990) showed an overall absence of treatment-related reproductive effects over three generations up to the highest tested dose of 5.0% cocoa powder, equivalent to 97 and 117 mg/kg bw/day theobromine for males and females, respectively (93% of the mean total methylxanthine in 5.0% cocoa power consisted of theobromine). Therefore, a NOAEL of 97 mg/kg bw/day for reproductive toxicity could be derived based on this well conducted study. Given that this NOAEL is the lowest and based on a 3-generation GLP study, the NOAEL of 97 mg/kg bw/day is used for this safety evaluation.

The U.S. population ages 2 years and older consumes on average 36.3 mg theobromine per day, although intakes among subpopulations of males ages 12-19 years is estimated at 54.6 mg per day (USDA ARS, 2018). The estimated intake of theobromine from the intended uses of cacao pulp products (as concentrate) is 3 mg/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 1.726 mg theobromine per 100 g cacao juice concentrate (Table 8).

Other Substances

Evidence of anti-nutrients or other substances of concern in cacao pulp and cacao fruit juice was not identified.

Potential Allergenicity

No reports of allergic responses to consumption of cacao pulp were identified in the literature. Cocoa powder, which is also sourced from *Theobroma cacao* L., has been identified as a food allergen for some individuals (Nunes et al., 2019). Quantitative and qualitative differences between protein species in the pulp and seed fractions of Theobroma have been identified (Perez-Mora et al., 2018), which may account for differences in potential allergenicity. In a proteomic analysis of pulp from three species of Theobroma, namely T. cacao, bicolor, and grandiflorum, class I chitinases which have been assumed to be the cause of allergic responses in some foods were not detected in Theobroma cacao L. (Perez-Mora et al., 2018).

GRAS Criteria

The regulatory framework for determining whether the use of a substance in food for animals can be considered GRAS in accordance with section 201(s) of the Federal Food, Drug, and Cosmetic Act ("the Act"), is set forth at 21 CFR §170.30, which states:

> General recognition of safety may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common

knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies, which may be corroborated by unpublished studies and other data information.

In the preamble to the final rule for GRAS notifications, FDA stated that a GRAS conclusion, based on scientific procedures may be supported by scientific data (such as human, animal, analytical or other scientific studies), information, methods and principles, published or unpublished, appropriate to establish the safety of a substance under the conditions of intended use (FDA, 2016). The safety standard requires that there be a reasonable certainty of no harm under the conditions of intended use of the substance. To be eligible for a GRAS conclusion based on scientific procedures, there must be evidence of a consensus among qualified experts that the proposed use is safe and the pivotal data and information supporting the safety of the ingredient's intended use must be publicly available.

Safety Assessment

The substance that is the subject of this dossier is cacao pulp as such, cacao fruit juice that is made from this pulp, and cacao fruit juice concentrate. The starting raw material used to make the product is the fruit of the cacao plant, Theobroma *cacao* L. Cacao pulp is the semi-solid fruit flesh found in the form of a wet mucilaginous layer surrounding the unfermented cacao bean.

The industrial collection of cacao pulp is done as part of the initial processing of the cacao bean after pod opening and prior to fermentation of the cacao bean. Cacao pulp is then pasteurized to ensure a safe product for consumption, or it is subjected to food-grade enzymes to produce cacao fruit juice which is subsequently pasteurized and packaged or concentrated by removal of water to form cacao fruit juice concentrate. The products are manufactured under conditions of Good Manufacturing Practices (cGMPs) and no processing aids other than these enzymes are used in the production process of cacao pulp, cacao fruit juice, or cacao fruit concentrate. Product specifications include physico-chemical and microbiological criteria established to ensure consistent safety and quality of the product. Monitoring is conducted to ensure that potential impurities including heavy metals, mycotoxins, pesticide residues, and polycyclic aromatic hydrocarbons meet specifications appropriate for a food ingredient. Analytical data from non-consecutive batches demonstrate that the product specifications are consistently met.

Cocoa and chocolate are foods with a long history of use. Cacao pulp, which is also derived from *Theobroma cacao* L. and is a by-product of cocoa and chocolate production, has traditional use in Brazil and elsewhere over the last several decades in food items such as sweets, jellies, liquors, alcoholic beverages, and vinegar. Cacao pulp or puree from the edible part of cacao (*Theobroma cacao* L.) currently is a product defined by Brazilian legislation and therefore recognized as a food for safe human consumption. Cacao fruit (*Theobroma cacao* L.) frozen

puree is recognized by Food Standards Australia New Zealand (FSANZ) as having a history of use in South America and in the European Union (EU), cacao pulp juice is recognized as a food traditionally consumed in countries outside the EU with no known safety concerns.

Compositional data demonstrate that cacao pulp products consist primarily of water and sugar as glucose. The products also contain fiber, predominantly present as soluble fiber, a low concentration of protein (<1%), trace amounts of fat (<0.2%), micronutrients primarily as the minerals potassium and a lower concentration of magnesium, organic acids, polyphenols, and alkaloids in the form of theobromine; these constituents are well known components in the diet overall and are typically found in other juices and considered to be safe.

The safety of cacao pulp, cacao fruit juice and cacao fruit juice concentrate was evaluated based on a review of available data and information on the key constituents in cacao including compositional data and assessment of potential intake of the constituents from the intended use. The constituents evaluated include carbohydrate and fiber, organic acids, minerals including potassium and magnesium, theobromine, and polyphenols. Dietary intakes of fiber, organic acids, micronutrients, polyphenols, and theobromine in cacao pulp, cacao fruit juice, and cacao fruit juice concentrate are expected to have the same metabolic fate as constituents from other dietary sources. No evidence of safety concerns from intake of cacao pulp, cacao fruit juice, cacao fruit juice concentrate, or the constituents of these cacao pulp products at levels of intake resulting from the intended uses of the pulp, juice and concentrate was identified in the searches of the published literature.

Cacao fruit juice concentrate is primarily carbohydrate in the form of glucose, fructose and sucrose, with these sugars accounting for the majority of the non-water portion, or approximately 51% by weight of the concentrate. Carbohydrates are a necessary and key source of energy in the diet and sugars from the intended use of cacao pulp, cacao fruit juice and cacao fruit juice concentrate will likely replace other sources of dietary carbohydrate and are of no safety concern. The estimated intake of fiber from the intended uses of cacao pulp products (as concentrate) is 2.1 g/day. Compositional data on cacao pulp demonstrate that fiber is present as high molar weight fibers including cellulose, pectin, hemicellulose, and lignin, all of which are common naturally occurring forms of dietary fiber. The small incremental increase in dietary fiber intake from the intended use of the cacao products presents no safety concern.

Cacao products are a source of minerals including potassium and magnesium. Fruit juices are a recognized source of minerals and compositional data indicate that concentrations of potassium and magnesium in cacao pulp and juice are similar to concentrations of these minerals present in commonly consumed juices such as orange juice or coconut water. The estimated intake of potassium from the intended uses of cacao pulp products (as concentrate) is 1,030 mg/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 586 mg potassium per 100 g cacao juice concentrate. The potential intake of potassium from current dietary sources and the intended uses is within the range of intakes that have been recommended by authoritative bodies including IOM, NASEM (previously known as the IOM), and EFSA. For the generally healthy population, there is UL for potassium as the available evidence provides no indication of adverse effects from high levels of potassium from foods.

The potential intake of potassium from the intended use therefore does not present a safety concern.

The estimated intake of magnesium from the intended uses of cacao pulp products (as concentrate) is 39 mg/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 22 mg potassium per 100 g cacao juice concentrate. The intended uses of the cacao pulp, cacao fruit juice, and cacao fruit juice concentrate therefore result in a small increase in magnesium intake and is well within recommended levels of intake. There is no UL for magnesium from dietary sources. The potential intake of magnesium from the intended use does not present a safety concern.

The estimated intake of citric acid from the intended uses of cacao pulp products (as concentrate) is 6.2 g/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean concentration of 3.5 g citric acid per 100 g cacao fruit juice concentrate. The estimated intake of succinic acid from the intended uses of cacao pulp products (as concentrate) is 0.5 g/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 0.1 g succinic acid per 100 g pulp and adjusted for moisture in the concentrate. Both citric acid and succinic acid are present in commonly consumed fruits at concentrations in the range of the concentration reported in cacao pulp, and both citric acid and succinic acid may be consumed as approved additives in foods. The intended uses of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate provide a source of citric acid and succinic acid and their respective intakes can be expected to fall within the range of background intake of these substances; the intended use does not present a safety concern.

The estimated intake of polyphenols from the intended uses of cacao pulp products (as concentrate) at the 90th percentile of intake is 282 mg gallic acid equivalents (GAE) which is likely an overestimate of true polyphenol intake, or in the range of 11-16 mg per day of flavan-3-ols based on testing of flavanols typically found in cocoa. Flavanols are ubiquitous in the diet and generally regarded as safe. Intakes of polyphenols from dietary sources may exceed 1,500 mg per day for the U.S. population, and the safe intake of a variety of polyphenols has been recognized in foods delivering in the range of 100 to 2,600 mg polyphenols per person per day in the diet. The estimated intake of polyphenols from the intended use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate will provide a small incremental increase in intake above background intakes of polyphenols and presents no safety concern.

The estimated intake of theobromine from the intended uses of cacao pulp products (as concentrate) is 3 mg/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 1.726 mg theobromine per 100 g cacao juice concentrate.

The estimated intake of theobromine from the intended uses of cacao pulp products (as concentrate) is 3 mg/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 1.726 mg theobromine per 100 g cacao juice concentrate. Assuming a 60 kg body weight, the 90th percentile EDI for theobromine is 0.05 mg/kg bw/day. The NOAEL for theobromine based on a sub-chronic, 3-generation reproductive toxicity study is 97 mg/kg bw/day. The margin of exposure (MOE) between the theobromine

NOAEL and the per user 90th percentile EDI for the population ages 2 years and older based is therefore 1940.

Cocoa products have a long history of use, and in turn there is a long history of dietary exposure to theobromine; thus, the existing exposure to theobromine from dietary sources provides another safety benchmark for comparison with intake from the intended uses of cacao pulp products. The U.S. population ages 2 years and older consumes on average 36.3 mg theobromine per day, with mean intakes among some subpopulations as high as 54.6 mg per day (i.e., males ages 12-19 years) (USDA ARS, 2018). The current mean intake of theobromine from the diet provides in the range of 12 to 18 times the per user 90th percentile of intake of theobromine from the intended uses of cacao pulp products. The cacao products that are the subject of this GRAS evaluation therefore provide an amount of theobromine equivalent to a small fraction of current theobromine intake by the U.S. population. The estimated intake of theobromine from the intended uses presents no safety concern.

Safety Conclusion

Cacao pulp, cacao fruit juice, and cacao fruit juice concentrate are intended for use in select foods. Compositional analyses of the cacao pulp, cacao fruit juice, and cacao fruit juice concentrate shows that the products consist primarily of water, carbohydrate (sugars and a small amount of fiber), organic acids, minerals, and small concentrations of theobromine and polyphenols. These constituents are found in other commonly consumed foods in the diet and have a long history of safe consumption as part of the normal diet. The intended use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate will result in intakes of these constituents that are within the range of background levels of intake and therefore can be concluded to be safe. The safety of intake of the proposed uses is supported by a safe history of consumption of cacao pulp and products derived therefrom. It can be concluded that the proposed use of cacao fruit juice concentrate in beverages, bakery products, candy and confections (non-chocolate), cereal bars and chips/crackers, cocoa and chocolate products, edible ices - ice cream type, edible ices - sorbet type, gelatin/fruit mousse spreads, jams/jellies/fruit syrups and toppings, nutrition bars, plant-based spreads, and yogurt/yogurt drinks at maximum use levels ranging from 10 to 65% by weight as concentrate; use of cacao fruit juice as such; and use of cacao pulp in bakery products, candy and confections (non-chocolate), jams/jellies/fruit syrups and toppings, plant-based spreads, and yogurt/yogurt drinks at maximum concentrations ranging from 15 to 50% by weight, produced using cGMP, is safe and GRAS based on scientific procedures within the meaning of the FD&C Act, and meets the standard of reasonable certainty of no harm.

Discussion of Information Inconsistent with GRAS Determination

No information has been identified that would be inconsistent with a finding that the proposed use of cacao pulp, cacao fruit juice and cacao fruit juice concentrate in select foods, meeting appropriate specifications specified herein and used according to cGMP, is safe and GRAS based on scientific procedures, under the conditions of intended use in food.

Conclusion Regarding Safety and General Recognition of Safety

General recognition of safety through scientific procedures requires common knowledge throughout the scientific community knowledgeable about the safety of food ingredients, and that there is a reasonable certainty that a substance is not harmful under the intended conditions of use in foods. The aforementioned regulatory, scientific reviews, and compositional data related to the consumption and safety of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate have been published in the scientific literature and, therefore, are generally available and generally known among the community of qualified food ingredient safety experts. There is broad-based and widely disseminated knowledge concerning cacao pulp, cacao fruit juice, and cacao fruit juice concentrate. The data and publicly available information supporting the safety of the proposed use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate, for the intended use in food, are not only widely known and disseminated, but are also commonly accepted among qualified food safety experts.

The Expert Panel convened by CABOSSE Naturals NV independently and critically evaluated all data and information presented herein, and concluded that cacao pulp, cacao fruit juice, and cacao fruit juice concentrate are GRAS for the intended uses in select foods based on scientific procedures. It is also the unanimous consensus opinion of this GRAS Panel that other qualified experts would concur with these conclusions. The GRAS Panel Signed Consensus Statement is located in Appendix G.

The intended use of use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate in select foods and beverages has been determined to be safe through scientific procedures as set forth in 21 CFR§170.30(b), thus satisfying the so-called “technical” element of the GRAS determination. Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called “common knowledge” element of a GRAS determination.

Part 7. List of Supporting Data and Information in GRAS Notice

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Appendices

Appendix A. Quality Assurance Statement

Quality Assurance Statement

STATEMENT ON CONTAMINANTS

At Barry Callebaut, we take food safety and conformity with legislative and regulatory standards very seriously. Therefore, in addition to our commitment to following Good Manufacturing Practices (GMPs) and implementing HACCP and other quality control measures for assuring food safety, we conduct an annual Surveillance Program to periodically monitor for contaminants and assure they are maintained at the lowest level currently feasible.

In this Surveillance Program, samples are screened for heavy metals; mycotoxins (aflatoxins and ochratoxins); polycyclic aromatic hydrocarbons; dioxins; and dioxin-like polychlorinated biphenyls. For these analyses, Barry Callebaut contracts with independent ISO 17025 accredited labs to conduct the screenings.

These analyses are carried out on samples of cacao beans, cacao semi-finished products and bulk, industrial chocolate products (chocolates, compounds, fat based fillings). Our program also includes analyses of dairy and nut ingredients. Samples used in the analyses are collected from our production sites worldwide.

In addition to our own Surveillance Program, we typically require our suppliers of processed raw materials to monitor for certain contaminants in the products they supply to us or otherwise certify the raw materials as meeting applicable requirements.

We thus have [state-of-the-art] systems and controls in place to ensure our products are in compliance with relevant chemical contaminants legislations

Appendix B. Certificates of Analysis from 3 Non-consecutive Batches

ifp Institut für Produktqualität

TESTING WITH RESPONSIBILITY.

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DAkkS Deutsche Akkreditierungsstelle D-PL-14013-01-01

DIN EN ISO/IEC 17025:2005

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Berlin, 28 January 2020

TEST REPORT

Sample number:	ifp19-49764-002-01
Sample code:	CFP-18
Material type:	Cacao fruit pulp
Date of receipt:	12 December 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Uncooled and without abnormalities
Packaging:	Closed foil bag
Lot/batch:	1921501011
Begin/end of analysis:	13 December 2019 / 23 December 2019

Analysis and results:
See next page

Elements / Heavy metals / Minerals:

Antimony	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.04
Arsenic	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.05
Lead	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.02
Cadmium	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.02
Mercury	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.005

Physical-analytical parameters:

pH value	PV-192-pH : 2017-03 (a)	:	3.3
Brix	PV-255 : 2017-11 (a)	%mas :	17.9

Microbiological testing:

Total viable aerobic count	ISO 4833 (a)	cfu/g :	< 10
Enterobacteriaceae	ISO 21528-2 : 2017-09 (a)	cfu/g :	< 10
Yeasts	ISO 21527-2 : 2008-07(a)	cfu/g :	< 10
Moulds	ISO 21527-2 : 2008-07(a)	cfu/g :	< 10
Listeria monocytogenes	DIN EN ISO 11290-1 : 2017-09 (a)	per 25 g :	not detected
Salmonella spp.	DIN EN ISO 6579-1 : 2017-07 (a)	per 25 g :	not detected

Organic acids:

Total acidity (as citric acid)	ASU L 31.00-3 : 1997-09 (a)	g/100 ml :	0.94

This document was proved by Katharina Birkelbach, issued electronically and is therefore valid without signature.

Katharina Birkelbach
Food Chemist
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Berlin, 27 January 2020

TEST REPORT

Sample number:	ifp19-49764-002-01-01
Sample code:	CFP-18
Material type:	Cacao fruit pulp
Date of receipt:	12 December 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Uncooled and without abnormalities
Packaging:	Closed foil bag
Lot/batch:	1921501011
Begin/end of analysis:	20 January 2020 / 26 January 2020

Analysis and results:

Microbiological testing:

Thermophilic acidophilic bacteria (TAB)	IFU Method No. 12 C1, 10 min, 80°C, 2 - 5 d, 45 °C (b)	per 10 g :	not detected

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Katharina Birkelbach
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Berlin, 28 January 2020

TEST REPORT

Sample number:	ifp19-49764-002-02
Sample code:	CFP-18
Material type:	Cacao fruit pulp
Date of receipt:	12 December 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Uncooled and without abnormalities
Packaging:	Closed foil bag
Lot/batch:	1922201011
Begin/end of analysis:	13 December 2019 / 23 December 2019

Analysis and results:
See next page

Elements / Heavy metals / Minerals:

Antimony	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.04
Arsenic	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.05
Lead	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.02
Cadmium	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.02
Mercury	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.005

Physical-analytical parameters:

pH value	PV-192-pH : 2017-03 (a)	:	3.4
Brix	PV-255 : 2017-11 (a)	%mas :	17.9

Microbiological testing:

Total viable aerobic count	ISO 4833 (a)	cfu/g :	< 10
Enterobacteriaceae	ISO 21528-2 : 2017-09 (a)	cfu/g :	< 10
Yeasts	ISO 21527-2 : 2008-07(a)	cfu/g :	< 10
Moulds	ISO 21527-2 : 2008-07(a)	cfu/g :	< 10
Listeria monocytogenes	DIN EN ISO 11290-1 : 2017-09 (a)	per 25 g :	not detected
Salmonella spp.	DIN EN ISO 6579-1 : 2017-07 (a)	per 25 g :	not detected

Organic acids:

Total acidity (as citric acid)	ASU L 31.00-3 : 1997-09 (a)	g/100 ml :	0.92

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Brusselsesteenweg 450
1500 Halle

Contact person
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Berlin, 27 January 2020

TEST REPORT

Sample number:	ifp19-49764-002-02-01
Sample code:	CFP-18
Material type:	Cacao fruit pulp
Date of receipt:	12 December 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Uncooled and without abnormalities
Packaging:	Closed foil bag
Lot/batch:	1922201011
Begin/end of analysis:	20 January 2020 / 26 January 2020

Analysis and results:

Microbiological testing:

Thermophilic acidophilic bacteria (TAB)	IFU Method No. 12 C1, 10 min, 80°C, 2 - 5 d, 45 °C (b)	per 10 g :	not detected

This document was proved by Katharina Birkelbach, issued electronically and is therefore valid without signature.

Katharina Birkelbach
Food Chemist
Account Management

(a) accredited; (b) validated, not accredited method; (f) outsourced, not ifp accredited
(B) location Berlin; (L) location Leipzig; (O) location Ohrdruf; (A) location Aachen

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DIN EN ISO/IEC 17025:2005

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Berlin, 20 February 2020

TEST REPORT

Sample number:	ifp20-05169-001
Sample code:	CFP-18
Material type:	Cacao fruit pulp - 30CPAS001
Date of receipt:	06 February 2020
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Cooled (-2.6°C) and without abnormalities
Packaging:	Closed plastic bag
Lot/batch:	1931301011
Net quantity:	ca. 1900 g
Number of packages:	1
Begin/end of analysis:	07 February 2020 / 20 February 2020

Analysis and results:
See next page

Microbiological testing:

Total viable aerobic count	ISO 4833 (a)	cfu/g :	< 10
Enterobacteriaceae	ISO 21528-2 : 2017-09 (a)	cfu/g :	< 10
Yeasts	ISO 21527-1 : 2008-07(a)	cfu/g :	< 10
Moulds	ISO 21527-1 : 2008-07(a)	cfu/g :	< 10
Thermophilic acidophilic bacteria (TAB)	IFU Method No. 12 C1, 10 min, 80°C, 2 - 5 d, 45 °C (b)	per 10 g :	not detected
Listeria monocytogenes	DIN EN ISO 11290-1 : 2017-09 (a)	per 25 g :	not detected
Salmonella spp.	DIN EN ISO 6579-1 : 2017-07 (a)	per 25 g :	not detected

Elements / Heavy metals / Minerals:

Aluminum	ASU L 00.00-157 (ICP-MS) : 2016-03 (a)	mg/kg :	0.64
Antimony	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.04
Arsenic	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.05
Lead	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.02
Cadmium	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.02
Chrome	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	0.026
Molybdenum	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.06
Nickel	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	0.20
Mercury	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.005
Tin	ASU L 00.00-128 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.11

Physical-analytical parameters:

pH value	PV-192-pH : 2017-03 (a)	:	3.4
Brix	PV-255 : 2017-11 (a)	%mas :	18.5
aw-Value	ISO 21807 : 2004-09 (a)	:	0.972

Stability conditions (monitioring time = 5 min) : aw = ± 0.001 and temperature = 25 ± 0.1 °C

Organic acids:

Total acidity (as citric acid)	ASU L 31.00-3 : 1997-09 (a)	g/100 g :	0.94

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Berlin, 28 January 2020

TEST REPORT

Sample number:	ifp19-49764-001-02
Sample code:	CFJ-18
Material type:	Cacao fruit juice
Date of receipt:	12 December 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Uncooled and without abnormalities
Packaging:	Closed foil bag
Lot/batch:	1924301011
Begin/end of analysis:	13 December 2019 / 23 December 2019

Analysis and results:
See next page

Elements / Heavy metals / Minerals:

Antimony	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.04
Arsenic	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.05
Lead	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.02
Cadmium	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.02
Mercury	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.005

Physical-analytical parameters:

pH value	PV-192-pH : 2017-03 (a)	:	3.2
Brix	PV-255 : 2017-11 (a)	%mas :	16.9

Microbiological testing:

Total viable aerobic count	ISO 4833 (a)	cfu/g :	< 10
Enterobacteriaceae	ISO 21528-2 : 2017-09 (a)	cfu/g :	< 10
Yeasts	ISO 21527-2 : 2008-07(a)	cfu/g :	< 10
Moulds	ISO 21527-2 : 2008-07(a)	cfu/g :	< 10
Listeria monocytogenes	DIN EN ISO 11290-1 : 2017-09 (a)	per 25 g :	not detected
Salmonella spp.	DIN EN ISO 6579-1 : 2017-07 (a)	per 25 g :	not detected

Organic acids:

Total acidity (as citric acid)	ASU L 31.00-3 : 1997-09 (a)	g/100 ml :	0.86

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Berlin, 27 January 2020

TEST REPORT

Sample number:	ifp19-49764-001-02-01
Sample code:	CFJ-18
Material type:	Cacao fruit juice
Date of receipt:	12 December 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Uncooled and without abnormalities
Packaging:	Closed foil bag
Lot/batch:	1924301011
Begin/end of analysis:	20 January 2020 / 26 January 2020

Analysis and results:

Microbiological testing:

Thermophilic acidophilic bacteria (TAB)	IFU Method No. 12 C1, 10 min, 80°C, 2 - 5 d, 45 °C (b)	per 10 g :	not detected

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Berlin, 28 January 2020

TEST REPORT

Sample number:	ifp19-49764-001-01
Sample code:	CFJ-18
Material type:	Cacao fruit juice
Date of receipt:	12 December 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Uncooled and without abnormalities
Packaging:	Closed foil bag
Lot/batch:	1925001011
Begin/end of analysis:	13 December 2019 / 23 December 2019

Analysis and results:
See next page

Elements / Heavy metals / Minerals:

Antimony	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.04
Arsenic	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.05
Lead	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.02
Cadmium	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.02
Mercury	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.005

Physical-analytical parameters:

pH value	PV-192-pH : 2017-03 (a)	:	3.2
Brix	PV-255 : 2017-11 (a)	%mas :	16.9

Microbiological testing:

Total viable aerobic count	ISO 4833 (a)	cfu/g :	< 10
Enterobacteriaceae	ISO 21528-2 : 2017-09 (a)	cfu/g :	< 10
Yeasts	ISO 21527-2 : 2008-07(a)	cfu/g :	< 10
Moulds	ISO 21527-2 : 2008-07(a)	cfu/g :	< 10
Listeria monocytogenes	DIN EN ISO 11290-1 : 2017-09 (a)	per 25 g :	not detected
Salmonella spp.	DIN EN ISO 6579-1 : 2017-07 (a)	per 25 g :	not detected

Organic acids:

Total acidity (as citric acid)	ASU L 31.00-3 : 1997-09 (a)	g/100 ml :	0.86

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Berlin, 27 January 2020

TEST REPORT

Sample number:	ifp19-49764-001-01-01
Sample code:	CFJ-18
Material type:	Cacao fruit juice
Date of receipt:	12 December 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Uncooled and without abnormalities
Packaging:	Closed foil bag
Lot/batch:	1925001011
Begin/end of analysis:	20 January 2020 / 26 January 2020

Analysis and results:

Microbiological testing:

Thermophilic acidophilic bacteria (TAB)	IFU Method No. 12 C1, 10 min, 80°C, 2 - 5 d, 45 °C (b)	per 10 g :	not detected

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Berlin, 28 January 2020

TEST REPORT

Sample number:	ifp19-45730-001
Sample code:	CFJ-18
Material type:	Cacao fruit juice
Date of receipt:	14 November 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Cooled (-6.8°C) and without abnormalities
Packaging:	Closed plastic bag
Lot/batch:	1926401011
Order number:	2019007
Net quantity:	ca. 2700 g
Number of packages:	1
Begin/end of analysis:	14 November 2019 / 11 December 2019

Analysis and results:
See next page

Elements / Heavy metals / Minerals:

Calcium	PV-347 ICP-MS : 2016-10 (a)	mg/kg	:	71.9
Magnesia	PV-347 ICP-MS : 2016-10 (a)	mg/kg	:	182
Potassium	PV-347 ICP-MS : 2016-10 (a)	mg/kg	:	1441
Phosphorus	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	74.3
Manganese	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 1.7
Aluminum	ASU L 00.00-157 (ICP-MS) : 2016-03 (a)	mg/kg	:	0.84
Arsenic	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.05
Lead	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.02
Cadmium	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.02
Chrome	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	0.021
Iron	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	2.6
Copper	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	1.4
Mercury	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.005
Zinc	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	3.0
Antimony	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.04
Molybdenum	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.06
Nickel	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	0.34
Tin	ASU L 00.00-128 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.11

Organic acids:

Total acidity (as citric acid)	ASU L 31.00-3 : 1997-09 (a)	g/100 g	:	1.0

Physical-analytical parameters:

pH value	PV-192-pH : 2017-03 (a)		:	3.3
Brix	PV-255 : 2017-11 (a)	%mas	:	16.6

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Katharina Birkelbach
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Micro • Smedt
LABORATORIUM MICROBIOLOGIE

ISO 17025
Certificaat: BELAC 086-TEST

Barry Callebaut

Aalstersestraat 122
9280 Wieze

Certificate of Analysis - Correction

Certificate of Analysis
19-CAL- 653

Date analysis	2019-11-04	**Date reception**	2019-11-04
Sample	Total shelf life CFJ-18	Sampling by: Sampling according: Date sampling: Hour sampling: Transport	Client - - - - Micro-Smedt
Sample number	-	Packaging	Intact
Batch	1926401011	Condition	Ok Cooled

Number of analysis
1911-CAL- 3

Analysis	Method	Tolerance	Result	
Total plate count	MS-W1 30°C	< 1000	10	CFU/g
Yeasts	MS-W2	< 50	< 10	CFU/g
Moulds	MS-W2	< 50	< 10	CFU/g
Enterobacteriaceae	MS-W4B	< 10	< 10	CFU/g
Escherichia coli	MS-W10	not detected	not detected	/g
Salmonella	MS-W7	not detected	not detected	/250g
Listeria monocytogenes	MS-W9	not detected	not detected	/25g
Thermophilic acidophilic bacteria*	IFU12	< 10	not detected	/50g
Heat resistant Moulds spores*	IFU4	< 10	not detected	/50g

End of analysis

Tolerance set by client.

Validation date 2020-05-06

Dr. J. De Smedt
Technical Manager

K. De Smedt
QA Manager

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TESTING WITH RESPONSIBILITY.

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Berlin, 28 January 2020

TEST REPORT

Sample number:	ifp19-36550-005
Sample code:	CFJC-60F
Material type:	Cacao fruit juice concentrate
Date of receipt:	05 September 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Uncooled and without abnormalities
Packaging:	Closed plastic container
Lot/batch:	1920301011
Net quantity:	ca. 190 g, ca. 230 g
Number of packages:	2
Begin/end of analysis:	06 September 2019 / 02 October 2019

Analysis and results:
See next page

Organic acids:

Total acidity (as citric acid)	ASU L 31.00-3 : 1997-09 (a)	g/100 g	:	3.4

Elements / Heavy metals / Minerals:

Arsenic	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.05
Lead	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.02
Cadmium	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	0.053
Mercury	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.005

Physical-analytical parameters:

pH value	PV-192-pH : 2017-03 (a)		:	3.1
Brix	PV-255 : 2017-11 (a)	%mas	:	60.0

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ISO 17025
Certificaat: BELAC 086-TEST

Barry Callebaut

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Certificate of Analysis - Correction

Certificate of Analysis
19-CAL- 590

Date analysis	2019-07-29	**Date reception**	2019-07-29
Sample	Total shelf life CFJC-60F	Sampling by: Sampling according: Date sampling: Hour sampling: Transport	Client - - - - Client
Sample number	-	Packaging	Intact
Batch	1920301011	Condition	Ok Frozen

Number of analysis
1907-CAL- 147

Analysis	Method	Tolerance	Result	
Total plate count	MS-W1 30°C	< 50	< 10	CFU/g
Yeasts	MS-W2	< 50	< 10	CFU/g
Moulds	MS-W2	< 1000	< 10	CFU/g
Enterobacteriaceae	MS-W4B	< 10	< 10	CFU/g
Escherichia coli	MS-W10	not detected	not detected	/1g
Salmonella	MS-W7	not detected	not detected	/250g
Listeria monocytogenes	MS-W9	not detected	not detected	/25g
Thermophilic acidophilic bacteria*	IFU12	not detected	not detected	/50g
Heat resistant Moulds spores*	IFU4	not detected	not detected	/50g

End of analysis

Tolerance set by client.

Validation date 2020-05-06

Dr. J. De Smedt
Technical Manager

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QA Manager

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Berlin, 28 January 2020

TEST REPORT

Sample number:	ifp19-47882-001
Sample code:	CFJC-60
Material type:	Cacao fruit juice concentrate
Date of receipt:	20 November 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	Uncooled (6.8°C) and without abnormalities
Packaging:	Closed plastic jar
Article No.:	1926701011
ORDER number:	2019008
Net quantity:	ca. 500 ml
Number of packages:	1
Begin/end of analysis:	21 November 2019 / 12 December 2019

Analysis and results:
See next page

Elements / Heavy metals / Minerals:

Manganese	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	2.4
Aluminum	ASU L 00.00-157 (ICP-MS) : 2016-03 (a)	mg/kg	:	0.80
Arsenic	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.05
Lead	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.02
Cadmium	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	0.051
Chrome	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	0.025
Iron	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	8.1
Copper	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	1.9
Mercury	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.005
Zinc	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	7.2
Antimony	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.04
Calcium	PV-347 ICP-MS : 2016-10 (a)	mg/kg	:	238
Magnesia	PV-347 ICP-MS : 2016-10 (a)	mg/kg	:	694
Potassium	PV-347 ICP-MS : 2016-10 (a)	mg/kg	:	5256
Molybdenum	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	0.073
Nickel	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	1.1
Phosphorus	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg	:	320
Tin	ASU L 00.00-128 (ICP-MS) : 2011-01 (a)	mg/kg	:	< 0.11

Physical-analytical parameters:

pH value	PV-192-pH : 2017-03 (a)		:	3.0
Brix	PV-255 : 2017-11 (a)	%mas	:	61.4

Organic acids:

Total acidity (as citric acid)	ASU L 31.00-3 : 1997-09 (a)	g/100 g	:	3.6

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Katharina Birkelbach
Food Chemist
Account Management

Micro • Smedt
LABORATORIUM MICROBIOLOGIE

ISO 17025
Certificaat: BELAC 086-TEST

Barry Callebaut

Aalstersestraat 122
9280 Wieze

Certificate of Analysis - Correction

Certificate of Analysis
19-CAL- 652

Date analysis	2019-11-04	**Date reception**	2019-11-04
Sample	Total shelf life CFJC-60	Sampling by: Sampling according: Date sampling: Hour sampling: Transport	Client - - - - Micro-Smedt
Sample number	-	Packaging	Intact
Batch	1926701011	Condition	Ok Cooled

Number of analysis
1911-CAL- 2

Analysis	Method	Tolerance	Result	
Total plate count	MS-W1 30°C	< 1000	< 10	CFU/g
Yeasts	MS-W2	< 50	< 10	CFU/g
Moulds	MS-W2	< 50	< 10	CFU/g
Enterobacteriaceae	MS-W4B	< 10	< 10	CFU/g
Escherichia coli	MS-W10	not detected	not detected	/g
Salmonella	MS-W7	not detected	not detected	/250g
Listeria monocytogenes	MS-W9	not detected	not detected	/25g
Thermophilic acidophilic bacteria*	IFU12	< 10	not detected	/50g
Heat resistant Moulds spores*	IFU4	< 10	not detected	/50g

End of analysis

Tolerance set by client.

Validation date 2020-05-06

Dr. J. De Smedt
Technical Manager

K. De Smedt
QA Manager

TESTING WITH RESPONSIBILITY.

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Cabosse Naturals
Ms. Sylvie Verstuyft
Brusselsesteenweg 450
1500 Halle

Contact person	Phone	Email
Katharina Birkelbach	+49 30 / 74 73 33 - 1148	birkelbach@produktqualitaet.com

Berlin, 10 March 2020

TEST REPORT

Sample number:	ifp19-49966-002 ***- revision****
Sample code:	CFJC-60
Material type:	Cacao fruit juice concentrate
Date of receipt:	06 December 2019
Client:	Cabosse Naturals
Sampling by:	Client
Condition of received samples:	3.6°C and without abnormalities
Packaging:	Closed aluminium bag
Lot/batch:	1929901011 / 30CCAS007
Order number:	2019009
Net quantity:	ca. 2670 g
Number of packages:	1
Begin/end of analysis:	07 December 2019 / 31 December 2019

Analysis and results:
See next page

Microbiological testing:

Total viable aerobic count	ISO 4833 (a)	cfu/g :	< 1
Enterobacteriaceae	ISO 21528-2 : 2017-09 (a)	cfu/g :	< 1
Yeasts	ISO 21527-2 : 2008-07(a)	cfu/g :	< 1
Moulds	ISO 21527-2 : 2008-07(a)	cfu/g :	< 1
Thermophilic acidophilic bacteria (TAB)	IFU Method No. 12 C1, 10 min, 80°C, 2 - 5 d, 45 °C (b)	per 10 g :	not detected
Listeria monocytogenes	DIN EN ISO 11290-1 : 2017-09 (a)	per 25 g :	not detected
Salmonella spp.	DIN EN ISO 6579-1 : 2017-07 (a)	per 25 g :	not detected

Elements / Heavy metals / Minerals:

Potassium	PV-347 ICP-MS : 2016-10 (a)	mg/kg :	6531
Calcium	PV-347 ICP-MS : 2016-10 (a)	mg/kg :	275
Magnesia	PV-347 ICP-MS : 2016-10 (a)	mg/kg :	813
Manganese	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	2.6
Phosphorus	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	400
Aluminum	ASU L 00.00-157 (ICP-MS) : 2016-03 (a)	mg/kg :	< 0.05
Antimony	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.04
Arsenic	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.05
Lead	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.02
Cadmium	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	0.073
Chrome	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	0.047
Iron	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	10.1
Copper	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	2.4
Molybdenum	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	0.083
Nickel	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	1.5
Mercury	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.005
Zinc	ASU L 00.00-135 (ICP-MS) : 2011-01 (a)	mg/kg :	6.5
Tin	ASU L 00.00-128 (ICP-MS) : 2011-01 (a)	mg/kg :	< 0.11

Physical-analytical parameters:

pH value	PV-192-pH : 2017-03 (a)		:	2.9
Brix	PV-255 : 2017-11 (a)	%mas	:	59.5

Organic acids:

Total acidity (as citric acid)	ASU L 31.00-3 : 1997-09 (a)	g/100 g	:	3.6

** This test report substitutes the report ifp19-49966-002 from 31 December 2019. In response to client request the unit of microbiological results was amended from "/g" in "/ml".*

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Katharina Birkelbach
Food Chemist
Account Management

Appendix C. Monitoring of Potential Contaminants

Potential contaminant monitoring data for cacao fruit juice, cacao fruit juice concentrate, and cacao pulp

Parameter	Units	Pulp	Juice	Conc.
Mycotoxins (average of 5 lots)				
Ochratoxin A	µg/kg	<1.0	<0.4	<0.4
Aflatoxin B1	µg/kg	<0.25	<0.1	<0.1
Aflatoxin B2	µg/kg	<0.25	<0.04	<0.04
Aflatoxin G1	µg/kg	<0.25	<0.1	<0.1
Aflatoxin G2	µg/kg	<0.25	<0.06	<0.06
Aflatoxins (sum B1, B2, G1, G2)	µg/kg	<1	<0.30	<0.30
PAHs (average of 5 lots)				
Benz(a)anthracene	µg/kg	<0.5	<0.5	<0.5
Chrysene	µg/kg	<0.5	<0.5	<0.5
Benzo(b)fluoranthene	µg/kg	<0.5	<0.5	<0.5
Benzo(a)pyrene	µg/kg	<0.5	<0.5	<0.5
Benz(a)anthracene	µg/kg	<0.5	<0.5	<0.5
Pesticide Residues (average of 5 lots)				
GC-MS TQ	mg/kg	ND	ND	ND*
LC-MS	mg/kg	ND	ND	ND
PCB / PCDD/Fs (1 lot)				
Total 6 ndl-PCB (LB)	pg/g wet wt	0	-	0.0118
Total 6 ndl-PCB (MB)	pg/g wet wt	0.00597	-	0.0251
Total 6 ndl-PCB (UB)	pg/g wet wt	0.0119	-	0.0383
WHO(2005)-PCB TEQ (LB)	pg/g wet wt	0	-	0
WHO(2005)-PCB TEQ (MB)	pg/g wet wt	0.00336	-	0.00895
WHO(2005)-PCB TEQ (UB)	pg/g wet wt	0.00673	-	0.0179
WHO(2005)-PCDD/F TEQ (LB)	pg/g wet wt	0	-	0
WHO(2005)-PCDD/F TEQ (MB)	pg/g wet wt	0.00629	-	0.0167
WHO(2005)-PCDD/F TEQ (UB)	pg/g wet wt	0.0126	-	0.0335

*biphenyl = 0.025 in 1 of 5 analysis; all other analysis ND
Abbreviations: LB – lower bound, MB – medium bound, UB – upper bound, ND – not detected.

Appendix D. NHANES food codes representative of the proposed use of cacao juice, pulp, and concentrate

Food Codes Included in the Assessment of Estimated Daily Intakes

FNDDS Food Code	Food Description
	Bakery Products
13252600	Tiramisu
51160000	Roll, sweet, no frosting
51160100	Roll, sweet, cinnamon bun, no frosting
51160110	Roll, sweet, cinnamon bun, frosted
51161000	Pan Dulce, with fruit, no frosting
51161020	Roll, sweet, with fruit, frosted
51161050	Roll, sweet, frosted
51161250	Pan Dulce, no topping
51161270	Pan Dulce, with sugar topping
51161280	Pan Dulce, with raisins and icing
51165000	Coffee cake, yeast type
51166000	Croissant
51166100	Croissant, cheese
51166200	Croissant, chocolate
51166500	Croissant, fruit
51167000	Brioche
51187020	Anisette toast
51188100	Pannetone
52101000	Biscuit, baking powder or buttermilk type, NS as to made from mix, refrigerated dough, or home recipe
52101030	Biscuit dough, fried
52101040	Crumpet
52101100	Biscuit, baking powder or buttermilk type, made from mix
52102040	Biscuit, baking powder or buttermilk type, made from refrigerated dough
52103000	Biscuit, baking powder or buttermilk type, commercially baked
52104010	Biscuit, baking powder or buttermilk type, made from home recipe
52104040	Biscuit, whole wheat
52104100	Biscuit, cheese
52104200	Biscuit, cinnamon-raisin
52105100	Scone
52105200	Scone, with fruit
52201000	Cornbread, prepared from mix
52202060	Cornbread, made from home recipe
52206010	Cornbread muffin, stick, round
52206060	Cornbread muffin, stick, round, made from home recipe
52208010	Corn pone, baked
52209010	Hush puppy
52220110	Arepa Dominicana
52301000	Muffin, NFS
52302010	Muffin, fruit
52302020	Muffin, fruit, low fat
52302500	Muffin, chocolate chip
52302600	Muffin, chocolate
52303010	Muffin, whole wheat
52304000	Muffin, whole grain
52304010	Muffin, wheat bran
52304040	Muffin, bran with fruit, lowfat
52304100	Muffin, oatmeal
52304150	Muffin, oat bran
52306010	Muffin, plain
52306500	Muffin, pumpkin
52306550	Muffin, zucchini
52306700	Muffin, carrot
52311010	Popover
52401000	Bread, Boston Brown

FNDDS Food Code	Food Description
52403000	Bread, nut
52404060	Bread, pumpkin
52405010	Bread, fruit
52407000	Bread, zucchini
52408000	Bread, Irish soda
53100050	Cake batter, raw, chocolate
53100070	Cake batter, raw, not chocolate
53100100	Cake or cupcake, NS as to type
53101100	Cake, angel food, without icing or filling
53101200	Cake, angel food, with icing or filling
53101250	Cake, angel food, with fruit and icing or filling
53102100	Cake or cupcake, applesauce, without icing or filling
53102200	Cake or cupcake, applesauce, with icing or filling
53102600	Cake or cupcake, banana, without icing or filling
53102700	Cake or cupcake, banana, with icing or filling
53102800	Cake or cupcake, Black Forest
53103000	Cake, Boston cream pie
53104100	Cake or cupcake, carrot, without icing or filling
53104260	Cake or cupcake, carrot, with icing or filling
53104400	Cake or cupcake, coconut, with icing or filling
53104500	Cheesecake
53104550	Cheesecake with fruit
53104600	Cheesecake, chocolate
53105270	Cake or cupcake, chocolate, devil's food or fudge, with icing or filling
53105275	Cake or cupcake, chocolate, devil's food or fudge, without icing or filling
53105300	Cake or cupcake, German chocolate, with icing or filling
53105500	Cake, chocolate, with icing, diet
53106500	Cake, cream, without icing or topping
53108200	Snack cake, chocolate, with icing or filling
53108220	Snack cake, chocolate, with icing or filling, reduced fat and calories
53109200	Snack cake, not chocolate, with icing or filling
53110000	Cake, fruit cake, light or dark, holiday type cake
53111000	Cake or cupcake, gingerbread
53112000	Cake, ice cream and cake roll, chocolate
53112100	Cake, ice cream and cake roll, not chocolate
53113000	Cake, jelly roll
53114000	Cake or cupcake, lemon, without icing or filling
53114100	Cake or cupcake, lemon, with icing or filling
53115100	Cake or cupcake, marble, without icing or filling
53115200	Cake or cupcake, marble, with icing or filling
53115310	Cake or cupcake, nut, without icing or filling
53115320	Cake or cupcake, nut, with icing or filling
53115410	Cake or cupcake, oatmeal
53115450	Cake or cupcake, peanut butter
53116000	Cake, pound, without icing or filling
53116020	Cake, pound, with icing or filling
53116500	Cake or cupcake, pumpkin, without icing or filling
53116510	Cake or cupcake, pumpkin, with icing or filling
53116550	Cake or cupcake, raisin-nut
53116570	Cake, Ravani
53116600	Cake, rice flour, without icing or filling
53116650	Cake, Quezadilla, El Salvadorian style
53117100	Cake or cupcake, spice, without icing or filling
53117200	Cake or cupcake, spice, with icing or filling
53118100	Cake, sponge, without icing or filling
53118200	Cake, sponge, with icing or filling
53118300	Cake, sponge, chocolate

FNDDS Food Code	Food Description
53118410	Rum cake, without icing
53118500	Cake, torte
53118550	Cake, tres leche
53119000	Cake, pineapple, upside down
53120270	Cake or cupcake, white, with icing or filling
53120275	Cake or cupcake, white, without icing or filling
53121270	Cake or cupcake, yellow, with icing or filling
53121275	Cake or cupcake, yellow, without icing or filling
53122070	Cake, shortcake, biscuit type, with whipped cream and fruit
53122080	Cake, shortcake, biscuit type, with fruit
53123070	Cake, shortcake, sponge type, with whipped cream and fruit
53123080	Cake, shortcake, sponge type, with fruit
53124110	Cake or cupcake, zucchini
53200100	Cookie, batter or dough, raw
53201000	Cookie, NFS
53202000	Cookie, almond
53203000	Cookie, applesauce
53203500	Cookie, biscotti
53204000	Cookie, brownie, NS as to icing
53204010	Cookie, brownie, without icing
53204100	Cookie, brownie, with icing or filling
53204840	Cookie, brownie, reduced fat, NS as to icing
53205250	Cookie, butterscotch, brownie
53205260	Cookie, bar, with chocolate
53206000	Cookie, chocolate chip
53206020	Cookie, chocolate chip, made from home recipe or purchased at a bakery
53206030	Cookie, chocolate chip, reduced fat
53206100	Cookie, chocolate chip sandwich
53206500	Cookie, chocolate, made with rice cereal
53206550	Cookie, chocolate, made with oatmeal and coconut, no bake
53207000	Cookie, chocolate or fudge
53207020	Cookie, chocolate or fudge, reduced fat
53207050	Cookie, chocolate, with chocolate filling or coating, fat free
53208000	Cookie, marshmallow, chocolate-covered
53208200	Cookie, marshmallow pie, chocolate covered
53209005	Cookie, chocolate, with icing or coating
53209010	Cookie, sugar wafer, chocolate-covered
53209015	Cookie, chocolate sandwich
53209020	Cookie, chocolate sandwich, reduced fat
53209100	Cookie, chocolate, sandwich, with extra filling
53209500	Cookie, chocolate and vanilla sandwich
53210000	Cookie, chocolate wafer
53210900	Cookie, graham cracker with chocolate and marshmallow
53215500	Cookie, coconut
53220000	Cookie, fruit-filled bar
53220010	Cookie, fruit-filled bar, fat free
53220030	Cookie, fig bar
53220040	Cookie, fig bar, fat free
53222010	Cookie, fortune
53222020	Cookie, cone shell, ice cream type, wafer or cake
53223000	Cookie, gingersnaps
53223100	Cookie, granola
53224000	Cookie, ladyfinger
53224250	Cookie, lemon bar
53225000	Cookie, macaroon
53226000	Cookie, marshmallow, with coconut
53226500	Cookie, marshmallow, with rice cereal, no bake

FNDDS Food Code	Food Description
53226550	Cookie, marshmallow, with rice cereal and chocolate chips
53228000	Cookie, meringue
53230000	Cookie, molasses
53231000	Cookie, Lebkuchen
53231400	Cookie, multigrain, high fiber
53233000	Cookie, oatmeal
53233010	Cookie, oatmeal, with raisins
53233040	Cookie, oatmeal, reduced fat, NS as to raisins
53233050	Cookie, oatmeal sandwich, with creme filling
53233060	Cookie, oatmeal, with chocolate chips
53233080	Cookie, oatmeal sandwich, with peanut butter and jelly filling
53233100	Cookie, oatmeal, with chocolate and peanut butter, no bake
53234000	Cookie, peanut butter
53234100	Cookie, peanut butter, with chocolate
53234250	Cookie, peanut butter with rice cereal, no bake
53235000	Cookie, peanut butter sandwich
53235500	Cookie, with peanut butter filling, chocolate-coated
53236000	Cookie, Pizzelle
53236100	Cookie, pumpkin
53237000	Cookie, raisin
53237010	Cookie, raisin sandwich, cream-filled
53237500	Cookie, rum ball, no bake
53238000	Cookie, sandwich-type, not chocolate or vanilla
53239000	Cookie, shortbread
53239010	Cookie, shortbread, reduced fat
53239050	Cookie, shortbread, with icing or filling
53239100	Pocky
53240000	Cookie, animal
53240010	Cookie, animal, with frosting or icing
53241500	Cookie, butter or sugar
53241510	Marie biscuit
53241600	Cookie, butter or sugar, with fruit and/or nuts
53242000	Cookie, sugar wafer
53243000	Cookie, vanilla sandwich
53243010	Cookie, vanilla sandwich, extra filling
53243050	Cookie, vanilla sandwich, reduced fat
53244010	Cookie, butter or sugar, with chocolate icing or filling
53244020	Cookie, butter or sugar, with icing or filling other than chocolate
53247000	Cookie, vanilla wafer
53247050	Cookie, vanilla wafer, reduced fat
53247500	Cookie, vanilla with caramel, coconut, and chocolate coating
53251100	Cookie, rugelach
53261000	Cookie, gluten free
53270100	Cookies, Puerto Rican style
53300100	Pie, NFS
53300170	Pie, individual size or tart, NFS
53301000	Pie, apple, two crust
53301070	Pie, apple, individual size or tart
53301080	Pie, apple, fried pie
53301500	Pie, apple, one crust
53303000	Pie, blackberry, two crust
53303500	Pie, berry, not blackberry, blueberry, boysenberry, huckleberry, raspberry, or strawberry; two crust
53303570	Pie, berry, not blackberry, blueberry, boysenberry, huckleberry, raspberry, or strawberry, individual size or tart
53304000	Pie, blueberry, two crust
53304050	Pie, blueberry, one crust
53304070	Pie, blueberry, individual size or tart

FNDDS Food Code	Food Description
53305000	Pie, cherry, two crust
53305010	Pie, cherry, one crust
53305070	Pie, cherry, individual size or tart
53305700	Pie, lemon, not cream or meringue
53305720	Pie, lemon, not cream or meringue, individual size or tart
53306000	Pie, mince, two crust
53307000	Pie, peach, two crust
53307050	Pie, peach, one crust
53307070	Pie, peach, individual size or tart
53308000	Pie, pineapple, two crust
53309000	Pie, raisin, two crust
53310050	Pie, raspberry, two crust
53311000	Pie, rhubarb, two crust
53311050	Pie, rhubarb, one crust
53311070	Pie, rhubarb, individual size or tart
53312000	Pie, strawberry, one crust
53313000	Pie, strawberry-rhubarb, two crust
53314000	Pie, strawberry, individual size or tart
53341000	Pie, banana cream
53341500	Pie, buttermilk
53341750	Pie, chess
53342000	Pie, chocolate cream
53342070	Pie, chocolate cream, individual size or tart
53343000	Pie, coconut cream
53343070	Pie, coconut cream, individual size or tart
53344000	Pie, custard
53344200	Mixed fruit tart filled with custard or cream cheese
53344300	Dessert pizza
53345000	Pie, lemon cream
53345070	Pie, lemon cream, individual size or tart
53346000	Pie, peanut butter cream
53346500	Pie, pineapple cream
53347000	Pie, pumpkin
53347070	Pie, pumpkin, individual size or tart
53347600	Pie, squash
53348000	Pie, strawberry cream
53360000	Pie, sweet potato
53365000	Pie, vanilla cream
53366000	Pie, yogurt, frozen
53381000	Pie, lemon meringue
53385000	Pie, pecan
53385500	Pie, oatmeal
53386000	Pie, pudding, flavors other than chocolate
53387000	Pie, Toll house chocolate chip
53390000	Pie, shoo-fly
53391000	Pie shell
53391100	Pie shell, graham cracker
53410100	Cobbler, apple
53410300	Cobbler, berry
53410500	Cobbler, cherry
53410800	Cobbler, peach
53410860	Cobbler, pineapple
53410900	Cobbler, rhubarb
53415100	Crisp, apple, apple dessert
53415120	Fritter, apple
53415200	Fritter, banana
53415220	Fritter, berry

FNDDS Food Code	Food Description
53415400	Crisp, cherry
53415500	Crisp, peach
53420100	Cream puff, eclair, custard or cream filled, not iced
53420200	Cream puff, eclair, custard or cream filled, iced
53420300	Air filled fritter or fried puff, without syrup, Puerto Rican style
53420310	Wheat flour fritter, without syrup
53420400	Sopaipilla, without syrup or honey
53420410	Sopaipilla with syrup or honey
53430700	Tamale, sweet
53430750	Tamale, sweet, with fruit
53440000	Strudel, apple
53440300	Strudel, berry
53440500	Strudel, cherry
53440600	Strudel, cheese
53441110	Baklava
53441210	Basbousa
53450000	Turnover or dumpling, apple
53450300	Turnover or dumpling, berry
53450500	Turnover or dumpling, cherry
53450800	Turnover or dumpling, lemon
53451500	Turnover, guava
53452100	Pastry, fruit-filled
53452120	Pastry, made with bean or lotus seed paste filling, baked
53452130	Pastry, made with bean paste and salted egg yolk filling, baked
53452150	Pastry, Chinese, made with rice flour
53452170	Pastry, cookie type, fried
53452200	Pastry, Italian, with cheese
53452400	Pastry, puff
53452420	Pastry, puff, custard or cream filled, iced or not iced
53452450	Cheese pastry puffs
53452500	Pastry, mainly flour and water, fried
53453150	Empanada, Mexican turnover, fruit-filled
53453170	Empanada, Mexican turnover, pumpkin
53510000	Danish pastry, plain or spice
53510100	Danish pastry, with fruit
53511000	Danish pastry, with cheese
53520000	Doughnut, NS as to cake or yeast
53520110	Doughnut, cake type
53520120	Doughnut, chocolate, cake type
53520140	Doughnut, cake type, chocolate covered
53520150	Doughnut, cake type, chocolate covered, dipped in peanuts
53520160	Doughnut, chocolate, cake type, with chocolate icing
53520200	Churros
53520600	Cruller, NFS
53520700	French cruller
53521100	Doughnut, chocolate, raised or yeast, with chocolate icing
53521110	Doughnut, raised or yeast
53521120	Doughnut, chocolate, raised or yeast
53521130	Doughnut, raised or yeast, chocolate covered
53521140	Doughnut, jelly
53521210	Doughnut, custard-filled
53521230	Doughnut, custard-filled, with icing
53530000	Breakfast tart
53530010	Breakfast tart, lowfat
53610100	Coffee cake, crumb or quick-bread type
53610170	Coffee cake, crumb or quick-bread type, with fruit
53610200	Coffee cake, crumb or quick-bread type, cheese-filled

FNDDS Food Code	Food Description
54102010	Graham crackers
54102015	Graham crackers (Teddy Grahams)
54102020	Graham crackers, chocolate covered
54102050	Crackers, oatmeal
54102060	Crackers, Cuban
54102100	Graham crackers, reduced fat
54102200	Graham crackers, sandwich, with filling
55100005	Pancakes, NFS
55100010	Pancakes, plain, from frozen
55100015	Pancakes, plain, reduced fat, from fozen
55100020	Pancakes, with fruit, from frozen
55100025	Pancakes, with chocolate, from frozen
55100030	Pancakes, whole grain, from frozen
55100035	Pancakes, whole grain, reduced fat, from frozen
55100050	Pancakes, plain, from fast food / restaurant
55100055	Pancakes, with fruit, from fast food / restaurant
55100060	Pancakes, with chocolate, from fast food / restaurant
55100065	Pancakes, whole grain, from fast food / restaurant
55100080	Pancakes, from school, NFS
55101000	Pancakes, plain
55101015	Pancakes, plain, reduced fat
55101020	Pancakes, plain, fat free
55103000	Pancakes, with fruit
55103020	Pancakes, pumpkin
55103100	Pancakes, with chocolate
55105000	Pancakes, buckwheat
55105100	Pancakes, cornmeal
55105200	Pancakes, whole grain
55105205	Pancakes, whole grain, reduced fat
55105210	Pancakes, whole wheat, fat free
55106000	Pancakes, gluten free
55200010	Waffle, NFS
55200020	Waffle, plain, from frozen
55200030	Waffle, plain, reduced fat, from frozen
55200040	Waffle, fruit, from frozen
55200050	Waffle, chocolate, from frozen
55200060	Waffle, whole grain, from frozen
55200070	Waffle, whole grain, reduced fat, from frozen
55200090	Waffle, gluten free, from frozen
55200100	Waffle, plain, from fast food / restaurant
55200110	Waffle, chocolate, from fast food / restaurant
55200120	Waffle, fruit, from fast food / restaurant
55200130	Waffle, whole grain, from fast food / restaurant
55200200	Waffle, from school, NFS
55201000	Waffle, plain
55202000	Waffle, wheat, bran, or multigrain
55203000	Waffle, fruit
55203500	Waffle, nut and honey
55203600	Waffle, chocolate
55203700	Waffle, cinnamon
55205000	Waffle, whole grain
55207000	Waffle, multi-bran
55208000	Waffle, gluten free
55211000	Waffle, plain, fat free
55211050	Waffle, plain, reduced fat
55212000	Waffle, whole grain, reduced fat
55610300	Dumpling, plain

FNDDS Food Code	Food Description
55801000	Funnel cake with sugar
55801010	Funnel cake with sugar and fruit
56201550	Cornmeal dumpling
58117110	Cornmeal fritter, Puerto Rican style
58123120	Sweet bread dough, filled with bean paste, meatless, steamed
58124210	Pastry, cheese-filled
71945020	Yam buns; Puerto Rican style
	Beverages
11320000	Soy milk
11320100	Soy milk, light
11320200	Soy milk, nonfat
11321000	Soy milk, chocolate
11321100	Soy milk, light, chocolate
11321200	Soy milk, nonfat, chocolate
11340000	Imitation milk, non-soy, sweetened
11350000	Almond milk, sweetened
11350010	Almond milk, sweetened, chocolate
11360000	Rice milk
11370000	Coconut milk
11511000	Chocolate milk, NFS
11511100	Chocolate milk, ready to drink, whole
11511200	Chocolate milk, ready to drink, reduced fat
11511300	Chocolate milk, ready to drink, fat free
11511400	Chocolate milk, ready to drink, low fat
11511550	Chocolate milk, ready to drink, reduced sugar, NS as to milk
11511600	Chocolate milk, ready to drink, low fat (Nesquik)
11511610	Chocolate milk, ready to drink, fat free (Nesquik)
11511700	Chocolate milk, ready to drink, low fat, no sugar added (Nesquik)
11512010	Hot chocolate / Cocoa, ready to drink
11512020	Hot chocolate / Cocoa, ready to drink, made with nonfat milk
11512030	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk
11512100	Hot chocolate / Cocoa, ready to drink, with whipped cream
11512110	Hot chocolate / Cocoa, ready to drink, made with nonfat milk and whipped cream
11512120	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk and whipped cream
11513000	Chocolate milk, made from dry mix, NS as to type of milk
11513100	Chocolate milk, made from dry mix with whole milk
11513150	Chocolate milk, made from dry mix with reduced fat milk
11513200	Chocolate milk, made from dry mix with low fat milk
11513300	Chocolate milk, made from dry mix with fat free milk
11513310	Chocolate milk, made from dry mix with non-dairy milk
11513355	Chocolate milk, made from reduced sugar mix with whole milk
11513360	Chocolate milk, made from reduced sugar mix with reduced fat milk
11513365	Chocolate milk, made from reduced sugar mix with low fat milk
11513380	Chocolate milk, made from dry mix, NS as to type of milk (Nesquik)
11513381	Chocolate milk, made from dry mix with whole milk (Nesquik)
11513382	Chocolate milk, made from dry mix with reduced fat milk (Nesquik)
11513383	Chocolate milk, made from dry mix with low fat milk (Nesquik)
11513384	Chocolate milk, made from dry mix with fat free milk (Nesquik)
11513395	Chocolate milk, made from no sugar added dry mix with non-dairy milk (Nesquik)
11513400	Chocolate milk, made from syrup, NS as to type of milk
11513500	Chocolate milk, made from syrup with whole milk
11513550	Chocolate milk, made from syrup with reduced fat milk
11513600	Chocolate milk, made from syrup with low fat milk
11513700	Chocolate milk, made from syrup with fat free milk
11513750	Chocolate milk, made from syrup with non-dairy milk
11513801	Chocolate milk, made from light syrup with whole milk

FNDDS Food Code	Food Description
11513802	Chocolate milk, made from light syrup with reduced fat milk
11513803	Chocolate milk, made from light syrup with low fat milk
11513804	Chocolate milk, made from light syrup with fat free milk
11513805	Chocolate milk, made from light syrup with non-dairy milk
11514100	Hot chocolate / Cocoa, made with dry mix and water
11514110	Hot chocolate / Cocoa, made with dry mix and whole milk
11514120	Hot chocolate / Cocoa, made with dry mix and reduced fat milk
11514130	Hot chocolate / Cocoa, made with dry mix and low fat milk
11514140	Hot chocolate / Cocoa, made with dry mix and fat free milk
11514150	Hot chocolate / Cocoa, made with dry mix and non-dairy milk
11519040	Strawberry milk, NFS
11519050	Strawberry milk, whole
11519105	Strawberry milk, reduced fat
11519200	Strawberry milk, low fat
11519205	Strawberry milk, fat free
11519215	Strawberry milk, non-dairy
11525000	Milk, malted, natural flavor, made with milk
11526000	Milk, malted
11531000	Eggnog, regular
11531500	Eggnog, lowfat / light
11551050	Licuado or Batido
11553100	Fruit smoothie, NFS
11553110	Fruit smoothie, with whole fruit and dairy
11553120	Fruit smoothie, with whole fruit and dairy, added protein
11553130	Fruit smoothie juice drink, with dairy
11560000	Chocolate milk drink
11830100	Hot chocolate / Cocoa, dry mix, not reconstituted ~
11830160	Chocolate beverage powder, dry mix, not reconstituted ~
11830165	Chocolate beverage powder, reduced sugar, dry mix, not reconstituted ~
11830400	Strawberry beverage powder, dry mix, not reconstituted ~
42401010	Coconut milk, used in cooking
42402010	Coconut cream, canned, sweetened
42403010	Coconut water, unsweetened**
42404010	Coconut water, sweetened**
64100100	Fruit juice, NFS**
64101010	Apple cider
64134015	Fruit smoothie, with whole fruit, no dairy
64134020	Fruit smoothie, with whole fruit, no dairy, added protein
64134030	Fruit smoothie juice drink, no dairy
64134100	Fruit smoothie, light
64134200	Fruit smoothie, bottled
64200100	Fruit nectar, NFS
64201010	Apricot nectar
64201500	Banana nectar
64202010	Cantaloupe nectar
64203020	Guava nectar
64204010	Mango nectar
64205010	Peach nectar
64210010	Papaya nectar
64215010	Pear nectar
64221010	Soursop, nectar
74302000	Tomato juice cocktail
75132000	Mixed vegetable juice
75132100	Celery juice
75200700	Aloe vera juice drink
78101100	Fruit and vegetable smoothie
78101110	Fruit and vegetable smoothie, added protein

FNDDS Food Code	Food Description
78101120	Fruit and vegetable smoothie, bottled
92101810	Coffee, macchiato
92101820	Coffee, macchiato, sweetened
92101850	Coffee, cafe con leche
92101851	Coffee, cafe con leche, decaffeinated
92101904	Coffee, Latte, flavored
92101905	Coffee, Latte, nonfat, flavored
92101906	Coffee, Latte, with non-dairy milk, flavored
92101917	Coffee, Latte, decaffeinated, flavored
92101918	Coffee, Latte, decaffeinated, nonfat, flavored
92101920	Frozen coffee drink
92101921	Frozen coffee drink, nonfat
92101923	Frozen coffee drink, with non-dairy milk
92101925	Frozen coffee drink, with whipped cream
92101926	Frozen coffee drink, nonfat, with whipped cream
92101930	Frozen coffee drink, decaffeinated
92101931	Frozen coffee drink, decaffeinated, nonfat
92101935	Frozen coffee drink, decaffeinated, with whipped cream
92101936	Frozen coffee drink, decaffeinated, nonfat, with whipped cream
92101950	Coffee, Cafe Mocha
92101955	Coffee, Cafe Mocha, nonfat
92101960	Coffee, Cafe Mocha, with non-dairy milk
92101965	Coffee, Cafe Mocha, decaffeinated
92101970	Coffee, Cafe Mocha, decaffeinated, nonfat
92101975	Coffee, Cafe Mocha, decaffeinated, with non-dairy milk
92102000	Frozen mocha coffee drink
92102010	Frozen mocha coffee drink, nonfat
92102020	Frozen mocha coffee drink, with non-dairy milk
92102030	Frozen mocha coffee drink, with whipped cream
92102040	Frozen mocha coffee drink, nonfat, with whipped cream
92102050	Frozen mocha coffee drink, with non-dairy milk and whipped cream
92102090	Frozen mocha coffee drink, decaffeinated, with whipped cream
92102450	Iced Coffee, pre-lightened and pre-sweetened
92102503	Coffee, Iced Latte, flavored
92102600	Coffee, Iced Cafe Mocha
92102602	Coffee, Iced Cafe Mocha, with non-dairy milk
92121000	Coffee, instant, pre-lightened and pre-sweetened with sugar, reconstituted
92121001	Coffee, instant, decaffeinated, pre-lightened and pre-sweetened with sugar, reconsitituted
92121010	Coffee, instant, pre-sweetened with sugar, reconstituted
92121020	Coffee, mocha, instant, pre-lightened and pre-sweetened with sugar, reconstituted
92130000	Coffee, pre-lightened and pre-sweetened with sugar
92130001	Coffee, decaffeinated, pre-lightened and pre-sweetened with sugar
92130020	Coffee, pre-sweetened with sugar
92130021	Coffee, decaffeinated, pre-sweetened with sugar
92171000	Coffee, bottled/canned
92171010	Coffee, bottled/canned, light
92305040	Tea, iced, instant, black, pre-sweetened with sugar
92305050	Tea, iced, instant, black, decaffeinated, pre-sweetened with sugar
92305910	Tea, iced, instant, green, pre-sweetened with sugar
92307400	Tea, iced, instant, black, pre-sweetened, dry
92307500	Iced Tea / Lemonade juice drink
92307510	Iced Tea / Lemonade juice drink, light
92308000	Tea, iced, brewed, black, pre-sweetened with sugar
92308030	Tea, iced, brewed, black, decaffeinated, pre-sweetened with sugar
92308500	Tea, iced, brewed, green, pre-sweetened with sugar
92308530	Tea, iced, brewed, green, decaffeinated, pre-sweetened with sugar
92309000	Tea, iced, bottled, black

FNDDS Food Code	Food Description
92309010	Tea, iced, bottled, black, decaffeinated
92309500	Tea, iced, bottled, green
92410110	Carbonated water, sweetened
92432000	Fruit juice drink, citrus, carbonated
92433000	Fruit juice drink, noncitrus, carbonated
92510610	Fruit juice drink
92510650	Tamarind drink
92510720	Fruit punch, made with fruit juice and soda
92510730	Fruit punch, made with soda, fruit juice, and sherbet or ice cream
92510955	Lemonade, fruit juice drink
92510960	Lemonade, fruit flavored drink
92511015	Fruit flavored drink
92512040	Frozen daiquiri mix, frozen concentrate, not reconstituted ~
92512090	Pina Colada, nonalcoholic
92512110	Margarita mix, nonalcoholic
92513000	Fruit flavored smoothie drink, frozen, no dairy
92530410	Fruit flavored drink, with high vitamin C
92530510	Cranberry juice drink, with high vitamin C
92530610	Fruit juice drink, with high vitamin C
92530950	Vegetable and fruit juice drink, with high vitamin C
92531030	Fruit juice drink (Sunny D)
92541010	Fruit flavored drink, powdered, reconstituted
92542000	Fruit flavored drink, with high vitamin C, powdered, reconstituted
92550030	Fruit juice drink, with high vitamin C, light
92550035	Fruit juice drink, light
92550110	Cranberry juice drink, with high vitamin C, light
92550200	Grape juice drink, light
92550350	Orange juice beverage, 40-50% juice, light
92550360	Apple juice beverage, 40-50% juice, light
92550370	Lemonade, fruit juice drink, light
92550380	Pomegranate juice beverage, 40-50% juice, light
92550405	Vegetable and fruit juice drink, with high vitamin C, light
92552020	Fruit juice drink, reduced sugar (Sunny D)
92552030	Fruit juice drink (Capri Sun)
92582100	Fruit juice drink, with high vitamin C, plus added calcium
92582110	Fruit juice drink, added calcium (Sunny D)
92610020	Horchata beverage, made with water
92610030	Horchata beverage, made with milk
92611010	Oatmeal beverage with water
92611100	Oatmeal beverage with milk
92612010	Sugar cane beverage**
92613010	Cornmeal beverage
92613510	Cornmeal beverage with chocolate milk
92804000	Shirley Temple
92900110	Fruit flavored drink, powdered, not reconstituted ~
94100300	Water, bottled, flavored (Capri Sun Roarin' Waters)
95102000	Nutritional drink or shake, ready-to-drink (Carnation Instant Breakfast)
95201000	Nutritional powder mix (Carnation Instant Breakfast) ~
95310200	Energy drink (Full Throttle)
95310400	Energy drink (Monster)
95310500	Energy drink (Mountain Dew AMP)
95310560	Energy drink (NOS)
95310600	Energy drink (Red Bull)
95310700	Energy drink (Rockstar)
95310750	Energy drink (SoBe Energize Energy Juice Drink)
95311000	Energy Drink
95312560	Energy drink (Ocean Spray Cran-Energy Juice Drink)

FNDDS Food Code	Food Description
95312900	Energy drink (XS)
95320200	Sports drink (Gatorade G)
95320500	Sports drink (Powerade)
95321000	Sports drink, NFS
95342000	Fruit juice, acai blend**
	Candy and Confections (non chocolate)
91700010	Candy, NFS
91701020	Almonds, sugar-coated
91701030	Almonds, yogurt-covered
91702010	Butterscotch morsels
91703010	Caramel, chocolate-flavored roll
91703020	Caramel, flavor other than chocolate
91703030	Caramel, with nuts
91703500	Nuts, carob-coated
91705430	Kit Kat White
91706100	Coconut candy, no chocolate covering
91706400	Coconut candy, Puerto Rican style
91707000	Fondant
91708000	Fruit peel, candied
91708010	Date candy
91708020	Soft fruit confections
91708030	Fruit leather and fruit snacks candy
91708070	Tamarind candy
91708100	Fruit snacks candy, with high vitamin C
91708150	Yogurt covered fruit snacks candy, with added vitamin C
91713050	Fudge, peanut butter
91713060	Fudge, peanut butter, with nuts
91713070	Fudge, vanilla
91718000	Honey-combed hard candy with peanut butter
91718300	Ladoo, round ball, Asian-Indian dessert
91721000	Licorice
91723000	Marshmallow
91723020	Marshmallow, candy-coated
91726000	Nougat, plain
91728500	Sugared pecans, sugar and egg white coating
91731100	Peanuts, sugar-coated
91731150	Peanuts, yogurt covered
91732000	Peanut bar
91733000	Peanut brittle
91734200	Reese's Pieces
91734500	Peanut butter morsels
91735000	Pralines
91739600	Raisins, yogurt covered
91742010	Sesame Crunch, Sahadi
91745010	Gumdrops
91745020	Hard candy
91745040	Butterscotch hard candy
91745100	Skittles
91750000	Taffy
91760000	Toffee, plain
91770020	Dietetic or low calorie hard candy
91800100	Chewing gum, NFS
91801000	Chewing gum, regular
	Cereal bars and chips/crackers
41310900	Bean chips

FNDDS Food Code	Food Description
41410015	Soy chips
42500000	Trail mix, NFS
42500100	Trail mix with nuts
42501000	Trail mix with nuts and fruit
42502100	Trail mix with pretzels, cereal, or granola
51184000	Breadsticks, hard, NFS
51185000	Croutons
51187000	Melba toast
51188500	Zwieback toast
53710400	Cereal or granola bar (General Mills Fiber One Chewy Bar)
53710500	Cereal or granola bar (Kellogg's Nutri-Grain Cereal Bar)
53710502	Cereal or granola bar (Kellogg's Nutri-Grain Yogurt Bar)
53710504	Cereal or granola bar (Kellogg's Nutri-Grain Fruit and Nut Bar)
53710600	Milk 'n Cereal bar
53710700	Cereal or granola bar (Kellogg's Special K bar)
53710900	Cereal or granola bar (General Mills Nature Valley Chewy Trail Mix)
53710902	Cereal or granola bar, with yogurt coating (General Mills Nature Valley Chewy Granola Bar)
53710904	Cereal or granola bar (General Mills Nature Valley Sweet and Salty Granola Bar)
53710906	Cereal or granola bar (General Mills Nature Valley Crunchy Granola Bar)
53711000	Cereal or granola bar (Quaker Chewy Granola Bar)
53711002	Cereal or granola bar (Quaker Chewy 90 Calorie Granola Bar)
53711004	Cereal or granola bar (Quaker Chewy 25% Less Sugar Granola Bar)
53711006	Cereal or granola bar (Quaker Chewy Dipps Granola Bar)
53711100	Cereal or granola bar (Quaker Granola Bites)
53712000	Snack bar, oatmeal
53712100	Cereal or Granola bar, NFS
53712200	Cereal or granola bar, lowfat, NFS
53712210	Cereal or granola bar, nonfat
53713100	Cereal or granola bar, peanuts , oats, sugar, wheat germ
53714200	Cereal or granola bar, chocolate coated, NFS
53714210	Cereal or granola bar, with coconut, chocolate coated
53714220	Cereal or granola bar with nuts, chocolate coated
53714230	Cereal or granola bar, oats, nuts, coated with non-chocolate coating
53714250	Cereal or granola bar, coated with non-chocolate coating
53714300	Cereal or granola bar, high fiber, coated with non-chocolate yogurt coating
53714400	Cereal or granola bar, with rice cereal
53714500	Breakfast bar, NFS
53714520	Breakfast bar, cereal crust with fruit filling, lowfat
54001000	Crackers, NFS
54103000	Crackers, breakfast biscuit
54200100	Crackers, butter, reduced sodium
54202010	Crackers, saltine, low sodium
54202020	Crackers, saltine, reduced sodium
54203010	Crackers, toast thins (rye, wheat, white flour), low sodium
54204010	Cracker, 100% whole wheat, low sodium
54204020	Crackers, wheat, reduced sodium
54204030	Crackers, woven wheat, reduced sodium
54205010	Cracker, snack, low sodium
54205100	Cracker, snack, reduced fat, reduced sodium
54301000	Cracker, snack
54301010	Crackers, butter, plain
54301020	Crackers, butter, flavored
54301030	Crackers, butter (Ritz)
54301100	Crackers, butter, reduced fat
54304000	Crackers, cheese
54304005	Crackers, cheese (Cheez-It)
54304020	Crackers, cheese (Goldfish)

FNDDS Food Code	Food Description
54304100	Crackers, cheese, reduced fat
54304150	Crackers, cheese, whole grain
54304500	Cracker, high fiber, no added fat
54305000	Crispbread, wheat, no added fat
54305010	Crackers, crispbread
54305020	Crackers, flatbread
54307000	Crackers, matzo
54308000	Crackers, milk
54313000	Crackers, oyster
54318000	Chips, rice
54318500	Rice cake
54319000	Crackers, rice
54319005	Crackers, rice and nuts
54319010	Puffed rice cake
54319020	Popcorn cake
54319500	Rice paper
54322000	Crispbread, rye, no added fat
54325000	Crackers, saltine
54325010	Crackers, saltine, reduced fat
54325050	Crackers, saltine, whole wheat
54325060	Crackers, saltine, multigrain
54326000	Crackers, multigrain
54327950	Crackers, cylindrical, peanut-butter filled
54328000	Crackers, sandwich
54328100	Crackers, sandwich, peanut butter filled
54328105	Crackers, sandwich, peanut butter filled (Ritz)
54328110	Crackers, sandwich, reduced fat, peanut butter filled
54328120	Crackers, whole grain, sandwich, peanut butter filled
54328200	Crackers, sandwich, cheese filled
54328210	Crackers, sandwich, cheese filled (Ritz)
54334000	Crackers, toast thins (rye, pumpernickel, white flour)
54336000	Crackers, water
54336100	Crackers, wonton
54337000	Cracker, 100% whole wheat
54337010	Crackers, woven wheat
54337020	Crackers, woven wheat, plain (Triscuit)
54337030	Crackers, woven wheat, flavored (Triscuit)
54337050	Cracker, 100% whole wheat, reduced fat
54337060	Crackers, woven wheat, reduced fat
54338000	Crackers, wheat
54338010	Crackers, wheat, plain (Wheat Thins)
54338020	Crackers, wheat, flavored (Wheat Thins)
54338100	Crackers, wheat, reduced fat
54339000	Crackers, corn
54340100	Crackers, gluten free, plain
54340110	Crackers, gluten free, flavored
54401010	Salty snacks, corn or cornmeal base, nuts or nuggets, toasted
54401011	Corn nuts
54401020	Salty snacks, corn or cornmeal base, corn chips, corn-cheese chips
54401021	Corn chips, plain
54401026	Corn chips, flavored
54401031	Corn chips, plain (Fritos)
54401035	Corn chips, flavored (Fritos)
54401050	Salty snacks, corn or cornmeal base, corn puffs and twists; corn-cheese puffs and twists
54401055	Cheese flavored corn snacks
54401065	Cheese flavored corn snacks, reduced fat
54401075	Tortilla chips, plain

FNDDS Food Code	Food Description
54401080	Salty snacks, corn or cornmeal base, tortilla chips
54401081	Cheese flavored corn snacks (Cheetos)
54401085	Tortilla chips, flavored
54401090	Corn chips, reduced sodium
54401100	Salty snacks, corn or cornmeal base, tortilla chips, light (baked with less oil)
54401110	Tortilla chips, nacho cheese flavor (Doritos)
54401111	Tortilla chips, cool ranch flavor (Doritos)
54401112	Tortilla chips, other flavors (Doritos)
54401120	Salty snacks, corn or cornmeal base, tortilla chips, fat free, made with Olean
54401121	Tortilla chips, reduced fat, plain
54401122	Tortilla chips, reduced fat, flavored
54401150	Salty snacks, corn or cornmeal base, tortilla chips, lowfat, baked without fat
54401170	Tortilla chips, low fat, unsalted
54401210	Salty snacks, corn based puffs and twists, cheese puffs and twists, lowfat
54402080	Tortilla chips, reduced sodium
54402200	Snack mix
54402600	Salty snacks, multigrain, whole grain, chips (made with whole corn, whole wheat, rice flour, and whole oat flour)
54402610	Potato chips, restructured, multigrain
54402700	Pita chips
54404010	Popcorn chips, other flavors
54404020	Popcorn chips, sweet flavors
54406010	Onion flavored rings
54406200	Shrimp chips
54408000	Pretzels, NFS
54408010	Pretzels, hard
54408015	Pretzels, hard, NFS
54408016	Pretzels, hard, plain, salted
54408017	Pretzels, hard, plain, lightly salted
54408020	Pretzels, soft
54408030	Pretzels, hard, plain, unsalted
54408035	Pretzels, hard, flavored
54408040	Pretzels, soft, unsalted
54408070	Pretzels, hard, multigrain
54408080	Pretzel, gluten free
54408081	Pretzels, hard, plain, gluten free
54408082	Pretzels, hard, flavored, gluten free
54408105	Pretzel chips, hard, plain
54408110	Pretzel chips, hard, flavored
54408190	Pretzels, hard, coated, NFS
54408200	Pretzels, hard, chocolate coated
54408210	Pretzels, hard, white chocolate coated
54408250	Pretzels, hard, yogurt coated
54408290	Pretzels, hard, filled, NFS
54408300	Pretzels, hard, cheese filled
54408310	Pretzels, hard, peanut butter filled
54408405	Pretzels, soft, ready-to-eat, NFS
54408410	Pretzels, soft, ready-to-eat, salted, buttered
54408415	Pretzels, soft, ready-to-eat, salted, no butter
54408416	Pretzels, soft, ready-to-eat, unsalted, no butter
54408420	Pretzels, soft, ready-to-eat, cinnamon sugar coated
54408422	Pretzels, soft, ready-to-eat, coated or flavored
54408432	Pretzels, soft, ready-to-eat, topped with cheese
54408456	Pretzels, soft, from frozen, unsalted
54408470	Pretzels, soft, filled with cheese
54408475	Pretzels, soft, from school lunch
54408485	Pretzels, soft, gluten free

FNDDS Food Code	Food Description
54408487	Pretzels, soft, gluten free, coated or flavored
54420010	Multigrain mixture, pretzels, cereal and/or crackers, nuts
54420200	Multigrain mixture, bread sticks, sesame nuggets, pretzels, rye chips
54420210	Multigrain chips (Sun Chips)
54420220	Snack mix, plain (Chex Mix)
54440010	Bagel chips
54440020	Cracker chips
56116000	Noodles, chow mein
71200010	Potato chips, NFS
71200100	Potato chips, plain
71200110	Potato chips, barbecue flavored
71200120	Potato chips, sour cream and onion flavored
71200130	Potato chips, cheese flavored
71200140	Potato chips, other flavored
71200200	Potato chips, ruffled, plain
71200210	Potato chips, ruffled, barbecue flavored
71200220	Potato chips, ruffled, sour cream and onion flavored
71200230	Potato chips, ruffled, cheese flavored
71200240	Potato chips, ruffled, other flavored
71200300	Potato chips, restructured, plain
71200310	Potato chips, restructured, flavored
71200400	Potato chips, baked, plain
71200410	Potato chips, baked, flavored
71201015	White potato chips, regular cut
71201020	White potato chips, ruffled, rippled, or crinkle cut
71201050	Potato chips, reduced fat
71201060	Potato chips, fat free
71201080	White potato, chips, fat free
71201090	White potato, chips, fat free, made with Olean
71201100	White potato, chips, restructured
71201200	Potato chips, restructured, reduced fat, lightly salted
71201210	Potato chips, restructured, fat free
71201250	White potato, chips, restructured, baked
71202000	Potato chips, unsalted
71202100	Potato chips, reduced fat, unsalted
71202500	Potato chips, lightly salted
71202510	Potato chips, restructured, lightly salted
71203020	Potato chips, popped, flavored
71204000	Potato puffs, cheese-filled
71205000	White potato, sticks
71205020	Potato sticks, plain
71205030	Potato sticks, flavored
71205040	Potato sticks, fry shaped
71220000	Vegetable chips
71905410	Plantain chips
73410210	Sweet potato chips
	Cocoa and Chocolate Products
11830150	Cocoa powder, not reconstituted
13121000	Ice cream sundae, NS as to topping, with whipped cream *
13121300	Ice cream sundae, chocolate or fudge topping, with whipped cream *
13140660	Light ice cream, sundae, soft serve, chocolate or fudge topping, without whipped cream *
13210220	Pudding, chocolate, NS as to from dry mix or ready-to-eat *
13220120	Pudding, chocolate, prepared from dry mix, milk added *
13220230	Pudding, ready-to-eat, chocolate, reduced fat *
13220235	Pudding, ready-to-eat, chocolate, fat free *
13230130	Pudding, ready-to-eat, chocolate *

FNDDS Food Code	Food Description
13230200	Pudding, ready-to-eat, chocolate and non-chocolate flavors combined *
13250000	Mousse, chocolate *
13250200	Mousse, chocolate, lowfat, reduced calorie, prepared from dry mix, water added *
27146160	Chicken with mole sauce *
28522000	Mole poblano sauce *
42501500	Trail mix with chocolate *
54403160	Popcorn, chocolate coated *
63401070	Fruit, chocolate covered *
63401990	Banana, chocolate-covered with nuts *
91301080	Chocolate syrup, thin type
91301081	Chocolate syrup, thin type, light
91304020	Topping, chocolate, thick, fudge type
91304090	Topping, chocolate flavored hazelnut spread
91304300	Topping, chocolate, hard coating
91305010	Icing, chocolate
91306030	Chocolate dip *
91700500	M&M's Almond Chocolate Candies
91701010	Almonds, chocolate covered
91703040	Caramel candy, chocolate covered
91703060	Caramel with nuts, chocolate covered
91703070	Rolo
91703150	Toblerone, milk chocolate with honey and almond nougat
91703200	TWIX Caramel Cookie Bars
91703250	TWIX Chocolate Fudge Cookie Bars
91703300	TWIX Peanut Butter Cookie Bars
91703400	Whatchamacallit
91703600	Espresso coffee beans, chocolate-covered
91705010	Milk chocolate candy, plain
91705020	Milk chocolate candy, with cereal
91705030	Kit Kat
91705040	Chocolate, milk, with nuts, not almond or peanuts
91705050	Milk chocolate candy, with fruit and nuts
91705060	Milk chocolate candy, with almonds
91705070	Chocolate, milk, with peanuts
91705090	Chocolate candy with fondant and caramel
91705200	Chocolate, semi-sweet morsel
91705300	Chocolate, sweet or dark
91705310	Chocolate, sweet or dark, with almonds
91705400	Chocolate, white
91705420	Chocolate, white, with cereal
91705500	Mexican chocolate, tablet
91706000	Coconut candy, chocolate covered
91707010	Fondant, chocolate covered
91709000	Gumdrops, chocolate covered
91713010	Fudge, chocolate, chocolate-coated
91713030	Fudge, chocolate
91713040	Fudge, chocolate, with nuts
91715100	SNICKERS Bar
91715200	Baby Ruth
91715300	100 GRAND Bar
91718100	Butterfinger
91718110	Butterfinger Crisp
91718200	Chocolate-flavored sprinkles
91723010	Marshmallow, chocolate covered
91726110	Nougat, with caramel, chocolate covered
91726130	MILKY WAY Bar
91726140	MILKY WAY MIDNIGHT Bar

FNDDS Food Code	Food Description
91726150	MARS Almond Bar
91726410	Nougat, chocolate covered
91726420	3 MUSKETEERS Bar
91727010	Nuts, chocolate covered, not almonds or peanuts
91728000	Nut roll, fudge or nougat, caramel and nuts
91731000	Peanuts, chocolate covered
91731010	M&M's Peanut Chocolate Candies
91731060	M&M's Peanut Butter Chocolate Candies
91733200	Peanut Bar, chocolate covered candy
91734000	Peanut butter, chocolate covered
91734100	Reese's Peanut Butter Cup
91734300	Reese's Sticks
91734400	Reese's Fast Break
91739010	Raisins, chocolate covered
91746010	Sugar-coated chocolate discs
91746100	M&M's Milk Chocolate Candies
91746120	Sixlets
91746150	Easter egg, candy coated chocolate
91746200	M&M's Pretzel Chocolate Candies
91760100	Toffee, chocolate covered
91760200	Toffee, chocolate-coated, with nuts
91760500	Truffles
91770030	Dietetic or low calorie candy, chocolate covered
	Edible Ices - ice cream type
11459990	Yogurt, frozen, NS as to flavor, NS as to type of milk
11460000	Yogurt, frozen, flavors other than chocolate, NS as to type of milk
11460100	Yogurt, frozen, chocolate, NS as to type of milk
11460160	Yogurt, frozen, chocolate, lowfat milk
11460170	Yogurt, frozen, flavors other than chocolate, lowfat milk
11460200	Yogurt, frozen, chocolate, nonfat milk
11460250	Yogurt, frozen, flavors other than chocolate, with sorbet or sorbet-coated
11460300	Yogurt, frozen, flavors other than chocolate, nonfat milk
11461000	Yogurt, frozen, chocolate-coated
11461250	Yogurt, frozen, cone, chocolate
11461260	Yogurt, frozen, cone, flavors other than chocolate
11461270	Yogurt, frozen, cone, flavors other than chocolate, lowfat milk
11541110	Milk shake, home recipe, chocolate
11541120	Milk shake, home recipe, flavors other than chocolate *
11541130	Milk shake, home recipe, chocolate, light *
11541135	Milk shake, home recipe, flavors other than chocolate, light *
11541400	Milk shake with malt
11542100	Milk shake, fast food, chocolate
11542200	Milk shake, fast food, flavors other than chocolate
11543000	Milk shake, bottled, chocolate
11543010	Milk shake, bottled, flavors other than chocolate
13110000	Ice cream, NFS
13110100	Ice cream, regular, flavors other than chocolate
13110110	Ice cream, regular, chocolate
13110120	Ice cream, rich, flavors other than chocolate
13110130	Ice cream, rich, chocolate
13110200	Ice cream, soft serve, flavors other than chocolate
13110210	Ice cream, soft serve, chocolate
13110220	Ice cream, soft serve, NS as to flavor
13120050	Ice cream bar or stick, not chocolate covered or cake covered
13120100	Ice cream bar or stick, chocolate covered
13120110	Ice cream bar or stick, chocolate or caramel covered, with nuts

FNDDS Food Code	Food Description
13120120	Ice cream bar or stick, rich chocolate ice cream, thick chocolate covering
13120121	Ice cream bar or stick, rich ice cream, thick chocolate covering
13120130	Ice cream bar or stick, rich ice cream, chocolate covered, with nuts
13120140	Ice cream bar or stick, chocolate ice cream, chocolate covered
13120300	Ice cream bar, cake covered
13120310	Ice cream bar, stick or nugget, with crunch coating
13120400	Ice cream bar or stick with fruit
13120500	Ice cream sandwich
13120550	Ice cream cookie sandwich
13120700	Ice cream cone with nuts, flavors other than chocolate
13120710	Ice cream cone, chocolate covered, with nuts, flavors other than chocolate
13120720	Ice cream cone, chocolate covered or dipped, flavors other than chocolate
13120730	Ice cream cone, no topping, flavors other than chocolate
13120760	Ice cream cone, chocolate covered or dipped, chocolate ice cream
13120770	Ice cream cone, no topping, chocolate ice cream
13120790	Ice cream sundae cone
13120800	Ice cream soda, flavors other than chocolate
13120810	Ice cream soda, chocolate
13121000	Ice cream sundae, NS as to topping, with whipped cream *
13121100	Ice cream sundae, fruit topping, with whipped cream
13121300	Ice cream sundae, chocolate or fudge topping, with whipped cream *
13122100	Ice cream pie, no crust
13122500	Ice cream pie, with cookie crust, fudge topping, and whipped cream
13127000	Dippin' Dots, flash frozen ice cream snacks, flavors other than chocolate
13127010	Dippin' Dots, flash frozen ice cream snacks, chocolate
13130300	Light ice cream, flavors other than chocolate
13130310	Light ice cream, chocolate
13130600	Light ice cream, soft serve, flavors other than chocolate
13130610	Light ice cream, soft serve, chocolate
13130620	Light ice cream, soft serve cone, flavors other than chocolate
13130630	Light ice cream, soft serve cone, chocolate
13130700	Light ice cream, soft serve, blended with candy or cookies
13135000	Ice cream sandwich, made with light ice cream, flavors other than chocolate
13135010	Ice cream sandwich, made with light chocolate ice cream
13140100	Light ice cream, bar or stick, chocolate coated
13140110	Light ice cream, bar or stick, chocolate covered, with nuts
13140500	Light ice cream, cone, flavors other than chocolate
13140660	Light ice cream, sundae, soft serve, chocolate or fudge topping, without whipped cream *
13140670	Light ice cream, sundae, soft serve, fruit topping, without whipped cream
13140680	Light ice cream, sundae, soft serve, not fruit or chocolate topping, without whipped cream
13140700	Light ice cream, creamsicle or dreamsicle
13140900	Light ice cream, fudgesicle
13150000	Sherbet, all flavors
13160400	Fat free ice cream, flavors other than chocolate
13160410	Fat free ice cream, chocolate
13161000	Milk dessert bar, frozen, made from lowfat milk
13161500	Milk dessert sandwich bar, frozen, made from lowfat milk
41480000	Tofu, frozen dessert, flavors other than chocolate
56205230	Rice dessert bar, frozen, flavors other than chocolate, nondairy, carob covered
58157210	Rice pudding made with coconut milk, Puerto Rican style
63402990	Fruit salad, including citrus fruits, with pudding
63403000	Fruit salad, excluding citrus fruits, with pudding
63403100	Fruit dessert with cream and/or pudding and nuts
	Edible Ices - sorbet type
63420110	Fruit juice bar, frozen, flavor other than orange
63430100	Sorbet, fruit, noncitrus flavor

FNDDS Food Code	Food Description
63430500	Fruit juice bar with cream, frozen
91601000	Ice, fruit
91611000	Ice pop
91621000	Snow cone
	Gelatin/fruit mousse spreads
14610200	Cheese, cottage cheese, with gelatin dessert
14610210	Cheese, cottage cheese, with gelatin dessert and fruit
91501010	Gelatin dessert
91501020	Gelatin dessert with fruit
91501030	Gelatin dessert with whipped cream
91501050	Gelatin dessert with cream cheese
91501060	Gelatin dessert with sour cream
91501090	Gelatin dessert with fruit, vegetable, and nuts
	Jams, jellies, fruit syrups, and toppings
42203000	Peanut butter and jelly *
42302010	Peanut butter and jelly sandwich, NFS *
42302015	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on white bread *
42302020	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on wheat bread *
42302025	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on whole wheat bread *
42302055	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on white bread *
42302060	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on wheat bread *
42302065	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on whole wheat bread *
42302105	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on white bread *
42302110	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on wheat bread *
42302115	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on whole wheat bread *
42302155	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on white bread *
42302160	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on wheat bread *
42302165	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on whole wheat bread *
42303100	Peanut butter and jelly sandwich, frozen commercial product without crusts *
58201005	Jelly sandwich, regular jelly, on white bread *
58201015	Jelly sandwich, regular jelly, on wheat bread *
58201025	Jelly sandwich, regular jelly, on whole wheat bread *
58201045	Jelly sandwich, reduced sugar jelly, on wheat bread *
61113500	Lemon pie filling
63113030	Cherry pie filling
63409020	Chutney
73406010	Sweet potato with fruit
91300010	Syrup, NFS
91300100	Pancake syrup, NFS
91301020	Cane and corn pancake syrup
91301040	Buttered blends syrup
91301050	Fruit syrup
91301060	Maple syrup
91301130	Fruit flavored syrup used for milk beverages
91301250	Maple and corn and/or cane pancake syrup blends
91301510	Syrup, pancake, reduced calorie
91304010	Topping, butterscotch or caramel
91304030	Topping, fruit
91304040	Topping, marshmallow
91304060	Topping, nuts and syrup
91304070	Topping, peanut butter, thick, fudge type
91306020	Caramel dip, regular
91306040	Dessert dip
91361020	Fruit sauce
91361040	Dessert sauce

FNDDS Food Code	Food Description
91401000	Jelly, all flavors
91402000	Jam, preserve, all flavors
91403000	Fruit butter, all flavors
91404000	Marmalade, all flavors
91405500	Jelly, reduced sugar, all flavors
91406500	Jam, preserve, marmalade, sweetened with fruit juice concentrates, all flavors
91406600	Jam, preserve, marmalade, reduced sugar, all flavors
91407100	Guava paste
91407120	Sweet potato paste
91407150	Bean paste, sweetened
	Nutrition bars
53710800	Cereal or granola bar (Kashi Chewy)
53710802	Cereal or granola bar (Kashi Crunchy)
53710804	Kashi GOLEAN Crunchy Bars
53710806	Kashi TLC Crunchy Granola Bar
53720100	Nutrition bar (Balance Original Bar)
53720200	Nutrition bar (Clif Bar)
53720210	Nutrition bar (Clif Kids Organic Zbar)
53720300	Nutrition bar (PowerBar)
53720400	Nutrition bar (Slim Fast Original Meal Bar)
53720500	Nutrition bar (Snickers Marathon Protein Bar)
53720600	Nutrition bar (South Beach Living Meal Bar)
53720610	Nutrition bar (South Beach Living High Protein Bar)
53720700	Nutrition bar (Tiger's Milk)
53720800	Nutrition bar (Zone Perfect Classic Crunch)
53729000	Nutrition bar or meal replacement bar, NFS
	Plant-based spreads
11440010	Chipotle dip, yogurt based
11440020	Dill dip, yogurt based
11440040	Ranch dip, yogurt based
11440050	Spinach dip, yogurt based
11440060	Tzatziki dip
11440070	Vegetable dip, yogurt based
12350000	Dip, sour cream base
12350010	Dip, NFS
12350100	Spinach dip
12350110	Spinach and artichoke dip
12350200	Chipotle dip, regular
12350210	Dill dip, regular
12350220	Onion dip, regular
12350225	Onion dip, light
12350230	Ranch dip, regular
12350235	Ranch dip, light
12350240	Spinach dip, regular
12350245	Spinach dip, light
12350250	Vegetable dip, regular
12350255	Vegetable dip, light
14620100	Dip, cream cheese base
14620110	Artichoke dip
14620115	Spinach and artichoke dip
14620120	Shrimp dip, cream cheese base
14620130	Seafood dip
14640026	Cheese sandwich, American cheese, on white bread, with mayonnaise *
14640028	Cheese sandwich, American cheese, on wheat bread, with mayonnaise *
14640030	Cheese sandwich, American cheese, on whole wheat bread, with mayonnaise *

FNDDS Food Code	Food Description
14640032	Cheese sandwich, Cheddar cheese, on white bread, with mayonnaise *
14640034	Cheese sandwich, Cheddar cheese, on wheat bread, with mayonnaise *
14640036	Cheese sandwich, Cheddar cheese, on whole wheat bread, with mayonnaise *
14640046	Cheese sandwich, reduced fat Cheddar cheese, on wheat bread, with mayonnaise *
14640048	Cheese sandwich, reduced fat Cheddar cheese, on whole wheat bread, with mayonnaise *
14670000	Mozzarella cheese, tomato, and basil, with oil and vinegar dressing *
27220080	Ham croquette *
27246300	Chicken or turkey cake, patty, or croquette *
27250040	Crab cake *
27250070	Salmon cake or patty *
27250160	Tuna cake or patty *
27250400	Shrimp cake or patty *
27416250	Beef salad *
27420020	Ham or pork salad *
27446200	Chicken or turkey salad, made with mayonnaise *
27446205	Chicken or turkey salad with nuts and/or fruits *
27446220	Chicken or turkey salad with egg *
27446225	Chicken or turkey salad, made with light mayonnaise *
27446230	Chicken or turkey salad, made with mayonnaise-type salad dressing *
27446235	Chicken or turkey salad, made with light mayonnaise-type salad dressing *
27446240	Chicken or turkey salad, made with creamy dressing *
27446260	Chicken or turkey salad, made with any type of fat free dressing *
27450010	Crab salad *
27450020	Lobster salad *
27450030	Salmon salad *
27450060	Tuna salad, made with mayonnaise *
27450061	Tuna salad, made with light mayonnaise *
27450062	Tuna salad, made with mayonnaise-type salad dressing *
27450063	Tuna salad, made with light mayonnaise-type salad dressing *
27450064	Tuna salad, made with creamy dressing *
27450065	Tuna salad, made with light creamy dressing *
27450066	Tuna salad, made with Italian dressing *
27450068	Tuna salad, made with any type of fat free dressing *
27450070	Shrimp salad *
27450080	Seafood salad *
27450090	Tuna salad with cheese *
27450100	Tuna salad with egg *
27450130	Crab salad made with imitation crab *
27500050	Sandwich, NFS *
27510145	Cheeseburger, 1 miniature patty, with condiments, on miniature bun, from fast food / restaurant *
27510171	Cheeseburger, 1 small patty, with condiments, on bun, from fast food / restaurant (Burger King WHOPPER Jr. with cheese) *
27510175	Cheeseburger, 1 small patty, with condiments, on bun, from fast food / restaurant (Wendy's Jr. Cheeseburger Deluxe) *
27510205	Cheeseburger, 1 small patty, with condiments, on white bun *
27510206	Cheeseburger, 1 small patty, with condiments, on wheat bun *
27510207	Cheeseburger, 1 small patty, with condiments, on whole wheat bun *
27510220	Cheeseburger, with mayonnaise or salad dressing, on bun *
27510230	Cheeseburger, with mayonnaise or salad dressing, and tomato and/or catsup, on bun *
27510231	Cheeseburger, 1 medium patty, with condiments, on bun, from fast food / restaurant (Burger King WHOPPER with cheese) *
27510233	Cheeseburger, 1 medium patty, with condiments, on bun, from fast food / restaurant (Wendy's 1/4 lb Single with cheese) *
27510250	Cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing, on bun *
27510251	Cheeseburger, 1 medium patty, with condiments, on white bun *
27510252	Cheeseburger, 1 medium patty, with condiments, on wheat bun *
27510253	Cheeseburger, 1 medium patty, with condiments, on whole wheat bun *

FNDDS Food Code	Food Description
27510266	Cheeseburger, 1 large patty, with condiments, on bun, from fast food / restaurant *
27510280	Double cheeseburger (2 patties), with mayonnaise or salad dressing, on bun *
27510340	Double cheeseburger (2 patties), with mayonnaise or salad dressing and tomatoes and/or catsup, on bun *
27510341	Bacon cheeseburger, 1 medium patty, with condiments, on white bun *
27510342	Bacon cheeseburger, 1 medium patty, with condiments, on wheat bun *
27510343	Bacon cheeseburger, 1 medium patty, with condiments, on whole wheat bun *
27510346	Bacon cheeseburger, 1 large patty, with condiments, on bun, from fast food / restaurant *
27510350	Cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing, and tomato and/or catsup, on bun *
27510355	Cheeseburger, 1/3 lb meat, with mayonnaise or salad dressing, tomato and/or catsup on bun *
27510359	Cheeseburger, 1/3 lb meat, with mayonnaise or salad dressing, and mushrooms, on bun *
27510370	Double cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun *
27510380	Triple cheeseburger (3 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes and/or catsup, on bun *
27510385	Double bacon cheeseburger (2 patties), with tomato and/or catsup, on bun *
27510425	Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun *
27510430	Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, and tomato and/or catsup, on bun *
27510431	Double bacon cheeseburger, 2 small patties, with condiments, on bun, from fast food / restaurant (Burger King Bacon Double Cheeseburger) *
27510435	Double bacon cheeseburger (2 patties,1/3 lb meat each), with mayonnaise or salad dressing, on bun *
27510440	Bacon cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing, and tomato and/or catsup, on bun *
27510451	Double bacon cheeseburger, 2 medium patties, with condiments, on bun, from fast food / restaurant *
27510465	Double bacon cheeseburger, 2 medium patties, with condiments, on bun, from fast food / restaurant (Wendy's Baconator) *
27510506	Hamburger, 1 miniature patty, with condiments, on miniature bun, from fast food / restaurant *
27510520	Hamburger, with mayonnaise or salad dressing, and tomato and/or catsup, on bun *
27510552	Hamburger, 1 small patty, with condiments, on bun, from fast food / restaurant (Burger King WHOPPER Jr.) *
27510560	Hamburger, 1/4 lb meat, with mayonnaise or salad dressing, and tomato and/or catsup, on bun *
27510585	Hamburger, 1 small patty, with condiments, on white bun *
27510587	Hamburger, 1 small patty, with condiments, on whole wheat bun *
27510615	Hamburger, 1 medium patty, with condiments, on bun, from fast food / restaurant (Burger King WHOPPER) *
27510616	Hamburger, 1 medium patty, with condiments, on bun, from fast food / restaurant (Wendy's 1/4 lb Single) *
27510641	Hamburger, 1 medium patty, with condiments, on white bun *
27510642	Hamburger, 1 medium patty, with condiments, on wheat bun *
27510643	Hamburger, 1 medium patty, with condiments, on whole wheat bun *
27510667	Double hamburger, 2 small patties, with condiments, on bun, from fast food / restaurant *
27510670	Double hamburger (2 patties), with mayonnaise or salad dressing and tomatoes, on bun *
27510676	Double hamburger, 2 medium patties, with condiments, on bun, from fast food / restaurant *
27510681	Double hamburger, 2 medium patties, with condiments, on bun, from fast food / restaurant (Burger King Double WHOPPER) *
27510682	Double hamburger, 2 medium patties, with condiments, on bun, from fast food / restaurant (Wendy's 1/2 lb Double) *
27510690	Double hamburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes and/or catsup, on double-decker bun *
27510950	Reuben sandwich, corned beef sandwich with sauerkraut and cheese, with spread *
27513040	Roast beef submarine sandwich, with lettuce, tomato and spread *
27513041	Roast beef submarine sandwich, with cheese, lettuce, tomato and spread *
27517000	Wrap sandwich filled with beef patty, cheese and spread and/or sauce *
27517010	Wrap sandwich filled with beef patty, cheese, tomato and/or catsup, and spread and/or sauce *
27520130	Bacon, chicken, and tomato club sandwich, with lettuce and spread *
27520135	Bacon, chicken, and tomato club sandwich, with cheese, lettuce and spread *
27520150	Bacon, lettuce, and tomato sandwich with spread *
27520156	Bacon, lettuce, tomato, and cheese submarine sandwich, with spread *
27520160	Bacon, chicken, and tomato club sandwich, on multigrain roll with lettuce and spread *
27520165	Bacon, breaded fried chicken fillet, and tomato club with lettuce and spread *
27520166	Bacon, breaded fried chicken fillet, and tomato club sandwich with cheese, lettuce and spread *

FNDDS Food Code	Food Description
27520300	Ham sandwich, with spread *
27520320	Ham and cheese sandwich, with lettuce and spread *
27520350	Ham and cheese sandwich, with spread, grilled *
27520370	Hot ham and cheese sandwich, on bun *
27540110	Chicken sandwich, with spread *
27540111	Chicken sandwich, with cheese and spread *
27540120	Chicken salad or chicken spread sandwich *
27540150	Chicken fillet, breaded, fried, sandwich with lettuce, tomato and spread *
27540151	Chicken fillet, breaded, fried, sandwich with cheese, lettuce, tomato and spread *
27540170	Chicken patty sandwich, miniature, with spread *
27540190	Chicken patty sandwich, with lettuce and spread *
27540235	Chicken fillet, broiled, sandwich with lettuce, tomato, and spread *
27540240	Chicken fillet, broiled, sandwich, on whole wheat roll, with lettuce, tomato and spread *
27540270	Chicken fillet, broiled, sandwich, with lettuce, tomato, and non-mayonnaise type spread *
27540285	Chicken, bacon, and tomato club sandwich, with lettuce and spread *
27540295	Buffalo chicken submarine sandwich *
27540296	Buffalo chicken submarine sandwich with cheese *
27540361	Turkey and bacon submarine sandwich, with cheese, lettuce, tomato and spread *
27541000	Turkey, ham, and roast beef club sandwich, with lettuce, tomato and spread *
27545010	Turkey or chicken burger, with condiments, on bun, from fast food / restaurant *
27545200	Turkey or chicken burger, with condiments, on white bun *
27545210	Turkey or chicken burger, with condiments, on wheat bun *
27545220	Turkey or chicken burger, with condiments, on whole wheat bun *
27550720	Tuna salad sandwich *
27560500	Pepperoni and salami submarine sandwich, with lettuce, tomato and spread *
27570310	Hors d'oeuvres, with spread *
32102000	Egg, deviled *
32103000	Egg salad, made with mayonnaise *
32103015	Egg salad, made with light mayonnaise *
32103020	Egg salad, made with mayonnaise-type salad dressing *
32103025	Egg salad, made with light mayonnaise-type salad dressing *
32103035	Egg salad, made with light creamy dressing *
32103050	Egg Salad, made with any type of fat free dressing *
32202025	Egg, cheese and ham on bagel *
41203030	Black bean salad *
41205070	Hummus, plain
41205075	Hummus, flavored
42200500	Almond butter
42200510	Almond butter, lower sodium
42200600	Almond paste
42201000	Cashew butter
42202000	Peanut butter
42202010	Peanut butter, lower sodium
42202100	Peanut butter, lower sodium and lower sugar
42202130	Peanut butter, lower sugar
42202150	Peanut butter, reduced fat
42202200	Peanut butter, vitamin and mineral fortified
42203000	Peanut butter and jelly *
42204050	Peanut sauce *
42301015	Peanut butter sandwich, with regular peanut butter, on white bread *
42301020	Peanut butter sandwich, with regular peanut butter, on wheat bread *
42301025	Peanut butter sandwich, with regular peanut butter, on whole wheat bread *
42301115	Peanut butter sandwich, with reduced fat peanut butter, on white bread *
42301125	Peanut butter sandwich, with reduced fat peanut butter, on whole wheat bread *
42302010	Peanut butter and jelly sandwich, NFS *
42302015	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on white bread *
42302020	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on wheat bread *

FNDDS Food Code	Food Description
42302025	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on whole wheat bread *
42302055	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on white bread *
42302060	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on wheat bread *
42302065	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on whole wheat bread *
42302105	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on white bread *
42302110	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on wheat bread *
42302115	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on whole wheat bread *
42302155	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on white bread *
42302160	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on wheat bread *
42302165	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on whole wheat bread *
42303100	Peanut butter and jelly sandwich, frozen commercial product without crusts *
43103300	Tahini
58127500	Vegetable submarine sandwich, with fat free spread *
58134640	Tortellini, cheese-filled, meatless, with vinaigrette dressing *
58148110	Macaroni or pasta salad, made with mayonnaise *
58148111	Macaroni or pasta salad, made with light mayonnaise *
58148112	Macaroni or pasta salad, made with mayonnaise-type salad dressing *
58148114	Macaroni or pasta salad, made with Italian dressing *
58148115	Macaroni or pasta salad, made with light Italian dressing *
58148117	Macaroni or pasta salad, made with light creamy dressing *
58148118	Macaroni or pasta salad, made with any type of fat free dressing *
58148120	Macaroni or pasta salad with egg *
58148130	Macaroni or pasta salad with tuna *
58148140	Macaroni or pasta salad with crab meat *
58148150	Macaroni or pasta salad with shrimp *
58148160	Macaroni or pasta salad with tuna and egg *
58148170	Macaroni or pasta salad with chicken *
58148180	Macaroni or pasta salad with cheese *
58148550	Macaroni or pasta salad with meat *
63401010	Apple salad with dressing *
63402950	Fruit salad, excluding citrus fruits, with salad dressing or mayonnaise *
63402980	Fruit salad, excluding citrus fruits, with marshmallows *
63403010	Fruit salad, including citrus fruits, with salad dressing or mayonnaise *
63403040	Fruit salad, including citrus fruits, with marshmallows *
71600950	Potato salad with egg, from restaurant *
71601010	Potato salad with egg, made with mayonnaise *
71601015	Potato salad with egg, made with light mayonnaise *
71601020	Potato salad with egg, made with mayonnaise-type salad dressing *
71601025	Potato salad with egg, made with light mayonnaise-type salad dressing *
71601035	Potato salad with egg, made with light creamy dressing *
71601040	Potato salad with egg, made with Italian dressing *
71601050	Potato salad with egg, made with any type of fat free dressing *
71602950	Potato salad, from restaurant *
71603010	Potato salad, made with mayonnaise *
71603015	Potato salad, made with light mayonnaise *
71603020	Potato salad, made with mayonnaise-type salad dressing *
71603025	Potato salad, made with light mayonnaise-type salad dressing *
71603030	Potato salad, made with creamy dressing *
71603040	Potato salad, made with Italian dressing *
71603050	Potato salad, made with any type of fat free dressing *
73101110	Carrots, raw, salad *
73101210	Carrots, raw, salad with apples *
75140500	Broccoli salad with cauliflower, cheese, bacon bits, and dressing *
75140510	Broccoli slaw salad *
75140990	Cabbage salad or coleslaw, from fast food / restaurant *
75141000	Cabbage salad or coleslaw, made with coleslaw dressing *
75141005	Cabbage salad or coleslaw, made with light coleslaw dressing *

FNDDS Food Code	Food Description
75141020	Cabbage salad or coleslaw, made with Italian dressing *
75141025	Cabbage salad or coleslaw, made with light Italian dressing *
75141030	Cabbage salad or coleslaw, made with creamy dressing *
75141040	Cabbage salad or coleslaw, made with any type of fat free dressing *
75141100	Cabbage salad or coleslaw with apples and/or raisins, with dressing *
75141200	Cabbage salad or coleslaw with pineapple, with dressing *
75302080	Bean salad, yellow and/or green string beans *
75412030	Eggplant dip
75416600	Pea salad with cheese *
81302040	Sandwich spread
81302050	Tartar sauce
83100100	Salad dressing, NFS, for salads
83100200	Salad dressing, NFS, for sandwiches
83101000	Blue or roquefort cheese dressing
83102000	Caesar dressing
83103000	Coleslaw dressing
83104000	French or Catalina dressing
83105500	Honey mustard dressing
83106000	Italian dressing, made with vinegar and oil
83107000	Mayonnaise, regular
83108000	Mayonnaise, imitation
83109000	Russian dressing
83110000	Mayonnaise-type salad dressing
83112000	Avocado dressing
83112500	Creamy dressing
83112950	Poppy seed dressing
83112990	Sesame dressing
83114000	Thousand Island dressing
83200100	Salad dressing, light, NFS
83201000	Blue or roquefort cheese dressing, light
83201400	Coleslaw dressing, light
83202020	French or Catalina dressing, light
83203000	Caesar dressing, light
83204000	Mayonnaise, light
83204030	Mayonnaise, reduced fat, with olive oil
83204050	Mayonnaise-type salad dressing, light
83204500	Honey mustard dressing, light
83205450	Italian dressing, light
83206500	Sesame dressing, light
83207000	Thousand Island dressing, light
83210100	Creamy dressing, light
83300100	Blue or roquefort cheese dressing, fat free
83300200	Caesar dressing, fat free
83300300	Creamy dressing, fat free
83300400	French or Catalina dressing, fat free
83300500	Honey mustard dressing, fat free
83300600	Italian dressing, fat free
83300700	Mayonnaise, fat free
83300900	Salad dressing, fat free, NFS
83301000	Thousand Island dressing, fat free
	Yogurt/Yogurt Drinks
11115000	Buttermilk, fat free (skim)
11115100	Buttermilk, low fat (1%)
11115200	Buttermilk, reduced fat (2%)
11115300	Buttermilk, whole
11115400	Kefir, NS as to fat content

FNDDS Food Code	Food Description
11400000	Yogurt, NFS
11400010	Yogurt, Greek, NS as to type of milk or flavor
11410000	Yogurt, NS as to type of milk or flavor
11411010	Yogurt, NS as to type of milk, plain
11411100	Yogurt, whole milk, plain
11411200	Yogurt, low fat milk, plain
11411300	Yogurt, nonfat milk, plain
11411390	Yogurt, Greek, NS as to type of milk, plain
11411400	Yogurt, Greek, whole milk, plain
11411410	Yogurt, Greek, low fat milk, plain
11411420	Yogurt, Greek, nonfat milk, plain
11420000	Yogurt, vanilla, NS as to type of milk
11421000	Yogurt, vanilla, whole milk
11422000	Yogurt, vanilla, low fat milk
11423000	Yogurt, vanilla, nonfat milk
11424500	Yogurt, Greek, vanilla, whole milk
11424510	Yogurt, Greek, vanilla, low fat
11424520	Yogurt, Greek, vanilla, nonfat
11426000	Yogurt, chocolate, whole milk
11427000	Yogurt, chocolate, nonfat milk
11428000	Yogurt, Greek, chocolate, nonfat
11430000	Yogurt, NS as to type of milk, fruit
11431000	Yogurt, whole milk, fruit
11432000	Yogurt, low fat milk, fruit
11433000	Yogurt, nonfat milk, fruit
11433990	Yogurt, Greek, NS as to type of milk, fruit
11434000	Yogurt, Greek, whole milk, fruit
11434010	Yogurt, Greek, low fat milk, fruit
11434020	Yogurt, Greek, nonfat milk, fruit
11434090	Yogurt, NS as to type of milk, flavors other than fruit
11434100	Yogurt, whole milk, flavors other than fruit
11434200	Yogurt, low fat milk, flavors other than fruit
11434300	Yogurt, nonfat milk, flavors other than fruit
11435000	Yogurt, Greek, NS as to type of milk, flavors other than fruit
11435010	Yogurt, Greek, whole milk, flavors other than fruit
11435020	Yogurt, Greek, low fat milk, flavors other than fruit
11435030	Yogurt, Greek, nonfat milk, flavors other than fruit
11435100	Yogurt, Greek, with oats *
11436000	Yogurt, liquid
11446000	Yogurt parfait, low fat, with fruit
27116100	Beef curry *
27120160	Pork curry *
27130100	Lamb or mutton curry *
27146150	Chicken curry *
27150100	Shrimp curry *
27150320	Fish curry *
27213010	Biryani with meat *
27243100	Biryani with chicken *
27516010	Gyro sandwich (pita bread, beef, lamb, onion, condiments), with tomato and spread *
32101530	Egg curry *
41420380	Yogurt, soy
42401100	Yogurt, coconut milk
75440600	Vegetable curry *
77316600	Eggplant and meat casserole *
83115000	Yogurt dressing *
~: reconstituted; * <100% of food code intended for proposed use, ** representative of intended use as a juice	

Appendix E. PubMed Literature Searches

Search Number	Search String	Search Date	Filters	Results
1	("cacao"[MeSH Terms] OR "cacao"[All Fields] OR "cocoa"[All Fields]) AND ("pulp"[All Fields] OR "fruit"[MeSH Terms] OR "fruit"[All Fields] OR "juice"[All Fields] OR "nectar"[All Fields] OR "jelly"[all fields] or "jam"[All Fields] OR concentrate[All Fields])	5/15/2019	English	595
2	("cacao"[MeSH Terms] OR "cacao"[All Fields] OR "cocoa"[All Fields] OR "Theobroma"[all fields]) AND ("pulp"[All Fields] OR "juice"[All Fields] OR "sweatings"[all fields])	5/20/2019	English	130
3	Search 1 OR Search 2	2/26/2020	English, Publication date from 2019/01/01 to 2020/12/31	59
4	(cocoa OR cacao OR chocolate) AND (polyphenol OR flavanol OR catechin OR epicatechin OR Anthocyanins OR Proanthocyanidins) AND ("randomized controlled trial" [pt] OR "controlled clinical trial" [PT] OR "Clinical Trial"[pt] OR randomized OR randomised OR "controlled trial" OR "clinical trial" OR crossover OR cross-over OR pilot)	6/4/2019	English	248
5	Search 4	2/27/2020	English, Publication date from 2019/01/01 to 2020/12/31	26
6	(cocoa OR cacao OR chocolate) AND (polyphenol OR flavanol OR catechin OR epicatechin OR Anthocyanins OR Proanthocyanidins) and (safe* OR toxic OR toxicity OR toxicology OR hazard OR chronic OR subchronic OR subacute OR genotox* OR "in vivo" OR "in vitro" OR mutag*) and (review OR meta-analysis OR meta analysis)	6/7/2019	English	91

Search Number	Search String	Search Date	Filters	Results
7	Search 6	2/27/2020	English, Publication date from 2019/01/01 to 2020/12/31	10
8	(polyphenol OR flavanol OR catechin OR epicatechin OR anthocyanins OR proanthocyanidins) and (safe* OR toxic OR toxicity OR toxicology or hazard OR chronic OR subchronic OR subacute OR genotox* OR "in vivo" OR "in vitro" OR mutag*) and (systematic review OR meta-analysis OR meta analysis)	6/19/2019	English	111
9	Search 8	2/27/2020	English, Publication date from 2019/01/01 to 2020/12/31	31
10	(((cocoa[tiab] OR cacao[tiab]) AND (polyphenol OR flavanoid)) OR (anthocyanin OR proanthocyanidin OR flavanol OR flavan-3-ol OR catechin OR epicatechin)) AND (“randomized controlled trial” [pt] OR “controlled clinical trial” [pt] OR "Clinical Trial"[pt] OR randomized OR “controlled trial” OR “clinical trial” OR crossover OR cross-over) AND (safe[tiab] OR safety[tiab] OR toxic[tiab] OR toxicity[tiab] OR toxicology[tiab] OR hazard[tiab] OR adverse[tiab])	6/24/2019	English	159
11	Search 10	2/26/2020	English, Publication date from 2019/01/01 to 2020/12/31	37

Appendix F. Reproductive Toxicity of Theobromine

Appendix F, Table 1. Oral administration, multiple dose groups reproductive toxicity studies conducted in rats

Reference	Species	Duration	Dosage	Primary results	NOAEL for reproductive toxicity
Dietary exposure					
Hostetler et al., 1990	Male and female Sprague-Dawley rats	Three generations during the initial 12-wk growth period	0, 1.5, 3.5, or 5.0% cocoa powder equivalent to mean total methylxanthine exposures (of which 93% was theobromine) of (males/females) 30/36, 72/86, and 104/126 mg/kg bw/day, respectively	-No treatment-related reproductive effects were observed over 3 generations -Non-reproductive toxicity effects were reported such as renal tubular mineralization in F0 males at highest dose of cocoa powder -No effects on pup survival	A NOAEL was not reported by the study authors. Based on the absence of treatment-related effects up to the highest tested dose, a NOAEL of 5.0% cocoa powder, equivalent to 97 and 117 mg/kg bw/day theobromine for males and females, respectively, could be derived for reproductive toxicity.
Tarka et al., 1981	Breeder male Sprague-Dawley rats	49 days followed by a 49-day recovery period on a theobromine-free diet	0, 0.2, 0.6, 0.8% theobromine	-Histological results revealed that 70-90% of seminiferous tubules from rats treated with 0.6 and 0.8% theobromine lacked well-formed spermatozoa, and the effects were largely irreversible	A NOAEL was not reported by the study authors. EFSA (2008) reviewed Tarka et al. (1981) and determined that doses above 300 mg/kg bw/day (dose conversions were unspecified) caused testicular toxicity.
Tarka et al., 1979	Male and female Sprague-Dawley rats	28 days	0, 144, 291, 382, 425, or 562 mg/kg bw/day for males; 0, 110, 236, 355, 489, and 596 mg/kg	-Severe testicular atrophy observed at 425 and 562 mg/kg bw/day doses -Seminiferous tubular-cell degeneration observed in all animals that received 382 mg/kg bw/day dose	A NOAEL was not reported by the study authors. A NOAEL of 291 mg/kg bw/day could be derived for male reproductive toxicity based on the effects observed at 382, 425, and 562

Reference	Species	Duration	Dosage	Primary results	NOAEL for reproductive toxicity
			bw/day for females	-No adverse effects on female reproductive system organ were observed up to the highest tested dose	mg/kg bw/day doses. A NOAEL for female reproductive toxicity was determined to be the highest tested dose of 596 mg/kg bw/day.
Oral gavage					
Funabashi et al., 2000	Male Sprague-Dawley rats	6-week-old rats were dosed for 2 to 4 weeks; 8-week-old rats were dosed for 2 weeks	0, 250, or 500 mg/kg bw/day	-Decreased BW gain at the highest tested dose -Effects observed on testicular and thymus tissue, decreased relative prostate and seminal vesicle weights at the highest dose -Histopath showed testicular toxicity at highest dose after 2 wk at both ages and at both tested doses after 4 wk of dosing -Degeneration, necrosis and desquamatic spermatids and spermatocytes, vacuolization of seminiferous tubules, and multinucleated giant cell formation were observed	A NOAEL was not reported by the study authors. Based on the presence of effects at all tested doses, a NOAEL for reproductive toxicity could not be established.

Appendix F, Table 2. Oral administration, multiple dose groups reproductive toxicity studies conducted in additional animal species

Reference	Species	Duration	Dosage	Primary results	NOAEL for reproductive toxicity
Dietary exposure					
Gans et al., 1980	Male Beagle dogs	1 y	0, 25, 50, 100, or 150 mg/kg bw/day	-No testicular atrophy was observed	A NOAEL was not reported by the study authors. A NOAEL of 150 mg/kg bw/day for testicular toxicity was derived by EFSA (2008) based on the absence of reproductive effects up to the highest tested dose.
Soffietti et al., 1989	Mature and immature male New Zealand Hy/Cr rabbits	Mature male rabbits: 120 days Immature male rabbits: 20 days	0, 0.5, 1.0, or 1.5% theobromine in the diet	-Mature and immature male rabbits: -Dose-dependent degeneration and necrosis of the seminiferous tubules from data reported for 1.0 and 1.5% doses -At all tested doses of theobromine, damaged tubules, aspermia, initial vacuolation of spermatids and spermatocytes followed by multinucleated cell formation were observed	A NOAEL was not reported by the study authors. Based on the presence of effects at all tested doses, a NOAEL for reproductive toxicity could not be established.
Lamb et al., 1997	Male and female Swiss CD-1 mice	Throughout continuous breeding protocol of pairs	0, 126, 335, or 630 mg/kg bw/day	-Doses ≤ 126 mg/kg bw/day resulted in decreased litter numbers, decreased numbers of pups born alive, and decreased pup body weights -Females were determined to be more sensitive than males	The study authors reported a NOAEL of ≤126 mg/kg bw/day for reproductive toxicity.
Skopinska-Rozewska et al., 2003; limited study details available;	Female BALB/c and BALB/cxC3H F1 mice	Exposure during pregnancy and lactation	3 and 6 mg	-Both doses led to decreased fetal BWs that were no longer observed in adult progeny; minimal increase in VEGF; ACE activity increased in mouse embryonic tissue homogenates (tissues unspecified)	A NOAEL was not reported by the study authors. Based on the presence of effects at all tested doses, a NOAEL for reproductive toxicity could not be established.

Reference	Species	Duration	Dosage	Primary results	NOAEL for reproductive toxicity
paper requested					
Tarka et al., 1979	Male and female Swiss albino mice	28 days	Males: 0, 301, 634, 928, 1138, or 1843 mg/kg bw/day Females: 0, 297, 600, 862, 1411, or 1886 mg/kg bw/day	-Testicular changes observed at concentrations that caused significant mortality, e.g. 50% mortality reported at the highest tested dose -Reproductive effects were not evaluated or reported for females	A NOAEL was not reported by the study authors. A NOAEL of 1138 mg/kg bw/day could be derived based on effects observed in males at the highest tested dose.
Tarka et al., 1979	Male hamsters	28 days	0, 182, 406, 638, 848, or 1027 mg/kg bw/day	-Treated animals were completely resistant to any theobromine-induced testicular changes	A NOAEL was not reported by the study authors. A NOAEL of 1027 mg/kg bw/day could be derived based on the absence of reproductive effects up to the highest tested dose.

Appendix F, Table 3. Single dose group reproductive toxicity studies

Reference	Species	Duration	Dosage	Primary results
Dietary exposure				
Friedman et al., 1978 Only the abstract is available	Immature (4- to 6-wk-old) male Osborne-Mendel rats	3 to 61 wk	~500 mg/kg bw/day for 3 wk and ~250 mg/kg bw/day for an additional 61 wk	-Severe testicular atrophy (94%) and aspermatogenesis (82%)
Friedman et al., 1978 Only the abstract is available	Holtzman rats	19 wk	~250 mg/kg bw/day	-All rats exhibited testicular atrophy and 79% had aspermatogenesis
Vander Ploeg et al., 1992 Only the abstract is available	Ovarian-hormone treated, mature nulliparous female BALB/C mice	30 days	500 mg/l in drinking water	-No effect on mammary gland developmental growth
Oral gavage				
Wang and Waller, 1994	Male Sprague-Dawley rats	7 days	500 mg/kg bw/day	-Decreased BW gain -38% decrease in cauda epididymal sperm reserve -33% decrease in seminiferous tubule fluid (STF) -22% decrease in [lactate] in STF -21% inhibition in androgen binding protein (ABP) activity -Decreased ABP in STF -Higher [theobromine] in serum and tested compared to treatment with cocoa extract -Authors reported that Sertoli cells are the primary target cells for theobromine toxicity -Cocoa extract w/ equivalent amount of theobromine did not produce significant toxicity in treated rats
Wang et al., 1992 Only the abstract is available	Male Sprague-Dawley rats	31 days	0, 250 mg/kg bw/day theobromine, or cocoa extract containing an	-Decreased BW gain and epididymal weights from theobromine and high-dose cocoa-extract-treated groups -Sertoli cell vacuolation, abnormally shaped spermatids, failed release of late spermatids in theobromine and high-dose cocoa-extract-treated groups

Reference	Species	Duration	Dosage	Primary results
			equivalent amount of 250 mg/kg bw/day of theobromine	-Vacuolation detected in early and middle stage seminiferous tubules -Frequency of testis changes were lower from cocoa extract compared to pure theobromine
Ettlin et al., 1986 Only the abstract is available	Fu albino rats	3 or 5 days	500 mg/kg bw/day	-Effects observed on germ cell kinetics -Delayed release of late spermatids into the tubular lumen 2-wk post-treatment -Partial disruption of rigid spermatogenic synchronization was not followed by significant germ cell death -Authors hypothesized that Sertoli cell toxicity contributed to the observed effects

Appendix F, Table 4. *Ex vivo* reproductive toxicity studies

Reference	Sample	Dosage	Primary results
Pollard et al., 2001	13-d-old fetal testis (i.e. fetal testis organ explant) cultured for 4 d *in vitro*	Graded doses of theobromine	-Normal tissue differentiation w/ developing seminiferous cords consisting of Sertoli and germ cells followed by differentiation of functionally active - Leydig cells that appeared in the newly formed interstitium

Appendix G. Expert Panel Consensus Statement

GRAS PANEL CONSENSUS STATEMENT

The Generally Recognized as Safe (GRAS) Conclusion for the Use of Cacao Pulp, Juice and Concentrate as an Ingredient in Select Foods

Introduction

The undersigned, an independent panel of experts, qualified by their scientific training and national and international experience to evaluate the safety of food and food ingredients (the "GRAS Panel"), was specially convened to conduct a critical and comprehensive evaluation of the available pertinent data and safety information, and to determine whether under the conditions of intended use in select foods, cacao pulp, cacao fruit juice, and cacao fruit juice concentrate would be generally recognized as safe (GRAS) based on scientific procedures. For purposes of this review, "safe" or "safety" means that there is "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use," as defined by the United States Food and Drug Administration (FDA) in 21 CFR § 170.30.

At the request of Barry Callebaut Belgium NV, Exponent, Inc. ("Exponent") performed a comprehensive search of the scientific literature relating to the safety of cacao pulp, cacao fruit juice and cacao fruit juice concentrate with respect to the proposed uses. Exponent summarized results of the literature searches and prepared a draft safety dossier, "Documentation Supporting a Generally Recognized As Safe (GRAS) Conclusion for the Use of Cacao Pulp, Juice and Concentrate as an Ingredient in Select Foods" (July 26, 2019) for consideration by the GRAS Panel.

The GRAS Panel consisted of the following individuals: Stanley M. Tarka, Jr., Ph.D. (The Tarka Group, Inc. and Adjunct Associate Professor, The Pennsylvania State University College of Medicine); Robert Nicolosi, Ph.D., MS, CNS (Emeritus Professor, University of Massachusetts, Lowell); and Gary Murray Williams, M.D. (Professor, Retired, New York Medical College). The GRAS Panel, independently and collectively, critically evaluated Exponent's safety documentation (the dossier) and other available data and information that the members of the GRAS Panel believed to be pertinent to the safety of the proposed use of cacao pulp, cacao fruit juice and cacao fruit juice concentrate.

On August 7, 2019, the GRAS Panel convened via teleconference and independently, jointly, and unanimously concluded that under the conditions of intended use described herein, cacao pulp, cacao fruit juice and cacao fruit juice concentrate, produced consistent with current good manufacturing practice (cGMP) and meeting the stated specifications, is safe for the intended use. The GRAS Panel further concluded unanimously that the intended use of cacao pulp, cacao

fruit juice and cacao fruit juice concentrate is GRAS based on scientific procedures. It is also the unanimous consensus opinion of this GRAS Panel that other qualified experts would concur with these conclusions.

Summarized below are the data, information, and interpretive analysis supporting the GRAS Panel's conclusions.

Description

The starting raw material used to make cacao pulp, cacao fruit juice and cacao fruit juice concentrate is the fruit of the cacao plant, *Theobroma cacao* L. Cacao pulp is the semi-solid fruit flesh found in the form of a wet mucilaginous layer surrounding the unfermented cacao bean.

The industrial collection of cacao pulp is done as part of the initial processing of the cacao bean after pod opening and prior to fermentation of the cacao bean. Cacao pulp is then pasteurized to ensure a safe product for consumption, or it is subjected to food-grade enzymes to produce cacao fruit juice which is subsequently pasteurized and packaged or concentrated by removal of water to form cacao fruit juice concentrate. The products are manufactured under conditions of Good Manufacturing Practices (cGMPs) and no processing aids other than these enzymes are used in the production process of cacao pulp, cacao fruit juice, or cacao fruit concentrate. Product specifications include physico-chemical and microbiological criteria established to ensure consistent safety and quality of the product. Monitoring is conducted to ensure that potential impurities including heavy metals, mycotoxins, pesticide residues, and polycyclic aromatic hydrocarbons meet specifications appropriate for a food ingredient. Analytical data from non-consecutive batches demonstrate that the product specifications are consistently met.

Intended Use and Estimated Daily Intake

The cacao ingredients that are the subject of this dossier are intended for use in a variety of foods. Cacao fruit juice concentrate is intended for use in beverages, bakery products, candy and confections (non-chocolate), cereal bars and chips/crackers, cocoa and chocolate products, edible ices - ice cream type, edible ices - sorbet type, gelatin/fruit mousse spreads, jams/jellies/fruit syrups and toppings, nutrition bars, plant-based spreads, and yogurt/yogurt drinks at maximum use levels ranging from 10 to 65% by weight as concentrate; cacao fruit juice is intended for use in juice as such; or use of cacao pulp in bakery products, candy and confections (non-chocolate), jams/jellies/fruit syrups and toppings, plant-based spreads, and yogurt/yogurt drinks at maximum concentrations ranging from 15 to 50% by weight. Only one type of cacao ingredient (pulp, fruit juice, or fruit juice concentrate) would be used in any specific use category at a time.

For the population ages 2 years and older, the *per user* mean and 90th percentile estimated daily intakes (EDIs) of cacao juice concentrate from the intended use are 85 and 176 g/day, respectively. Intake of each constituent of interest was estimated from the 90th percentile EDI of

cacao fruit juice concentrate and the concentration of each component in the concentrate based on compositional analyses.

Assessment of Safety

The safety of cacao pulp, cacao fruit juice and cacao fruit juice concentrate was evaluated based on a review of available data and information on the key constituents in cacao including compositional data and assessment of potential intake of the constituents from the intended use. The constituents evaluated include carbohydrate and fiber, organic acids, minerals including potassium and magnesium, theobromine, and polyphenols. Dietary intakes of fiber, organic acids, micronutrients, polyphenols, and theobromine in cacao pulp, cacao fruit juice, and cacao fruit juice concentrate are expected to have the same metabolic fate as constituents from other dietary sources. No evidence of safety concerns from intake of cacao pulp, cacao fruit juice, cacao fruit juice concentrate, or the constituents of these cacao pulp products at levels of intake resulting from the intended uses of the pulp, juice and concentrate was identified in the searches of the published literature.

Cacao fruit juice concentrate is primarily carbohydrate in the form of glucose, fructose and sucrose, with these sugars accounting for the majority of the non-water portion, or approximately 51% by weight of the concentrate. Carbohydrates are a necessary and key source of energy in the diet and sugars from the intended use of cacao pulp, cacao fruit juice and cacao fruit juice concentrate will likely replace other sources of dietary carbohydrate and are of no safety concern. The estimated intake of fiber from the intended uses of cacao pulp products (as concentrate) is 2.1 g/day. Compositional data on cacao pulp demonstrate that fiber is present as high molar weight fibers including cellulose, pectin, hemicellulose, and lignin, all of which are common naturally-occurring forms of dietary fiber. The small incremental increase in dietary fiber intake from the intended use of the cacao products presents no safety concern.

Cacao products are a source of minerals including potassium and magnesium. Fruit juices are a recognized source of minerals and compositional data indicate that concentrations of potassium and magnesium in cacao pulp and juice are similar to concentrations of these minerals present in commonly consumed juices such as orange juice or coconut water. The estimated intake of potassium from the intended uses of cacao pulp products (as concentrate) is 1,030 mg/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 586 mg potassium per 100 g cacao juice concentrate. The potential intake of potassium from current dietary sources and the intended uses is within the range of intakes that have been recommended by authoritative bodies including the Institute of Medicine (IOM), the National Academy of Medicine (NAM) (previously known as the IOM), and the European Food Safety Authority (EFSA). For the generally healthy population, there is no tolerable upper intake level (UL) for potassium as the available evidence provides no indication of adverse effects from high

levels of potassium from foods. The potential intake of potassium from the intended use therefore does not present a safety concern.

The estimated intake of magnesium from the intended uses of cacao pulp products (as concentrate) is 39 mg/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 22 mg potassium per 100 g cacao juice concentrate. The intended uses of the cacao pulp, cacao fruit juice, and cacao fruit juice concentrate therefore result in a small increase in magnesium intake and is well within recommended levels of intake. There is no UL for magnesium from dietary sources. The potential intake of magnesium from the intended use does not present a safety concern.

The estimated intake of citric acid from the intended uses of cacao pulp products (as concentrate) is 6.9 g/day based on the 90th percentile intake of 176 g cacao juice concentrate and assuming a conservatively high concentration of 1.3 g citric acid per 100 g pulp or juice and adjusted for moisture in the concentrate (a factor of three). The estimated intake of succinic acid from the intended uses of cacao pulp products (as concentrate) is 0.5 g/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 0.1 g succinic acid per 100 g pulp and adjusted for moisture in the concentrate. Both citric acid and succinic acid are present in commonly consumed fruits at concentrations in the range of the concentration reported in cacao pulp, and both citric acid and succinic acid may be consumed as approved additives in foods. The intended uses of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate provide a source of citric acid and succinic acid and their respective intakes can be expected to fall within the range of background intake of these substances; the intended use does not present a safety concern.

The estimated intake of polyphenols from the intended uses of cacao pulp products (as concentrate) at the 90th percentile of intake is 282 mg gallic acid equivalents (GAE) which is likely an overestimate of true polyphenol intake, or in the range of 11-16 mg per day of flavan-3-ols based on testing of flavanols typically found in cocoa. Flavanols are ubiquitous in the diet and generally regarded as safe. Intakes of polyphenols from dietary sources may exceed 1,500 mg per day for the U.S. population, and the safe intake of a variety of polyphenols has been recognized in foods delivering in the range of 100 to 2,600 mg polyphenols per person per day in the diet. The estimated intake of polyphenols from the intended use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate will provide a small incremental increase in intake above background intakes of polyphenols and presents no safety concern.

The estimated intake of theobromine from the intended uses of cacao pulp products (as concentrate) is 3 mg/day based on the 90th percentile intake of 176 g cacao juice concentrate and a mean typical concentration of 1.726 mg theobromine per 100 g cacao juice concentrate. The cacao products provide a small incremental increase in theobromine intake by the U.S. population and presents no safety concern.

Summary

Cacao pulp, cacao fruit juice, and cacao fruit juice concentrate are intended for use in select foods. Compositional analyses of the cacao pulp, cacao fruit juice, and cacao fruit juice concentrate shows that the products consist primarily of water, carbohydrate (sugars and a small amount of fiber), organic acids, minerals, and small concentrations of theobromine and polyphenols. These constituents are found in other commonly consumed foods in the diet and have a long history of safe consumption as part of the normal diet. The intended use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate will result in intakes of these constituents that are within the range of background levels of intake and therefore can be concluded to be safe. The safety of intake of the proposed uses is supported by a safe history of consumption of cacao pulp and products derived therefrom. Cacao pulp or puree from the edible part of cacao (*Theobroma cacao*) currently is a product defined by the Brazilian legislation (Normative Instruction No 01 of January 7, 2000) and therefore recognized as a food that is safe for human consumption. The Codex Alimentarius General Standard for fruit juices and nectars (CODEX STAN 247-2005) includes specifications for a variety of juices including *Theobroma cacao* L. (cacao pulp), thus indicating that cacao pulp is a recognized source of juice. Cacao fruit (*Theobroma cacao*) frozen puree was evaluated by Food Standards Australia New Zealand and was recognized as a non-traditional food (i.e., not a novel food) with history of use in South America and no indication of safety concerns. In the European Union (EU), cacao pulp juice is recognized as a food traditionally consumed in countries outside the EU but must be regarded as "Novel when used as or in foods" within the EU.

It can be concluded that the proposed use of cacao fruit juice concentrate in beverages, bakery products, candy and confections (non-chocolate), cereal bars and chips/crackers, cocoa and chocolate products, edible ices - ice cream type, edible ices - sorbet type, gelatin/fruit mousse spreads, jams/jellies/fruit syrups and toppings, nutrition bars, plant-based spreads, and yogurt/yogurt drinks at maximum use levels ranging from 10 to 65% by weight as concentrate; use of cacao fruit juice as such; and use of cacao pulp in bakery products, candy and confections (non-chocolate), jams/jellies/fruit syrups and toppings, plant-based spreads, and yogurt/yogurt drinks at maximum concentrations ranging from 15 to 50% by weight, produced using current cGMP, is safe.

General recognition of safety through scientific procedures requires common knowledge throughout the scientific community knowledgeable about the safety of food ingredients, and that there is a reasonable certainty that a substance is not harmful under the intended conditions of use in foods. The aforementioned regulatory, scientific reviews, and compositional data related to the consumption and safety of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate have been published in the scientific literature and, therefore, are generally available and generally known among the community of qualified food ingredient safety experts. There is broad-based and widely disseminated knowledge concerning cacao pulp, cacao fruit juice, and

cacao fruit juice concentrate. The data and publicly available information supporting the safety of the proposed use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate, for the intended use in food, are not only widely known and disseminated, but are also commonly accepted among qualified food safety experts. The proposed use of cacao fruit juice concentrate in beverages, bakery products, candy and confections (non-chocolate), cereal bars and chips/crackers, cocoa and chocolate products, edible ices - ice cream type, edible ices - sorbet type, gelatin/fruit mousse spreads, jams/jellies/fruit syrups and toppings, nutrition bars, plant-based spreads, and yogurt/yogurt drinks at maximum use levels ranging from 10 to 65% by weight as concentrate; use of cacao fruit juice as such; and use of cacao pulp in bakery products, candy and confections (non-chocolate), jams/jellies/fruit syrups and toppings, plant-based spreads, and yogurt/yogurt drinks at maximum concentrations ranging from 15 to 50% by weight therefore can be concluded to be safe and GRAS through scientific procedures.

Conclusion

We, the undersigned independent qualified members of the GRAS Panel, have individually and collectively, critically evaluated the published and unpublished data and information summarized above that is pertinent to the proposed use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate in specified foods. We unanimously conclude that the proposed use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate, produced in a manner that is consistent with current Good Manufacturing Practice (cGMP) and meeting appropriate food-grade specifications as presented in the supporting dossier ["Documentation Supporting a Generally Recognized As Safe (GRAS) Conclusion for the Use of Cacao Pulp, Juice and Concentrate as an Ingredient in Select Foods"] is safe.

We, the members of the GRAS Panel, further unanimously conclude that the intended use of cacao pulp, cacao fruit juice, and cacao fruit juice concentrate, produced consistent with current Good Manufacturing Practice (cGMP) and meeting appropriate food-grade specifications as presented in the supporting dossier is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in select foods specified herein.

It is our professional opinion that other qualified experts would also concur with this conclusion.

By:

[redacted]

09 August 2019

Stanley M. Tarka, Jr., Ph.D. (Panel Chair) — Date
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The Tarka Group, Inc. and Adjunct Associate Professor,
The Pennsylvania State University College of Medicine

Robert Nicolosi, Ph.D., MS, CNS — Date
Emeritus Professor
University of Massachusetts, Lowell

Gary Murray Williams, M.D. — Date
Professor, Retired
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