



DEPARTMENT OF HEALTH

FOOD AND DRUG ADMINISTRATION

CITIZEN'S CHARTER

2023 (4th Edition)

CENTER FOR FOOD REGULATION AND RESEARCH (CFRR)

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Profile

I. Mandate:

To protect the general public by ensuring the safety, efficacy, and quality of health products.

II. Vision:

To be an internationally recognized center of excellence in health product regulation by 2026.

III. Mission:

To guarantee the safety, quality, purity, efficacy of health products in order to protect and promote the right to health of the general public.

IV. Service Pledge:

Ensure the safety, efficacy, quality, and purity of health products by fostering integrity, transparency, and excellence-based standards and policies, in a healthy and safe work environment





Center for Food Regulation and Research

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 B. CERTIFICATE OF PRODUCT REGISTRATION (CPR) – INITIAL/ RENEWAL DATA CAPTURE (REGULAR)/ AMENDMENT DATA CAPTURE/ RE-APPLICATION DATA CAPTURE II. CERTIFICATE OF PRODUCT REGISTRATION (CPR) – AMENDMENT (INITIAL APPLICATION APPROVED FROM MODIFIED E-REGISTRATION (VERSION 2)) III. CERTIFICATE OF PRODUCT REGISTRATION (CPR) – AUTOMATIC RENEWAL APPLICATION (INITIAL APPLICATION APPROVED FROM MODIFIED E-REGISTRATION (VERSION 2)) IV. CERTIFICATE OF PRODUCT REGISTRATION (CPR): AUTOMATIC RENEWAL (DATA CAPTURE) V. CERTIFICATE OF PRODUCT REGISTRATION (CPR) – RE-APPLICATION (INITIAL APPLICATION DISAPPROVED FROM MODIFIED E-REGISTRATION VI.CERTIFICATE OF PRODUCT REGISTRATION (CPR) – RE-APPLICATION (INITIAL APPLICATION DISAPPROVED FROM MODIFIED E-REGISTRATION VI.CERTIFICATE OF PRODUCT REGISTRATION (CPR) – RE-APPLICATION (INITIAL APPLICATION DISAPPROVED FROM MODIFIED E-REGISTRATION VI.CERTIFICATE OF PRODUCT REGISTRATION (CPR) – RE-APPLICATION (INITIAL APPLICATION DISAPPROVED FROM MODIFIED E-REGISTRATION VI.CERTIFICATE OF PRODUCT REGISTRATION (CPR) – RE-APPLICATION (INITIAL APPLICATION DISAPPROVED FROM MODIFIED E-REGISTRATION VI.CERTIFICATE OF PRODUCT REGISTRATION (CPR) – RE-APPLICATION (INITIAL APPLICATION DISAPPROVED FROM MODIFIED E-REGISTRATION VI.CERTIFICATE OF PRODUCT REGISTRATION (CPR) – RE-APPLICATION (INITIAL APPLICATION DISAPPROVED FROM MODIFIED E-REGISTRATION VI.CERTIFICATE OF PRODUCT REGISTRATION (CPR) – FOR EXPORT MARKET ONLY 	8 118 127 130 135 139
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CENTER FOR FOOD REGULATION AND RESEARCH

A. E-REGISTRATION PORTAL USER ACCOUNT

Center/Office/Division :	Center for Food Regulation and Research (CFRR)	
Classification :	Government to Business	
Type of Transaction :	Simple	
Who May Avail :	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)	
Fees to be Paid :	NONE	
	CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
GENERAL GUIDELINES		FDA Website
Please refer to:		
	. GUIDELINES, pages 5-6 of FDA Circular No. 2020-033 Procedure for the Use of the Modified	
5	em for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-	
014 "Procedure for the Use of	of Electronic Registration System for Prepackaged Processed Food Products"	
ISSUANCE OF CFRR E-RE	GISTRATION USER ACCOUNT	
☑ Send a request for a user	account to cfrr@fda.gov.ph	Applicant Company
SUBJECT: CFRR: E-Regist	ration	
BODY:		
Email Address:		
Last Name:		
First Name:		
Middle Name:		
Company Name:		
LTO No.:		
LTO validity:		





☑ The email must contain an attached scanned copy of notarized authorization letter (please see Annex B of <u>FDA Circular No.</u> <u>2020-033</u>) from a company with a valid License-to-Operate (LTO).	Applicant Company
CHANGE IN THE APPLICANT COMPANY'S REPRESENTATIVE	Applicant Company
Send a request for change in credentials of the CFRR E-Registration User Account to cfrr@fda.gov.ph	Applicant Company
SUBJECT: CFRR: E-Registration	
BODY:	
Email Address: Last Name: First Name: Middle Name: Company Name: LTO No.: LTO validity:	
☑ The email must contain an attached scanned copy of notarized Affidavit of Undertaking (please see Annex C of <u>FDA Circular</u> <u>No. 2020-033</u>) from a company with a valid License-to-Operate (LTO).	Applicant Company
RENEWAL OF USER ACCOUNT AT LEAST 90 DAYS PRIOR TO EXPIRATION	Applicant Company
Send a request for renewal of user account to cfrr@fda.gov.ph	Applicant Company
SUBJECT: CFRR: E-Registration	
BODY:	
Email Address: Last Name: First Name: Middle Name: Company Name: LTO No.: LTO validity:	





ISSUED USER ACCOUNT BY THE FDAC FOR E-LTO CAN BE REVALIDATED TO ACCESS E-REGISTRATION	Applicant Company
Send a request for revalidation of user account to cfrr@fda.gov.ph	Applicant Company
SUBJECT: CFRR: E-Registration	
BODY:	
Email Address:	
Last Name:	
First Name:	
Middle Name:	
Company Name: LTO No.:	
LTO validity:	
RETRIEVAL OF USER NAME AND/OR PASSWORD OF E-REGISTRATION ACCOUNT (IN CASES OF PROBLEMS WITH	Applicant Company
USER NAME AND/OR PASSWORD)	
Send a request for retrieval of user name and/or password to cfrr@fda.gov.ph	Applicant Company
SUBJECT: CFRR: E-Registration	
BODY:	
Email Address:	
Last Name:	
First Name:	
Middle Name:	
Company Name:	
LTO No.:	
LTO validity:	





CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1) The applicant company/ authorized representative submits	1) The FDA/CFRR Personnel checks the e-mail request.	3 Working Days	Food Drug Action Center (FDAC) or Center for Food Regulation and
required documents/information to the above-mentioned e-mail address.	If compliant, user name and password will be issued to the client, via e-mail.		Research (CFRR) STAFF
	Otherwise, the personnel will send an e-mail to the applicant company/authorized representative to request for lacking document(s) or clarify information.		
Please be advised that as per RA 11032 IRR, p indicated in the Citizen's Charter.	age 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the	e Act may be extended only once	for the same number of days, which shall be





B. CERTIFICATE OF PRODUCT REGISTRATION (CPR)

(COVERING ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS)

I. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – INITIAL/ RENEWAL DATA CAPTURE (REGULAR)/ AMENDMENT DATA CAPTURE/ RE-APPLICATION DATA CAPTURE

(DATA CAPTURE in the modified e-Registration System/Portal refers to applications processed in the old e-Registration Portal (Version 1) or thru manual registration system).

RENEWAL DATA CAPTURE (REGULAR) in the modified e-Registration System/Portal refers to applications processed in the old e-Registration Portal (Version 1) or thru manual registration system) which is not qualified to the General Guideline/s of AUTOMATIC RENEWAL.

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical
Who May Avail	:	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	:	In accordance to Administrative Order No. 50 s. 2001 + Legal Research Fee (LRF).
		Conventional Food (Category 1): Php 200.00/year of validity + 1% LRF
		Conventional Food (Category 2): Php 250.00/year of validity + 1% LRF
		Food Supplement: Php 1,000.00/year of validity + 1% LRF
		Bottled Water: Php 1,000.00/year of validity + 1% LRF





GENERAL GUIDELINES

Please refer to:

1) A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of <u>FDA Circular No. 2020-033</u> || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and

2) III. General Guidelines, and IV. Specific Guidelines of <u>FDA Circular No. 2020-033-A</u> || Addendum to FDA Circular 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food

CHECKLIST OF REQUIREMENTS

FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS

GENERAL REQUIREMENTS FOR APPLICATION OF CERTIFICATE OF PRODUCT REGISTRATION	BASIS/ISSUANCE	WHERE TO SECURE
☑ ANNEX D - REQUIREMENTS FOR APPLICATION OF CERTIFICATE OF PRODUCT REGISTRATION	Administrative Order No. 2014-0029	
 Accomplished Initial Application Form as prescribed by current FDA regulations. e.g. E-Registration System 	FDA Circular No.2020-033 FDA Circular No.2020-033-A	FDA Website
Proof of Payment of Fees as prescribed by FDA regulations. Please refer to the table <i>Fees to be Paid:</i>	Administrative Order No. 50 s. 2001	Systems/Means prescribed by FDA
☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations.	Administrative Order No. 2014-0030 Other existing FDA regulation/s with specific labelling requirement/s (e.g. Republic Act No. 8172 Republic Act No. 8976 and its IRR Department Circular No. 2008-0006 Bureau Circular No. 2 s. 1999 and etc.)	Applicant Company/ Manufacturer/Source/Supplier





☑ Pictures of the product in all angles and in different packaging sizes, and from at	Administrative Order No. 2014-0029	Applicant Company/
least two different perspectives allowing visual recognition of a product as the		Manufacturer/Source/Supplier
same with the one being registered, as applicable.		
☑ For FOOD SUPPLEMENT, a sample in actual commercial presentation shall be	Administrative Order No. 2014-0029	Applicant Company/
submitted.	FDA Circular No. 2020-033	Manufacturer/Source/Supplier
☑ As applicable, documents to substantiate claims, such as technical, nutritional or	Administrative Order No. 2014-0029	Applicant Company/
health studies or reports, market-research studies, Certificate of Analysis,	Administrative Order No. 2014-0030	Manufacturer/Source/Supplier
quantitative analysis and computations, scientific report or studies published in		
peer-reviewed scientific journals, certificates or certification to support use of		
logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with		
current labeling regulations.		
☑ VALID AND APPROPRIATE FDA LICENSE TO OPERATE (REQUIRED FOR	Administrative Order No. 2014-0029	FDA Philippines
ALL TYPES OF CPR APPLICATION)		
SOURCE DOCUMENTS		
For locally produced products:	FDA Circular No. 2020-033	Applicant Company/
☑ Distributorship Agreement or Contract Agreement signed by duly authorized	FDA Circular No. 2016-007	Manufacturer/Source/Supplier
representative of the establishment or Certificate of Distributorship or Appointment		
Letter or Memorandum of Agreement from each supplier.		
e.g.		
For WHOLESALER:		
Valid, notarized, and duly signed Distributorship Agreement or Memorandum of		
Agreement		
For TRADER:		
Valid, notarized, and duly signed Toll Manufacturing Agreement		
For imported products:	FDA Circular No. 2020-033	Applicant Company/
Distributorship Agreement or Contract Agreement signed by duly authorized	FDA Circular No. 2016-007	Manufacturer/Source/Supplier
representative of the establishment or Foreign Agency Agreement, Certificate of		
Distributorship or Appointment Letter or Proforma Invoice or Memorandum of		
Agreement from each supplier; and		
Scanned copy of ANY of the following original and valid documents issued to the		





source by the regulatory or health authority i) Valid manufacturer's certificate of registra (GMP) compliance or its equivalent; or ii) Valid Sanitary Phytosanitary Certificate/ iii) Valid ISO 22000 Certification/FSSC Cert iv) Valid Hazard Analysis and Critical Cont v) Certificate of Free Sale (CFS issued by by recognized Association or duly authenti the country of origin) USE AND DECLARATION OF BRAND NA artworks, applicable to Raw Materials, Low Broducts: or as applicable (ONLX WHENT	ation with Good Manufacturing Practices Health Certificate; or rtificate; or rol Point (HACCP) Certificate; or the Regulatory/Health Authority attested cated by the Philippine Consulate from ME on the submitted loose labels or r Risk, Medium Risk and High Risk Food		
 Products; or as applicable (ONLY WHEN I Materials and For Institutional Use Only. Affidavit of undertaking (a) to change the proper authority decides with finality that he utilize said brand name; and (b) to acknow 	e brand name so submitted should the e/she/it has no right to appropriate and ledge and agree to indemnify and/or	Administrative Order No. 2005-0016	Applicant Company
 hold BFAD (FDA) free and harmless again from the acceptance of such brand name of (FDA). ☑ Authorization Letter or equivalent certific 	of the product for registration with BFAD	Administrative Order No. 2005-0016	Brand Name Owner
(legally binding) for the use of Brand Name registered with the CFRR-FDA. Refer to: F ADDITIONAL REQUIREMENT/S PER FO	which is identical to those already DA Verification Portal	Administrative Order No. 2014-0030	
RAW MATERIALS FOOD CATEGORIES	☑ ADDITIONAL REQUIREMENT/S	BASIS/ISSUANCE	WHERE TO SECURE
RAW MATERIALS - all substances that are employed in the processing of a finished product, packed in bulk containers and not labelled as finished product. Raw materials or ingredients would have product specifications that	As applicable, certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations.	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier





comply with the client requirements and			
not necessarily a single component.			
RM01 – Fats, Oils and Fat Emulsions e.g. Cooking Oils (Coconut, Palm, Soybean and Corn)	☑ Valid Certificate of Analysis for Vitamin A fortificant used for COOKING OILS (e.g.Coconut, Palm, Soybean and Corn)	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier
	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).		
RM02 - Processed Fruits, Vegetable and Edible Fungi, Seaweeds and Nuts	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	
RM03 - Confectionery	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through	Administrative Order No. 2014-0029	





	declaration in the E-Registration data entry (e.g. under Product Specifications).		
RM04 - Cereals	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	
RM05 - Bakery Wares and Bakery Related Products e.g. Wheat Flour	 Valid Certificate of Analysis for Vitamin A and Iron fortificant used for WHEAT FLOUR *Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications). 	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier
RM06 - Sweeteners including Honey e.g. Refined Sugar, Brown Sugar, Cane Sugar	✓ Valid Certificate of Analysis for Vitamin A fortificant used for REFINED SUGAR	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier
	*Finished food products in bulk intended for further processing shall		





	conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).		
RM07 - Salt, Spices, Soups, Sauces, Salads and Protein Products e.g. lodized Salt, Soy Sauce	☑ Valid Certificate of Analysis for lodine Content used for IODIZED SALT	Republic Act No. 8172 FDA Circular No. 2013-007	Applicant Company/ Manufacturer/Source/Supplier
	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).		
	Valid Certificate of Analysis for 3MCPD content of SOY SAUCE	FDA Memorandum No. 2011-028	Applicant Company/ Manufacturer/Source/Supplier
RM08 - Beverages (excluding Dairy Products) Non-Alcoholic	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).		Applicant Company/ Manufacturer/Source/Supplier





RM09 - Beverages (excluding Dairy Products) Alcoholic	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Applicant Company/ Manufacturer/Source/Supplier
RM10- Dairy products and Analogues	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Applicant Company/ Manufacturer/Source/Supplier
RM11- Frozen Desserts	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Applicant Company/ Manufacturer/Source/Supplier
RM12 - Processed Fish and Fish Products Including Molluscs, Crustaceans and Echinoderms	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-	Applicant Company/ Manufacturer/Source/Supplier





	Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	
RM13 - Herbal Products	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Applicant Company/ Manufacturer/Source/Supplier
RM14 - Vitamins and Minerals	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Applicant Company/ Manufacturer/Source/Supplier
RM15 - Products with Nutritional Substances	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data	Applicant Company/ Manufacturer/Source/Supplier





	entry (e.g. under Product Specifications).	
RM16 - Food Additives	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Applicant Company/ Manufacturer/Source/Supplier
RM17 - Edible Casings (except natural casings from animal sources)	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Applicant Company/ Manufacturer/Source/Supplier
RM18 - Processed Meat and Meat Products, including poultry and game	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low- Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Applicant Company/ Manufacturer/Source/Supplier





LOW RISK FOOD PRODUCTS	☑ ADDITIONAL REQUIREMENT/S	BASIS/ISSUANCE	WHERE TO SECURE
LOW RISK FOOD PRODUCTS - foods that are unlikely to contain pathogenic microorganisms and will not normally support their growth because of food characteristics and foods that are unlikely to contain harmful chemicals.			
A1 - Butter oil, anhydrous milkfat, ghee	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: %Milk Fat by weight; % Milk Solids not fat by weight; % water by weight; Salt (optional) for BUTTER (Whipped, Pasteurized)	Administrative Order 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: %Milk Fat by weight; % Milk Solids not fat by weight; % water by weight; Salt (optional) for WHEY BUTTER	Administrative Order 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	 ☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: % Fat; % Moisture for MARGARINE 	Administrative Order No. 232 s. 1974	Applicant Company/ Manufacturer/Source/Supplier





	*The product shall conform with the standards for optional ingredients and additional label declaration for MARGARINE.		
A2 - Vegetable Oils and Fats e.g. Coconut, Palm, Soybean and Corn	 Valid Certificate of Analysis for Vitamin A fortificant (in mg RE/L) used for COOKING OILS (e.g. Coconut, Palm, Soybean and Corn) *The specific form of Vitamin A fortificant used (e.g. Retinol Palmitate) shall be declared in the Electronic Registration Data Entry. 	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier
A3 - Animal Fats	 In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Saponification Value; Iodine Value for LARD 	Administrative Order No. 231 s. 1974	Applicant Company/ Manufacturer/Source/Supplier
A4 - Fat emulsions mainly of type oil- in-water			
e.g. Imitation milk - a fat-substituted milk produced from nonfat milk solids by addition of vegetable fats (coconut, safflower or corn oil), non-dairy whipped cream, non-dairy toppings and vegetable cream			
A5 - Fat emulsions mainly of type water-in-oil			





A6 - Fat-based desserts excluding			
dairy-based desserts			
e.g. Ice cream like product made			
with vegetable fats			
B1 - Dehydrated fruits or vegetables,			
including candied fruits			
		Administrative Order No. 220 a. 1075	Applicant Company/
B2 - Jams, jellies, marmalades	 In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Soluble Solids for JELLY/JELLIES *The product shall conform with the standard of quality and additional label declaration for JELLY/JELLIES. 	Administrative Order No. 239 s. 1975	Applicant Company/ Manufacturer/Source/Supplier
	 ☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Soluble Solids for PRESERVES OR JAMS *The product shall conform with the standard of quality and additional label declaration for PRESERVES OR JAMS. 	Administrative Order No. 238 s. 1975	Applicant Company/ Manufacturer/Source/Supplier
B3 - Dehydrated vegetable protein products			
B4 - Fruits or Vegetables in vinegar, oil or brine			





Note: Fruits or vegetables in		
vinegar, oil or brine in canned, bottled or		
hermetically sealed containers must be		
file under Medium Risk Food Product -		
MRC3		
B5 - Fruit-based spreads excluding		
jams, jellies and marmalades		
e.g. Apple butter, lemon curd,		
mango chutney, raisin chutney		
B6 - Fruit Preparations		
e.g. fruit pulp, purees, fruit toppings,		
fruit sauce, fruit syrup, coconut milk and		
cream		
B7 - Cooked fruits		
e.g. Baked apples, fried apple rings,		
peach dumplings (baked peaches with a		
sweet dough covering		
B8 - Frozen vegetables, seaweeds,		
and nuts and seeds		
B9 - Vegetable seaweeds, nut and		
seed in pulps and preparations other		
than food in HR Letter B2		
e.g. Aloe extract, potato pulp,		
horseradish pulp		
B10 - Cooked or fried vegetables and		
seaweeds		
C1 - Confectionery		
e.g. Includes all types of products		
that mainly contain sugar and other		
dietetic counterparts and may or may not		





contain cocoa (e.g. Hard candy, soft			
candy, nougats and marzipans			
C2 - Chewing gum			
C3 - Decorations, toppings (non-fruit),			
and sweet sauces			
e.g. Ready-to-eat icings and			
frostings for cakes, cookies etc, maple,			
caramel and flavoured syrups			
D1 - Flour, starches (including	☑ Valid Certificate of Analysis for	Republic Act No. 8976	Applicant Company/
soybean powder) and flour mixes	Vitamin A fortificant (in mg/kg as	Implementing Rules and Regulation of	Manufacturer/Source/Supplier
e.g. Wheat flour, corn flour, bran	retinol) and Iron fortificant (in mg Fe/kg)	Republic Act No. 8976	
	used for WHEAT FLOUR		
	*The specific form of Vitamin A		
	fortificant used (e.g. Retinol Palmitate)		
	and Iron fortificant used (e.g. Elemental		
	Iron, Ferrous Sulfate, Ferrous		
	Fumarate) shall be declared in the		
	Electronic Registration Data Entry.		
D2 - Breakfast cereals including rolled			
oats			
e.g. granola type breakfast cereals,			
corn flakes, multi-grain			
D3a - Fresh pastas and noodles and			
like products			
e.g. Unboiled noodles, lumpia			
wrapper			
D3b - Dried pastas and noodles and			
like products			
e.g. spaghetti pasta, bean			





vermicelli, rice vermicelli, macaroni, rice noodles			
D3c - Pre-cooked pastas and noodles and like products e.g. Instant noodles			
D4 - Cereal and starch-based desserts e.g. rice pudding, tapioca pudding			
D5 - Batters e.g. for breading or batters for fish or poultry			
D6 - Pre-cooked or processed rice products e.g. Prepackaged Rice in Retail Size, Iron Rice Premix	 Valid Certificate of Analysis for Iron fortificant (in mg Fe/kg) used for RICE *The specific form of Iron fortificant used (e.g. Ferrous Sulfate) shall be declared in the Electronic Registration Data Entry. 	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier
	 Valid Certificate of Analysis for Iron Content (in mg iron (Fe)/100g) and Moisture Content for IRON RICE PREMIX *The specific form of Iron fortificant used (e.g. Ferrous Sulfate) shall be declared in the Electronic Registration Data Entry. **The product shall conform with the Composition and Quality Factors for Iron Rice Premix 	FDA Circular No. 2007-010-A	Applicant Company/ Manufacturer/Source/Supplier
D7a - Soybean based beverages			





D7b - Soybean based film		
e.g. Fuzhu - asian food which is a		
protein–lipid film isolated from soymilk		
surface through high-temperature		
incubation		
D7c - Soybean curd (tofu)		
D7d - Semi-dehydrated soybean curd		
D7e - Dehydrated soybean curd		
D7f - Other soybean protein products		
e.g. Soy-based "chicken" meat		
F1a - Breads and rolls - yeast leavened		
breads and specialty breads, soda		
breads		
e.g. White bread, raisin bread,		
whole wheat bread, hamburger rolls,		
hotdog buns		
F1b - Crackers excluding sweet		
crackers		
F1c - Other ordinary bakery products		
e.g. Bagels, pita, English muffins		
F1d - Bread-type products, including		
bread stuffing and bread crumbs		
e.g. Croutons		
F1e - Steamed bread and buns		
e.g. Mantou		
F1f - Mixes for bread and ordinary		
bakery wares		
e.g. French bread mix, ciabatta mix		
F2 - Fine bakery wares and mixes -		
Mixes for fine bakery wares		





G1 - Refined and raw sugars	☑ Valid Certificate of Analysis for	Republic Act No. 8976	Applicant Company/
e.g. Refined Sugar, Raw Cane Sugar	Vitamin A fortificant used for REFINED SUGAR	Implementing Rules and Regulation of Republic Act No. 8976	Manufacturer/Source/Supplier
G2 - Brown Sugar			
G3 - Sugar solutions and syrups e.g. Maple Syrup, Vanilla Syrupm Flavoured Syrups			
G4 - Other sugars and syrups including coconut sugar e.g. Coloured sugar crystals for cookies			
G5- Honey			
G6- Table-top sweeteners, including those containing high-intensity sweeteners			
I1 - Salt and Salt substitutes	 Valid Certificate of Analysis for Iodine Content for SALT, ROCK SALT, SEA SALT (Excluding Himalayan Pink Salt, Gourmet Salt) * "All food manufacturers processors using food-grade salt are also required to use iodized salt in the processing of their products and must comply with the provisions of this Act not later than one (1) year from its effectivity. Provided, That the use of iodized salt shall not prejudice the quality and safety of their food products: Provided, however, That the burden of proof and testing for any prejudicial effects due to 	Republic Act No. 8172 FDA Circular No. 2013-007	Applicant Company/ Manufacturer/Source/Supplier





	iodized salt fortification lies on the said food manufacturers/processor." – RA No. 8172		
I2 - Herbs, spices, seasonings and condiments			
I3 - Vinegars	 In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: % Acidity; % Total Solids; % Ash; Lead Content; Copper Content and Arsenic Content; *Additional for Malt Vinegar: Phosphorus Pentoxide and Nitrogen Contents for VINEGAR 	Administrative Order No. 134 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
I4 - Mustards			
I5 - Soups and broths e.g. Mixes for soup and broths - bouillon powders and cubes			
I6a - Mixes for sauces and gravies			
I6b - Clear Sauces (Fish Sauce)	 In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Specific Gravity; Total Solids; Salt Content; Protein Content for PATIS 	Administrative Order No. 325 s. 1977	Applicant Company/ Manufacturer/Source/Supplier
I7 - Yeast and like products			
I8a - Fermented Soybean Paste (e.g. Miso)			





I8b- Soybean Sauce	✓ Valid Certificate of Analysis for 3- MCPD for SOY SAUCE	FDA Memorandum 2011-028	Applicant Company/ Manufacturer/Source/Supplier
I9- Protein products other than from soybeans, marinades e.g. Vegetable Protein Analogues			
J1a - Non-alcoholic (soft) beverages without herbal ingredients e.g. Roasted coffee beans, coffee	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological,	Administrative Order No. 136-A s. 1985	Applicant Company/ Manufacturer/Source/Supplier
grounds, Freeze-dried coffee	declare the results (under specification) for the following Parameters: Moisture Content (%w/w); Caffeine (%w/w dry basis); Ash (%w/w dry basis; Water- insoluble Solids (%w/w, dry basis); pH; Solubility; Sensory Attributes; Arsenic Content; Lead Content for INSTANT COFFEE	Administrative Order No. 136-B s. 1985	Applicant Company/ Manufacturer/Source/Supplier
J1b - Non-alcoholic (soft) beverages with herbal ingredients e.g. Green Tea, Chamomile Tea			
J2a - Beer and Malt Beverages	For IMPORTED ALCOHOLIC BEVERAGES: a) Technical specifications of raw materials and	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
	finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b)	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
J2b - Cider and Perry			





J2c - Grape Wines e.g. Still grape wine, sparkling and semi- sparkling grape wines, fortified grape wine, grape liquor wine, sweet grape wine, red wine, white wine, rose wine	✓ For IMPORTED ALCOHOLIC BEVERAGES: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b)	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
	✓ For LOCALLY MANUFACTURED ALCOHOLIC BEVERAGE: a) Technical specifications of raw materials and finished product (including methanol content); b) source of ethyl alcohol, used as raw material for compounded alcoholic beverages	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
J2d - Wines other than grape e.g. Fruit wine, rice wine	✓ For IMPORTED ALCOHOLIC BEVERAGES: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b)	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
	✓ For LOCALLY MANUFACTURED ALCOHOLIC BEVERAGE: a) Technical specifications of raw materials and finished product (including methanol content); b) source	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier





	of ethyl alcohol, used as raw material for compounded alcoholic beverages		
J2e - Mead e.g. Honey wine	☑For IMPORTED ALCOHOLIC BEVERAGES: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b)	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
	✓For LOCALLY MANUFACTURED ALCOHOLIC BEVERAGE: a) Technical specifications of raw materials and finished product (including methanol content); b) source of ethyl alcohol, used as raw material for compounded alcoholic beverages	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
J2f - Distilled spirituous beverages (>15%alcohol) e.g. Brandy, whisky, rhum, tequila, vodka	✓ For IMPORTED ALCOHOLIC BEVERAGES: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b)	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
	✓ For LOCALLY MANUFACTURED ALCOHOLIC BEVERAGE: a) Technical specifications of raw	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier





	1		
	materials and finished product (including methanol content); b) source of ethyl alcohol, used as raw material for compounded alcoholic beverages		
J2g - Aromatized alcoholic beverages e.g. Aperitif wine	✓ For IMPORTED ALCOHOLIC BEVERAGES: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b)	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
	✓ For LOCALLY MANUFACTURED ALCOHOLIC BEVERAGE: a) Technical specifications of raw materials and finished product (including methanol content); b) source of ethyl alcohol, used as raw material for compounded alcoholic beverages	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
K1 - Snacks - potato - cereal - or starch-based (from roots and tubers, pulses and legumes) e.g. Corn chips, crunchies, potato chips			
K2 - Chicharon e.g. Pork chicharon, mushroom chicharon			
K3 - Snacks - fish-based e.g. Fish Crackers, dried fish chips			





☑ ADDITIONAL REQUIREMENT/S	BASIS/ISSUANCE	WHERE TO SECURE
 ✓ Valid Certificate of Analysis for % Total Milk Solids and % Milk Fat for EVAPORATED MILK, EVAPORATED WHOLE MILK, EVAPORATED FULL CREAM MILK, UNSWEETENED CONDENSED WHOLE MILK, UNSWEETENED FULL CREAM CONDENSED MILK 	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
 ✓ Valid Certificate of Analysis for % Total Milk Solids and % Milk Fat for SWEETENED CONDENSED MILK, SWEETENED CONDENSED WHOLE MILK, SWEETENED FULL CREAM CONDENSED MILK *The product shall conform with the standards for optional ingredients and additional label declaration for 	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	 ✓ Valid Certificate of Analysis for % Total Milk Solids and % Milk Fat for EVAPORATED MILK, EVAPORATED WHOLE MILK, EVAPORATED FULL CREAM MILK, UNSWEETENED CONDENSED WHOLE MILK, UNSWEETENED FULL CREAM CONDENSED MILK ✓ Valid Certificate of Analysis for % Total Milk Solids and % Milk Fat for SWEETENED CONDENSED MILK, SWEETENED CONDENSED MILK, SWEETENED CONDENSED MILK, SWEETENED CONDENSED WHOLE MILK, SWEETENED FULL CREAM CONDENSED MILK *The product shall conform with the standards for optional ingredients and 	✓ Valid Certificate of Analysis for % Total Milk Solids and % Milk Fat for Administrative Order No. 132 s. 1970 EVAPORATED MILK, EVAPORATED WHOLE MILK, EVAPORATED FULL CREAM MILK, UNSWEETENED CONDENSED WHOLE MILK, UNSWEETENED FULL CREAM CONDENSED MILK Administrative Order No. 132 s. 1970 I Valid Certificate of Analysis for % Total Milk Solids and % Milk Fat for SWEETENED CONDENSED MILK, SWEETENED CONDENSED MILK, SWEETENED CONDENSED WHOLE MILK, SWEETENED FULL CREAM CONDENSED MILK Administrative Order No. 132 s. 1970 * The product shall conform with the standards for optional ingredients and additional label declaration for Sweetened Condensed Milk, Administrative Order No. 132 s. 1970





Sweetened Full Cream Condensed Milk. Valid Certificate of Analysis for % Milk Solids for EVAPORATED	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
SKIMMED MILK, UNSWEETENEDCONDENSED SKIMMED MILK✓ Valid Certificate of Analysis for %Milk Solids for SWEETENEDCONDENSED SKIMMED MILK	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
 Valid Certificate of Analysis for Milk Fat and % Solids-Not-Fat for RECONSTITUTED, RECONSTRUCTED OR RECOMBINED EVAPORATED MILK *The product shall conform with the standards for optional ingredients and additional label declaration for Reconstituted, Reconstructed or Recombined Evaporated Milk. 	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
 ✓ Valid Certificate of Analysis for % Milk Fat and % Solids-Not-Fat for RECONSTITUTED, RECONSTRUCTED OR RECOMBINED SWEETENED CONDENSED MILK 	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
☑ Valid Certificate of Analysis for % Milk Solids for RECONSTITUTED, RECONSTRUCTED OR	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier





RECOMBINED EVAPORATED SKIMMED MILK		
✓ Valid Certificate of Analysis for % Non-Fat Milk Solids, Vitamin A and Vitamin D (if added) for EVAPORATED FILLED MILK	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
*The % Total Oil Content shall be declared in the Electronic Registration Data Entry. **The product shall conform with the identity, standards for optional ingredients and additional label declaration for Evaporated Filled Milk.		
 ✓ Valid Certificate of Analysis for % Non-Fat Milk Solids, Vitamin A and Vitamin D (if added) for SWEETENED CONDENSED FILLED MILK *The % Total Oil Content shall be declared in the Electronic Registration Data Entry. **The product shall conform with the identity, standards for optional ingredients and additional label declaration for Sweetened Condensed Filled Milk. 	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
✓ Valid Certificate of Analysis for Microbiological parameters for SWEETENED CONDENSED	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	MILK: Coliforms CFU/g, Yeast & Mold Count CFU/g & SPC/APC CFU/g		
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012		
	☑ Valid Certificate of Analysis for Microbiological parameters for		
	SWEETENED CONDENSED MILK: Coliforms CFU/g, Yeast & Mold Count CFU/g & Aerobic Plate Count CFU/		
	 ✓ Valid Certificate of Analysis for Microbiological parameters for LIQUID MILK (EVAPORATED): Commercial Sterility 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for LIQUID MILK (EVAPORATED) : Commercial Starility		
A1b - Beverage whiteners (Includes condensed milk analogues, blends of evaporated skimmed milk and	Sterility		
vegetable fat and blends of sweetened condensed skimmed milk and vegetable fat) e.g. Condensed creamer			





A2 - Milk powder and cream powder and powder analogues (plain) e.g. imitation dry cream mix and blends of skimmed milk and vegetable fat in powdered form	✓ Valid Certificate of Analysis for % Milk Solids, % Milk Fat and % Water for WHOLE MILK POWDER (DRIED FULL CREAM MILK, FULL CREAM MILK POWDER, DRY WHOLE MILK, MILK POWDER, DRIED MILK)	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	✓ Valid Certificate of Analysis for % Solids, % Fat and % Water for SKIMMED MILK POWDER	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	✓ Valid Certificate of Analysis for % Milk Solids, % Milk Fat and % Water for PARTLY SKIMMED MILK POWDER	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Fat and Moisture Content for MALTED MILK POWDER	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	✓ Valid Certificate of Analysis for % Butterfat, % Total Milk Solids and Moisture Content for BUTTERMILK POWDER (DRIED BUTTERMILK)	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	 ✓ Valid Certificate of Analysis for Microbiological parameters for MILK POWDER (E.G. WHOLE, NONFAT, FILLED MILK, BUTTERMILK, WHEY & WHEY PROTEIN AND MILK INTENDED FOR CHILDREN MORE THAN 36 MONTHS OF AGE AND ADULTS): Salmonella/25g, SPC/APC CFU/g & Enterobacteriaceae CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for MILK POWDER (e.g. WHOLE, NONFAT, FILLED MILK, BUTTERMILK, WHEY & WHEY PROTEIN AND MILK INTENDED FOR CHILDREN MORE THAN 36 MONTHS OF AGE AND ADULTS): Salmonella/25g		
A3 - Milk products for specific age groups or target population e.g. Powdered milk for children above 3 years and pregnant women	 Valid Certificate of Analysis for Microbiological parameters for MILK POWDER (E.G. WHOLE, NONFAT, FILLED MILK, BUTTERMILK, WHEY & WHEY PROTEIN AND MILK INTENDED FOR CHILDREN MORE THAN 36 MONTHS OF AGE AND ADULTS): Salmonella/25g, SPC/APC CFU/g & Enterobacteriaceae CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for MILK POWDER (e.g. WHOLE, NONFAT, FILLED MILK, BUTTERMILK, WHEY & WHEY PROTEIN AND MILK INTENDED FOR CHILDREN MORE 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	THAN 36 MONTHS OF AGE AND ADULTS): Salmonella/25g		
	Valid Certificate of Analysis to support Nutrition Information declaration on the label	Administrative Order No. 2014-0029 Administrative Order No. 2014-0030	Applicant Company/ Manufacturer/Source/Supplier
B1 - Non-Dairy based frozen desserts e.g. Sherbet, sorbet	 ✓ Valid Certificate of Analysis for Microbiological parameters for ICE CREAM & SHERBET (PLAIN AND FLAVORED): Coliforms CFU/g, Listeria monocytogenes/25g, Salmonella/25g, SPC/APC CFU/g & S. aureus (coagulase +) CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for ICE CREAM & SHERBET (PLAIN AND FLAVORED): Coliforms CFU/g, Listeria monocytogenes/25g, Salmonella/25g, Aerobic Plate Count CFU/g & S. aureus CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 ✓ Valid Certificate of Analysis for Microbiological parameters for ICE CREAM WITH ADDED INGREDIENTS (NUTS, FRUITS, COCOA ETC.): Coliforms CFU/g, Listeria monocytogenes/25g, Salmonella/25g, SPC/APC CFU/g & S. aureus (coagulase +) CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for ICE CREAM WITH ADDED INGREDIENTS (NUTS, FRUITS, COCOA ETC.): Coliforms CFU/g, S. aureus CFU/g, Salmonella/25g, Aerobic Plate Count CFU/g & Listeria monocytogenes/25g		
B2 - Edible ices - popsicles e.g. Ice candy, ice popsicles	 Valid Certificate of Analysis for Microbiological parameters for FLAVORED ICE: SPC/APC cfu/g, Coliforms MPN/g, YMC cfu/g & Salmonella/25g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for FLAVORED ICE: Aerobic Plate Count CFU/g, Coliforms MPN/g or CFU/g or /25g, Yeast and Mold Count CFU/g & Salmonella/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
C1 - Tomato products e.g. Tomato Catsup, tomato sauce, tomato paste	✓ Valid Certificate of Analysis for Total Soluble Solids, Specific Gravity, Total Acidity in terms of acetic acid, Arsenic Content, Lead Content, Copper Content, Zinc Content and Tin Content for TOMATO CATSUP	Administrative Order No. 233 s. 1974	Applicant Company/ Manufacturer/Source/Supplier





	*The product shall conform with the identity and standard of quality of Tomato Catsup.		
C2 - Frozen fruits e.g. frozen fruit salad and frozen strawberries	 ✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN FRUITS: E. coli MPN/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN FRUITS (pH >4.5): E. coli CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
C3 - Canned or bottled (pasteurized) or retort pouch fruit and vegetable preserve in juice, syrup, brine e.g. Mushroom whole in brine, Lychee in heavy syrup, Pitted green olives in brine	 Valid Certificate of Analysis for Microbiological parameters for FRUITS AND VEGETABLE PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for FRUITS AND VEGETABLE PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
C4 - Fruit-based desserts, gelatin e.g. fruit-flavoured gelatin, rote gruze,			





frutgrod, fruit compote, nata de coco, and			
mitsumame (gelatin-like dessert of agar			
jelly, fruit pieces and syrup			
C5 - Fermented fruit products			
e.g. fermented plums			
C6 - Fruit fillings for pastry			
e.g. Cherry pie filling and raisin filling for			
oatmeal cookies			
C7 - Fermented vegetable products	Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
and seaweed products, excluding	Microbiological parameters for	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
fermented soybean products MR	FERMENTED VEGETABLE (READY		
Letter E.1 and E.2 (fermented	TO EAT): YMC CFU/g, Coliforms		
soybeans and fermented soybean	MPN/g, E. coli MPN/g, Salmonella/25g		
curd) and LR Letters I.8.b. 1 to 3)	& S.aureus CFU/g		
(soybean sauces)			
e.g. red pepper paste, fermented	Or upon effectivity of FDA Circular No.		
vegetable products, kimchi (fermented	<u>2022-012</u>		
Chinese cabbage and vegetable	☑ Valid Certificate of Analysis for		
preparation), and sauerkraut (fermented	Microbiological parameters for		
cabbage	FERMENTED VEGETABLE (READY		
	TO EAT) : Yeast and Mold Count cfu/g,		
	Coliforms MPN/g or CFU/g or /25g, E.		
	coli MPN/g or CFU/g or /25g,		
	Salmonella/25g & S. aureus cfu/g		
C8 - Vegetable protein products			
(canned and frozen)			
D - Cocoa products and chocolate	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
products	Microbiological parameters for COCOA	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
e.g bonbons, cocoa butter confectionery	POWDER: Molds CFU/g,		
(composed of cocoa butter, milk solids	Salmonella/25g, Coliforms, MPN/g &		
and sugar), white chocolate, chocolate	SPC/APC CFU/g		
		I	1





chips (e.g. for baking), milk chocolate, cream chocolate, sweet chocolate, bitter chocolate, enrobing chocolate, chocolate covered in a sugar-based "shell" or with coloured decorations, filled chocolate (chocolate with a texturally distinct center and external coating, cocoa based	Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for COCOA POWDER : Molds CFU/g, Salmonella/25g, Coliforms, MPN/g or CFU/g & Aerobic Plate Count CFU/g		
spreads, tablea, imitation chocolate, chocolate substitute products)	 Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE PRODUCTS/CONFECTIONARIES: Molds CFU/g, Salmonella/25g, Coliforms MPN/g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE PRODUCTS: Molds CFU/g, Salmonella/25g, Coliforms MPN/g or CFU/g & Aerobic Plate Count CFU/g. Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE CONFECTIONARIES: Molds CFU/g, Osmophilic yeast CFU/g, Salmonella/25g, Coliforms MPN/g or CFU/g & Aerobic Plate Count CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





 E1 - Fermented soybeans e.g. dou chi (China), natto (Japan), and tempe (Indonesia) E2 - Fermented soybean curd F1ai - Cured (including salted) non- 	 ✓ Valid Certificate of Analysis for 	FDA Circular No. 2013-010	Applicant Company/
heat treated processed meat, poultry and game products in whole pieces or cuts e.g. bacon (cured, dry-cured, immersion- cured, pump-cured); side bacon; corned beef; marinaded beef; and different types of Oriental pickled products: miso-pickled meat (miso-zuke), koji-pickled meat (koji-	Microbiological parameters for PACKAGED COOKED, CURED/SALTED MEAT: S. aureus (coagulase +) CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u>	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
zuke), and soy sauce-pickled meat (shoyu-zuke)	 ✓ Valid Certificate of Analysis for Microbiological parameters for PACKAGED COOKED, CURED/SALTED MEAT (HAM, BACON): S. aureus CFU/g, Salmonella/25g & Listeria monocytogenes/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Nitrate and/or Nitrite Content (if utilized)	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	Applicant Company/ Manufacturer/Source/Supplier
F1aii - Cured (including salted) and dried non-heat treated processed meat, poultry and game products in whole pieces or cuts e.g. dried salt pork, dehydrated meat, stuffed loin, Iberian ham, and prosciutto- type ham	 ✓ Valid Certificate of Analysis for Microbiological parameters for PACKAGED COOKED, CURED/SALTED MEAT: S. aureus (coagulase +) CFU/g, Salmonella/25g & Listeria monocytogenes/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for PACKAGED COOKED, CURED/SALTED MEAT (HAM, BACON) : S. aureus CFU/g, Salmonella/25g & Listeria monocytogenes/25g	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 Valid Certificate of Analysis for Nitrate and/or Nitrite Content (if utilized) 	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	Applicant Company/ Manufacturer/Source/Supplier
F1aiii - Fermented non-heat treated			
processed meat, poultry and game			
products - processed meat in whole pieces or cuts			
e.g. potted beef and pickled			
(fermented) pig's feet			
F2ai - Cured (including salted) non-			
heat treated processed comminuted			
meat, poultry and game products			
e.g. chorizos (spicy pork sausages),			
salami-type products, salchichon, tocino			
(fresh, cured sausage), pepperoni, and			
smoked sausage. F2aii - Cured (including salted) and		FDA Circular No. 2022-012	Applicant Company/
dried non-heat treated processed	upon effectivity of <u>FDA Circular No.</u>		Manufacturer/Source/Supplier
comminuted meat, poultry and game	2022-012		
products (jerky, shredded beef/pork)	☑ Valid Certificate of Analysis for		
e.g. pasturmas, dried sausages, cured	Microbiological parameters for DRIED ANIMAL PRODUCTS: S. aureus		
and dried sausages, beef jerky, Chinese	ANIMAL PRODUCTS: 5. aureus		





sausages (including traditional cured or smoked pork sausage), and sobrasada	CFU/g, Clostridium perfringens CFU/g and Salmonella/25		
F2aiii - Fermented non-heat treated processed comminuted meat, poultry and game products e.g. pre-grilled beef patties; foie gras and pates; brawn and head cheese; cooked, cured chopped meat; chopped meat boiled in soy sauce (tsukudani); canned corned beef; luncheon meats; meat pastes; cooked meat patties; cooked salami-type products; cooked meatballs; saucises de strasbourg; breakfast sausages; brown-and-serve sausages; and terrines (a cooked chopped meat mixture).	 ☑ Certificate of Analysis for Microbiological parameters for FERMENTED, COMMINUTED MEAT, NOT COOKED (DRY & SEMI-DRY FERMENTED SAUSAGES): E. coli MPN/g, S. aureus (coagulase +) cfu/g & Salmonella/25g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for FERMENTED, COMMINUTED MEAT, NOT COOKED (DRY & SEMI-DRY FERMENTED SAUSAGES): E. coli MPN/g, S. aureus CFU/g & Salmonella/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Valid Certificate of Analysis for Nitrate and/or Nitrite Content (if utilized)	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	Applicant Company/ Manufacturer/Source/Supplier
H1a - Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans and echinoderms (e.g. salted anchovies, shrimp, and shad; smoked chub, cuttlefish and octopus; fish ham; dried and salted species of the Gadidae species; smoked or salted fish paste and fish roe; cured and smoked sablefish, shad, and salmon; dried	upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for ETHNIC FOOD PRODUCTS - DRIED, SALTED FISH: Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g, Coliforms MPN/g, E. coli MPN/g and S. aureus MPN/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





shellfish, dried bonito (katsuobushi), and boiled, dried fish (niboshi)	 Valid Certificate of Analysis for Microbiological parameters for SMOKED FISH: Aerobic Plate Count CFU/g, Salmonella/25g, E. coli MPN/g and S. aureus CFU/g Valid Certificate of Analysis for Microbiological parameters for SALT FERMENTED FISH AND SHRIMPS (BAGOONG): Aerobic Plate Count CFU/g and Coliforms CFU/g 	
H2a - Fish and fish products, includings molluscs, crustaceans and		
echinoderms - marinated and/or in		
jelly		
e.g. "rollmops" (a type of marinated		
herring), sea eel (dogfish) in jelly and fish		
aspic		
H2b - Fish and fish products,		
includings molluscs, crustaceans and		
echinoderms - pickled and/or in		
MH2brine		
e.g. different types of Oriental pickled		
products: koji-pickled fish (koji-zuke),		
lees-pickled fish (kasu-zuke), miso-		
pickled fish (miso-zuke), soy sauce-		
pickled fish (shoyu-zuke), and vinegar- pickled fish (su-zuke); pickled whale		
meat; and pickled herring and sprat		
H2c - Salmon substitutes, caviar and		
other fish roe products		





e.g. salted salmon roe (sujiko),			
processed, salted salmon roe (ikura), cod			
roe, salted cod roe (tarako) and lumpfish			
caviar			
H2d - Semi-preserved fish and fish			
products, including molluscs,			
crustaceans and echinoderms,			
excluding products under MR Letter			
H.1 a to c.			
e.g. fish or crustacean pates and			
traditional Oriental fish paste			
I1 - Preserved eggs, including alkaline,			
salted and canned eggs (salted eggs,			
century eggs)			
e.g. salt-cured duck eggs (Hueidan),			
and alkaline treated "thousand-year-old-			
eggs" (pidan)			
I2 - Egg-based desserts			
e.g. flan and egg custard. Also			
includes custard fillings for fine bakery			
wares (e.g. pies)			
Ja - Cakes, cookies, pies pastries,	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
doughnuts, sweet rolls, scones,	Microbiological parameters for BAKED	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
muffins, waffles - plain/without filling	GOODS: S. aureus (coagulase +)		
e.g. pancakes, waffles, filled sweet	CFU/g, MYC CFU/g, SPČ/APC ĆFU/g		
buns (anpan), Danish pastry, wafers or	& Coliforms CFU/g		
cones for ice cream, flour confectionery,			
and trifles	Or upon effectivity of FDA Circular No.		
	2022-012		
	☑ Valid Certificate of Analysis for		
	Microbiological parameters for BAKED		
	more biological parameters for BANED		





	GOODS : Yeast CFU/g, Mold CFU/g, Aerobic Plate Count, CFU/g, Coliforms CFU/g & Salmonella/25g		
Jb - Frozen dough	 Valid Certificate of Analysis for Microbiological parameters for FROZEN AND REFRIGERATED DOUGHS: Molds cfu/g, Yeast & Yeastlike Fungi cfu/g, Coliforms cfu/g, Psychrotrophic bacteria cfu/g & SPC/APC cfu/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for FROZEN AND REFRIGERATED 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
K1 - Soups and broths	DOUGHS: Salmonella/25g		
e.g. bouillon, broths, consommés, water- and cream-based soups, chowders, and bisques			
K2a - Emulsified sauces and dips e.g salad dressing (e.g., French, Italian, Greek, ranch style), fat-based sandwich spreads (e.g., mayonnaise with mustard), salad cream, fatty sauces and snack dips (e.g., bacon and cheddar dip, onion dip)	☑ In the Electronic Registration Data Entry – under Complete List of Ingredients, declare the % by weight of edible vegetable oil content of the finished product for MAYONNAISE	Administrative Order No. 235 s. 1975	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate)		





or disodium EDTA (disodium ethylenediaminetetraacetate) content, IF ADDED in MAYONNAISE *The product shall conform with the identity, standards for optional ingredients and additional label declaration for MAYONNAISE.		
 ✓ Valid Certificate of Analysis for Microbiological parameters for SALAD DRESSING, pH ≤ 4.6: SPC/APC CFU/g, YMC CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for EMULSIFIED SAUCE PH ≤ 4.6 (E.G. MAYONNAISE, THOUSAND ISLAND, RANCH, FRENCH): Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g, Salmonella/25g & Listeria monocytogenes/25g ✓ Valid Certificate of Analysis for Microbiological parameters for 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
SALADS AND SANDWICH SPREADS (excluding cocoa milk based sandwich spreads): Aerobic Plate Count CFU/g, Yeast and Mold Count		





K2b - Non-emulsified sauces (ketchup, cheese sauce, cream sauce, brown gravy) e.g. barbecue sauce, cheese sauce, Worcestershire sauce, Oriental thick Worcestershire sauce (tonkatsu sauce), chili sauce, sweet and sour dipping sauce, and white (cream-based) sauce (sauce consisting primarily of milk or cream, with little added fat (e.g. butter) and flour, with or without seasoning or spices	 CFU/g, Salmonella/25g & Listeria monocytogenes/25g ✓ Valid Certificate of Analysis for Total Solids; Titratable Acidity (as acetic acid); pH for BANANA SAUCE/BANANA CATSUP *The product shall conform with the standards for the identity, essential composition, quality factors and label declaration for BANANA SAUCE/BANANA CATSUP. 	Administrative Order No. 123-A s. 1985	Applicant Company/ Manufacturer/Source/Supplier
K3 - Salads (e.g. macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads under HR Letter B.8 (peanut butter) and MR D.1.c (cocoa-based spreads) e.g. Includes prepared salads, milk- based sandwich spreads, non- standardized mayonnaise-like sandwich spreads, and dressing for coleslaw (cabbage salad)			
L1a - Fruit and vegetable juices - (fruit juice, vegetable juice, concentrates for fruit juice, concentrates for vegetable juice)	☑ Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC CFU/mL, Coliforms CFU/mL & SPC/APC CFU/mL	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL		
 Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: SPC/APC CFU/mL & YMC CFU/mL Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: Aerobic Plate Count CFU/ml & Yeast and Mold Count CFU/mL 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
 upon effectivity of <u>FDA Circular No.</u> 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for JUICES IN HERMETICALLY SEALED CONTAINERS (TETRA PACK ETC.): Commercial Sterility 	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	 Valid Certificate of Analysis for Microbiological parameters for POWDERED BEVERAGE: SPC/APC CFU/g & YMC CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate for Microbiological parameters for POWDERED BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES): Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g & Coliforms CFU/g upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for FRUIT BEVERAGE PRODUCTS: Aerobic 	FDA Circular No. 2013-010 FDA Circular No. 2022-012 FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier Applicant Company/ Manufacturer/Source/Supplier
1.4b Equit and vegetable postero (fruit	Plate Count CFU/ml, Yeast and Mold Count CFU/ml, Coliforms CFU/ml & E.coli CFU/ml.	EDA Circular No. 2012 010	Applicant Company/
L1b - Fruit and vegetable nectars (fruit nectar, vegetable nectar, concentrates for fruit nectar, concentrates for vegetable nectar)	✓ Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC CFU/mL, Coliforms CFU/mL & SPC/APC CFU/mL	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL		
 Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: SPC/APC CFU/mL & YMC CFU/mL Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: Aerobic Plate Count CFU/ml & Yeast and Mold Count CFU/ml 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
 upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for JUICES IN HERMETICALLY SEALED CONTAINERS (TETRA PACK ETC.): Commercial Sterility 	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	 ✓ Valid Certificate of Analysis for Microbiological parameters for POWDERED BEVERAGE: SPC/APC CFU/g & YMC CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate for Microbiological parameters for POWDERED BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES): Aerobic		
	 Plate Count CFU/g, Yeast and Mold Count CFU/g & Coliforms CFU/g upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for FRUIT BEVERAGE PRODUCTS: Aerobic Plate Count CFU/ml, Yeast and Mold Count CFU/ml, Coliforms CFU/ml & E.coli CFU/ml. 	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
L1c - "Sport," "energy", or "electrolyte drinks"	 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC CFU/mL, Coliforms CFU/mL & SPC/APC CFU/mL Or upon effectivity of <u>FDA Circular No.</u> 2022-012 Valid Certificate of Analysis for 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL Valid Certificate of Analysis for Caffeine and Vitamin B and/or	Administrative No. Order 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	mineral/s (whichever is applicable) contentLabel bearing the Precaution Statement: "Excessive intake of caffeine may cause sleeplessness,	Administrative Order No. 2014-0030	Applicant Company/ Manufacturer/Source/Supplier
	palpitation and other similar side effects. Not recommended for children, pregnant and lactating women, people who may have heart problems and/or those sensitive to caffeine."		
L1ci - Carbonated water-based flavored drinks e.g. colas, pepper-types, root beer, lemon-lime, and citrus types, both diet/light and regular types)	☑ Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC CFU/mL, Coliforms CFU/mL & SPC/APC CFU/mL	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, 		





	ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL Valid Certificate of Analysis for Caffeine Content for COLA-TYPE BEVERAGE	Administrative Order 88-A s. 1984	Applicant Company/ Manufacturer/Source/Supplier
L1cii - Non-carbonated water-based flavored drinks e.g. almond, aniseed, coconut-based drinks, and ginseng drink, lemonade, orangeade, citrus-based soft drinks, iced tea, fruit-flavoured iced tea, chilled canned cappuccino drinks	 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC CFU/mL, Coliforms CFU/mL & SPC/APC CFU/mL Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 ✓ Valid Certificate of Analysis for Microbiological parameters for CHILLED YOUNG COCONUT WATER (BUKO JUICE): Aerobic Plate Count CFU/mL, Yeast and Mold Count CFU/mL and Coliforms CFU/mL 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





L1ciii - Concentrates (liquid or solid) for water-based flavored drinks e.g. fountain syrups (e.g. cola syrup), fruit syrups for soft drinks, frozen or powdered concentrate for lemonade and iced tea mixes	 ☑ Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: SPC/APC CFU/mL & YMC CFU/mL Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: Aerobic Plate Count CFU/ml & Yeast and Mold Count CFU/ml 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
L1d - Powdered cocoa drink mixes (cocoa) e.g. drinking chocolate powder; breakfast cocoa; cocoa dust (fines), nibs, mass, press cake; chocolate liquor; cocoa mixes (powders for preparing the hot beverage); cocoa-sugar mixture; and dry mixes for sugar-cocoa confectionery)	 Valid Certificate of Analysis for Microbiological parameters for POWDERED BEVERAGE: SPC/APC CFU/g & YMC CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate for Microbiological parameters for POWDERED BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES): Aerobic Plate Count CFU/g, Yeast and Mold 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
M1 - Vitamins and minerals as Food Supplement e.g. Vitamin C + Zinc Food Supplement Capsule	Count CFU/g & Coliforms CFU/g Valid Shelf-life study with stability data containing relevant information on the critical parameters of the finished product, period conducted and conclusion	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier





	✓ Valid Certificate of Analysis of the physico-chemical (Vitamins or Minerals or Amino Acids Assays) and/or microbiological parameters of the finished product (whichever is applicable)	Administrative Order No. 2014-0029 Office Order No. 22 s 1991 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	*The amount of Vitamins shall conform with the prescribed level of <u>Office</u> <u>Order No. 22 s 1991</u>		
	 Clear and complete loose labels or artworks declaring the term "Food Supplement" and the phrase "NO APPROVED THERAPEUTIC CLAIMS" based on 	Bureau Circular No. 2 s 1999	Applicant Company/ Manufacturer/Source/Supplier
	 Sample in actual commercial presentation *for the procedure on submission, please refer to: IV. Guidelines, C. Procedural Guidelines 2. L. ii., Pages 7-8 of FDA Circular No. 2020-033 	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
M2 - Amino acids as Food Supplement e.g. Branched-Chain Amino Acids (BCAA) Food Supplement Powder		Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis of the physico-chemical (Vitamins or Minerals or Amino Acids Assays) and/or microbiological parameters of the	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier





	 finished product (whichever is applicable) *The amount of Vitamins shall conform with the prescribed level of <u>Office</u> <u>Order No. 22 s 1991</u> ☑ Clear and complete loose labels or artworks declaring the term "Food Supplement" and the phrase "NO APPROVED THERAPEUTIC CLAIMS" based on 	Bureau Circular No. 2 s 1999	Applicant Company/ Manufacturer/Source/Supplier
	 ✓ Sample in actual commercial presentation *for the procedure on submission, please refer to: IV. Guidelines, C. Procedural Guidelines 2. L. ii., Pages 7-8 of FDA Circular No. 2020-033 	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
N - Processed buts, including coated nuts and nut mixtures (with e.g. dried fruits) e.g. Yoghurt-, cereal-, and honey- covered nuts, and dried fruit-nut-and- cereal snacks (e.g. "trail mixes")			
HIGH RISK FOOD PRODUCTS	☑ ADDITIONAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE
HIGH RISK FOOD PRODUCTS - foods that may contain pathogenic microorganisms and will support the formation of toxins and or the growth or pathogenic microorganisms and foods that may contain harmful chemicals.			





A1a - Milk (plain) and buttermilk (plain) Includes pasteurized, ultra-high temperature (UHT) treated, sterilized, 1 homogenized, or fat adjusted milk. Includes, but is not limited to, skim, part-	✓ Valid Certificate of Analysis for % Milk Solids Not Fat and % Milk Fat for MILK, CARABAO'S AND/OR BUFFALO'S MILK AND GOAT'S (NATIVE) MILK	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
skim, low-fat and whole milk Includes plain recombined fluid milks, plain reconstituted fluid milks, plain	✓ Valid Certificate of Analysis for % Milk Solids Not Fat and % Milk Fat for SKIM MILK OR SKIMMED MILK	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks, lactose reduced milk, and plain milk-based beverages	 Valid Certificate of Analysis for % Milk Solids Not Fat and % Milk Fat for RECONSTITUTED, RECONSTRUCTED OR RECOMBINED MILK 	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	 ✓ Valid Certificate of Analysis for % Milk Solids Not Fat for RECONSTITUTED, RECONSTRUCTED OR RECOMBINED SKIMMED MILK 	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Solids Not Fat for BUTTERMILK	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	✓ Valid Certificate of Analysis for % Milk Fat for LOWFAT MILK AND RECONSTITUTED, RECONSTRUCTED OR RECOMBINED LOWFAT MILK	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Non-Fat Milk Solids, Vitamin A and Vitamin D (if added) for FILLED MILK *The % Total Oil Content shall be	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier





Data Entry. **The product identity, standa ingredients and declaration for *PASTEURIZE STERILISED	ED MILK AND A MILK shall conform with	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
quality ☑ Valid Certifie Microbiologica MILK (EVAPO DRINK)-UHT/S Commercial St	I parameters for LIQUID RATED & READY TO STERILIZED:	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
☑ Valid Certifi Microbiologica	terility		
Microbiologica PASTEURIZE CFU/mL, Salm monocytogene	I parameters for D MILK : Coliforms nonella/25mL, Listeria es/25mL, Psychrotrophic L & SPC/APC CFU/mI	<u>FDA Circular No. 2013-010</u> FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





A1b - Dairy-based drinks, flavored and/or fermented e.g. Chocolate Milk, Chocolate Malt Drinks, Drinking Yoghurt, Whey-based drinks	Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED MILK: Coliforms CFU/mL, Salmonella/25mL, Listeria monocytogenes/25mL, Psychrotrophic bacteria cfu/mL & Aerobic Plate Count CFU/g (Plain/Flavored) *FLAVORED MILK, FLAVORED RECONSTITUTED MILK, FLAVORED DRINK OR FLAVORED DAIRY DRINK, AND CHOCOLATE DRINK OR CHOCOLATE FLAVORED DRINK shall conform with the prescribed atendered of identify and quality	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	 standard of identity and quality ✓ Valid Certificate of Analysis for Microbiological parameters for LIQUID MILK (EVAPORATED & READY TO DRINK)- UHT/STERILIZED: Commercial Sterility Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for LIQUID MILK (READY TO DRINK)- UHT/STERILIZED: Commercial 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





A2ai - Fermented milk (plain), non heat-treated after fermentation	 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC CFU/mL, Coliforms CFU/mL & SPC/APC CFU/mL Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL Valid Certificate of Analysis for % Milk Fat Content by weight; % Milk 	FDA Circular No. 2013-010 FDA Circular No. 2022-012 Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
e.g. Yoghurt and plain drinks based on fermented milk	Solids Non-Fat Content by weight; Acidity of the product when solid for YOGURT AND FLAVORED YOGURT		Applicant Company/ Manufacturer/Source/Supplier
	* Toned Milk shall conform with the prescribed standard of identity and quality	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	 Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK: S. aureus (coagulase +) CFU/mL, Coliforms CFU/mL, Salmonella/25mL & Lactic acid CFU/mL 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK : S. aureus CFU/mL, Coliforms CFU/mL, Salmonella/25mL & Lactic acid CFU/mL (required minimum level: ≥10^6 CFU/mL)		
A2aii - Fermented milks (plain), heat- treated after fermentation e.g. Sterilized or pasteurized plain drinks based on fermented milk	✓ Valid Certificate of Analysis for % Milk Fat Content by weight; % Milk Solids Non-Fat Content by weight; Acidity of the product when solid for YOGURT AND FLAVORED YOGURT	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	* Toned Milk shall conform with the prescribed standard of identity and quality	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	 ✓ Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK: S. aureus (coagulase +) CFU/mL, Coliforms CFU/mL, Salmonella/25mL & Lactic acid CFU/mL 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK : S. aureus CFU/mL, Coliforms CFU/mL,		





A2b - Renneted milk (plain)	Salmonella/25mL & Lactic acid CFU/mL (required minimum level: ≥10^6 CFU/mL)		
e.g. Curdled milk			
A3a - Pasteurized cream (plain)	✓ Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED CREAM: Coliforms cfu/g, Salmonella/25g, Listeria monocytogenes/25g, Psychrotrophic bacteria cfu/g & SPC/APC cfu/g	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED CREAM : Coliforms cfu/g, Salmonella/25g, Listeria monocytogenes/25g, Aerobic Plate Count cfu/g		
A3b - Sterilized and UHT creams, whipping and whipped creams, and	☑ Valid Certificate of Analysis for % Butterfat for CREAM	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
reduced fat creams (plain) e.g. whipping cream, heavy cream, whipped pasteurized cream, and whipped	✓ Valid Certificate of Analysis for % Butterfat for LIGHT CREAM TABLE CREAM OR COFFEE CREAM	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
cream-type dairy toppings and fillings	☑ Valid Certificate of Analysis for % Milk Fat for WHIPPING CREAM	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	Valid Certificate of Analysis for % Butterfat for LIGHT WHIPPING CREAM	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier





	Valid Certificate of Analysis for % Milk Fat for HEAVY CREAM OR HEAVY WHIPPING CREAM	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	Valid Certificate of Analysis for % Milk Fat for HALF-AND HALF	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	✓ Valid Certificate of Analysis for Microbiological parameters for CREAM (UHT/STERILIZED): Commercial Sterility	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for CREAM (UHT/STERILIZED): Commercial Sterility		
A3c - Clotted cream (plain)			
A3d - Cream analogues			
A4a - Unripened cheese e.g. cottage cheese (a soft, unripened, coagulated curd cheese), creamed cottage cheese (cottage cheese covered	☑ Valid Certificate of Analysis for % Milk Fat and % Moisture for CREAM CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
with a creaming mixture),2 cream cheese (rahmfrischkase, an uncured, soft spreadable cheese),3 mozzarella and	*The product shall conform with the identity and standards for optional ingredients for Cream Cheese.		
scamorza cheeses. Includes the whole unripened cheese and unripened cheese rind (for those unripened cheeses with a "skin" such as mozzarella)	☑ Valid Certificate of Analysis for % Milk Fat and % Moisture for COTTAGE CHEESE DRY CURD or DRY CURD COTTAGE CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier





*The product shall conform with the identity, standards for optional ingredients and additional label declaration for Cottage Cheese Dry Curd or Dry Curd Cottage Cheese. ☑ Valid Certificate of Analysis for % Milk Fat and % Moisture for COTTAGE CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity, standards for optional ingredients and additional label declaration for Cottage Cheese.		
Valid Certificate of Analysis for % Milk Fat and % Moisture for LOW FAT COTTAGE CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity, standards for optional ingredients and additional label declaration for Low Fat Cottage Cheese.		
☑ Valid Certificate of Analysis for % Milk Fat for SKIM MILK CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity for Skim Milk Cheese.		
 Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





(MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g	
Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g	
✓ Valid Certificate of Analysis for Microbiological parameters for HARD AND SEMI-HARD CHEESE: Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g	
✓ Valid Certificate of Analysis for Microbiological parameters for CREAN CHEESE PRODUCTS: Coliforms CFU/g or MPN/g or /25g. E. coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g	





	 ✓ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE: Campylobacter/25g, Salmonella/25g, Listeria monocytogenes/25g and S. aureus (coagulase +) CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE; RAW MILK UN- RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0: Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g		
A4bi - Ripened cheese, includes rind e.g. Ripened cheese may be soft (e.g., camembert), firm (e.g., edam, gouda), hard (e.g., cheddar), or extra-hard.	☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for CHEDDAR CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
Includes cheese in brine, which is a ripened semi-hard to soft cheese, white to yellowish in colour with a compact	*The product shall conform with the identity and standards for optional ingredients for Cheddar Cheese.		
texture, and without actual rind that has been preserved in brine until presented to the consumer	✓ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for WASHED CURD CHEESE (SOAKED CURD CHEESE)	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	*The product shall conform with the		





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identity and standards for Washed Curd Cheese (Soaked Curd Cheese).		
☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for COLBY CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity and standards for Colby Cheese.		
☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for GRANULAR CHEESE (STIRRED CURD CHEESE)	<u>Administrative Order No. 200-A s.</u> <u>1973</u>	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity and standards for Granular Cheese (Stirred Curd Cheese).		
☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for BRICK CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity and standards for optional ingredients for Brick Cheese.		
☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for SWISS CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the		





identity and standards for optional ingredients Swiss Cheese.		
☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for GRUYERS CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity and standards for optional ingredients Gruyers Cheese.		
☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for EDAM CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity and standards for optional ingredients Edam Cheese.		
☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for PARMESAN CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity and standards for optional ingredients Parmesan Cheese.		
☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for PARMESAN CHEESE	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity and standards for optional ingredients Parmesan Cheese.		





 ✓ Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ✓ Valid Certificate of Analysis for Microbiological parameters for HARD AND SEMI-HARD CHEESE: Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ✓ Valid Certificate of Analysis for Microbiological parameters for HARD AND SEMI-HARD CHEESE: Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ✓ Valid Certificate of Analysis for 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
✓ Valid Certificate of Analysis for Microbiological parameters for CREAM CHEESE PRODUCTS: Coliforms		





	 CFU/g or MPN/g or /25g. E. coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE: Campylobacter/25g, Salmonella/25g, Listeria monocytogenes/25g and S. aureus (coagulase +) CFU/g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE; RAW MILK UN-RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0: Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A4bii - Rind of ripened cheese			
A4biii - Cheese powder (for			
reconstitution)			
e.g. Spray-dried cheese			
A4c - Whey cheese			
A4di - Plain processed cheese	Valid Certificate of Analysis for %	Administrative Order No. 200-A s.	Applicant Company/
e.g. American Cheese, requeson	Moisture Content, % Fat Content in Dry Matter and % Lactose for PASTEURIZED PROCESS CHEESE	<u>1973</u>	Manufacturer/Source/Supplier
	*The product shall conform with the identity, standards for optional		





ingredients and additional label declaration for Pasteurized Proces Cheese.		
✓ Valid Certificate of Analysis for Moisture Content, % Fat Content % Milk Fat (when the food contain other foodstuffs) for PASTEURIZE PROCESS CHEESE FOOD	and <u>1973</u> าร	Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity, standards for optional ingredients and additional label declaration for Pasteurized Process Cheese Food.		
☑ Valid Certificate of Analysis for Moisture Content and % Fat Content for PASTEURIZED PROCESS CHEESE SPREAD		Applicant Company/ Manufacturer/Source/Supplier
*The product shall conform with the identity, standards for optional ingredients and additional label declaration for Pasteurized Process Cheese Spread.		
✓ Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUC (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. c MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g,	CTS	Applicant Company/ Manufacturer/Source/Supplier





Salmonella/25g & Listeria		
monocytogenes/25g		
Or upon effectivity of <u>FDA Circular No.</u>		
<u>2022-012</u>		
☑ Valid Certificate of Analysis for		
Microbiological parameters for SOFT		
CHEESE (FROM PASTEURIZED		
MILK): Enterobacteriaceae CFU/g,		
E.coli CFU/g, Salmonella/ 25g, Listeria		
monocytogenes/ 25g & S. aureus		
CFU/g		
☑ Valid Certificate of Analysis for		
Microbiological parameters for HARD		
AND SEMI-HARD CHEESE:		
Enterobacteriaceae CFU/g, E.coli		
CFU/g, Salmonella/ 25g, Listeria		
monocytogenes/ 25g & S. aureus		
CFU/g		
☑ Valid Certificate of Analysis for		
Microbiological parameters for CREAM		
CHEESE PRODUCTS: Coliforms		
CFU/g or MPN/g or /25g. E. coli CFU/g		
or MPN/g or /25g and Yeast and Molds		
CFU/g		
	FDA Circular No. 2013-010	Applicant Company/
☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Manufacturer/Source/Supplier
Microbiological parameters for ALL		
RAW MILK CHEESE:		





		1	1
	Campylobacter/25g, Salmonella/25g,		
	Listeria monocytogenes/25g and S.		
	aureus (coagulase +) CFU/g		
	Or upon offectivity of EDA Circular No		
	Or upon effectivity of <u>FDA Circular No.</u>		
	2022-012		
	☑ Valid Certificate of Analysis for		
	Microbiological parameters for ALL		
	RAW MILK CHEESE; RAW MILK UN-		
	RIPENED CHEESE W/ MOISTURE >		
	50%, pH > 5.0: Campylobacter/25g,		
	Listeria monocytogenes/25g,		
	Salmonella/25g & S. aureus CFU/g		
	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
	Microbiological parameters for	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
	PROCESSED CHEESE SPREAD: S.		
	aureus (coagulase +) CFU/g, Coliforms		
	CFU/g & SPC /APC CFU/g		
	Or upon effectivity of FDA Circular No.		
	2022-012		
	☑ Valid Certificate of Analysis for		
	Microbiological parameters for		
	PROCESSED CHEESE SPREAD:		
	Coliforms CFU/g, S. aureus CFU/g &		
	Aerobic Plate Count CFU/g		
A4dii - Flavored processed cheese	✓ Valid Certificate of Analysis for %	Administrative Order No. 200-A s.	Applicant Company/
e.g. eufchatel cheese spread with	Moisture Content, % Fat Content in Dry	1973	Manufacturer/Source/Supplier
vegetables, pepper jack cheese, cheddar	Matter and % Lactose for	<u></u>	
cheese spread with wine, and cheese	PASTEURIZED PROCESS CHEESE		
choose opread with whic, and one of	FASTEURIZED FRUGESS GREESE		





balls (formed processed cheese coated in nuts, herbs or spices)	*The product shall conform with the identity, standards for optional ingredients and additional label declaration for Pasteurized Process Cheese.		
	✓ Valid Certificate of Analysis for % Moisture Content, % Fat Content and % Milk Fat (when the food contains other foodstuffs) for PASTEURIZED PROCESS CHEESE FOOD	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	*The product shall conform with the identity, standards for optional ingredients and additional label declaration for Pasteurized Process Cheese Food.		
	☑ Valid Certificate of Analysis for % Moisture Content and % Fat Content for PASTEURIZED PROCESS CHEESE SPREAD	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	*The product shall conform with the identity, standards for optional ingredients and additional label declaration for Pasteurized Process Cheese Spread.		
	 ✓ Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





Psychrotro	liforms MPN/g, phic bacteria CFU/g, /25g & Listeria enes/25g	
2022-012 ☑ Valid Co Microbiolo CHEESE MILK): En E.coli CFU	ectivity of <u>FDA Circular No.</u> rtificate of Analysis for ical parameters for SOFT FROM PASTEURIZED erobacteriaceae CFU/g, g, Salmonella/ 25g, Listeria enes/ 25g & S. aureus	
Microbiolo AND SEM Enterobac CFU/g, Sa	rtificate of Analysis for ical parameters for HARD HARD CHEESE: eriaceae CFU/g, E.coli monella/ 25g, Listeria enes/ 25g & S. aureus	
Microbiolo CHEESE CFU/g or I	rtificate of Analysis for ical parameters for CREAM RODUCTS: Coliforms IPN/g or /25g. E. coli CFU/g r /25g and Yeast and Molds	





 ✓ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE: Campylobacter/25g, Salmonella/25g, Listeria monocytogenes/25g and S. aureus (coagulase +) CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE; RAW MILK UN- RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0: Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g ✓ Valid Certificate of Analysis for Microbiological parameters for PROCESSED CHEESE SPREAD: S. 	FDA Circular No. 2013-010 FDA Circular No. 2022-012 FDA Circular No. 2013-010 FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier Applicant Company/ Manufacturer/Source/Supplier
 aureus (coagulase +) CFU/g, Coliforms CFU/g & SPC /APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for PROCESSED CHEESE SPREAD: Coliforms CFU/g, S. aureus CFU/g & Aerobic Plate Count CFU/g 		





A4e - Cheese analogues e.g. imitation cheese, imitation cheese mixes, and imitation cheese powders	 ✓ Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g		
	 ✓ Valid Certificate of Analysis for Microbiological parameters for HARD AND SEMI-HARD CHEESE: Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g 		
	☑ Valid Certificate of Analysis for Microbiological parameters for CREAM CHEESE PRODUCTS: Coliforms		





CFU/g or MPN/g or /25g. E. coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for ALL	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
RAW MILK CHEESE: Campylobacter/25g, Salmonella/25g, Listeria monocytogenes/25g and S. aureus (coagulase +) CFU/g		
Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE; RAW MILK UN- RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0: Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g		
✓ Valid Certificate of Analysis for Microbiological parameters for PROCESSED CHEESE SPREAD: S. aureus (coagulase +) CFU/g, Coliforms CFU/g & SPC /APC CFU/g	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
 Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for PROCESSED CHEESE SPREAD: 		





	Coliforms CFU/g, S. aureus CFU/g &		
	Aerobic Plate Count CFU/g		
A4f - Whey protein cheese			
e.g. ricotta cheese			
A5 - Dairy-based desserts	☑ Valid Certificate of Analysis for %	Administrative Order No. 132 s. 1970	Applicant Company/
e.g. Includes flavoured yoghurt (a milk	Milk Fat Content by weight; % Milk		Manufacturer/Source/Supplier
product obtained by fermentation of milk	Solids Non-Fat Content by weight;		
and milk products to which flavours and	Acidity of the product when solid for		
ingredients (e.g., fruit, cocoa, coffee)	YOGURT AND FLAVORED YOGURT		
have been added) that may or may not	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
be heat-treated after fermentation. Other	Microbiological	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
junket (sweet custard-like dessert made	parameters for YOGURT AND		
from flavoured milk set with rennet),	FERMENTED MILK: S. aureus		
dulce de leche (cooked milk with sugar	(coagulase +) CFU/mL, Coliforms		
and added ingredients such as coconut	CFU/mL, Salmonella/25mL & Lactic		
or chocolate), butterscotch pudding and	acid CFU/mL		
chocolate mousse. Includes traditional			
milk-based sweets prepared from milk	Or upon effectivity of FDA Circular No.		
concentrated partially, from khoa (cow or	2022-012		
buffalo milk concentrated by boiling), or	☑ Valid Certificate of Analysis for		
chhena (cow or buffalo milk, heat	Microbiological parameters for		
coagulated aided by acids like citric acid,	YOGURT AND FERMENTED MILK: S.		
lactic acid, malic acid, etc), sugar or	aureus CFU/mL, Coliforms CFU/mL,		
synthetic sweetener, and other	Salmonella/25mL & Lactic acid		
ingredients (e.g. maida (refined wheat flour), flavours and colours (e.g. peda,	CFU/mL (required minimum level:		
burfee, milk cake, gulab jamun, rasgulla,	≥10^6 CFU/mL)		
rasmalai, basundi			
	☑ Valid Certificate of Analysis for		
	Microbiological parameters for ETHNIC		
	MILK-BASED CONFECTIONERIES		





ACc. Liquid where and where products	(e.g. PASTILLAS and YEMA): Yeast and Mold Count CFU/g, Salmonella/25, Coliforms MPN/g or CFU/g and Aerobic Plate Count CFU/g		
A6a - Liquid whey and whey products			
A6b - Dried whey and whey products			
A7 - Milk for manufacture			
A8 - Dairy-based frozen desserts e.g. ice cream (frozen dessert that may contain whole milk, skim milk products, cream or butter, sugar, vegetable oil, egg products, and fruit, cocoa, or coffee), ice milk (product similar to ice cream with reduced whole or skim milk content, or made with nonfat milk), jellied milk, frozen flavoured yoghurt	 ✓ Valid Certificate of Analysis for Microbiological parameters for ICE CREAM & SHERBET (PLAIN AND FLAVORED): Coliforms CFU/g, Listeria monocytogenes/25g, Salmonella/25g, SPC/APC CFU/g & S. aureus (coagulase +) CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for ICE CREAM & SHERBET (PLAIN AND FLAVORED): Coliforms CFU/g, Listeria monocytogenes/25g, Salmonella/25g, Aerobic Plate Count CFU/g & S. aureus CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 ✓ Valid Certificate of Analysis for Microbiological parameters for ICE CREAM WITH ADDED INGREDIENTS (NUTS, FRUITS, COCOA ETC.): Coliforms CFU/g, Listeria monocytogenes/25g, Salmonella/25g, SPC/APC CFU/g & S. aureus 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





B1 - Dried fruits and vegetable - plain/sun-dried seaweeds, and nuts and seeds e.g. Includes vegetable powders that are obtained from drying the juice, such as tomato powder and beet powder, dried potato flakes and dried lentil, dried sea tangle (kelp; kombu), dried sea tangle with seasoning (shio-kombu), dried seaweed (tororo-kombu), dried gourd strips (kampyo), dried laver (nori), and dried laminariales (wakame)	 (coagulase +) CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for ICE CREAM WITH ADDED INGREDIENTS (NUTS, FRUITS, COCOA ETC.): Coliforms CFU/g, S. aureus CFU/g, Salmonella/25g, Salmonella/25g CFU/g & Listeria monocytogenes/25g ✓ Valid Certificate of Analysis for Microbiological parameters for SUN DRIED FRUITS: Mold CFU/g, Osmophilic Yeasts cfu/g & E. coli MPN/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for SUN DRIED FRUITS: Mold CFU/g, Osmophilic Yeasts cfu/g & E. coli MPN/g ✓ Valid Certificate of Analysis for Microbiological parameters for SUN DRIED FRUITS: Mold CFU/g, Osmophilic Yeasts cfu/g & E. coli MPN/g ✓ Valid Certificate of Analysis for Microbiological parameters for SUN DRIED FRUITS: Mold CFU/g, Osmophilic Yeasts cfu/g & E. coli MPN/g ✓ Valid Certificate of Analysis for Microbiological parameters for SUN 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier Applicant Company/ Manufacturer/Source/Supplier
	 Valid Certificate of Analysis for Microbiological parameters for DRIED VEGETABLE: E. coli MPN/g Or upon effectivity of <u>FDA Circular No.</u> 2022-012 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Manufacturer/Source/Supplier





	☑ Valid Certificate of Analysis for Microbiological parameters for DRIED VEGETABLE: E. coli MPN/g		
B2 - Vegetable seaweed, and nut and seed - purees, spreads e.g. tomato puree, peanut butter (a spreadable paste made from roasted and ground peanuts by the addition of peanut oil), other nut butters (e.g., cashew butter), and pumpkin butter)	 Valid Certificate of Analysis for % Fat Content and % Water Insoluble Inorganic Residue for Peanut Butter *The product shall conform with the identity and label statement for optional ingredients for Peanut Butter. 	Administrative Order No. 228 s. 1974	Applicant Company/ Manufacturer/Source/Supplier
	 Valid Certificate of Analysis for Microbiological parameters for PEANUT BUTTER & OTHER NUT BUTTERS: Salmonella/25g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for PEANUT BUTTER & OTHER NUT BUTTERS: Salmonella/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
D - Chocolate with nuts	 ✓ Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE PRODUCTS/CONFECTIONARIES: Molds CFU/g, Salmonella/25g, Coliforms MPN/g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	 Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE PRODUCTS: Molds CFU/g, Salmonella/25g, Coliforms MPN/g or CFU/g & Aerobic Plate Count CFU/g. Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE CONFECTIONARIES: Molds CFU/g, Osmophilic yeast CFU/g, Salmonella/25g, Coliforms MPN/g or CEU/g & Aerobic Plate Count CEU/g 		
F1 - Fine bakery products with fillings: meat, milk, poultry, cream, and other perishable foods; icings and coatings e.g. butter cake, cheesecake, fruit-filled cereal bars, pound cake (including kasutera), moist cake (type of starchy dessert (Nama Gashi)), western cakes, moon cakes, sponge cake, fruit-filled pies (e.g. apple pie), oatmeal cookies, sugar cookies and British "biscuits" (cookies or sweet crackers)	 CFU/g & Aerobic Plate Count CFU/g ✓ Valid Certificate of Analysis for Microbiological parameters for BAKED GOODS (MICROBIOLOGICALLY SENSITIVE TYPES E.G. CONTAINING EGGS & DAIRY PRODUCTS): S. aureus (coagulase +) cfu/g, MYC cfu/g, SPC/APC cfu/g & Coliforms cfu/g) Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for BAKED GOODS: Yeast CFU/g, Mold CFU/g, Aerobic Plate Count CFU/g, Coliforms CFU/g & Salmonella/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





 ✓ Valid Certificate of Analysis for Microbiological parameters for COATED OR FILLED, DRIED SHELF- STABLE BISCUITS: Coliforms MPN/g & Salmonella/25g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for COATED OR FILLED, DRIED SHELF- STABLE BISCUITS: Coliforms MPN/g & Salmonella/25g ✓ Valid Certificate of Analysis for Microbiological parameters for ETHNIC FLOUR-BASED CONFECTIONERIES 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
e.g. PIAYA): Yeast and Mold Count CFU/g and Coliforms CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for FROZEN BAKERY PRODUCTS (READY TO EAT) WITH LOW ACID OR HIGH Aw FILLINGS OR TOPPINGS: S. aureus (coagulase +) CFU/g & Salmonella/25g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	Microbiological parameters for FROZEN BAKERY PRODUCTS (READY TO EAT) WITH LOW ACID OR HIGH Aw FILLINGS OR TOPPINGS: S. aureus CFU/g & Salmonella/25g		
	 ✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN BAKERY PRODUCTS (TO BE COOKED) WITH LOW ACID OR HIGH Aw FILLINGS OR TOPPINGS: S. aureus (coagulase +) CFU/g & Salmonella/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for FROZEN BAKERY PRODUCTS (TO BE COOKED) WITH LOW ACID OR HIGH Aw FILLINGS OR TOPPINGS: S. aureus CFU/g & Salmonella/25g		
F2 - Cookies with nuts	 ✓ Valid Certificate of Analysis for Microbiological parameters for BAKED GOODS (MICROBIOLOGICALLY SENSITIVE TYPES E.G. CONTAINING EGGS & DAIRY PRODUCTS): S. aureus (coagulase +) cfu/g, MYC cfu/g, SPC/APC cfu/g & Coliforms cfu/g) 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	 Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for BAKED GOODS: Yeast CFU/g, Mold CFU/g, Aerobic Plate Count CFU/g, Coliforms CFU/g & Salmonella/25g 		
G1a - Heat-treated processed meat, poultry and game products in whole pieces or cuts (canned) e.g. cured, cooked ham; cured, cooked pork shoulder; canned chicken meat; and meat pieces boiled in soy sauce (tsukudani)	 Valid Certificate of Analysis for Microbiological parameters for MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Nitrate and Nitrite Content (if utilized)	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	Applicant Company/ Manufacturer/Source/Supplier
G1b - Frozen processed meat, poultry and game products in whole pieces or cuts (marinated pork/beef/chicken cuts) e.g. frozen whole chickens, frozen, marinated chicken, frozen chicken parts, and frozen beef steaks	 ✓ Valid Certificate of Analysis for Microbiological parameters for FRESH/FROZEN RAW CHICKEN: SPC/APC cfu/g Or upon effectivity of <u>FDA Circular No.</u> 2022-012: NONE 	FDA Circular No. 2013-010	Applicant Company/ Manufacturer/Source/Supplier





G2a - Heat-treated processed comminuted meat, poultry and game products (canned) e.g. pre-grilled beef patties; foie gras and pates; brawn and head cheese; cooked, cured chopped meat; chopped meat boiled in soy sauce (tsukudani); canned corned beef; luncheon meats; meat pastes; cooked meat patties; cooked salami-type products; cooked meatballs; saucises de strasbourg; breakfast sausages; brown-and-serve sausages; and terrines (a cooked chopped meat mixture)	 Valid Certificate of Analysis for Microbiological parameters for MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility Valid Certificate of Analysis for Nitrate and Nitrite Content (if utilized) 	FDA Circular No. 2013-010 FDA Circular No. 2022-012 Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	Applicant Company/ Manufacturer/Source/Supplier Applicant Company/ Manufacturer/Source/Supplier
G2b - Frozen processed comminuted meat, poultry and game products (nuggets, patties, dumplings salami, meat loaf, hotdog) e.g. frozen hamburger patties; frozen breaded or battered chicken fingers	 Nitrate and Nitrite Content (if utilized) ✓ Valid Certificate of Analysis for Microbiological parameters for COLD CUTS, FROZEN & CHILLED HOTDOGS: E. coli MPN/g, Salmonella/25g, S. aureus (coagulase +) CFU/g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for COLD CUTS, FROZEN & CHILLED HOTDOGS: E. coli MPN/g or CFU/g or /25g, Salmonella/25g, S. aureus, L. 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





mor	ocytogenes/25g & Aerobic Plate	
	nt CFU/g	
	-	
	alid Certificate of Analysis for	
	-	
	obiological parameters for	
	OKED POULTRY MEAT, FROZEN	
	BE REHEATED BEFORE EATING	
	. prepared frozen meals chicken	
bur	gers, chicken turkey rolls,	
chie	ken nuggets, other breaded	
pou	Itry meat products): Aerobic Plate	
Cou	nt CFU/g, S. aureus CFU/g,	
	eria monocytogenes/25g,	
	nonella/25 and Campylobacter	
	ni/25g	
joju	1/20g	
	alial Cantificate of Analysis for	
	alid Certificate of Analysis for	
	obiological parameters for	
	RINATED MEAT PRODUCTS (e.g.	
Mar	inated meat and meat	
pre	parations (tapa, sisig, etc.), -	
Mar	inated poultry, Dim sum made	
fror	n meat (siomai)): Salmonella/25g,	
	eria monocytogenes/25g and S.	
	eus CFU/g	
ן הם איז	alid Certificate of Analysis for	
	-	
	obiological parameters for FOODS	
	OKED IMMEDIATELY PRIOR TO	
	E OR CONSUMPTION (e.g.	
Tak	eaway food, burgers, kebabs,	





sausages, pizza, ready meals (cook/chill and cook/freeze) after regeneration): Aerobic Plate Count CFU/g, Enterobacteriaceae CFU/g, E. coli CFU/g, S. aureus (coagulase +) CFU/g, Salmonella/25g and Listeria monocytogenes/25g		
Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for MINCED MEAT AND MEAT PREPARATIONS MADE FROM POULTRY MEAT INTENDED TO BE EATEN COOKED: Aerobic Plate Count CFU/g, E. coli CFU/g and Salmonella/25g ☑ Valid Certificate of Analysis for Microbiological parameters for MINCED MEAT AND MEAT PREPARATIONS MADE FROM Selfes OTHER TAND MEAT PREPARATIONS MADE FROM SPECIES OTHER THAN POULTRY INTENDED TO BE EATEN COOKED: Salmonella/25g, Aerobic Plate Count CFU/g and E. coli CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
 ✓ Valid Certificate of Analysis for Microbiological parameters for MEAT PASTE & PATE: Salmonella/25g, Clostridium perfringens CFU/g, S. aureus (coagulase +) CFU/g, Coliforms 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





H1a - Frozen fish, fish fillets and fish products e.g. frozen or deep frozen clams, cod fillets, crab, finfish, haddock, hake, lobster, minced fish, prawns and shrimp; frozen fish roe; frozen surimi; and frozen whale meat	 CFU/g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for MEAT PASTE & PATE: Salmonella/25g, Clostridium perfringens CFU/g, S. aureus CFU/g, Coliforms CFU/g & Aerobic Plate Count CFU/g ☑ Valid Certificate of Analysis for Nitrate and Nitrite Content (if utilized) ☑ Valid Certificate of Analysis for Microbiological parameters for FRESH FROZEN FISH: E. coli MPN/g, S. aureus (coagulase +) CFU/g, V. parahaemolyticus CFUu/g, Salmonella/25g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for FRESH 	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016 FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier Applicant Company/ Manufacturer/Source/Supplier
	,		
	✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN RAW CRUSTACEANS: E.	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





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	coli MPN/g, S. aureus (coagulase +) CFU/g, V. parahaemolyticus CFU/g, Salmonella/25g & SPC/APC CFU/g		
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN RAW CRUSTACEANS : E. coli MPN/g, S. aureus CFU/g,		
	Salmonella/25g, V. parahaemolyticus MPN/g, Aerobic Plate Count CFU/g ☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
	Microbiological parameters for FRESH & FROZEN BIVALVE MOLLUSCS : E. coli MPN/g, V. parahaemolyticus CFU/g, Salmonella/25g & SPC/APC CFU/g	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for FRESH & FROZEN BIVALVE MOLLUSCS : E. coli MPN/g, Salmonella/25g, V. parahaemolyticus MPN/g & Aerobic Plate Count CFU/g		
H1b - Frozen battered fish, fish fillets and fish products, including molluscs, crustaceans and echinoderms e.g. frozen raw breaded or batter-	 ✓ Valid Certificate of Analysis for Microbiological parameters for PRE- COOKED BREADED FISH: E. coli 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





coated shrimp; and frozen or quick-frozen breaded or batter-coated fish fillets, fish portions and fish sticks (fish fingers)	 MPN/g, S. aureus (coagulase +) CFU/g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for PRE-COOKED BREADED FISH: E. coli MPN/g, S. aureus CFU/g & Aerobic Plate Count CFU/g ✓ Valid Certificate of Analysis for Microbiological parameters for FISH AND CRUSTACEAN BASED PROCESSED MEAT (e.g. fish ball, squid ball): Aerobic Plate Count CFU/g, V. parahaemolyticus MPN/g and E. coli MPN/g. 		
H1c - Frozen minced and creamed fish products			
e.g. Uncooked product prepared from			
minced fish pieces in cream-type sauce			
H1di - Cooked fish and fish products	upon effectivity of FDA Circular No.	FDA Circular No. 2022-012	Applicant Company/
e.g. fish sausage; cooked fish products			Manufacturer/Source/Supplier
boiled down in soy sauce (tsukudani);	Valid Certificate of Analysis for		
cooked surimi product (kamaboko); crab-	Microbiological parameters for		
flavoured cooked kamaboko product	AQUATIC PRODUCTS:		
(kanikama); cooked fish roe; cooked	Salmonella/25g, V. parahaemolyticus		
surimi; cooked, tube-shaped surimi	MPN/g and S. aureus CFU/g		





product (chikuwa); and cooked fish and lobster paste (surimi-like products.)			
H1dii - Cooked molluscs, crustaceans and echinoderms e.g. cooked crangon crangon and crangon vulgaris (brown shrimp; cooked shrimp, clams and crabs	 ✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN COOKED CRUSTACEANS: E. coli MPN/g, S. aureus (coagulase +) CFU/g, V. parahaemolyticus CFU/g, Salmonella/25g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN COOKED CRUSTACEANS: E. coli MPN/g, S. aureus CFU/g, V. parahaemolyticus CFU/g, Salmonella/25g & Aerobic Plate Count CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 Valid Certificate of Analysis for Microbiological parameters for COOKED, CHILLED & FROZEN CRABMEAT: E. coli MPN/g, V. parahaemolyticus CFU/g, Salmonella/25g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for COOKED, CHILLED & FROZEN 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





H1diii - Fried fish and fish products e.g. ready-to-eat fried surimi, fried	CRABMEAT : E. coli MPN/g, S. aureus CFU/g, V. parahaemolyticus CFU/g & SPC/APC CFU/g		
calamari, and fried soft-shell crabs H2 - Fully preserved including canned or fermented fish and fish products e.g. canned tuna, clams, crab, fish roe and sardines; gefilte fish balls; and surimi (heat-pasteurized)	 Valid Certificate of Analysis for Microbiological parameters for FISH & SHELLFISH PRODUCTS IN HERMETICALLY SEALED CONTAINERS (THERMALLY PROCESSED): Commercial Sterility Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for FISH & SHELLFISH PRODUCTS, COOKED CRUSTACEANS IN HERMETICALLY SEALED CONTAINERS (THERMALLY PROCESSED) EG. COOKED BAGOONG/SHRIMP PASTE: Commercial Sterility 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	✓ Valid Certificate of Analysis for Total Solids, Protein and NaCl for BAGOONG (FISH AND SHRIMP)	Administrative Order No. 128 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
la - Liquid egg products	 Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED EGG PRODUCTS (LIQUID, FROZEN, DRIED): Coliforms 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	 CFU/g, Salmonella/25g, YMC CFU/g (for dried products) & SPC/APC CFU/g Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED EGG PRODUCTS (SMOKED LIQUID, FROZEN, DRIED): Coliforms CFU/g, Salmonella/25g, Yeast and Mold Count CFU/g (for dried products) & SPC/APC CFU/g 		
Ib - Frozen egg products	 Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED EGG PRODUCTS (LIQUID, FROZEN, DRIED): Coliforms CFU/g, Salmonella/25g, YMC CFU/g (for dried products) & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED EGG PRODUCTS (SMOKED LIQUID, FROZEN, DRIED): Coliforms CFU/g, Salmonella/25g, Yeast and Mold Count CFU/g (for dried products) & SPC/APC CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





Ic - Dried and/or heat coagulated egg products	 Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED EGG PRODUCTS (LIQUID, FROZEN, DRIED): Coliforms CFU/g, Salmonella/25g, YMC CFU/g (for dried products) & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED EGG PRODUCTS (SMOKED LIQUID, FROZEN, DRIED): Coliforms CFU/g, Salmonella/25g, Yeast and Mold Count CFU/g (for dried products) & SPC/APC CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
J1 - Infant formula, follow-on formula and formula for special medical purposes for infants	· · · · ·	AS FOR SPECIAL MEDICAL PURPOS Codex Stan 72-1981 Rev. 2007 FDA Circular No. 2013-010 FDA Circular No. 2022-012	SES INTENDED FOR INFANTS Applicant Company/ Manufacturer/Source/Supplier Applicant Company/ Manufacturer/Source/Supplier





Cronobacter spp./10g, Salmonella/25g, SPC/APC CFU/g & Enterobacteriaceae/10g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Valid Certificate of Analysis for Microbiological parameters for POWDERED INFANT FORMULA WITH OR WITHOUT ADDED LACTIC ACID PRODUCING CULTURES (INTENDED FOR 0 TO 6 MONTHS OLD): Cronobacter spp./10g, Salmonella/25g, SPC/APC cfu/g & Enterobacteriaceae/10g ☑ Valid Certificate of Analysis for Microbiological parameters for INFANT FORMULA- LIQUID (UHT/STERILIZED): Commercial Sterility Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for INFANT FORMULA- LIQUID (UHT/STERILIZED): Commercial	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
FORMULA- LIQUID (UHT/STERILIZED): Commercial Sterility		





 ✓ Clear and complete loose labels or artworks compliant with Department Circular No. 2008-0006 ✓ For FSMP: Scientific Studies indicating safety and benefits of the product for intended medical condition 	Department Circular No. 2008-0006 Codex Stan 72-1981 Rev. 2007 and Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier Applicant Company/ Manufacturer/Source/Supplier
	LOW-UP FORMULA/MILK SUPPLEM	= FNT
✓ Valid Certificate of Analysis for Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates per 100g, Vitamins and Minerals, Trace Minerals and Other Substances, Lauric/Mystiric/Trans Fatty Acids, Optional Ingredients- suitable for 6 months onwards and scientifically proven.	Codex Stan 156-1987	Applicant Company/ Manufacturer/Source/Supplier
 ✓ Valid Certificate of Analysis for Microbiological parameters for FOLLOW-UP FORMULA MILK/SUPPLEMENT (INTENDED FOR INFANTS 6 MONTHS ON AND FOR YOUNG CHILDREN 12-36 MONTHS): Salmonella/25g, SPC/APC CFU/g & Enterobacteriaceae/10g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for FOLLOW-UP FORMULA/MILK 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	SUPPLEMENT (FROM 6 MONTHS INFANTS TO 36 MONTHS YOUNG CHILDREN); FORMULA FOR SPECIAL MEDICAL PURPOSES FOR YOUNG CHILDREN: Salmonella/25g, Aerobic Plate Count CFU/g & Enterobacteriaceae/10g		
	✓ Clear and complete loose labels or artworks compliant with Department Circular No. 2008-0006.	Department Circular No. 2008-0006	Applicant Company/ Manufacturer/Source/Supplier
J2 - Complementary foods for infants	CEREAL-BA	SED FOODS FOR INFANTS & YOUNG	G CHILDREN
and young children e.g. cereal-, fruit-, vegetable-, and meat- based "baby foods" for infants, "toddler foods," and "junior foods"; lactea flour,	✓ Valid Certificate of Analysis for Energy, Protein, Carbohydrates, Lipids, Minerals and Vitamins per 100 kcal or 100 kJ	Codex Stan 074-1981, Rev 1-2006	Applicant Company/ Manufacturer/Source/Supplier
biscuits and rusks for children.	 ✓ Valid Certificate of Analysis for Microbiological parameters for CEREAL-BASED FOODS FOR INFANTS: Bacillus cereus CFU/g, Clostridium perfringes CFU/g, SPC/APC CFU/g, Salmonella/25g & Coliforms MPN/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for CEREAL-BASED FOODS FOR INFANTS : Bacillus cereus CFU/g, Clostridium perfringes CFU/g, Aerobic		









	 Valid Certificate of Analysis for Microbiological parameters for BABY FOODS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for BABY FOODS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks declaring the statement "Infants six months onwards should be given fresh, indigenous and natural food in combination with continued breastfeeding based on Department Circular No. 2008-0006.	Department Circular No. 2008-0006	Applicant Company/ Manufacturer/Source/Supplier
J3. Dietetic foods intended for special medical purposes (excluding products under HR Letter J.1.)	☑ Scientific Studies indicating safety and benefits of the product for intended medical condition	Codex Stan 180-1991 and Administrative No. Order 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis to support Nutrition Information	Codex Stan 180-1991	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks compliant with Codex Stan 180-1991.	Codex Stan 180-1991	Applicant Company/ Manufacturer/Source/Supplier
J4 - Dietetic formula for slimming purposes and weight reduction	Valid Certificate of Analysis to support Nutrition Information	Codex Stan 181-1991	Applicant Company/ Manufacturer/Source/Supplier





	☑ Clear and complete loose labels or artworks compliant with Codex Stan 181-1991	Codex Stan 181-1991	Applicant Company/ Manufacturer/Source/Supplier
J5 - Dietetic foods (e.g. supplementary foods for dietary use) excluding products under HR Letter J.1 to 4 and Letter K, Food Supplements)	Scientific Studies indicating safety and suitability of the product to specific disease and disorder to which it is intended	Codex Stan 146-1985 and Administrative No. Order 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis to support Nutrition Information	Codex Stan 146-1985	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks compliant with Codex Stan146-1985	Codex Stan 146-1985	Applicant Company/ Manufacturer/Source/Supplier
J6 - Weaning foods for infants and growing children			
J7 - Dietetic foods for special medical purpose	Scientific Studies indicating safety and benefits of the product for intended medical condition	Codex Stan 180-1991 and Administrative No. Order 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis to support Nutrition Information	Codex Stan 180-1991	Applicant Company/ Manufacturer/Source/Supplier
	Clear and complete loose labels or artworks compliant with Codex Stan 180-1991	Codex Stan 180-1991	Applicant Company/ Manufacturer/Source/Supplier
	 upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for READY- TO-USE THERAPEUTIC FOODS (RUTF) AND READY-TO-USE- SUPPLEMENTARY FOODS (RUFS), 	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	6-59 MONTHS OF AGE: Salmonella/25g		
J8 - Dietetic formulas for weight control	Valid Certificate of Analysis to support Nutrition Information	Codex Stan 181-1991	Applicant Company/ Manufacturer/Source/Supplier
	Clear and complete loose labels or artworks compliant with Codex Stan 181-1991	Codex Stan 181-1991	Applicant Company/ Manufacturer/Source/Supplier
J - Bottled Water	 Valid Certificate of Analysis for Physico-Chemical Properties (Turbidity, Color, Odor, Taste, pH, TDS, Conductivity, Calcium. Magnesium, Sodium, Potassium, Chloride, Sulfate), Contaminants (Nitrates, Nitrites, Iron, manganese, Copper, Zinc, Aluminum, Fluoride, organic Matter, Surfactants), Toxic Contaminants (Arsenic, Cadmium, Cyanide, Chromium, Lead, Mercury, Selenium, Phenolic Substances), Volatile Organic Compounds (Carbon tetrachloride, Benzene, Trihalomethanes), Pesticides & Related Substances (Carbamates, Organochlorines, Organophosphates, Herbicides, Fungicides, PCB), Radionuclides (Gross Alpha Activity, Gross Beta Activity) and Microbiological Parameters (Coliforms, Fecal Strepcocci, Pseudomonas Aeruginosa, HPC) 	Administrative Order No. 18-A s. 1993	Applicant Company/ Manufacturer/Source/Supplier





	Clear and complete loose labels or artworks compliant with Administrative Order No. 39 s. 1996 and Administrative Order No. 18-A s. 1993.	Administrative Order No. 39 s. 1996 and Administrative Order No. 18-A s. 1993	Applicant Company/ Manufacturer/Source/Supplier
K1 - Herbs and botanicals and/or Products with other nutritional substances and/or combination as Food Supplement e.g. Ginkgo Biloba + Co-Q10 + Korean	Shelf-life study with stability data containing relevant information on the critical parameters of the finished product, period conducted and conclusion	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
Ginseng Food Supplement Capsule	Valid Certificate of Analysis of the physico-chemical (Vitamins or Minerals or Amino Acids or Ingredient Assays) and/or microbiological parameters of the finished product (whichever is applicable)	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	Clear and complete loose labels or artworks declaring the term "Food Supplement" and the phrase "NO APPROVED THERAPEUTIC CLAIMS" based on BC 2 S. 1999	Bureau Circular No. 2 s 1999	Applicant Company/ Manufacturer/Source/Supplier
	Sample in actual commercial presentation	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	For TRADITIONALLY USED HERBAL PRODUCTS : Valid Certificate of Analysis for Heavy Metals in the finished product	Administrative Order No. 184 s. 2004	Applicant Company/ Manufacturer/Source/Supplier
	For VIRGIN COCONUT OIL FOOD SUPPLEMENT WITH FLAVOR: 1) That the raw material (virgin coconut oil) used conforms with the Philippine National Standards for Virgin Coconut	Bureau Circular 2006-018	Applicant Company/ Manufacturer/Source/Supplier





A 11		[]
Oil;		
2) That the flavoring added should be		
generally recognized as safe and		
suitable for human consumption as		
evidenced by a certification from the		
supplier. The nature of flavor used		
(natural, nature-identical, artificial) shall		
be indicated in the list of ingredients;		
3) No other food additive shall be		
allowed except the flavor;		
4) The label shall conform with BC 2 s.		
1999;		
5) The term "Food Supplement" shall		
be part of the product name		
upon effectivity of FDA Circular No.	FDA Circular No. 2022-012	
2022-012		
☑ Valid Certificate of Analysis for		
Microbiological parameters for VIRGIN		
COCONUT OIL: Aerobic Plate Count		
CFU/ml, Coliform MPN/ml or CFU/ml,		
Yeast and Mold Count CFU/ml,		
Salmonella spp. /25ml and E. coli MPN/ml or CFU/ml		
For GINKGO BILOBA :	Burgou Circular No. 02 o. 2004	Applicant Company/
	Bureau Circular No. 02 s. 2004	Applicant Company/
1.) Valid Certificate of Analysis for the		Manufacturer/Source/Supplier
Ginkgo Biloba Content;		
2.) Clear and complete label declaring		
the precaution "It is advised that		
Ginkgo Biloba should not be taken for 6		
months and longer and it should not be		





	Ι	
used with warfarin and other		
thrombolytic agents"		
For TAHEEBO / Pau d'arco /	Bureau Circular No. 17 s. 2004	Applicant Company/
Lapacho:		Manufacturer/Source/Supplier
Clear and complete label declaring the		
precautions:		
1. "This product is not intended to		
•		
diagnose, treat, cure, and prevent		
disease"		
2. "Maximum daily intake up to 3 cups		
per day only"		
3. "should not be taken with aspirin,		
ticlopidine, ginkgo biloba, ginseng,		
warfarin &		
heparin"		
4. "should not be taken by pregnant or		
breast-feeding mother"		
5. "should not be taken at least one		
week before contemplated operation"		
6. Stop intake of this product in the		
event of nausea, vomiting, diarrhea,		
skin pallor,		
bruises and nose bleeding.		
For PROBIOTICS WHICH BACTERIAL	Bureau Circular No. 16 a. 2004	Applicant Company/
STRAINS NOT FOUND IN THE	Bureau Circular No. 16 s. 2004	Applicant Company/
ACCEPTABLE LIST shall be subject to (1)		Manufacturer/Source/Supplier
demonstration of evidence of safe use as		
food supplement and (2) analysis of the		
bacterial species found in formulation.		
Likewise, BFAD shall use as reference:		
WHO-FAO "Guidelines for the Evaluation		
of Probiotics in Food" (2002).		





A. The BFAD also would lik	e to inform
everyone concerned that, for	or a Probiotic to
the effective, the	
following properties should	be
demonstrated:	
a. beneficial effect on the h	ost organism
b. should be able to survive	
tract	
c. should adhere to the muc	cosal epithelial
cells	
d. should exhibit enhancem	ent and
protection of the intestinal e	cology
e. should remain viable dur	
storage and use.	
B. For the demonstration of	the safety of a
Probiotic, the following doc	
be submitted:	
a. Determination of antibiot	c resistance
patterns	
b. Assessment of certain m	etabolic
activities (e.g., D-lactate pro	
salt deconjugation)	
c. Assessment of side-effect	ts during
human studies	
d. Epidemiological surveilla	nce of adverse
incidents in consumers (pos	
e. If the strain under evalua	
a species that is a known m	
producer,	
it must be tested for toxin p	aduction One
possible scheme for testing	
possible scheme for testing	





	been recommended by the EU Scientific Committee on Animal Nutrition (SCAN, 2000) f. If the strain under evaluation belongs to a species with known hemolytic potential, determination of hemolytic activity is required.		
K2 - Herbs and botanicals and/or Products with other nutritional substances and/or combination as Conventional Food Product e.g. Powdered Juice with marine collagen, coffee powder with barley grass, tongkat ali and royal jelly	 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC CFU/mL, Coliforms CFU/mL & SPC/APC CFU/mL Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 Valid Certificate of Analysis for Microbiological parameters for POWDERED BEVERAGE: SPC/APC CFU/g & YMC CFU/g Or upon effectivity of <u>FDA Circular No.</u> 2022-012 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	 ✓ Valid Certificate for Microbiological parameters for POWDERED BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES): Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g & Coliforms CFU/g 		
L. New in the international or local market/Other New Products/Unclassified or Unlisted in A.O. 2014-0029 Annex A			
FOOD PRODUCTS CONTAINING TRANS-FATTY ACIDS (TFA) Upon effectivity of FDA Circular 2021- 028, FDA Circular No.2021-028-A	 ✓ technical specifications of raw materials indicating specific oil(s) and/or fat(s) used and the processing it underwent; ✓ recent (within 12 months from date of application) certificate of analysis of the finished product from an accredited laboratory of the FDA and Philippine Accreditation Board/Office (PAB/PAO) or from the country of origin (for imported products), reflecting the TFA content per 100g or ml, validated reference methods of analysis, and the limit of detection for the method used in the analysis of TFA; and ✓ for prepackaged processed food containing naturally-occurring TFA of more than 2g TFA per 100g or ml of 	FDA Circular 2021-028 FDA Circular No.2021-028-A	Applicant Company/ Manufacturer/Source/Supplier





the total fat, recent (within 12 months from date of application) certificate of analysis showing that the TFA is naturally-occurring and/or obtained from ruminant animal, from an accredited laboratory of the FDA and Philippine Accreditation Board/Office (PAB/PAO) or from the country of	
of analysis and the limit of detection for the method used in the analysis.	





FOR AMENDMENT DATA CAPTURE DATA CAPTURE in the modified E-Registration System refers to applications processed in the old E-Registration System (Version 1) or thru manual registration			
system.			
GENERAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE	
Accomplished Application Form as prescribed by FDA regulations e.g. E-Registration System	FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	FDA Website	
☑ Proof of Payment of Fees as prescribed by current FDA regulations.	Administrative Order No. 50 s. 2001	Systems/Means prescribed by FDA	
☑ Scanned Application Letter stating the intended changes (indicate ALL the changes/amendments to be made)	Administrative Order No. 2014- 0029 FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	Applicant Company/ Manufacturer/Source/Supplier	
☑ Upload ALL INITIAL requirements.	FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	Applicant Company/ Manufacturer/Source/Supplier	
☑ Additional Requirements per Amendment Type. Please refer to TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – AMENDMENT (INITIAL APPLICATION APPROVED FROM MODIFIED E-REGISTRATION (VERSION 2) - III. ADDITIONAL Requirements per Amendment Type.	Administrative Order No. 2014- 0029 FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	Applicant Company/ Manufacturer/Source/Supplier	

FOR RE-APPLICATION DATA CAPTURE DATA CAPTURE in the modified E-Registration System refers to applications processed in the old E-Registration System (Version 1) or thru manual registration				
system.				
GENERAL REQUIREMENTS BASIS/ISSUANCE WHERE TO SECURE				
Accomplished Application Form as prescribed by FDA regulations	FDA Circular No. 2020-033	FDA Website		
e.g. E-Registration System				
Upload ALL INITIAL requirements AND compliance to the deficiencies stated in the <u>Administrative Order No. 2014-0029</u> Applicant Company/ In				
previously issued Letter of Denial (LOD) within 6 months upon receipt of LOD. FDA Circular No. 2020-033 reference to the				
FDA Circular No. 2020-033-A				





		previously filed and disapproved INITIAL application
☑ Proof of Payment of Fees as prescribed by current FDA regulations.	Administrative Order No. 50 s. 2001	Systems/Means prescribed by FDA

DATA CAPTURE in the modified E-Registration System refers to applications p	A CAPTURE (REGULAR) processed in the old E-Registration System (Versic stem.	on 1) or thru manual registration
GENERAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE
Accomplished Application Form as prescribed by FDA regulations e.g. E-Registration System	FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	FDA Website
☑ Upload ALL INITIAL requirements.	Administrative Order No. 2014-0029 FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	Applicant Company/ Manufacturer/Source/Supplier
☑ Proof of Payment of Fees as prescribed by current FDA regulations.	Administrative Order No. 50 s. 2001	Systems/Means prescribed by FDA

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the applicant company accomplishes (including uploading of the COMPLETE documentary requirements) the E- Registration System through the E-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to current FDA regulation/s on the use of the E-Registration Portal/E-Services.	 PRE-ASSESSMENT FDA Personnel will pre-assess ONLY the completeness of the submitted documents through E- Registration System/E-Portal https://eportal.fda.gov.ph. Result of Pre-assessment will be received by the account holder. 	Day 0	Center for Food Regulation and Research (CFRR) PRE-ASSESSOR (e.g. Food-Drug Regulation Officer (FDRO))





The client shall forward the application to PRE-ASSESSMENT . A system generated E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.	If found COMPLETE , an Order of Payment will be automatically generated and will be sent to the email of the account holder/client. If found INCOMPLETE , a notification with result of Pre- Assessment from FDA will be received. To refile, the applicant must start a NEW CASE and upload initially submitted documentary requirements together with the documents for compliance to the deficiencies mentioned. <i>For Food Supplement application, the proof of</i> <i>submission of sample can be re-uploaded to the new</i> <i>application.</i>		
(PRE-ASSESSMENT: COMPLETE)2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee through Systems/Means prescribed by FDA	 2) POSTING of payment FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then post the payment. The application will then be forwarded to CFRR, once payment is posted. 	Day 0 <i>Refer to FDA</i> <i>Cashier 's</i> <i>Citizen Charter</i>	Administrative and Finance Services (AFS) STAFF
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	3) EVALUATION The CFRR-Licensing and Registration Division (LRD) Technical Personnel will evaluate the application and	8 Working Days (Days 1-8)	LRD EVALUATOR (e.g. FDRO)





and Quality Work/Standard Procedures. The CFRR Approving Authority will then finalize the application by issuing Certificate of Product Registration (CPR) (for APPROVED application) or		
The CFRR Approving Authority will review the checked application, ALL the submitted documentary requirements, and the drafted recommendation of the CHECKER, in accordance to existing FDA regulation/s		
5) FINAL DECISION	5 Working Days (Days 16-20)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the APPROVING AUTHORITY.		
The CFRR-LRD Technical Personnel will review the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures.		
4) CHECKING or Quality Assurance (QA)	7 Working Days (Days 9-15)	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the CHECKER.		
ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures.		





	Letter of Denial (LOD) (for DISAPPROVED application), through the E-Registration System.		
5) If the application is APPROVED , an e- mail notification from FDA regarding the	6) GENERATION OF RESULT OF APPLICATION		Information and Communication Technology Management Division
ssuance of Certificate of Product Registration (CPR) will be received.	The E-Registration System generates electronically signed CPR or LOD.		(ICTMD) STAFF
f DISAPPROVED , an e-mail notification rom FDA regarding the issuance of Letter of Denial/Disapproval (LOD) will be received.			
For Amendment:			
If the application is approved, the applicant company will receive an e-mail notification from FDA indicating that the application is approved (this includes those amendments with multiple applications with approved and disapproved results) and another e- mail notification containing the Amendment Decision Summary Table.			
f disapproved, a Letter of Denial/Disapproval (LOD) and another e- nail notification containing the Amendment Decision Summary Table will be received.			
		TOTAL: 20 Working Days	
Always refer to the current FDA regulation/s on the use o	f the E-Registration System/E-Services: <u>FDA Website</u> 2 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1)		ly once for the same number of days which she
be indicated in the Citizen's Charter.		or the Act may be extended of	





II. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – AMENDMENT (INITIAL APPLICATION APPROVED FROM MODIFIED E-REGISTRATION (VERSION 2))

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical
Who May Avail	:	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	:	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF).
		Change or Extension of Shelf-life: Php 1,000.00 + 1% LRF
		Other Types of Amendment: Php 200.00 + 1% LRF

GENERAL GUIDELINES

Please refer to:

 A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of <u>FDA Circular No. 2020-033</u> || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and

2) III. General Guidelines, and IV. Specific Guidelines of <u>FDA Circular No. 2020-033-A</u> || Addendum to FDA Circular No. 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food

CHECKLIST OF REQUIREMENTS FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS		
GENERAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE
Accomplished Application Form as prescribed by FDA regulations	Administrative No. Order 2014-	FDA Website
e.g. E-Registration System	<u>0029</u>	
☑ Proof of Payment of Fees as prescribed by current FDA regulations.	Administrative Order 50 s. 2001	Systems/Means
		prescribed by FDA





be made)		Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company No. 2020-033	
☑ Valid and appropriate FDA License to Operate (required for all types of CPR application)		Administrative No. Order 2014- 0029 Republic Act 9711	FDA Philippines	
ADDITIONAL Requirements per Amendmen	t Type	· · ·		
AMENDMENT TYPE	ADDITIONAL REQUIREMENTS	BASIS	WHERE TO SECURE	
2a. Change in Brand Name	Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company	
	equivalents as defined by FDA regulations ☑ Authority from the source or the owner of the brand (imported & local)	FDA Circular No. 2020-035	Source/Supplier/Brand Owner	
	☑ IPO registration, if available.		IPO/Source/ Supplier	
2b. Change in Product Name/Additional Product Description	☑ Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier	
2c. Change in Company Name/Business Name	 Proof of change in business name (e.g. License to Operate) Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations 	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier	
2d. Change in/Additional Supplier	Any of the following scanned copy of the original documents: Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from the new supplier.	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier	





2e. Change in Packaging Material and/or Additional Packaging Type	 Clear and complete proposed loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations Pictures of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered. Proof of suitability of packaging material for food, 	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2f. Change of Packaging in Commercial Presentation (Change/Additional Packaging Size)	 including stability of the product in the new packaging. ☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations 	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2g. Change or Extension in Shelf-Life	Stability study results with conclusion to support extension or change in shelf-life	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2h. Change in/Additional Packaging design	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hi. Addition of Claims for Logos	 Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. Valid Certificate (e.g. HALAL, Sangkap pinoy seal, Organic, Kosher, etc.) 	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hii. Change in Label Color	Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hiii. Change in Font Size for Product Information	Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier





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2hiv. Change/Additional Claims for Source of Vitamins/Minerals and Health and Nutrition Claims	 Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. Certificate of Analysis (duly signed by competent technical staff including the complete name with appropriate parameters and result) or documents to substantiate claims. 	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hv. Change /Update in Nutrition Information (Vitamin and Mineral)	 Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. Certificate of Analysis (duly signed by competent technical staff including the complete name with appropriate parameters and result). 	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hvi. Change/Additional Menu or Serving suggestion (Photograph)	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hvii. Compliance to CPR Remarks	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hviii. Declaration of Distributor	 Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. Distributorship Agreement (Notarized, signed by the MAH/ Applicant Company and distributor reflecting the correct address 	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hix. Change of Manufacturer's Name	 Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. Attestation letter from the manufacturer stating the 	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier





	reason for change in manufacturer's name. ☑ ANY of the scanned copy of the original document issued by the Regulatory/ Health Authority/Recognized Issuing body/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin: Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or		
	FSSC Certificate or HACCP Certificate or Certificate of Free Sale. (if available).		
2hx. Locally Produced with Additional Activity for Export	 Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. LTO as food exporter if the company is not manufacturer. 	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hxi. Declaration of "Exclusively Distributed by"	 Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. Terms of Agreement/Exclusive Distributorship Agreement. 	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hxii. Declaration of Manufacturer's Office Address on the Label	Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2i. Transfer of Ownership of a Registered Product	 Proof of Agreement between previous and current owners of the product transferring ownership Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations 	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier





2j. Change in Importer/Distributor/Trader	☑ Termination of agreement/Deed of assignment	Administrative No. Order 2014-	Applicant Company/
_,	☑ Agreement of new manufacturer/importer/distributor or	0029	Source/Supplier
	Appointment letter	FDA Circular No. 2020-033	
	☑ Clear and complete loose labels or artworks, as		
	applicable, of all packaging sizes, or equivalents, reflecting		
	the change/s, as defined by FDA Regulations		
2k. For Change in	☑ Termination of agreement/Deed of assignment	Administrative No. Order 2014-	Applicant Company/
Importer/Distributor/Trader using a new	☑ Agreement of new manufacturer/importer/distributor or	0029 EDA Circular No. 0000 000	Source/Supplier
user account:	Appointment letter	FDA Circular No. 2020-033	
	Clear and complete loose labels or artworks, as		
	applicable, of all packaging sizes, or equivalents, reflecting		
	the change/s, as defined by FDA Regulations.		
	☑ Upload ALL INITIAL requirements		
21. Change in Company	☑ Proof of change in business name (e.g. License to	Administrative No. Order 2014-	Applicant Company/
Address/Business Address (Not	Operate)	0029 EDA Circular No. 2020 022	Source/Supplier
Applicable to Manufacturer and Repacker)	☑ Clear and complete loose labels or artworks reflecting	FDA Circular No. 2020-033	
Repacker	the change, as applicable, of all packaging sizes, or		
2m Change in LTO Number and/or LTO	equivalents as defined by FDA regulations	Administrative No. Order 2014	Applicant Company/
2m. Change in LTO Number and/or LTO Validity	Copy of updated License to Operate	Administrative No. Order 2014- 0029	Applicant Company/ Source/Supplier
Vanany		FDA Circular No. 2020-033	Source/Supplier
2n. Exportation of Previously	☑ Clear and complete loose labels or artworks as	Administrative No. Order 2014-	Applicant Company/
Registered Product Initially for Local	applicable, of all packaging sizes, or equivalents as	0029	Source/Supplier
Distribution.	defined by FDA regulations or reflecting compliance to	FDA Circular No. 2020-033	
	labelling requirements of importing country (if label is		
	different from the approved one)		
	Copy of License to Operate as Food Exporter		





20. Other Cases as Declared in	e.g. Change in Product Specification	Administrative No. Order 2014-	Applicant Company/
Succeeding FDA Issuances (Examples	☑ Copy of updated Product Specification Sheet	<u>0029</u>	Source/Supplier
but not limited to the following; as long		FDA Circular No. 2020-033	
as there is no change in formulation and	e.g. Change in Lot Code and Interpretation		
no change in manufacturer's address)	Copy of updated Product Specification Sheet		
	☑ Clear and complete loose labels or artworks reflecting		
	the change, as applicable, of all packaging sizes, or		
	equivalents as defined by FDA regulations		

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the	1) PRE-ASSESSMENT	Day 0	Center for Food
applicant company double clicks on the			Regulation and Research
specific product/CASE NUMBER in the	FDA Personnel will pre-assess ONLY the completeness of the		(CFRR) PRE-
INBOX folder, accomplishes (including	submitted documents through E-Registration System/E-Portal		ASSESSOR
uploading of the COMPLETE documentary	https://eportal.fda.gov.ph.		(e.g. Food-Drug
requirements) the E-Registration System	Description of Description will be received by the second balance		Regulation Officer
through the E-Portal	Result of Pre-assessment will be received by the account holder.		(FDRO))
https://eportal.fda.gov.ph based on the desired type of application in accordance to	If found COMPLETE, an Order of Payment will be automatically		
current FDA regulation/s on the use of the	If found COMPLETE , an Order of Payment will be automatically generated and will be sent to the email of the account		
E-Registration Portal/E-Services.	holder/client.		
The client shall forward the application to	If found INCOMPLETE , a notification with result of Pre-		
PRE-ASSESSMENT.	Assessment from FDA will be received. The application will return		
	to client's E-Registration System INBOX. The client may refile by		
A system generated E-mail notification from	proceeding as stated on CLIENT STEPS: 1).		
FDA will be received by the client upon			
submission of application for Pre-			
Assessment.			





(PRE-ASSESSMENT: COMPLETE) 2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee through Systems/Means prescribed by FDA	 2) POSTING of payment FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then post the payment. 	Day 0 Refer to FDA Cashier 's Citizen Charter	Administrative and Finance Services (AFS) STAFF
	The application will then be forwarded to CFRR, once payment is posted .		
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	 3) EVALUATION The CFRR-Licensing and Registration Division (LRD) Technical Personnel will evaluate the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the CHECKER. 	8 Working Days (Days 1-8)	LRD EVALUATOR (e.g. FDRO)
	4) CHECKING or Quality Assurance (QA) The CFRR-LRD Technical Personnel will review the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures.	7 Working Days (Days 9-15)	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)





Always refer to the current FDA regulation/s on the use of the Please be advised that as per RA No.11032 IRR, page 22 of be indicated in the Citizen's Charter.	e E-Registration System/E-Services: <u>FDA Website</u> 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be	extended only once for the sa	ame number of days, which shall
		TOTAL: 20 Working Days	
If DISAPPROVED , a Letter of Denial/Disapproval (LOD) and another e-mail notification containing the Amendment Decision Summary Table will be received.			
5) If the application is APPROVED , the applicant company will receive an e-mail notification from FDA indicating that the application is approved (this includes amendment with multiple applications with approved and disapproved results) and another e-mail notification containing the Amendment Decision Summary Table.	 6) GENERATION OF RESULT OF APPLICATION The E-Registration System generates electronically signed CPR or LOD. 		Information and Communication Technology Management Division (ICTMD) STAFF
	The CFRR Approving Authority will then finalizes the application by issuing Certificate of Product Registration (CPR) (for APPROVED application) or Letter of Denial (LOD) (for DISAPPROVED application) , through the E-Registration System.		
	 then will forward the same to the APPROVING AUTHORITY. 5) FINAL DECISION The CFRR Approving Authority will review the checked application, ALL the submitted documentary requirements, and the drafted recommendation of the CHECKER, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. 	5 Working Days (Days 16-20)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
	The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval,		





III. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – AUTOMATIC RENEWAL APPLICATION (INITIAL APPLICATION APPROVED FROM MODIFIED E-REGISTRATION (VERSION 2))

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical
Who May Avail	:	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	:	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF).
		Conventional Food (Category 1): Php 1,000.00/5 years of validity + 1% LRF Conventional Food (Category 2): Php 1,250.00/5 year of validity + 1% LRF Food Supplement: Php 5,000.00/5 years of validity + 1% LRF Bottled Water: Php 5,000.00/5 years of validity + 1% LRF

GENERAL GUIDELINES

Please refer to:

1) A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of <u>FDA Circular No. 2020-033</u> || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and

2) III. General Guidelines, and IV. Specific Guidelines of <u>FDA Circular No. 2020-033-A</u> || Addendum to FDA Circular No. 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food

GENERAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE
Accomplished Application Form as prescribed by FDA regulations.	FDA Circular No.2020-033	FDA Website
e.g. E-Registration System.	FDA Circular No.2020-033-A	
Select "RENEWAL" as type of application using the same case number used in initial		
application.		





☑ Proof of payment of fees as prescribed by current FDA regulations	Administrative Order 50 s. 2001	Systems/Means prescribed by FDA
☑ Valid and appropriate FDA License to Operate (required for all types of CPR application)	Administrative No. Order 2014- 0029 Republic Act 9711	FDA Philippines
☑ A sworn statement indicating no change in or variation whatsoever in the product is attached to the application.	Implementing Rules and Regulations of Republic Act No. 9711	Applicant Company

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the applicant	1) PRE-ASSESSMENT	Day 0	Center for Food
company double clicks on the specific product/CASE NUMBER in the INBOX folder,	FDA Personnel will pre-assess ONLY the completeness of		Regulation and Research
accomplishes (including uploading of the	the submitted documents through E-Registration System/E-		(CFRR) PRE- ASSESSOR
COMPLETE documentary requirements) the E-	Portal https://eportal.fda.gov.ph.		(e.g. Food-Drug
Registration System through the E-Portal			Regulation Officer
https://eportal.fda.gov.ph based on the desired	Result of Pre-assessment will be received by the account		(FDRO))
type of application in accordance to current FDA regulation/s on the use of the E-	holder.		
Registration Portal/E-Services.	If found COMPLETE , an Order of Payment will be		
	automatically generated and will be sent to the email of the		
The client shall forward the application to PRE- ASSESSMENT .	account holder/client.		
	If found INCOMPLETE , a notification with result of Pre-		
A system generated E-mail notification from	Assessment from FDA will be received. The application will		
FDA will be received by the client upon submission of application for Pre-Assessment.	return to client's E-Registration System INBOX. The client may refile by proceeding as stated on CLIENT STEPS: 1) .		
(PRE-ASSESSMENT: COMPLETE)		Day 0	
2) The applicant company receives the Order			
of Payment			





3) The applicant company pays the assessed fee through Systems/Means prescribed by FDA	 2) POSTING of payment FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then post the payment. The application will then be forwarded to CFRR, once payment is posted. 	Day 0 Refer to FDA Cashier 's Citizen Charter	Administrative and Finance Services (AFS) STAFF
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	3) FINAL DECISION The CFRR Approving Authority will then finalizes the application by issuing Certificate of Product Registration (CPR) (for APPROVED application) or Letter of Denial (LOD) (for DISAPPROVED application) , through the E-Registration System.	3 Working Days (Days 1-3)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
 5) If the application is APPROVED, an e-mail notification from FDA regarding the issaunce of Certificate of Product Registration (CPR) will be received. If DISAPPROVED, an e-mail notification from FDA regarding the issuance of Letter of Denial/Disapproval (LOD) will be received. 	4) GENERATION OF RESULT OF APPLICATION The E-Registration System generates electronically signed CPR or LOD.		Information and Communication Technology Management Division (ICTMD) STAFF
		TOTAL: 3 Working Days	
Always refer to the current FDA regulation/s on the use of the Please be advised that as per RA 11032 IRR, page 22 of 48, 5 <i>be indicated in the Citizen's Charter.</i>	E-Registration System/E-Services: FDA Website Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act ma	ay be extended only once for the sa	me number of days, which shall





IV. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR): AUTOMATIC RENEWAL (DATA CAPTURE)

(DATA CAPTURE in the modified e-Registration System/Portal (Version 2) refers to applications processed in the old e-Registration Portal (Version 1) or thru manual registration system)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical
Who May Avail	:	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	:	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF).
		Conventional Food (Category 1): Php 1,000.00/5 years of validity + 1% LRF Conventional Food (Category 2): Php 1,250.00/5 year of validity + 1% LRF Food Supplement: Php 5,000.00/5 years of validity + 1% LRF Bottled Water: Php 5,000.00/5 years of validity + 1% LRF

GENERAL GUIDELINES

Please refer to:

1) A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of <u>FDA Circular No. 2020-033</u> || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and

2) III. General Guidelines, and IV. Specific Guidelines of <u>FDA Circular No. 2020-033-A</u> || Addendum to FDA Circular No. 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food





CHECKLIST OF REQUIREMENTS FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS

GENERAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE
 Accomplished Application Form as prescribed by FDA regulations. e.g. E-Registration System. 	FDA Circular No.2020-033 FDA Circular No. 2020-033-A	FDA Website
☑ Proof of payment of fees as prescribed by current FDA regulations	Administrative Order 50 s. 2001	Systems/Means prescribed by FDA
☑ Valid and appropriate FDA License to Operate (required for all types of CPR application)	Administrative No. Order 2014- 0029 Republic Act No. 9711	FDA
☑ A sworn statement indicating no change in or variation whatsoever in the product is attached to the application.	Implementing Rules and Regulations of Republic Act No. 9711	Applicant Company
Upload ALL INITIAL requirements.	Administrative No. Order 2014- 0029 FDA Circular No. 2020-033	Applicant Company/ In reference to the previously filed and approved INITIAL application (The validity of the documents to be submitted must be in accordance to current FDA regulation/s).

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the	1) PRE-ASSESSMENT	Day 0	Center for Food
applicant company accomplishes (including			Regulation and Research
uploading of the COMPLETE documentary	FDA Personnel will pre-assess ONLY the completeness of the		(CFRR) PRE-
requirements) the E-Registration System	submitted documents through E-Registration System/E-Portal		ASSESSOR
through the E-Portal https://eportal.fda.gov.ph	https://eportal.fda.gov.ph.		(e.g. Food-Drug
based on the desired type of application in			Regulation Officer
accordance to current FDA regulation/s on the	Result of Pre-assessment will be received by the account holder.		(FDRO))
use of the E-Registration Portal/E-Services.			
	If found COMPLETE , an Order of Payment will be automatically		
The client shall forward the application to PRE-	generated and will be sent to the email of the account		
ASSESSMENT.	holder/client.		





A system generated E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.	If found INCOMPLETE , a notification with result of Pre- Assessment from FDA will be received. To refile, the applicant must start a NEW CASE and upload initially submitted documentary requirements together with the documents for compliance to the deficiencies mentioned. <i>For Food Supplement application, the proof of submission of</i> <i>sample can be re-uploaded to the new application.</i>		
(PRE-ASSESSMENT: COMPLETE)2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee through Systems/Means prescribed by FDA	 2) POSTING of payment FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then post the payment. The application will then be forwarded to CFRR, once payment is posted. 	Day 0 Refer to FDA Cashier 's Citizen Charter	Administrative and Finance Services (AFS) STAFF
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	 3) EVALUATION The CFRR-Licensing and Registration Division (LRD) Technical Personnel will evaluate the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR-LRD Technical Personnel will then draft 	3 Working Days (Days 1-3)	LRD EVALUATOR (e.g. FDRO)





			[]
	recommendation if the application is for Approval or Disapproval,		
	then will forward the same to the CHECKER.		
	4) CHECKING or Quality Assurance (QA) The CFRR-LRD Technical Personnel will review the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures.	2 Working Days (Days 4-5)	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
	The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the APPROVING AUTHORITY.		
	5) FINAL DECISION The CFRR Approving Authority will review the checked application, ALL the submitted documentary requirements, and the drafted recommendation of the CHECKER, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR Approving Authority will then finalizes the application by issuing Certificate of Product Registration (CPR) (for APPROVED application) or Letter of Denial (LOD) (for DISAPPROVED application) , through the E-Registration System.	2 Working Days (Days 6-7)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
 5) If the application is APPROVED, an e-mail notification from FDA regarding the issuance of Certificate of Product Registration (CPR) will be received. If DISAPPROVED, an e-mail notification from 	6) GENERATION OF RESULT OF APPLICATION The E-Registration System generates electronically signed CPR or LOD.		Information and Communication Technology Management Division (ICTMD) STAFF





FDA regarding the issuance of Letter of Denial/Disapproval (LOD) will be received.			
For Amendment:			
If the application is approved, the applicant company will receive an e-mail notification from FDA indicating that the application is approved (this includes those amendments with multiple applications with approved and disapproved results) and another e-mail notification containing the Amendment Decision Summary Table.			
If disapproved, a Letter of Denial/Disapproval (LOD) and another e-mail notification containing the Amendment Decision Summary Table will be received.			
		TOTAL: 7	
		Working Days	
Always refer to the current FDA regulation/s on the use of the E-	Registration System/E-Services: FDA Website		
	Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be exte	ended only once for the same number of days, wh	ich
shall be indicated in the Citizen's Charter.			





V. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – RE-APPLICATION (INITIAL APPLICATION DISAPPROVED FROM MODIFIED E-REGISTRATION)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical
Who May Avail	:	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	:	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF).
		Re-application Fee PhP 200.00 + 1% LRF

GENERAL GUIDELINES

Please refer to:

1) A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of <u>FDA Circular No. 2020-033</u> || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and

2) III. General Guidelines, and IV. Specific Guidelines of <u>FDA Circular No. 2020-033-A</u> || Addendum to FDA Circular No. 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food

CHECKLIST OF REQUIREMENTS FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS

GENERAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE
Accomplished Application Form as prescribed by current	FDA Circular No.2020-033	FDA Website
regulations.	FDA Circular No.2020-033-A	1) For the Certificate of Analysis:
5	Administrative No. Order	a) Applicant Company/ Manufacturer/Source/Supplier; or
Through the E-Registration System, upload/attach the compliance	<u>2014-0029</u>	 b) Laboratory analysis issued/conducted by FDA
to the deficiencies stated in the previously issued Letter of Denial		accredited laboratories.
(LOD) within 6 months upon receipt of LOD, using the same case		
number.		





		2) For other technical document(s):a) Applicant Company/ Manufacturer/Source/Supplier
Proof of payment of fees as prescribed by current FDA regulations.	Administrative Order 50 s. 2001	Systems/Means prescribed by FDA
☑ Valid and appropriate FDA License to Operate (required for all types of CPR application)	Administrative No. Order 2014-0029 Republic Act No. 9711	FDA Philippines

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the	1) PRE-ASSESSMENT	Day 0	Center for Food Regulation
applicant company double clicks on the			and Research (CFRR)
specific product/CASE NUMBER in the INBOX	FDA Personnel will pre-assess ONLY the completeness of the		PRE-ASSESSOR
folder, accomplishes (including uploading of	submitted documents through E-Registration System/E-Portal		(e.g. Food-Drug
the COMPLETE documentary requirements)	https://eportal.fda.gov.ph.		Regulation Officer
the E-Registration System through the E-Portal			(FDRO))
https://eportal.fda.gov.ph based on the desired	Result of Pre-assessment will be received by the account		
type of application in accordance to current	holder.		
FDA regulation/s on the use of the E-			
Registration Portal/E-Services.	If found COMPLETE , an Order of Payment will be automatically		
	generated and will be sent to the email of the account		
The client shall forward the application to PRE -	holder/client.		
ASSESSMENT.			
	If found INCOMPLETE , a notification with result of Pre-		
A system generated E-mail notification from	Assessment from FDA will be received. The application will		
FDA will be received by the client upon	return to client's E-Registration System INBOX. The client may		
submission of application for Pre-Assessment.	refile by proceeding as stated on CLIENT STEPS: 1) .		
(PRE-ASSESSMENT: COMPLETE)		Day 0	
2) The applicant company receives the Order			
of Payment			





3) The applicant company pays the assessed fee through Systems/Means prescribed by FDA	 2) POSTING of payment FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then post the payment. The application will then be forwarded to CFRR, once payment is posted. 	Day 0 <i>Refer to FDA Cashier 's Citizen Charter</i>	Administrative and Finance Services (AFS) STAFF
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	 3) EVALUATION The CFRR-Licensing and Registration Division (LRD) Technical Personnel will evaluate the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the CHECKER. 	8 Working Days (Days 1-8)	LRD EVALUATOR (e.g. FDRO)
	 4) CHECKING or Quality Assurance (QA) The CFRR-LRD Technical Personnel will review the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR-LRD Technical Personnel will then draft 	7 Working Days (Days 9-15)	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)





 application, ALL the drafted record existing FDA records and the drafted records and the drafted records existing FDA records and the drafted records and the	oving Authority will review the checked the submitted documentary requirements, and mmendation of the CHECKER, in accordance to julation/s and Quality Work/Standard oving Authority will then finalizes the application ficate of Product Registration (CPR) (for plication) or Letter of Denial (LOD) (for application) , through the E-Registration	5 Working Days (Days 16-20)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
company will receive an e-mail notification from FDA indicating that the application is approved (this includes amendment with multiple applications with approved and disapproved results) and another e-mail notification containing the Amendment Decision Summary Table.			
(LOD) and another e-mail notification containing the Amendment Decision Summary Table will be received.	N OF RESULT OF APPLICATION on System generates electronically signed CPR		Information and Communication Technology Management Division (ICTMD) STAFF
		TOTAL: 20 Working Days	
Always refer to the current FDA regulation/s on the use of the E-Registration System/E- Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The max			L





VI. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – FOR EXPORT MARKET ONLY

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical
Who May Avail	:	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	:	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF).
		Conventional Food (Category 1): Php 1,000.00/5 years of validity + 1% LRF Conventional Food (Category 2): Php 1,250.00/5 year of validity + 1% LRF Food Supplement: Php 5,000.00/5 years of validity + 1% LRF Bottled Water: Php 5,000.00/5 years of validity + 1% LRF

GENERAL GUIDELINES

Please refer to:

1) A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of <u>FDA Circular No. 2020-033</u> || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and

2) III. General Guidelines, and IV. Specific Guidelines of <u>FDA Circular No. 2020-033-A</u> || Addendum to FDA Circular No. 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food

CHECKLIST OF REQUIREMENTS FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS

GENERAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE
☑ ANNEX D - REQUIREMENTS FOR APPLICATION OF CERTIFICATE OF PRODUCT REGISTRATION	Administrative Order No. 2014-0029	FDA Website
 Accomplished Initial Application Form as prescribed by current FDA regulations. e.g. E-Registration System 	FDA Circular No.2020-033 FDA Circular No.2020-033-A	FDA Website





☑ Proof of Payment of Fees as prescribed by FDA regulations.	Administrative Order No. 50 s. 2001	Buyer/Recipient
Please refer to the table Fees to be Paid:		
☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or	Administrative Order No. 2014-0029	FDA Philippines
equivalents as defined by FDA regulations and <i>shall comply with existing regulations</i>		
of the importing country.		
Pictures of the product in all angles and in different packaging sizes, and from at least	Administrative Order No. 2014-0029	Applicant Company/
two different perspectives allowing visual recognition of a product as the same with the		Manufacturer/Source/Supplier
one being registered, as applicable.	Administrative Order No. 2014-0029	Applicant Company/
For FOOD SUPPLEMENT, a sample in actual commercial presentation shall be submitted.	Administrative Order No. 2014-0023	Manufacturer/Source/Supplier
As applicable, documents to substantiate claims, such as technical, nutritional or health	Administrative Order No. 2014-0029	Applicant Company/
studies or reports, market-research studies, Certificate of Analysis, quantitative analysis		Manufacturer/Source/Supplier
and computations, scientific report or studies published in peer-reviewed scientific		
journals, certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal,		
Organic, or Kosher food and in compliance with current labeling regulations.		
☑ VALID AND APPROPRIATE FDA LICENSE TO OPERATE (REQUIRED FOR ALL	Administrative Order No. 2014-0029	Applicant Company/
TYPES OF CPR APPLICATION)	Republic Act No. 9711	Manufacturer/Source/Supplier
SOURCE DOCUMENTS		and FDA Philippines
For locally produced products:	FDA Circular No.2020-033	Applicant Company/
☑ Distributorship Agreement or Contract Agreement signed by duly authorized	FDA Circular No.2020-033-A	Manufacturer/Source/Supplier
representative of the establishment or Certificate of Distributorship or Appointment Letter		
or Memorandum of Agreement from each supplier.		
e.g.		
For WHOLESALER:		
☑ Valid, notarized, and duly signed Distributorship Agreement or Memorandum of		
Agreement		
For TRADER:		
Valid, notarized, and duly signed Toll Manufacturing Agreement		





☑ copy of ANY of the following: Request for Quota	tion OR purchase order OR packing list		Buyer/Recipient
OR valid notarized agreement signed by importing			
Invoice, whichever is applicable, OR any supportin			
export market.	-		
RAW MATERIALS FOOD CATEGORIES	ADDITIONAL REQUIREMENTS	BASIS	WHERE TO SECURE
RAW MATERIALS - all substances that are			
employed in the processing of a finished			
product, packed in bulk containers and not			
labelled as finished product. Raw materials or			
ingredients would have product specifications			
that comply with the client requirements and not			
necessarily a single component.			
RM01 – Fats, Oils and Fat Emulsions			
e.g. Cooking Oils (Coconut, Palm, Soybean and			
Corn)			
RM02 - Processed Fruits, Vegetable and			
Edible Fungi, Seaweeds and Nuts			
RM03 - Confectionery			
RM04 - Cereals			
RM05 - Bakery Wares and Bakery Related			
Products			
e.g. Wheat Flour			
RM06 - Sweeteners including Honey			
e.g. Refined Sugar, Brown Sugar, Cane Sugar			
RM07 - Salt, Spices, Soups, Sauces, Salads			
and Protein Products			
e.g. lodized Salt, Soy Sauce			
RM08 - Beverages (excluding Dairy			
Products) Non-Alcoholic			
RM09 - Beverages (excluding Dairy			
Products) Alcoholic			





RM10- Dairy products and Analogues			
RM11- Frozen Desserts			
RM12 - Processed Fish and Fish Products			
Including Molluscs, Crustaceans and			
Echinoderms			
RM13 - Herbal Products			
RM14 - Vitamins and Minerals			
RM15 - Products with Nutritional Substances			
RM16 - Food Additives			
RM17 - Edible Casings (except natural			
casings from animal sources)			
RM18 - Processed Meat and Meat Products,			
including poultry and game			
LOW RISK FOOD PRODUCTS	ADDITIONAL REQUIREMENTS	BASIS	WHERE TO SECURE
LOW RISK FOOD PRODUCTS - foods that are			
unlikely to contain pathogenic microorganisms			
and will not normally support their growth			
because of food characteristics and foods that			
are unlikely to contain harmful chemicals.			
A1 - Butter oil, anhydrous milkfat, ghee			
A2 - Vegetable Oils and Fats			
e.g. Coconut, Palm, Soybean and Corn			
A3 - Animal Fats			
A4 - Fat emulsions mainly of type oil-in-water			
e.g. Imitation milk - a fat-substituted milk			
produced from nonfat milk solids by addition of			
vegetable fats (coconut, safflower or corn oil),			
non-dairy whipped cream, non-dairy toppings			
and vegetable cream			
A5 - Fat emulsions mainly of type water-in-oil			





based desserts e.g. loe cream like product made with vegetable fats	A6 Eat bacad descarts avaluding dainy		
e.g. Ice cream like product made with vegetable fats B1 - Dehydrated fruits or vegetables, including candied fruits B2 - Jams, jellies, marmalades B3 - Dehydrated vegetable protein products B4 - Fruits or Vegetables in vinegar, oil or brine in canned, bottled or hermetically sealed containers must be file under Medium Risk Food Product - MRC3 B5 - Fruits or vegetables, in vinegar, oil or brine in canned, bottled or hermetically sealed containers must be file under Medium Risk Food Product - MRC3 B5 - Fruit-based spreads excluding jams, jellies and marmalades e.g. Apple butter, lemon curd, mango chutney, raisin chutney B6 - Fruit Preparations e.g. fruit pulp, purees, fruit toppings, fruit sauce, fruit syrup, coconut milk and cream B7 - Cooked fruits e.g. Baked apples, tried apple rings, peach dumpings (baked peaches with a sweet dough covering B8 - Frozen vegetables, seaweeds, and nuts and seeds B9 - Vegetable seaweeds, nut and seed in pulps and preparations other than food in	A6 - Fat-based desserts excluding dairy-		
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B4 - Fruits or Vegetables in vinegar, oil or brine in canned, bottled or hermetically sealed containers must be file under Medium Risk Food Product - MRC3 Image: Content of the image: Content of t			
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and seeds Image: Seaweeds and seed in pulps and preparations other than food in			
B9 - Vegetable seaweeds, nut and seed in pulps and preparations other than food in			
pulps and preparations other than food in			
	-		
HR Letter B2	HR Letter B2		





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e.g. Aloe extract, potato pulp, horseradish		
pulp		
B10 - Cooked or fried vegetables and		
seaweeds		
C1 - Confectionery		
e.g. Includes all types of products that		
mainly contain sugar and other dietetic		
counterparts and may or may not contain cocoa		
(e.g. Hard candy, soft candy, nougats and		
marzipans		
C2 - Chewing gum		
C3 - Decorations, toppings (non-fruit), and		
sweet sauces		
e.g. Ready-to-eat icings and frostings for		
cakes, cookies etc, maple, caramel and		
flavoured syrups		
D1 - Flour, starches (including soybean		
powder) and flour mixes		
e.g. Wheat flour, corn flour, bran		
D2 - Breakfast cereals including rolled oats		
e.g. granola type breakfast cereals, corn		
flakes, multi-grain		
D3a - Fresh pastas and noodles and like		
products		
e.g. Unboiled noodles, lumpia wrapper		
D3b - Dried pastas and noodles and like		
products		
e.g. spaghetti pasta, bean vermicelli, rice		
vermicelli, macaroni, rice noodles		





D3c - Pre-cooked pastas and noodles and		
like products		
e.g. Instant noodles		
D4 - Cereal and starch-based desserts		
e.g. rice pudding, tapioca pudding		
D5 - Batters		
e.g. for breading or batters for fish or		
poultry		
D6 - Pre-cooked or processed rice products		
e.g. Prepackaged Rice in Retail Size, Iron Rice		
Premix		
D7a - Soybean based beverages		
D7b - Soybean based film		
e.g. Fuzhu - asian food which is a		
protein–lipid film isolated from soymilk surface		
through high-temperature incubation		
D7c - Soybean curd (tofu)		
D7d - Semi-dehydrated soybean curd		
D7e - Dehydrated soybean curd		
D7f - Other soybean protein products		
e.g. Soy-based "chicken" meat		
F1a - Breads and rolls - yeast leavened		
breads and specialty breads, soda breads		
e.g. White bread, raisin bread, whole wheat		
bread, hamburger rolls, hotdog buns		
F1b - Crackers excluding sweet crackers		
F1c - Other ordinary bakery products		
e.g. Bagels, pita, English muffins		
F1d - Bread-type products, including bread		
stuffing and bread crumbs		
e.g. Croutons		





	Image: series of the series





I9- Protein products other than from	
soybeans, marinades	
e.g. Vegetable Protein Analogues	
J1a - Non-alcoholic (soft) beverages without	
herbal ingredients	
e.g. Roasted coffee beans, coffee	
grounds, Freeze-dried coffee	
J1b - Non-alcoholic (soft) beverages with	
herbal ingredients	
e.g. Green Tea, Chamomile Tea	
J2a - Beer and Malt Beverages	
J2b - Cider and Perry	
J2c - Grape Wines	
e.g. Still grape wine, sparkling and semi-	
sparkling grape wines, fortified grape wine,	
grape liquor wine, sweet grape wine, red wine,	
white wine, rose wine	
J2d - Wines other than grape	
e.g. Fruit wine, rice wine	
J2e - Mead	
e.g. Honey wine	
J2f - Distilled spirituous beverages	
(>15%alcohol)	
e.g. Brandy, whisky, rhum, tequila, vodka	
J2g - Aromatized alcoholic beverages	
e.g. Aperitif wine	
K1 - Snacks - potato - cereal - or starch-	
based (from roots and tubers, pulses and	
legumes)	
e.g. Corn chips, crunchies, potato chips	





K2 - Chicharon			
e.g. Pork chicharon, mushroom chicharon K3 - Snacks - fish-based e.g. Fish Crackers, dried fish chips			
MEDIUM RISK FOOD PRODUCTS	ADDITIONAL REQUIREMENTS	BASIS	WHERE TO SECURE
MEDIUM RISK FOOD PRODUCTS - foods that are unlikely to contain pathogenic microorganisms and will not normally support their growth because of food characteristics; or food that is unlikely to contain pathogenic micro-organisms because of food type or processing, but may support the formation of toxins or the growth of pathogenic micro-organisms.			
A1a - Condensed milk (plain) (Includes partially dehydrated milk, evaporated milk, sweetened condensed milk, and khoa (cow or buffalo milk concentrated by boiling))	 Valid Certificate of Analysis for Microbiologicalparameters for SWEETENED CONDENSED MILK: Coliforms CFU/g, Yeast & Mold Count CFU/g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for SWEETENED CONDENSED MILK: Coliforms CFU/g, Yeast & Mold Count cfu/g & Aerobic Plate Count cfu/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 Valid Certificate of Analysis for Microbiological parameters for LIQUID MILK (EVAPORATED): Commercial Sterility 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





A1b - Beverage whiteners (Includes condensed milk analogues, blends of evaporated skimmed milk and vegetable fat and blends of sweetened condensed skimmed milk and vegetable fat) e.g. Condensed creamer			
A2 - Milk powder and cream powder and powder analogues (plain) e.g. imitation dry cream mix and blends of skimmed milk and vegetable fat in powdered form	 ✓ Valid Certificate of Analysis for Microbiological parameters for MILK POWDER (E.G. WHOLE, NONFAT, FILLED MILK, BUTTERMILK, WHEY & WHEY PROTEIN AND MILK INTENDED FOR CHILDREN MORE THAN 36 MONTHS OF AGE AND ADULTS): Salmonella/25g, SPC/APC CFU/g & Enterobacteriaceae CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for MILK POWDER (e.g. WHOLE, NONFAT, FILLED MILK, BUTTERMILK, WHEY & WHEY PROTEIN AND MILK INTENDED FOR CHILDREN MORE THAN 36 MONTHS OF AGE AND ADULTS): Salmonella/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A3 - Milk products for specific age groups or target population e.g. Powdered milk for children above 3 years and pregnant women	 ✓ Valid Certificate of Analysis for Microbiological parameters for MILK POWDER (E.G. WHOLE, NONFAT, FILLED MILK, 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





B1 - Non-Dairy based frozen desserts e.g. Sherbet, sorbet	BUTTERMILK, WHEY & WHEY PROTEIN AND MILK INTENDED FOR CHILDREN MORE THAN 36 MONTHS OF AGE AND ADULTS): Salmonella/25g, SPC/APC CFU/g & Enterobacteriaceae CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for MILK POWDER (e.g. WHOLE, NONFAT, FILLED MILK, BUTTERMILK, WHEY & WHEY PROTEIN AND MILK INTENDED FOR CHILDREN MORE THAN 36 MONTHS OF AGE AND ADULTS): Salmonella/25g ✓ Valid Certificate of Analysis for Microbiological parameters for ICE CREAM & SHERBET (PLAIN AND FLAVORED): Coliforms CFU/g, Listeria monocytogenes/25g, Selmanolla/25g	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	FLAVORED): Coliforms CFU/g,		
	CREAM & SHERBET (PLAIN AND FLAVORED) : Coliforms CFU/g,		





		•	
	Listeria monocytogenes/25g, Salmonella/25g, Aerobic Plate Count CFU/g & S. aureus CFU/g		
	 Valid Certificate of Analysis for Microbiological parameters for ICE CREAM WITH ADDED INGREDIENTS (NUTS, FRUITS, COCOA ETC.): Coliforms CFU/g, Listeria monocytogenes/25g, 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Salmonella/25g, SPC/APC CFU/g & S. aureus (coagulase +) CFU/g		
	 Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for ICE 		
	CREAM WITH ADDED INGREDIENTS (NUTS, FRUITS, COCOA ETC.): Coliforms CFU/g, S. aureus CFU/g, Salmonella/25g, Aerobic Plate Count CFU/g & Listeria		
B2 - Edible ices - popsicles e.g. Ice candy, ice popsicles	monocytogenes/25g ✓ Valid Certificate of Analysis for Microbiological parameters for FLAVORED ICE: SPC/APC cfu/g, Coliforms MPN/g, YMC cfu/g & Salmonella/25g	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012		





	 Valid Certificate of Analysis for Microbiological parameters for FLAVORED ICE: Aerobic Plate Count CFU/g, Coliforms MPN/g or CFU/g or /25g, Yeast and Mold Count CFU/g & Salmonella/25g Valid Certificate of Analysis for Microbiological parameters for ICE PRODUCTS (PRE-PACKAGED TUBED AND CUBED ICE): Coliforms MPN/100ml or /100ml, Thermo-tolerant MPN/100ml or Coliform/ E. coli /100ml and Heterotrophic Plate Count CFU/ml 		
C1 - Tomato products e.g. Tomato Catsup, tomato sauce, tomato paste			
C2 - Frozen fruits e.g. frozen fruit salad and frozen strawberries	 Valid Certificate of Analysis for Microbiological parameters for FROZEN FRUITS: E. coli MPN/g Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> Valid Certificate of Analysis for Microbiological parameters for 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Microbiological parameters for FROZEN FRUITS (pH >4.5) : E. coli CFU/g		





C3 - Canned or bottled (pasteurized) or retort pouch fruit and vegetable preserve in juice, syrup, brine	✓ Valid Certificate of Analysis for Microbiological parameters for FRUITS AND VEGETABLE	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
e.g. Mushroom whole in brine, Lychee in heavy syrup, Pitted green olives in brine	PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility		
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for FRUITS AND VEGETABLE PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility		
C4 - Fruit-based desserts, gelatin e.g. fruit-flavoured gelatin, rote gruze, frutgrod, fruit compote, nata de coco, and mitsumame (gelatin-like dessert of agar jelly,			
fruit pieces and syrup C5 - Fermented fruit products e.g. fermented plums			
C6 - Fruit fillings for pastry e.g. Cherry pie filling and raisin filling for oatmeal cookies			
C7 - Fermented vegetable products and seaweed products, excluding fermented soybean products MR Letter E.1 and E.2 (fermented soybeans and fermented soybean curd) and LR Letters I.8.b. 1 to 3) (soybean sauces) e.g. red pepper paste, fermented vegetable	 ✓ Valid Certificate of Analysis for Microbiological parameters for FERMENTED VEGETABLE (READY TO EAT): YMC CFU/g, Coliforms MPN/g, E. coli MPN/g, Salmonella/25g & S.aureus CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





products, kimchi (fermented Chinese cabbage and vegetable preparation), and sauerkraut (fermented cabbage	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for FERMENTED VEGETABLE (READY TO EAT) : Yeast and Mold Count cfu/g, Coliforms MPN/g or CFU/g or /25g, E. coli MPN/g or CFU/g or /25g, Salmonella/25g & S. aureus CFU/g		
C8 - Vegetable protein products (canned and frozen)			
D - Cocoa products and chocolate products e.g bonbons, cocoa butter confectionery (composed of cocoa butter, milk solids and sugar), white chocolate, chocolate chips (e.g. for baking), milk chocolate, cream chocolate, sweet chocolate, bitter chocolate, enrobing chocolate, chocolate covered in a sugar-based "shell" or with coloured decorations, filled chocolate (chocolate with a texturally distinct center and external coating, cocoa based spreads, tablea, imitation chocolate, chocolate substitute products)	 Valid Certificate of Analysis for Microbiological parameters for COCOA POWDER: Molds CFU/g, Salmonella/25g, Coliforms, MPN/g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for COCOA POWDER: Molds CFU/g, Salmonella/25g, Coliforms, MPN/g or CFU/g & Aerobic Plate Count CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 ✓ Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE PRODUCTS/CONFECTIONARIES: Molds CFU/g, Salmonella/25g, Coliforms MPN/g & SPC/APC CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	 Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE PRODUCTS: Molds CFU/g, Salmonella/25g, Coliforms MPN/g or CFU/g & Aerobic Plate Count CFU/g. ✓ Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE CONFECTIONARIES: Molds CFU/g, Osmophilic yeast CFU/g, Salmonella/25g, Coliforms MPN/g or CFU/g & Aerobic Plate Count CFU/g 		
E1 - Fermented soybeans			
e.g. dou chi (China), natto (Japan), and			
tempe (Indonesia)			
E2 - Fermented soybean curd			
F1ai - Cured (including salted) non-heat treated processed meat, poultry and game	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
products in whole pieces or cuts	Microbiological parameters for PACKAGED COOKED ,	FDA CIICUlai No. 2022-012	
e.g. bacon (cured, dry-cured, immersion-	CURED/SALTED MEAT: S. aureus		
cured, pump-cured); side bacon; corned beef;	(coagulase +) CFU/g, Salmonella/25g		
marinaded beef; and different types of Oriental	& Listeria monocytogenes/25g		
pickled products: miso-pickled meat (miso-			
zuke), koji-pickled meat (koji-zuke), and soy	Or upon effectivity of FDA Circular No.		
sauce-pickled meat (shoyu-zuke	2022-012		





	 Valid Certificate of Analysis for Microbiological parameters for PACKAGED COOKED, CURED/SALTED MEAT: S. aureus CFU/g, Salmonella/25g & Listeria monocytogenes/25g 		
	 Valid Certificate of Analysis for Microbiological parameters for CURED/SMOKED POULTRY: S. aureus (coagulase +) cfu/g & Salmonella/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for CURED/SMOKED POULTRY : S. aureus CFU/g & Salmonella/25g		
F1aii - Cured (including salted) and dried non-heat treated processed meat, poultry and game products in whole pieces or cuts e.g. dried salt pork, dehydrated meat, stuffed loin, Iberian ham, and proscuitto-type ham	 ✓ Valid Certificate of Analysis for Microbiological parameters for PACKAGED COOKED, CURED/SALTED MEAT: S. aureus (coagulase +) CFU/g, Salmonella/25g & Listeria monocytogenes/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for PACKAGED COOKED, 		





F1aiii - Fermented non-heat treated processed meat, poultry and game products - processed meat in whole pieces or cuts	CURED/SALTED MEAT: S. aureus CFU/g, Salmonella/25g & Listeria monocytogenes/25g ✓ Valid Certificate of Analysis for Microbiological parameters for CURED/SMOKED POULTRY: S. aureus (coagulase +) cfu/g & Salmonella/25g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for CURED/SMOKED POULTRY: S. aureus CFU/g & Salmonella/25g	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
e.g. potted beef and pickled (fermented) pig's feet			
F2ai - Cured (including salted) non-heat treated processed comminuted meat, poultry and game products e.g. chorizos (spicy pork sausages), salami- type products, salchichon, tocino (fresh, cured sausage), pepperoni, and smoked sausage.			
F2aii - Cured (including salted) and dried non-heat treated processed comminuted meat, poultry and game products (jerky, shredded beef/pork) e.g. pasturmas, dried sausages, cured and	 upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for DRIED ANIMAL PRODUCTS: S. aureus 	FDA Circular No. 2022-012	





dried sausages, beef jerky, Chinese sausages (including traditional cured or smoked pork sausage), and sobrasada	CFU/g, Clostridium perfringens CFU/g and Salmonella/25		
F2aiii - Fermented non-heat treated processed comminuted meat, poultry and game products e.g. pre-grilled beef patties; foie gras and pates; brawn and head cheese; cooked, cured chopped meat; chopped meat boiled in soy sauce (tsukudani); canned corned beef; luncheon meats; meat pastes; cooked meat patties; cooked salami-type products; cooked meatballs; saucises de strasbourg; breakfast sausages; brown-and-serve sausages; and terrines (a cooked chopped meat mixture).	 Certificate of Analysis for Microbiological parameters for FERMENTED, COMMINUTED MEAT, NOT COOKED (DRY & SEMI-DRY FERMENTED SAUSAGES): E. coli MPN/g, S. aureus (coagulase +) cfu/g & Salmonella/25g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for FERMENTED, COMMINUTED MEAT, NOT COOKED (DRY & SEMI-DRY FERMENTED SAUSAGES): E. coli MPN/g, S. aureus CFU/g & Salmonella/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
H1a - Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans and echinoderms e.g. salted anchovies, shrimp, and shad; smoked chub, cuttlefish and octopus; fish ham; dried and salted species of the Gadidae species; smoked or salted fish paste and fish roe; cured and smoked sablefish, shad, and salmon; dried shellfish, dried bonito (katsuobushi), and boiled, dried fish (niboshi)	 upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for ETHNIC FOOD PRODUCTS - DRIED, SALTED FISH: Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g, Coliforms MPN/g, E. coli MPN/g and S. aureus MPN/g ✓ Valid Certificate of Analysis for 	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





H2a - Fish and fish products, includings molluscs, crustaceans and echinoderms - marinated and/or in jelly e.g. "rollmops" (a type of marinated herring), sea eel (dogfish) in jelly and fish aspic	 Microbiological parameters for SMOKED FISH: Aerobic Plate Count CFU/g, Salmonella/25g, E. coli MPN/g and S. aureus CFU/g ✓ Valid Certificate of Analysis for Microbiological parameters for SALT FERMENTED FISH AND SHRIMPS (BAGOONG): Aerobic Plate Count CFU/g and Coliforms CFU/g ✓ Valid Certificate of Analysis for Microbiological parameters for PRE- COOKED BREADED FISH: E. coli MPN/g, S. aureus (coagulase +) CFU/g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for PRE- COOKED BREADED FISH: E. coli MPN/g, S. aureus CFU/g & Aerobic Plate Count CFU/g		
H2b - Fish and fish products, includings molluscs, crustaceans and echinoderms - pickled and/or in MH2brine e.g. different types of Oriental pickled products: koji-pickled fish (koji-zuke), lees-pickled fish (kasu- zuke), miso-pickled fish (miso-zuke), soy sauce-pickled fish (shoyu-zuke), and vinegar-pickled fish (su-zuke); pickled whale meat; and pickled herring and sprat			





H2c - Salmon substitutes, caviar and other			
fish roe products			
e.g. salted salmon roe (sujiko), processed,			
salted salmon roe (ikura), cod roe, salted cod			
roe (tarako) and lumpfish caviar			
H2d - Semi-preserved fish and fish products,			
including molluscs, crustaceans and			
echinoderms, excluding products under MR			
Letter H.1 a to c.			
e.g. fish or crustacean pates and traditional			
Oriental fish paste			
I1 - Preserved eggs, including alkaline,			
salted and canned eggs (salted eggs,			
century eggs)			
e.g. salt-cured duck eggs (Hueidan), and			
alkaline treated "thousand-year-old-eggs"			
(pidan)			
I2 - Egg-based desserts			
e.g. flan and egg custard. Also includes			
custard fillings for fine bakery wares (e.g. pies)			
Ja - Cakes, cookies, pies pastries,	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
doughnuts, sweet rolls, scones, muffins,	Microbiological parameters for BAKED	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
waffles - plain/without filling	GOODS: S. aureus (coagulase +)		
e.g. pancakes, waffles, filled sweet buns	CFU/g, MYC CFU/g, SPČ/APC ĆFU/g		
(anpan), Danish pastry, wafers or cones for ice	& Coliforms CFU/g		
cream, flour confectionery, and trifles	5		
	Or upon effectivity of FDA Circular No.		
	2022-012		
	☑ Valid Certificate of Analysis for		
	Microbiological parameters for BAKED		
	GOODS: Yeast CFU/g, Mold CFU/g,		





	Aerobic Plate Count, CFU/g, Coliforms CFU/g & Salmonella/25g		
Jb - Frozen dough	 Valid Certificate of Analysis for Microbiologicalparameters for FROZEN AND REFRIGERATED DOUGHS: Molds cfu/g, Yeast & Yeastlike Fungi cfu/g, Coliforms cfu/g, Psychrotrophic bacteria cfu/g & SPC/APC cfu/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for FROZEN AND REFRIGERATED 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
K1 - Soups and broths	DOUGHS: Salmonella/25g		
e.g. bouillon, broths, consommés, water- and cream-based soups, chowders, and bisques			
K2a - Emulsified sauces and dips e.g salad dressing (e.g., French, Italian, Greek, ranch style), fat-based sandwich spreads (e.g., mayonnaise with mustard), salad cream, fatty sauces and snack dips (e.g., bacon and cheddar dip, onion dip	 ✓ Valid Certificate of Analysis for Microbiological parameters for SALAD DRESSING, pH ≤ 4.6: SPC/APC CFU/g, YMC CFU/g, Salmonella/25g & Listeriamonocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for EMULSIFIED SAUCE PH ≤ 4.6 (E.G. 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	-	
	MAYONNAISE, THOUSAND ISLAND,	
	RANCH, FRENCH): Aerobic Plate	
	Count CFU/g, Yeast and Mold Count	
	CFU/g, Salmonella/25g & Listeria	
	monocytogenes/25g	
	☑ Valid Certificate of Analysis for	
	Microbiological parameters for	
	SALADS AND SANDWICH	
	SPREADS (excluding cocoa milk	
	based sandwich spreads): Aerobic	
	Plate Count CFU/g, Yeast and Mold	
	Count CFU/g, Salmonella/25g &	
	Listeria monocytogenes/25g	
K2b - Non-emulsified sauces (ketchup,		
cheese sauce, cream sauce, brown gravy)		
e.g. barbecue sauce, cheese sauce,		
Worcestershire sauce, Oriental thick		
Worcestershire sauce, Oriental linck Worcestershire sauce (tonkatsu sauce), chili		
sauce, sweet and sour dipping sauce, and white		
(cream-based) sauce (sauce consisting primarily		
of milk or cream, with little added fat (e.g. butter)		
and flour, with or without seasoning or spices		
K3 - Salads (e.g. macaroni salad, potato		
salad) and sandwich spreads excluding		
cocoa- and nut-based spreads under HR		
Letter B.8 (peanut butter) and MR D.1.c		
(cocoa-based spreads)		
e.g. Includes prepared salads, milk-based		
sandwich spreads, non-standardized		





mayonnaise-like sandwich spreads, and dressing for coleslaw (cabbage salad)			
L1a - Fruit and vegetable juices - (fruit juice, vegetable juice, concentrates for fruit juice, concentrates for vegetable juice)	 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC CFU/mL, Coliforms CFU/mL & SPC/APC CFU/mL Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: SPC/APC cfu/mL & YMC cfu/mL Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: Aerobic Plate Count CFU/ml & Yeast and Mold Count CFU/ml 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





2022-01 ☑ Valid Microbio IN HERM CONTAI	ectivity of <u>FDA Circular No.</u> 2 Certificate of Analysis for logical parameters for JUICES METICALLY SEALED NERS (TETRA PACK ETC.) : rcial Sterility	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
Microbio POWDE CFU/g & Or upon 2022-013 ☑ Valid paramete BEVERA POWDE Aerobic	Certificate for Microbiological ers for POWDERED AGES (e.g. ICED TEA, RED JUICES/MIXES): Plate Count CFU/g, Yeast and	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
upon effe 2022-012 ☑ Valid 0 Microbio BEVERA Plate Co	Certificate of Analysis for logical parameters for FRUIT AGE PRODUCTS: Aerobic unt CFU/ml, Yeast and Mold FU/ml, Coliforms CFU/ml &	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





L1b - Fruit and vegetable nectars (fruit nectar, vegetable bectar, concentrates for fruit nectar, concentrates for vegetable nectar)	 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC CFU/mL, Coliforms CFU/mL & SPC/APC CFU/mL Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL ☑ Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: SPC/APC CFU/mL & YMC CFU/mL Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: Aerobic Plate Count CFU/ml & Yeast and Mold Count CFU/ml 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	 upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for JUICES IN HERMETICALLY SEALED CONTAINERS (TETRA PACK ETC.): Commercial Sterility 	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 Valid Certificate of Analysis for Microbiological parameters for POWDERED BEVERAGE: SPC/APC CFU/g & YMC CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate for Microbiological parameters for POWDERED 		
	BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES): Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g & Coliforms CFU/g		
	 upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for FRUIT 	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	BEVERAGE PRODUCTS: Aerobic Plate Count CFU/ml, Yeast and Mold Count CFU/ml, Coliforms CFU/ml & E.coli CFU/ml.		
L1c - "Sport," "energy", or "electrolyte drinks"	 Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	CFU/mL, Coliforms CFU/mL &		
	SPC/APC CFU/mL		
	Or upon effectivity of <u>FDA Circular No.</u>		
	2022-012		
	Valid Certificate of Analysis for		
	Microbiological parameters for NON-		
	ALCOHOLIC BEVERAGES: Yeast and		
	Mold Count CFU/mL, Coliforms CFU/mL &		
	Aerobic Plate Count CFU/mL	EDA Oinsular Na. 0040.040	Ann line at One and the
L1ci - Carbonated water-based flavored	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
drinks	Microbiological	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
e.g. colas, pepper-types, root beer, lemon-	parameters for NON-ALCOHOLIC		
lime, and citrus types, both diet/light and regular	BEVERAGES: YMC CFU/mL,		
types)	Coliforms CFU/mL & SPC/APC		
	CFU/mL		
	Or upon effectivity of <u>FDA Circular No.</u>		
	<u>2022-012</u>		
	Valid Certificate of Analysis for		
	Microbiological parameters for NON-		
	ALCOHOLIC BEVERAGES (e.g.		
	READY TO DRINK, SOFTDRINKS,		
	ICED TEA, ENERGY DRINKS, JELLY		
	DRINKS): Yeast and Mold Count		
	CFU/mL, Coliforms CFU/mL & Aerobic		
	Plate Count CFU/mL		
L1cii - Non-carbonated water-based flavored	Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
drinks	Microbiological	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
e.g. almond, aniseed, coconut-based drinks,	parameters for NON-ALCOHOLIC		
and ginseng drink, lemonade, orangeade, citrus-	BEVERAGES: YMC CFU/mL,		





based soft drinks, iced tea, fruit-flavoured iced tea, chilled canned cappuccino drinks L1ciii - Concentrates (liquid or solid) for	Coliforms CFU/mL & SPC/APC CFU/mL Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL ✓ Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
water-based flavored drinks e.g. fountain syrups (e.g. cola syrup), fruit syrups for soft drinks, frozen or powdered concentrate for lemonade and iced tea mixes	Microbiological parameters for FROZEN JUICE CONCENTRATES: SPC/APC CFU/mL & YMC CFU/mL	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
	 Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for 		
	FROZEN JUICE CONCENTRATES : Aerobic Plate Count CFU/ml & Yeast and Mold Count CFU/ml		
L1d - Powdered cocoa drink mixes (cocoa) e.g. drinking chocolate powder; breakfast cocoa; cocoa dust (fines), nibs, mass, press cake; chocolate liquor; cocoa mixes (powders for preparing the hot beverage); cocoa-sugar	 Valid Certificate of Analysis for Microbiological parameters for POWDERED BEVERAGE: SPC/APC CFU/g & YMC CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





mixture; and dry mixes for sugar-cocoa confectionery)	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> Valid Certificate for Microbiological parameters for POWDERED BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES): Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g & Coliforms CFU/g		
M1 - Vitamins and minerals as Food Supplement e.g. Vitamin C + Zinc Food Supplement Capsule	☑ Valid Shelf-life study with stability data containing relevant information on the critical parameters of the finished product, period conducted and conclusion	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis of the physico-chemical (Vitamins or Minerals or Amino Acids Assays) and/or microbiological parameters of the finished product (whichever is applicable)	Administrative Order No. 2014-0029 Office Order No. 22 s 1991 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	*The amount of Vitamins shall conform with the prescribed level of <u>Office</u> <u>Order No. 22 s 1991</u>		
	Clear and complete loose labels or artworks compliant with the existing labelling regulation of the importing country.	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	 Sample in actual commercial presentation *for the procedure on submission, 	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier





	please refer to: IV. Guidelines, C. Procedural Guidelines 2. L. ii., Pages 7-8 of <u>FDA Circular No. 2020-033</u>		
M2 - Amino acids as Food Supplement e.g. Branched-Chain Amino Acids (BCAA) Food Supplement Powder	☑ Valid Shelf-life study with stability data containing relevant information on the critical parameters of the finished product, period conducted and conclusion	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	 ✓ Valid Certificate of Analysis of the physico-chemical (Vitamins or Minerals or Amino Acids Assays) and/or microbiological parameters of the finished product (whichever is applicable) *The amount of Vitamins shall conform with the prescribed level of Office Order No. 22 s 1991 	Administrative Order No. 2014-0029 Office Order No. 22 s 1991 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	Clear and complete loose labels or artworks compliant with the existing labelling regulation of the importing country.	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	 Sample in actual commercial presentation *for the procedure on submission, please refer to: IV. Guidelines, C. Procedural Guidelines 2. L. ii., Pages 7-8 of FDA Circular No. 2020-033 	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
N - Processed buts, including coated nuts and nut mixtures (with e.g. dried fruits) e.g. Yoghurt-, cereal-, and honey-covered			





nuts, and dried fruit-nut-and-cereal snacks (e.g.			
"trail mixes")			
HIGH RISK FOOD PRODUCTS	☑ ADDITIONAL REQUIREMENTS	BASIS	WHERE TO SECURE
HIGH RISK FOOD PRODUCTS - foods that may contain pathogenic microorganisms and will support the formation of toxins and or the growth or pathogenic microorganisms and foods that may contain harmful chemicals.			
A1a - Milk (plain) and buttermilk (plain) Includes pasteurized, ultra-high temperature (UHT) treated, sterilized, 1 homogenized, or fat adjusted milk. Includes, but is not limited to, skim, part-skim, low-fat and whole milk	 ✓ Valid Certificate of Analysis for Microbiological parameters for LIQUID MILK (EVAPORATED & READY TO DRINK)-UHT/STERILIZED: Commercial Sterility 	FDA Circular No. 2013-010	Applicant Company/ Manufacturer/Source/Supplier
Includes plain recombined fluid milks, plain reconstituted fluid milks, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks, lactose reduced milk, and plain milk-based beverages	✓ Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED MILK: Coliforms cfu/mL, Salmonella/25mL, Listeria monocytogenes/25mL, Psychrotrophic bacteria cfu/mL & Aerobic Plate Count cfu/g (for flavored milk)	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED MILK : Coliforms CFU/mL, Salmonella/25mL, Listeria monocytogenes/25mL, Psychrotrophic		
	bacteria cfu/mL & Aerobic Plate Count CFU/g (Plain/Flavored)		





A1b - Dairy-based drinks, flavored and/or fermented e.g. Chocolate Milk, Chocolate Malt Drinks, Drinking Yoghurt, Whey-based drinks	 Valid Certificate of Analysis for Microbiological parameters for LIQUID MILK (EVAPORATED & READY TO DRINK)-UHT/STERILIZED: Commercial Sterility Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for LIQUID MILK (READY TO DRINK)- UHT/STERILIZED: Commercial 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Sterility ☑ Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC CFU/mL, Coliforms CFU/mL & SPC/APC CFU/mL Or upon effectivity of FDA Circular No.	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL		





A2ai - Fermented milk (plain), non heat- treated after fermentation e.g. Yoghurt and plain drinks based on fermented milk	 ✓ Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK: S. aureus (coagulase +) CFU/mL, Coliforms CFU/mL, Salmonella/25mL & Lactic acid CFU/mL 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK : S. aureus CFU/mL, Coliforms CFU/mL, Salmonella/25mL & Lactic acid CFU/mL (required minimum level: ≥10^6 CFU/mL)		
A2aii - Fermented milks (plain), heat-treated after fermentation e.g. Sterilized or pasteurized plain drinks based on fermented milk	 Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK: S. aureus (coagulase +) CFU/mL, Coliforms CFU/mL, Salmonella/25mL & Lactic acid CFU/mL Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK: S. aureus CFU/mL, Coliforms CFU/mL, Salmonella/25mL & Lactic acid 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	CFU/mL (required minimum level: ≥10^6 CFU/mL)		
A2b - Renneted milk (plain) e.g. Curdled milk			
A3a - Pasteurized cream (plain)	 Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED CREAM: Coliforms cfu/g, Salmonella/25g, Listeria monocytogenes/25g, Psychrotrophic bacteria CFU/g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED CREAM: Coliforms 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	cfu/g, Salmonella/25g, Listeria monocytogenes/25g, Aerobic Plate Count cfu/g		
A3b - Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain) e.g. whipping cream, heavy cream, whipped pasteurized cream, and whipped cream-type	✓ Valid Certificate of Analysis for Microbiological parameters for CREAM (UHT/STERILIZED): Commercial Sterility	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
dairy toppings and fillings	 Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for CREAM (UHT/STERILIZED): Commercial Sterility 		





A3c - Clotted cream (plain)			
A3d - Cream analogues			
A4a - Unripened cheese e.g. cottage cheese (a soft, unripened, coagulated curd cheese), creamed cottage cheese (cottage cheese covered with a creaming mixture),2 cream cheese (rahmfrischkase, an uncured, soft spreadable cheese),3 mozzarella and scamorza cheeses. Includes the whole unripened cheese and unripened cheese rind (for those unripened cheeses with a "skin" such as mozzarella)	 ☑ Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for HARD AND SEMI-HARD CHEESE: Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for CREAM CHEESE PRODUCTS: Coliforms CFU/g or MPN/g or /25g, E.coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	[] \/alid Oartificate of Arrahasis for	EDA Circular No. 2012 010	Applicant Company/
	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Microbiological parameters for ALL	TDA Circular No. 2022-012	
	RAW MILK CHEESE:		
	Campylobacter/25g, Salmonella/25g,		
	Listeria monocytogenes/25g and S.		
	aureus (coagulase +) CFU/g		
	Or upon effectivity of FDA Circular No.		
	2022-012		
	Valid Certificate of Analysis for		
	Microbiological parameters for ALL		
	RAW MILK CHEESE; RAW MILK UN-		
	RIPENED CHEESE W/ MOISTURE >		
	50%, pH > 5.0: Campylobacter/25g,		
	Listeria monocytogenes/25g,		
	Salmonella/25g & S. aureus CFU/g		
A4bi - Ripened cheese, includes rind	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
e.g. Ripened cheese may be soft (e.g.,	Microbiological parameters for	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
camembert), firm (e.g., edam, gouda), hard	CHEESE AND CHEESE PRODUCTS		
(e.g., cheddar), or extra-hard. Includes cheese	(MOISTURE > 39% & PH > 5): S.		
in brine, which is a ripened semi-hard to soft	aureus (coagulase +) CFU/g, E. coli		
cheese, white to yellowish in colour with a	MPN/g, Coliforms MPN/g,		
compact texture, and without actual rind that has	Psychrotrophic bacteria CFU/g,		
been preserved in brine until presented to the	Salmonella/25g & Listeria		
consumer	monocytogenes/25g		
	Or upon effectivity of FDA Circular No.		
	2022-012		
	✓ Valid Certificate of Analysis for		
	•		
	Microbiological parameters for SOFT		





CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria		
monocytogenes/ 25g & S. aureus CFU/g		
✓ Valid Certificate of Analysis for Microbiological parameters for HARD AND SEMI-HARD CHEESE: Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g		
✓ Valid Certificate of Analysis for Microbiological parameters for CREAM CHEESE PRODUCTS: Coliforms CFU/g or MPN/g or /25g, E.coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g		
✓ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE: Campylobacter/25g, Salmonella/25g, Listeria monocytogenes/25g and S. aureus (coagulase +) CFU/g	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE; RAW MILK		





A4bii - Rind of ripened cheese A4biii - Cheese powder (for reconstitution) e.g. Spray-dried cheese	UN-RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0: Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g		
A4c - Whey cheese A4di - Plain processed cheese e.g. American Cheese, requeson	 ✓ Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





 ✓ Valid Certificate of Analysis for Microbiological parameters for HARD AND SEMI-HARD CHEESE: Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria 		
monocytogenes/ 25g & S. aureus CFU/g		
 Valid Certificate of Analysis for Microbiological parameters for CREAM CHEESE PRODUCTS: Coliforms CFU/g or MPN/g or /25g, E.coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g 		
 ✓ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE: Campylobacter/25g, Salmonella/25g, 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
Listeria monocytogenes/25g and S. aureus (coagulase +) CFU/g		
 Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for ALL 		
RAW MILK CHEESE; RAW MILK UN- RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0: Campylobacter/25g,		
Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
Microbiological parameters for	FDA Circular No. 2022-012	Manufacturer/Source/Supplier





vegetables, pepper jack cheese, cheddar cheese spread with wine, and cheese balls (formed processed cheese coated in nuts, herbs or spices) HEESE AND CHEESE PRODUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E. coli CFU/g, Salmonella/25g, Listeria monocytogenes/25g & S. aureus				
CFU/g & SPC / APC CFU/g [®] Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 Set Vaid Certificate of Analysis for Microbiological parameters for PROCESSED CHEESE SPREAD: Coliforms CFU/g & Aerobic Plate Count CFU/g FDA Circular No. 2013-010 Applicant Company/ A4dii - Flavored processed cheese or e.g. eufchatel cheese spread with vegetables, pepper jack cheese, cheddar cheese balls (formed processed cheese coated in nuts, herbo or spices) Ø Valid Certificate of Analysis for MICrobiological parameters for CHU/g, E. coli MINPN/g, Collforms MPN/g, Desychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g FDA Circular No. 2022-012 Applicant Company/ Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 Applicant Company/ MPN/g, Collforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 Applicant Company/ Or upon effectivity of FDA Circular No. 2022-012 Ø Valid Certificate of Analysis for Microbiological parameters for SOFT FDA Circular No. 2022-012 Applicant Company/ Or upon effectivity of FDA Circular No. 2022-012 Ø Valid Certificate of Analysis for Microbiological parameters for SOFT FDA Circular No. 2022-012 Applicant Company/ MICrobiological parameters for SOFT FDA Circular No. 2022-012 Ø Valid Certificate of Analysis for Microbiological parameters for SOFT FDA Circular No. 2022-012 </th <th></th> <th></th> <th></th> <th></th>				
A4dii - Flavored processed cheese e.g. eufchatel cheese spread with vine, and cheese balls (formed processed cheese coated in nuts, herbs) Ø Valid Certificate of Analysis for Microbiological parameters for CHUg S. aureus (CoPU/g S. aureus CFU/g S. aureus COPUCTS PDA Circular No. 2013-010 Applicant Company/ Manufacturer/Source/Supplier of processed cheese coated in nuts, herbs Ø Valid Certificate of Analysis for MPN/g, Colforms MPN/g, Salmonella/25g & Listeria monocytogenes/25g FDA Circular No. 2013-010 Applicant Company/ Microbiological parameters for or spices) Or upon effectivity of FDA Circular No. 2022-012 Manufacturer/Source/Supplier Or upon effectivity of FDA Circular No. 2022-012 Ø Valid Certificate of Analysis for Microbiological parameters for SOFT FDA Circular No. 2022-012 Applicant Company/ MILK): Enterobacteriaceae CFU/g, E. coli MILK): Enterobacteriaceae CFU/g, E. coli CFU/g, Salmonella/25g & S. aureus FDA Circular No. 2022-012 IValid Certificate of Analysis for Microbiological parameters for SOFT				
2022-012 Image: Second Structure Structure Valid Certificate of Analysis for Microbiological parameters for PROCESSED CHEESE SPREAD: Coliforms CFU/g, S. aureus CFU/g & Aerobic Plate Count CFU/g FDA Circular No. 2013-010 Applicant Company/ A4dii - Flavored processed cheese GV Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli FDA Circular No. 2022-012 Applicant Company/ Manufacturer/Source/Supplier or spices) Or upon effectivity of FDA Circular No. 2022-012 FDA Circular No. 2022-012 Applicant Company/ MINV/g, Coliforms MPN/g, Salmonella/25g Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 Applicant Company/ Valid Certificate of Analysis for Microbiological parameters for SoFT CHEESE (FROM PASTEURIZED MILK): Enterobacteria Ger CFU/g, Salmonella/25g & Listeria monocytogenes/25g FDA Circular No. 2022-012 Applicant Company/		CFU/g & SPC /APC CFU/g		
2022-012 Image: Second Structure Structure Valid Certificate of Analysis for Microbiological parameters for PROCESSED CHEESE SPREAD: Coliforms CFU/g, S. aureus CFU/g & Aerobic Plate Count CFU/g FDA Circular No. 2013-010 Applicant Company/ A4dii - Flavored processed cheese GV Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli FDA Circular No. 2022-012 Applicant Company/ Manufacturer/Source/Supplier or spices) Or upon effectivity of FDA Circular No. 2022-012 FDA Circular No. 2022-012 Applicant Company/ MINV/g, Coliforms MPN/g, Salmonella/25g Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 Applicant Company/ Valid Certificate of Analysis for Microbiological parameters for SoFT CHEESE (FROM PASTEURIZED MILK): Enterobacteria Ger CFU/g, Salmonella/25g & Listeria monocytogenes/25g FDA Circular No. 2022-012 Applicant Company/				
Addii - Flavored processed cheese e.g. eufchatel cheese spread with vegetables, pepper jack cheese cheddar cheese spread with wine, and cheese balls (formed processed cheese coated in nuts, herboi or spices) Ø Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PREDDUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g FDA Circular No. 2013-010 FDA Circular No. 2022-012 Applicant Company/ Manufacturer/Source/Soupplier Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 FDA Circular No. 2022-012 Applicant Company/ Manufacturer/Source/Soupplier Valid Certificate of Analysis for MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g FDA Circular No. 2022-012 Applicant Company/ Manufacturer/Source/Soupplier Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E. coli CFU/g, Salmonella/25g & S. aureus FDA Circular No. 2022-012 Applicant Company/ Microbiological parameters for SOFT				
Microbiological parameters for PROCESSED CHEESE SPREAD: Coliforms CFU/g, S, aureus CFU/g & Aerobic Plate Count CFU/g FDA Circular No. 2013-010 Applicant Company/ Manufacturer/Source/Supplier A4dii - Flavored processed cheese e.g. eufchatel cheese spread with vegetables, pepper jack cheese, cheddar I Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g FDA Circular No. 2022-012 Applicant Company/ Manufacturer/Source/Supplier Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 Cortificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E. coli CFU/g, Salmonella/25g, Listeria monocytogenes/25g & S. aureus Applicant Company/ PS/schortophic bacteria CFU/g, aureus		<u>2022-012</u>		
PROCESSED CHEESE SPREAD: Coliforms CFU/g, S. aureus CFU/g & Aerobic Plate Count CFU/g Aureus CFU/g & Aerobic Plate Count CFU/g Applicant Company/ A4dii - Flavored processed cheese e.g. eufchatel cheese spread with vegetables, pepper jack cheese, cheddar cheese spread with wine, and cheese balls formed processed cheese coated in nuts, herbs or spices) If Valid Certificate of Analysis for CHEESE AND CHEESE PRODUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g FDA Circular No. 2022-012 Applicant Company/ Manufacturer/Source/Supplier Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 Pice Circular No		Valid Certificate of Analysis for		
A4dii - Flavored processed cheese Coliforms CFU/g, S. aureus CFU/g & Aerobic Plate Count CFU/g FDA Circular No. 2013-010 Applicant Company/ vegetables, pepper jack cheese, cheddar cheese spread with vegetables, pepper jack cheese, cheddar cheese spread with wine, and cheese balls (formed processed cheese coated in nuts, herbs) Image: Coliforms CFU/g, S. aureus FDA Circular No. 2013-010 Applicant Company/ Molis TURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g Anuple Circular No. 2022-012 Anufacturer/Source/Supplier Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 Image: Coliforms MPN/g, Coliforms MPN/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 Image: Coliforms MPN/g, Coliforms MPN/g, Salmonella/25g & Listeria monocytogenes/25g Image: Coliform Manufacture/Source/Supplier MiLK): Enterobacteriace of Analysis for Milcrobiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E. coli CFU/g, Salmonella/25g & S. aureus E. coli CFU/g, Salmonella/25g & S. aureus Image: Coliform Milcrobiological parameters for SOFT		Microbiological parameters for		
Addii - Flavored processed cheese e.g. eufchatel cheese spread with vegetables, pepper jack cheese, cheddar cheese spread with wine, and cheese balls (formed processed cheese coated in nuts, herbs or spices) ✓ Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS (MOISTURE > 39% & PH > 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g FDA Circular No. 2022-012 Applicant Company/ Manufacturer/Source/Supplier Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E. coli CFU/g, Salmonella/25g & S. aureus FDA Circular No. E. Coli Salmonella/25g & S. aureus		PROCESSED CHEESE SPREAD:		
Addii - Flavored processed cheese		Coliforms CFU/g, S. aureus CFU/g &		
e.g. eufchatei cheese spread with vegetables, pepper jack cheese, cheddar cheese spread with wine, and cheese balls (formed processed cheese coated in nuts, herbs or spices)		Aerobic Plate Count CFU/g		
e.g. eufchatel cheese spread with vegetables, pepper jack cheese, cheddar cheese spread with wine, and cheese balls (formed processed cheese coated in nuts, herbs or spices)	A4dii - Flavored processed cheese	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
vegetables, pepper jack cheese, cheddar CHEESE AND CHEESE PRODUCTS cheese spread with wine, and cheese balls (MOISTURE > 39% & PH > 5): S. or spices) aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, BL.coli CFU/g, Salmonella/25g, Listeria monocytogenes/25g		Microbiological parameters for	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
(formed processed cheese coated in nuts, herbs or spices) aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus	vegetables, pepper jack cheese, cheddar			
or spices) MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 Image: Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/25g, Listeria monocytogenes/25g & S. aureus		(MOISTURE > 39% & PH > 5): S.		
Psychrotrophic bacteria CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of <u>FDA Circular No.</u> 2022-012 Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus	(formed processed cheese coated in nuts, herbs	aureus (coagulase +) CFU/g, E. coli		
Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus	or spices)	MPN/g, Coliforms MPN/g,		
monocytogenes/25g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus		Psychrotrophic bacteria CFU/g,		
Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus		Salmonella/25g & Listeria		
2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus		monocytogenes/25g		
2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus				
 ✓ Valid Certificate of Analysis for Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus 		Or upon effectivity of FDA Circular No.		
Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus		2022-012		
Microbiological parameters for SOFT CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus		☑ Valid Certificate of Analysis for		
CHEESE (FROM PASTEURIZED MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus		,		
MILK): Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus		e 1		
E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus		•		
monocytogenes/ 25g & S. aureus				
		CFU/g		





 ✓ Valid Certificate of Analysis for Microbiological parameters for HARD AND SEMI-HARD CHEESE: Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ✓ Valid Certificate of Analysis for Microbiological parameters for CREAM CHEESE PRODUCTS: Coliforms CFU/g or MPN/g or /25g, E.coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g ✓ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE: Campylobacter/25g, Salmonella/25g, Listeria monocytogenes/25g and S. aureus (coagulase +) CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE; RAW MILK UN- RIPENED CHEESE; RAW MILK UN- RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0: Campylobacter/25g, Listeria monocytogenes/25g, 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
Salmonella/25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	PROCESSED CHEESE SPREAD: S.		
	aureus (coagulase +) CFU/g, Coliforms		
	CFU/g & SPC /APC CFU/g		
	Or upon effectivity of <u>FDA Circular No.</u>		
	<u>2022-012</u>		
	Valid Certificate of Analysis for		
	Microbiological parameters for		
	PROCESSED CHEESE SPREAD:		
	Coliforms CFU/g, S. aureus CFU/g &		
	Aerobic Plate Count CFU/g		
A4e - Cheese analogues	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
e.g. imitation cheese, imitation cheese mixes,	Microbiological parameters for	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
and imitation cheese powders	CHEESE AND CHEESE PRODUCTS		
	(MOISTURE > 39% & PH > 5): S.		
	aureus (coagulase +) CFU/g, E. coli		
	MPN/g, Coliforms MPN/g,		
	Psychrotrophic bacteria CFU/g,		
	Salmonella/25g & Listeria		
	monocytogenes/25g		
	Or upon effectivity of <u>FDA Circular No.</u>		
	<u>2022-012</u>		
	☑ Valid Certificate of Analysis for		
	Microbiological parameters for SOFT		
	CHEESE (FROM PASTEURIZED		
	MILK): Enterobacteriaceae CFU/g,		
	E.coli CFU/g, Salmonella/ 25g, Listeria		
	monocytogenes/ 25g & S. aureus		
	CFU/g		





☑ Valid Certificate of Analysis for	 Valid Certificate of Analysis for Microbiological parameters for HARD AND SEMI-HARD CHEESE: Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g Valid Certificate of Analysis for Microbiological parameters for CREAM CHEESE PRODUCTS: Coliforms CFU/g or MPN/g or /25g, E.coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE: Campylobacter/25g, Salmonella/25g, Listeria monocytogenes/25g and S. aureus (coagulase +) CFU/g Or upon effectivity of FDA Circular No. 2022-012 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
RAW MILK CHEESE; RAW MILK UN- RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0: Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g Here is a structure of the	aureus (coagulase +) CFU/g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE; RAW MILK UN- RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0: Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for		Applicant Company/ Manufacturer/Source/Supplier





	 PROCESSED CHEESE SPREAD: S. aureus (coagulase +) CFU/g, Coliforms CFU/g & SPC /APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for PROCESSED CHEESE SPREAD: Coliforms CFU/g, S. aureus CFU/g & Aerobic Plate Count CFU/g 		
A4f - Whey protein cheese e.g. ricotta cheese			
A5 - Dairy-based desserts e.g. Includes flavoured yoghurt (a milk product obtained by fermentation of milk and milk products to which flavours and ingredients (e.g., fruit, cocoa, coffee) have been added) that may or may not be heat-treated after fermentation. Other junket (sweet custard-like dessert made from flavoured milk set with rennet), dulce de leche (cooked milk with sugar and added ingredients such as coconut or chocolate), butterscotch pudding and chocolate mousse. Includes traditional milk-based sweets prepared from milk concentrated partially, from khoa (cow or buffalo milk concentrated by boiling), or chhena (cow or buffalo milk, heat coagulated aided by acids like citric acid, lactic acid, malic acid, etc), sugar or synthetic sweetener, and other ingredients (e.g. maida (refined wheat	 ✓ Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK: S. aureus (coagulase +) CFU/mL, Coliforms CFU/mL, Salmonella/25mL & Lactic acid CFU/mL Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK: S. aureus CFU/mL, Coliforms CFU/mL, Salmonella/25mL & Lactic acid CFU/mL (required minimum level: ≥10^6 CFU/mL) 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





flour), flavours and colours (e.g. peda, burfee, milk cake, gulab jamun, rasgulla, rasmalai, basundi	 ✓ Valid Certificate of Analysis for Microbiological parameters for ETHNIC MILK-BASED CONFECTIONERIES (e.g. PASTILLAS and YEMA): Yeast and Mold Count CFU/g, Salmonella/25, Coliforms MPN/g or CFU/g and 		
Aca Liquid where and where are directed	Aerobic Plate Count CFU/g		
A6a - Liquid whey and whey products			
A6b - Dried whey and whey products			
A7 - Milk for manufacture			
A8 - Dairy-based frozen desserts e.g. ice cream (frozen dessert that may contain whole milk, skim milk products, cream or butter, sugar, vegetable oil, egg products, and fruit, cocoa, or coffee), ice milk (product similar to ice cream with reduced whole or skim milk content, or made with nonfat milk), jellied milk, frozen flavoured yoghurt	 Valid Certificate of Analysis for Microbiological parameters for ICE CREAM & SHERBET (PLAIN AND FLAVORED): Coliforms CFU/g, Listeria monocytogenes/25g, Salmonella/25g, SPC/APC CFU/g & S. aureus (coagulase +) CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for ICE CREAM & SHERBET (PLAIN AND FLAVORED): Coliforms CFU/g, Listeria monocytogenes/25g, Salmonella/25g, Aerobic Plate Count CFU/g & S. aureus CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	✓ Valid Certificate of Analysis for Microbiological parameters for ICE CREAM WITH ADDED	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	INGREDIENTS (NUTS, FRUITS, COCOA ETC.): Coliforms CFU/g,		
	Listeria monocytogenes/25g,		
	Salmonella/25g, SPC/APC CFU/g & S.		
	aureus (coagulase +) CFU/g		
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012		
	☑ Valid Certificate of Analysis for		
	Microbiological parameters for ICE		
	CREAM WITH ADDED		
	INGREDIENTS (NUTS, FRUITS,		
	COCOA ETC.) : Coliforms CFU/g, S.		
	aureus CFU/g, Salmonella/25g,		
	Salmonella/25g CFU/g & Listeria		
	monocytogenes/25g		
B1 - Dried fruits and vegetable - plain/sun-	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
dried seaweeds, and nuts and seeds	Microbiological parameters for SUN	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
e.g. Includes vegetable powders that are obtained	DRIED FRUITS: Mold CFU/g,		
from drying the juice, such as tomato powder and	Osmophilic Yeasts cfu/g & E. coli		
beet powder, dried potato flakes and dried lentil,	MPN/g		
dried sea tangle (kelp; kombu), dried sea tangle	ivii ivig		
with seasoning (shio-kombu), dried seaweed (tororo-kombu), dried gourd strips (kampyo), dried	Or upon effectivity of <u>FDA Circular No.</u> 2022-012		
laver (nori), and dried laminariales (wakame)	☑ Valid Certificate of Analysis for		
	Microbiological parameters for SUN		
	DRIED FRUITS: Mold CFU/g,		
	Osmophilic Yeasts cfu/g & E. coli		
	MPN/g		





	 Valid Certificate of Analysis for Microbiological parameters for DRIED VEGETABLE: E. coli MPN/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for DRIED 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
B2 - Vegetable seaweed, and nut and seed - purees, spreads e.g. tomato puree, peanut butter (a spreadable paste made from roasted and ground peanuts by the addition of peanut oil), other nut butters (e.g., cashew butter), and pumpkin butter)	 VEGETABLE: É. coli MPN/g ✓ Valid Certificate of Analysis for Microbiological parameters for PEANUT BUTTER & OTHER NUT BUTTERS: Salmonella/25g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for PEANUT BUTTER & OTHER NUT 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
D - Chocolate with nuts	BUTTERS: Salmonella/25g✓ Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE PRODUCTS/CONFECTIONARIES: Molds CFU/g, Salmonella/25g, Coliforms MPN/g & SPC/APC CFU/gOr upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	 Microbiological parameters for CHOCOLATE PRODUCTS: Molds CFU/g, Salmonella/25g, Coliforms MPN/g or CFU/g & Aerobic Plate Count CFU/g. ✓ Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE CONFECTIONARIES: Molds CFU/g, Osmophilic yeast CFU/g, Salmonella/25g, Coliforms MPN/g or CFU/g & Aerobic Plate 		
F1 - Fine bakery products with fillings: meat, milk, poultry, cream, and other perishable foods; icings and coatings e.g. butter cake, cheesecake, fruit-filled cereal bars, pound cake (including kasutera), moist cake (type of starchy dessert (namagashi)), western cakes, moon cakes, sponge cake, fruit-filled pies (e.g. apple pie), oatmeal cookies, sugar cookies and British "biscuits" (cookies or sweet crackers)	Count CFU/g☑ Valid Certificate of Analysis forMicrobiological parameters for BAKEDGOODS (MICROBIOLOGICALLYSENSITIVE TYPES E.G.CONTAINING EGGS & DAIRYPRODUCTS): S. aureus (coagulase +)cfu/g, MYC CFU/g, SPC/APC CFU/g &Coliforms CFU/g)Or upon effectivity of FDA Circular No.2022-012☑ Valid Certificate of Analysis forMicrobiological parameters for BAKEDGOODS: Yeast CFU/g, Mold CFU/g,Aerobic Plate Count CFU/g, ColiformsCFU/g & Salmonella/25g	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





[] Valid Cartificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
 ✓ Valid Certificate of Analysis for Microbiological parameters for COATED OR FILLED, DRIED SHELF- STABLE BISCUITS: Coliforms MPN/g & Salmonella/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Manufacturer/Source/Supplier
Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for COATED OR FILLED, DRIED SHELF- STABLE BISCUIT S: Coliforms MPN/g & Salmonella/25g		
☑ Valid Certificate of Analysis for Microbiological parameters for ETHNIC FLOUR-BASED CONFECTIONERIES e.g. PIAYA): Yeast and Mold Count CFU/g and Coliforms CFU/g		
 ✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN BAKERY PRODUCTS (READY TO EAT) WITH LOW ACID OR HIGH Aw FILLINGS OR TOPPINGS: S. aureus (coagulase +) CFU/g & Salmonella/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for		





	Microbiological parameters for FROZEN BAKERY PRODUCTS (READY TO EAT) WITH LOW ACID OR HIGH Aw FILLINGS OR TOPPINGS: S. aureus CFU/g & Salmonella/25g		
	 ✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN BAKERY PRODUCTS (TO BE COOKED) WITH LOW ACID OR HIGH Aw FILLINGS OR TOPPINGS: S. aureus (coagulase +) CFU/g & Salmonella/25g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN BAKERY PRODUCTS (TO BE COOKED) WITH LOW ACID OR HIGH Aw FILLINGS OR TOPPINGS : S. aureus CFU/g & Salmonella/25g		
F2 - Cookies with nuts	 ✓ Valid Certificate of Analysis for Microbiological parameters for BAKED GOODS (MICROBIOLOGICALLY SENSITIVE TYPES E.G. CONTAINING EGGS & DAIRY PRODUCTS): S. aureus (coagulase +) cfu/g, MYC cfu/g, SPC/APC cfu/g & Coliforms cfu/g) 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for BAKED GOODS: Yeast CFU/g, Mold CFU/g, Aerobic Plate Count CFU/g, Coliforms CFU/g & Salmonella/25g		
G1a - Heat-treated processed meat, poultry and game products in whole pieces or cuts (canned) e.g. cured, cooked ham; cured, cooked pork shoulder; canned chicken meat; and meat pieces boiled in soy sauce (tsukudani)	✓ Valid Certificate of Analysis for Microbiological parameters for MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINERS : Commercial Sterility		
G1b - Frozen processed meat, poultry and game products in whole pieces or cuts (marinated pork/beef/chicken cuts) e.g. frozen whole chickens, frozen, marinated chicken, frozen chicken parts, and frozen beef steaks	 Valid Certificate of Analysis for Microbiological parameters for FRESH/FROZEN RAW CHICKEN: SPC/APC cfu/g Or upon effectivity of FDA Circular No. 2022-012: NONE 	FDA Circular No. 2013-010	Applicant Company/ Manufacturer/Source/Supplier
G2a - Heat-treated processed comminuted meat, poultry and game products (canned) e.g. pre-grilled beef patties; foie gras and pates; brawn and head cheese; cooked, cured	 ✓ Valid Certificate of Analysis for Microbiological parameters for MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





chopped meat; chopped meat boiled in soy sauce (tsukudani); canned corned beef; luncheon meats; meat pastes; cooked meat patties; cooked salami-type products; cooked meatballs; saucises de strasbourg; breakfast sausages; brown-and-serve sausages; and terrines (a cooked chopped meat mixture)	Sterility Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> Valid Certificate of Analysis for Microbiological parameters for MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINERS : Commercial		
G2b - Frozen processed comminuted meat, poultry and game products (nuggets, patties, dumplings salami, meat loaf, hotdog) e.g. frozen hamburger patties; frozen breaded or battered chicken fingers	Sterility☑ Valid Certificate of Analysis for Microbiological parameters for COLD CUTS, FROZEN & CHILLED HOTDOGS: E. coli MPN/g, Salmonella/25g, S. aureus (coagulase +) CFU/g & SPC/APC CFU/gOr upon effectivity of FDA Circular No. 2022-012☑ Valid Certificate of Analysis for Microbiological parameters for COLD CUTS, FROZEN & CHILLED HOTDOGS: E. coli MPN/g or CFU/g or /25g, Salmonella/25g, S. aureus, L. monocytogenes/25g & Aerobic Plate Count CFU/g☑ Valid Certificate of Analysis for Microbiological parameters for COLD CUTS, FROZEN & CHILLED HOTDOGS: E. coli MPN/g or CFU/g or /25g, Salmonella/25g, S. aureus, L. monocytogenes/25g & Aerobic Plate Count CFU/g☑ Valid Certificate of Analysis for Microbiological parameters for COOKED POULTRY MEAT, FROZEN TO BE REHEATED BEFORE EATING	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	(e.g. prepared frozen meals chicken	
	burgers, chicken turkey rolls,	
	chicken nuggets, other breaded	
	poultry meat products): Aerobic	
	Plate Count CFU/g, S. aureus CFU/g,	
	Listeria monocytogenes/25g,	
	Salmonella/25 and Campylobacter	
	jejuni/25g	
	jojuni/20g	
	☑ Valid Certificate of Analysis for	
	-	
	Microbiological parameters for	
	MARINATED MEAT PRODUCTS (e.g. Marinated meat and meat	
	preparations (tapa, sisig, etc.), -	
	Marinated poultry, Dim sum made	
	from meat (siomai)): Salmonella/25g,	
	Listeria monocytogenes/25g and S.	
	aureus CFU/g	
	Valid Certificate of Analysis for	
	Microbiological parameters for FOODS	
	COOKED IMMEDIATELY PRIOR TO	
	SALE OR CONSUMPTION (e.g.	
	Takeaway food, burgers, kebabs,	
	sausages, pizza, ready meals	
	(cook/chill and cook/freeze) after	
	regeneration): Aerobic Plate Count	
	CFU/g, Enterobacteriaceae CFU/g, E.	
	coli CFU/g, S. aureus (coagulase +)	
	CFU/g, Salmonella/25g and Listeria	
	monocytogenes/25g	
<u></u>		





 upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for MINCED MEAT AND MEAT PREPARATIONS MADE FROM 	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
POULTRY MEAT INTENDED TO BE EATEN COOKED: Aerobic Plate Count CFU/g, E. coli CFU/g and Salmonella/25g		
 ✓ Valid Certificate of Analysis for Microbiological parameters for MINCED MEAT AND MEAT PREPARATIONS MADE FROM 		
SPECIES OTHER THAN POULTRY INTENDED TO BE EATEN COOKED: Salmonella/25g, Aerobic Plate Count CFU/g and E. coli CFU/g		Applicant Company/
✓ Valid Certificate of Analysis for Microbiological parameters for MEAT PASTE & PATE: Salmonella/25g, Clostridium perfringens CFU/g, S. aureus (coagulase +) CFU/g, Coliforms CFU/g & SPC/APC CFU/g	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for MEAT		





	PASTE & PATE : Salmonella/25g, Clostridium perfringens CFU/g, S. aureus CFU/g, Coliforms CFU/g & Aerobic Plate Count CFU/g		
H1a - Frozen fish, fish fillets and fish products e.g. Frozen or deep frozen clams, cod fillets, crab, finfish, haddock, hake, lobster, minced fish, prawns and shrimp; frozen fish roe; frozen surimi; and frozen whale meat	 ✓ Valid Certificate of Analysis for Microbiological parameters for FRESH FROZEN FISH: E. coli MPN/g, S. aureus (coagulase +) CFU/g, V. parahaemolyticus CFUu/g, Salmonella/25g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for FRESH FROZEN FISH: E. coli MPN/g, S. aureus CFU/g, V. parahaemolyticus MPN/g, Salmonella/25g & Aerobic Plate Count CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 ✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN RAW CRUSTACEANS: E. coli MPN/g, S. aureus (coagulase +) CFU/g, V. parahaemolyticus CFU/g, Salmonella/25g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	FROZEN RAW CRUSTACEANS: E. coli MPN/g, S. aureus CFU/g, Salmonella/25g, V. parahaemolyticus MPN/g, Aerobic Plate Count CFU/g ☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Microbiological parameters for FRESH & FROZEN BIVALVE MOLLUSCS : E. coli MPN/g, V. parahaemolyticus CFU/g, Salmonella/25g & SPC/APC CFU/g		
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for FRESH & FROZEN BIVALVE MOLLUSCS : E. coli MPN/g, Salmonella/25g, V. parahaemolyticus MPN/g & Aerobic Plate Count CFU/g		
H1b - Frozen battered fish, fish fillets and fish products, including molluscs, crustaceans and echinoderms e.g.frozen raw breaded or batter-coated shrimp; and frozen or quick-frozen breaded or batter-coated fish fillets, fish portions and fish sticks (fish fingers)	 ✓ Valid Certificate of Analysis for Microbiological parameters for PRE- COOKED BREADED FISH: E. coli MPN/g, S. aureus (coagulase +) CFU/g & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for PRE- COOKED BREADED FISH: E. coli 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	 MPN/g, S. aureus CFU/g & Aerobic Plate Count CFU/g Valid Certificate of Analysis for Microbiological parameters for FISH AND CRUSTACEAN BASED PROCESSED MEAT (e.g. fish ball, squid ball): Aerobic Plate Count CFU/g, S. aureus CFU/g, V. parahaemolyticus MPN/g and E. coli MPN/g. 		
H1c - Frozen minced and creamed fish products e.g. Uncooked product prepared from minced fish pieces in cream-type sauce	in rug.		
H1di - Cooked fish and fish products e.g. fish sausage; cooked fish products boiled down in soy sauce (tsukudani); cooked surimi product (kamaboko); crab-flavoured cooked kamaboko product (kanikama); cooked fish roe; cooked surimi; cooked, tube-shaped surimi product (chikuwa); and cooked fish and lobster paste (surimi-like products.)	 upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ☑ Valid Certificate of Analysis for Microbiological parameters for AQUATIC PRODUCTS: Salmonella/25g, V. parahaemolyticus MPN/g and S. aureus CFU/g 	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
H1dii - Cooked molluscs, crustaceans and echinoderms e.g. cooked crangon crangon and crangon vulgaris (brown shrimp; cooked shrimp, clams and crabs	 Valid Certificate of Analysis for Microbiological parameters for FROZEN COOKED CRUSTACEANS: E. coli MPN/g, S. aureus (coagulase +) CFU/g, V. parahaemolyticus CFU/g, Salmonella/25g & SPC/APC CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	 Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN COOKED CRUSTACEANS: E. coli MPN/g, S. aureus CFU/g, V. parahaemolyticus CFU/g, Salmonella/25g & Aerobic Plate Count CFU/g ✓ Valid Certificate of Analysis for 	FDA Circular No. 2013-010	Applicant Company/
	Microbiological parameters for COOKED, CHILLED & FROZEN CRABMEAT : E. coli MPN/g, V. parahaemolyticus CFU/g, Salmonella/25g & SPC/APC CFU/g Or upon effectivity of <u>FDA Circular No.</u>	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
	2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for COOKED, CHILLED & FROZEN CRABMEAT: E. coli MPN/g, S. aureus CFU/g, V. parahaemolyticus CFU/g & SPC/APC CFU/g		
H1diii - Fried fish and fish products e.g. ready-to-eat fried surimi, fried calamari, and fried soft-shell crabs			
H2 - Fully preserved including canned or fermented fish and fish products	✓ Valid Certificate of Analysis for Microbiological parameters for FISH & SHELLFISH PRODUCTS IN	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





e.g. canned tuna, clams, crab, fish roe and sardines; gefilte fish balls; and surimi (heat- pasteurized)	 HERMETICALLY SEALED CONTAINERS (THERMALLY PROCESSED): Commercial Sterility Or upon effectivity of FDA Circular No. 2022-012 ✓ Valid Certificate of Analysis for Microbiological parameters for FISH & SHELLFISH PRODUCTS, COOKED CRUSTACEANS IN HERMETICALLY SEALED CONTAINERS (THERMALLY PROCESSED) EG. COOKED BAGOONG/SHRIMP PASTE: Commercial Sterility 		
la - Liquid egg products	 Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED EGG PRODUCTS (LIQUID, FROZEN, DRIED): Coliforms CFU/g, Salmonella/25g, YMC CFU/g (for dried products) & SPC/APC CFU/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for PASTEURIZED EGG PRODUCTS (SMOKED LIQUID, FROZEN, DRIED): Coliforms CFU/g, Salmonella/25g, Yeast and Mold Count CFU/g (for dried products) & SPC/APC CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





			Applicant Company
Ib - Frozen egg products	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
	Microbiological parameters for	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
	PASTEURIZED EGG PRODUCTS		
	(LIQUID, FROZEN, DRIED): Coliforms		
	CFU/g, Salmonella/25g, YMC CFU/g		
	(for dried products) & SPC/APC CFU/g		
	Or upon effectivity of FDA Circular No.		
	2022-012		
	Valid Certificate of Analysis for		
	Microbiological parameters for		
	PASTEURIZED EGG PRODUCTS		
	(SMOKED LIQUID, FROZEN, DRIED):		
	Coliforms CFU/g, Salmonella/25g,		
	Yeast and Mold Count CFU/g (for		
	dried products) & SPC/APC CFU/g		
Ic - Dried and/or heat coagulated egg	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
products	Microbiological parameters for	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
	PASTEURIZED EGG PRODUCTS		
	(LIQUID, FROZEN, DRIED): Coliforms		
	CFU/g, Salmonella/25g, YMC CFU/g		
	(for dried products) & SPC/APC		
	CFU/g		
	Or upon effectivity of FDA Circular No.		
	<u>2022-012</u>		
	☑ Valid Certificate of Analysis for		
	Microbiological parameters for		
	PASTEURIZED EGG PRODUCTS		
	(SMOKED LIQUID, FROZEN, DRIED):		





	Coliforms CFU/g, Salmonella/25g, Yeast and Mold Count CFU/g (for dried products) & SPC/APC CFU/g INFANT FORMULA & FORMULAS		
J1 - Infant formula, follow-on formula and formula for special medical purposes for infants	 Valid Certificate of Analysis for Microbiological parameters for POWDERED INFANT FORMULA WITH OR WITHOUT ADDED LACTIC ACID PRODUCING CULTURES: Cronobacter spp./10g, Salmonella/25g, SPC/APC CFU/g & Enterobacteriaceae/10g Or upon effectivity of FDA Circular No. 2022-012 Valid Valid Certificate of Analysis for Microbiological parameters for POWDERED INFANT FORMULA WITH OR WITHOUT ADDED LACTIC ACID PRODUCING CULTURES (INTENDED FOR 0 TO 6 MONTHS OLD): Cronobacter spp./10g, Salmonella/25g, SPC/APC cfu/g & Enterobacteriaceae/10g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 Valid Certificate of Analysis for Microbiological parameters for INFANT FORMULA- LIQUID (UHT/STERILIZED): Commercial Sterility 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





Or upon effectivity of <u>FI</u>	DA Circular No.		
2022-012			
☑ Valid Certificate of An			
Microbiological parame	ers for INFAN I		
(UHT/STERILIZED): Co Sterility	ommercial		
Sterility		P FORMULA/MILK SUPPLEMEN	-
☑ Valid Certificate of A		<u>A Circular No. 2013-010</u> A Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
Microbiological parame		A CIrcular No. 2022-012	Manufacture/Source/Supplier
FOLLOW-UP FORMUL			
MILK/SUPPLEMENT (I FOR INFANTS 6 MON			
FOR YOUNG CHILDRI			
MONTHS): Salmonella/			
CFU/g & Enterobacteria			
	local, rog		
Or upon effectivity of FI	DA Circular No.		
2022-012			
☑ Valid Certificate of A	nalysis for		
Microbiological parame	-		
FOLLOW-UP FORMUL			
SUPPLEMENT (FROM	6 MONTHS		
INFANTS TO 36 MONT	HS YOUNG		
CHILDREN); FORMUL	A FOR		
SPECIAL MEDICAL PU	JRPOSES FOR		
YOUNG CHILDREN: S			
Aerobic Plate Count CF	•		
Enterobacteriaceae/10g			





J2 - Complementary foods for infants and	CEREAL-BASED	FOODS FOR INFANTS & YOUN	IG CHILDREN
J2 - Complementary foods for infants and young children e.g. cereal-, fruit-, vegetable-, and meat- based "baby foods" for infants, "toddler foods," and "junior foods"; lactea flour, biscuits and rusks for children.	 Valid Certificate of Analysis for Microbiological parameters for CEREAL-BASED FOODS FOR INFANTS: Bacillus cereus CFU/g, Clostridium perfringes CFU/g, SPC/APC CFU/g, Salmonella/25g & Coliforms MPN/g Or upon effectivity of FDA Circular No. 2022-012 Valid Certificate of Analysis for Microbiological parameters for CEREAL-BASED FOODS FOR INFANTS: Bacillus cereus CFU/g, 	FOODS FOR INFANTS & YOUN FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	 Clostridium perfringes CFU/g, SPC/APC CFU/g, Salmonella/25g & Coliforms MPN/g Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for DRIED AND INSTANT PRODUCTS REQUIRING RECONSTITUTION: Coliforms MPN/g, Aerobic Plate Count CFU/g, Salmonella/25g & Listeria monocytogenes/25g Or upon effectivity of <u>FDA Circular No.</u> 2022-012 ☑ Valid Certificate of Analysis for 	FDA Circular No. 2022-012 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier Applicant Company/ Manufacturer/Source/Supplier





	Microbiological parameters for DRIED PRODUCTS REQUIRING RECONSTITUTION AND BOILING BEFORE CONSUMPTION: Coliforms MPN/g, Salmonella/25g & Aerobic Plate Count CFU/g	CANNED BABY FOODS	
	✓ Valid Certificate of Analysis for Microbiological parameters for BABY FOODS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for BABY FOODS IN HERMETICALLY SEALED CONTAINERS : Commercial Sterility		
J3 - Dietetic foods intended for special medical purposes (excluding products under HR Letter J.1)			
J4 - Dietetic formula for slimming purposes and weight reduction			
J5 - Dietetic foods (e.g. supplementary foods for dietary use) excluding products under HR Letter J.1 to 4 and Letter K, Food Supplements)			
J6 - Weaning foods for infants and growing children			





J7 - Dietetic foods for special medical purpose	upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for READY-TO-USE THERAPEUTIC FOODS (RUTF) AND READY-TO- USE-SUPPLEMENTARY FOODS (RUFS), 6-59 MONTHS OF AGE: Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
J8 - Dietetic formulas for weight control			
J - Bottled Water			
K1 - Herbs and botanicals and/or Products with other nutritional substances and/or combination as Food Supplement e.g. Ginkgo Biloba + Co-Q10 + Korean Ginseng Food Supplement Capsule	☑ Valid Shelf-life study with stability data containing relevant information on the critical parameters of the finished product, period conducted and conclusion	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	 Valid Certificate of Analysis of the physico-chemical (Vitamins or Minerals or Amino Acids Assays) and/or microbiological parameters of the finished product (whichever is applicable) *The amount of Vitamins shall conform with the prescribed level of Office Order No. 22 s 1991 	Administrative Order No. 2014-0029 Office Order No. 22 s 1991 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks compliant with the existing labelling regulation of the importing country.	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier





	 Sample in actual commercial presentation *for the procedure on submission, please refer to: IV. Guidelines, C. 	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	Procedural Guidelines 2. L. ii., Pages 7-8 of FDA Circular No. 2020-033		
	upon effectivity of <u>FDA Circular No.</u> 2022-012	FDA Circular No. 2022-012	
	☑ Valid Certificate of Analysis for Microbiological parameters for VIRGIN COCONUT OIL: Aerobic Plate Count CFU/ml, Coliform MPN/ml or CFU/ml, Yeast and Mold Count CFU/ml, Salmonella spp. /25ml and E. coli MPN/ml or CFU/ml		
K2 - Herbs and botanicals and/or Products with other nutritional substances and/or combination as Conventional Food Product e.g. Powdered Juice with marine collagen, coffee powder with barley grass, tongkat ali and royal jelly	✓ Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES: YMC CFU/mL, Coliforms CFU/mL & SPC/APC CFU/mL	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> <u>2022-012</u> ✓ Valid Certificate of Analysis for Microbiological parameters for NON- ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS): Yeast and Mold Count		





	CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL		
	 ✓ Valid Certificate of Analysis for Microbiological parameters for POWDERED BEVERAGE: SPC/APC CFU/g & YMC CFU/g 	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012		
	✓ Valid Certificate for Microbiological parameters for POWDERED		
	BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES): Aerobic Plate Count CFU/g, Yeast and		
	Mold Count CFU/g & Coliforms CFU/g		
L. New in the international or local market/Other New Products/Unclassified or Unlisted in A.O. 2014-0029 Annex A			

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the applicant	1) PRE-ASSESSMENT	Day 0	Center for Food Regulation and
company accomplishes (including uploading of			Research (CFRR) PRE-ASSESSOR
the COMPLETE documentary requirements) the	FDA Personnel will pre-assess ONLY the		(e.g. Food-Drug Regulation Officer
E-Registration System through the E-Portal	completeness of the submitted documents		(FDRO))
https://eportal.fda.gov.ph based on the desired	through E-Registration System/E-Portal		
type of application in accordance to current FDA	https://eportal.fda.gov.ph.		
regulation/s on the use of the E-Registration			
Portal/E-Services.	Result of Pre-assessment will be received by		
	the account holder.		
The client shall forward the application to PRE-			
ASSESSMENT.			





A system generated E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.	If found COMPLETE , an Order of Payment will be automatically generated and will be sent to the email of the account holder/client. If found INCOMPLETE , a notification with result of Pre-Assessment from FDA will be received. To refile, the applicant must start a NEW CASE and upload initially submitted documentary requirements together with the documents for compliance to the deficiencies mentioned. <i>For Food Supplement application, the proof of</i> <i>submission of sample can be re-uploaded to</i> <i>the new application.</i>		
(PRE-ASSESSMENT: COMPLETE) 2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee through Systems/Means prescribed by FDA	 2) POSTING of payment FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then post the payment. The application will then be forwarded to CFRR, once payment is posted. 	Day 0 <i>Refer to FDA</i> <i>Cashier 's</i> <i>Citizen Charter</i>	Administrative and Finance Services (AFS) STAFF
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	





3) EVALUATION	8 Working Days	LRD EVALUATOR
The CFRR-Licensing and Registration	(Days 1-8)	(e.g. FDRO)
Division (LRD) Technical Personnel will		
evaluate the application and ALL the		
submitted documentary requirements in		
accordance to existing FDA regulation/s and		
Quality Work/Standard Procedures.		
The CFRR-LRD Technical Personnel will then		
draft recommendation if the application is for		
Approval or Disapproval, then will forward the		
same to the CHECKER.	7144	
4) CHECKING or Quality Assurance (QA)	7 Working Days (Days 9-15)	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
The CFRR-LRD Technical Personnel will	(Days 5 15)	
review the evaluated application, ALL the		
submitted documentary requirements, and		
the drafted recommendation of the		
EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard		
Procedures.		
The CFRR-LRD Technical Personnel will then		
draft recommendation if the application is for		
Approval or Disapproval, then will forward the		
same to the APPROVING AUTHORITY. 5) FINAL DECISION	5 Working Days	CFRR APPROVING AUTHORITY
	(Days 16-20)	(e.g. DIRECTOR IV)
The CFRR Approving Authority will review the	(
checked application, ALL the submitted		





documentary requirements, and the drafted recommendation of the CHECKER, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures.	
The CFRR Approving Authority will then finalize the application by issuing Certificate of Product Registration (CPR) (for APPROVED application) or Letter of Denial (LOD) (for DISAPPROVED application), through the E-Registration System.	





 5) If the application is APPROVED, an e-mail notification from FDA regarding the issuance of Certificate of Product Registration (CPR) will be received. If DISAPPROVED, an e-mail notification from FDA regarding the issuance of Letter of Denial/Disapproval (LOD) will be received. <i>For Amendment:</i> If the application is approved, the applicant company will receive an e-mail notification from FDA indicating that the application is approved (this includes those amendments with multiple applications with approved and disapproved results) and another e-mail notification containing the Amendment Decision Summary Table. If disapproved, a Letter of Denial/Disapproval (LOD) and another e-mail notification containing the Amendment Decision Summary Table will be received. 	6) GENERATION OF RESULT OF APPLICATION The E-Registration System generates electronically signed CPR or LOD.		Information and Communication Technology Management Division (ICTMD) STAFF
		TOTAL: 20 Working Days	
Always refer to the current FDA regulation/s on the use of the E-R			
Please be advised that as per RA No.11032 IRR, page 22 of 48, S shall be indicated in the Citizen's Charter.	Section 3, b) The maximum time prescribed in Section 9 (b) (1)) of the Act may be extended	l only once for the same number of days, which





C. OTHER CFRR AUTHORIZATIONS

I. TITLE OF CERTIFICATION/PERMIT: SANGKAP PINOY SEAL

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	•••	Government to Business
Type of Transaction	•••	Highly Technical Transaction
Who May Avail	•••	All FOOD Manufacturers of Fortified Products
Fees to be Paid	:	P8,000.00 non-refundable fee for the use of the seal (Regular Seal) P500.00 processing fee for every application (Regular Seal or Diamond Seal) + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Submit ONE (1) scanned copy of the required document.	
☑ Basic Requirements based on RA No. 8976 (Food Fortification Law of 2000), RA No. 8172 (ASIN Law), the Sangkap Pinoy Seal Program Manual of Operations (December 2000) and <u>Administrative Order No. 82 s. 2003</u> (Guidelines on the Granting of Diamond Sangkap Pinoy Seal to Manufacturers of Fortified Products):	FDA Website
☑ Duly accomplished application forms	FDA Philippines
☑ Copy of valid and appropriate LTO issued by the FDA	FDA Philippines
Results of product analysis for vitamin A, Iron and Iodine from an FDA recognized laboratory.	For the Certificate of Analysis: Laboratory analysis issued/conducted by FDA accredited laboratories.
☑ Sample label with Sangkap Pinoy Seal	Applicant Company/ Manufacturer/Source/Supplier
☑ Proof of payment	Systems/Means prescribed by FDA
☑ Inspection report with Certificate of Compliance	FDA Regional Field Office





CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	1) RECEIVING Receives document requirements from FDA Regional Field Office and decks the same to CFRR technical evaluators.	1 Working Day (Day 1)	LICENSING AND REGISTRATION DIVISION (LRD) EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))
	 2) EVALUATION The CFRR-LRD Technical Personnel will evaluate the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the CHECKER. 	8 Working Days (Day 2-9)	LRD EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))
	 3) CHECKING or Quality Assurance (QA) The CFRR-LRD Technical Personnel will review the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the APPROVING AUTHORITY. 	5 Working Days (Day 10-14)	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
	4) PRINTING	1 Working Day (Day 15)	CFRR ADMINISTRATIVE STAFF
	5) SIGNING OF CERTIFICATE/AUTHORIZATION	4 Working Days (Day 16-19)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
	6) ENDORSEMENT	1 Working Day (Day 20)	CFRR ADMINISTRATIVE STAFF





	The CFRR personnel will forward the Certificate/Authorization to the Office of Director General, for signature.		
		TOTAL: 20 Working Days	
Please be advised that a indicated in the Citizen	is per RA 11032 IRR, page 22 of 48, Section 3, b) <i>The maximum time prescribed in Section</i> section sec	9 (b) (1) of the Act may be extended only	once for the same number of days, which shall be





II. TITLE OF CERTIFICATION/PERMIT: DIAMOND SANGKAP PINOY SEAL

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)	
Classification	:	Government to Business	
Type of Transaction	:	Highly Technical Transaction	
Who May Avail	:	All FOOD Manufacturers of Fortified Products	
Fees to be Paid		P8,000.00 non-refundable fee for the use of the seal (Regular Seal)	
	•	P500.00 processing fee for every application (Regular Seal or Diamond Seal) + 1% LRF	

CHECKLIST OF REQUIREMENTS Submit ONE (1) scanned copy of the required document.	WHERE TO SECURE
☑ Basic Requirements based on RA No. 8976 (Food Fortification Law of 2000), RA No. 8172 (ASIN Law), the Sangkap Pinoy Seal Program Manual of Operations (December 2000) and <u>Administrative Order No. 82 s. 2003</u> (Guidelines on the Granting of Diamond Sangkap Pinoy Seal to Manufacturers of Fortified Products):	FDA Website
☑ Duly accomplished application forms	FDA Philippines
☑ Copy of valid and appropriate LTO issued by the FDA	FDA Philippines
☑ Results of product analysis for vitamin A, Iron and Iodine from an FDA recognized laboratory.	For the Certificate of Analysis: Laboratory analysis issued/conducted by FDA accredited laboratories.
☑ Sample label with Diamond Sangkap Pinoy Seal	Applicant Company/ Manufacturer/Source/Supplier
☑ Proof of payment	Systems/Means prescribed by FDA
☑ Inspection report with Certificate of Compliance	FDA Regional Field Office





CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	1) RECEIVING Receives document requirements from FDA Regional Field Office and	1 Working Day (Day 1)	LICENSING AND REGISTRATION DIVISION (LRD) EVALUATOR (e.g. Food-Drug Regulation Officer
	decks the same to CFRR technical evaluators.		(FDRO))
	2) EVALUATION	8 Working Days (Day 2-9)	LRD EVALUATOR (e.g. Food-Drug Regulation Officer
	The CFRR-LRD Technical Personnel will evaluate the application and ALL the submitted documentary requirements in accordance to existing		(FDRO))
	FDA regulation/s and Quality Work/Standard Procedures.		
	The CFRR-LRD Technical Personnel will then draft recommendation if		
	the application is for Approval or Disapproval, then will forward the same to the CHECKER.		
	3) CHECKING or Quality Assurance (QA)	5 Working Days (Day 10-14)	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
	The CFRR-LRD Technical Personnel will review the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures.		
	The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the APPROVING AUTHORITY.		
	4) PRINTING	1 Working Day (Day 15)	CFRR ADMINISTRATIVE STAFF
	5) SIGNING OF CERTIFICATE/AUTHORIZATION	4 Working Days (Day 16-19)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)





6) ENDORSEMENT	1 Working Day (Day 20)	CFRR ADMINISTRATIVE STAFF
The CFRR personnel will forward the Certificate/Authorization to the Office of Director General, for signature.		
	TOTAL: 20 Working Days	
Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.		





III. TITLE OF CERTIFICATION/PERMIT: GOOD MANUFACTURING PRACTICES (GMP) CERTIFICATE

Center/Office/Division	Center for Food Regulation and Research (CFRR)	
Classification	Government to Business	
Type of Transaction	Highly Technical Transaction	
Who May Avail	All FOOD Manufacturers (Importer of raw material for own use/Exporters)	
Fees to be Paid	GMP – Php 500.00 + LRF per year	

CHECKLIST OF REQUIREMENTS Submit ONE (1) scanned copy of the required document.	WHERE TO SECURE
☑ Inspection report with certificate of Compliance/ Recommendation Letter from RFO	FDA Regional Office
☑ Copy of valid and appropriate LTO issued by the FDA	FDA Philippines
☑ Proof of payment	Systems/Means prescribed by FDA

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	1) RECEIVING Receives document requirements from FDA Regional Field Office and decks the same to CFRR technical evaluators.	1 Working Day (Day 1)	LICENSING AND REGISTRATION DIVISION (LRD) EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))
	2) EVALUATION The CFRR-LRD Technical Personnel will evaluate the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the CHECKER.	8 Working Days (Day 2-9)	LRD EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))





	3) CHECKING or Quality Assurance (QA) The CFRR-LRD Technical Personnel will review the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the APPROVING AUTHORITY.	5 Working Days (Day 10-14)	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
	4) PRINTING	1 Working Day (Day 15)	CFRR ADMINISTRATIVE STAFF
	5) SIGNING OF CERTIFICATE/AUTHORIZATION	4 Working Days (Day 16-19)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
1) RECEIVING The applicant company receives the Certificate/Authorization.	6) RELEASING The FDA personnel will forward the Certificate/Authorization to Food and Drug Action Center (FDAC) for release.	1 Working Day (Day 20)	FDAC STAFF
	11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of	TOTAL: 20 Working Days	once for the same number of days, which shall be





IV. TITLE OF CERTIFICATION/PERMIT: HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) CERTIFICATE

Center/Office/Division	: Center for Food Regulation and Research (CFRR)
Classification	: Government to Business
Type of Transaction	: Highly Technical Transaction
Who May Avail	: All FOOD Manufacturers (Importer of raw material for own use/Exporters)
Fees to be Paid	: HACCP – Php1,000.00 + LRF per year

CHECKLIST OF REQUIREMENTS Submit ONE (1) scanned copy of the required document.	WHERE TO SECURE
Inspection report with certificate of Compliance/ Recommendation Letter from RFO	FDA Regional Office
☑ Copy of valid and appropriate LTO issued by the FDA	FDA Philippines
☑ Proof of payment	Systems/Means prescribed by FDA

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	1) RECEIVING Receives document requirements from FDA Regional Field Office and decks the same to CFRR technical evaluators.	1 Working Day (Day 1)	LICENSING AND REGISTRATION DIVISION (LRD) EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))
	2) EVALUATION The CFRR-LRD Technical Personnel will evaluate the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the CHECKER.	8 Working Days (Day 2-9)	LRD EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))





	3) CHECKING or Quality Assurance (QA)	5 Working Days (Day 10-14)	LRD CHECKER (e.g. SENIOR FDRO or
	The CFRR-LRD Technical Personnel will review the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures.		SUPERVISOR or DIVISION CHIEF)
	The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the APPROVING AUTHORITY.		
	4) PRINTING	1 Working Day (Day 15)	CFRR ADMINISTRATIVE STAFF
	5) SIGNING OF CERTIFICATE/AUTHORIZATION	4 Working Days (Day 16-19)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
1) RECEIVING	6) RELEASING	1 Working Day (Day 20)	FDAC STAFF
The applicant company receives the Certificate/Authorization.	The FDA personnel will forward the Certificate/Authorization to Food and Drug Action Center (FDAC) for release.		
		TOTAL: 20 Working Days	
Please be advised that as per RA <i>indicated in the Citizen's Charte</i>	 11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the er.		ce for the same number of days, which shall be





V. TITLE OF CERTIFICATION/PERMIT: IMPORT PERMIT

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	•••	Simple Transaction
Who May Avail	:	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters) and Donee/Consignee
Fees to be Paid	:	In accordance to Administrative Order No. 50 s. 2001 Import Permit: Php 500.00/invoice + 1% LRF

CHECKLIST OF REQUIREMENTS Submit ONE (1) scanned copy of the required document.	WHERE TO SECURE
FOR RELEASE OF SAMPLES:	
☑ Application Letter	FDA Website
☑ Notarized Affidavit of Undertaking	FDA Website
Certificate of Analysis/ Certificate of Free Sale	FDA Issued
☑ Pro Forma Invoice	Applicant Company
☑ Packing List	Product Source/company
☑ Bill of Lading/Airway Bill (if available)	Courier or Shipping company
☑ Valid License to Operate	FDA Issued
☑ Payment	FDA Cashier/Other FDA Authorized Payment Portals or Banks
FOR RELEASE OF DONATED FOOD:	
☑ BIHC Endorsement Letter	BIHC of DOH (The Director)
☑ Letter request from Donee	From Donee
Certificate of Quality (should reflect the expiration or last recommended date of consumption) / Certificate of Free Sale	Product Source/Company
☑ Certificate of Donation	From Donor
☑ Deed of Acceptance	From Donee
☑ Invoice Packing List	From product source/company





☑ Bill of Lading/Airway Bill (if available)	Courier or shipping company
☑ Payment (Php 510.00/inclusive of 1% LRF)	FDA Cashier/Other FDA Authorized Payment Portals or Banks

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1) The applicant company submits documents through email to the Food and Drug Action Center (FDAC) for pre- assessment	1) RECEIVING FDA Personnel will pre-assess the completeness of the submitted documents. If complete, Order of Payment will be generated and will be given to the client. Otherwise, all the documents will not be received and will be returned to the client for compliance. The client may refile by proceeding as stated on CLIENT STEPS:	Day 0	Food Drug Action Center (FDAC) or Center for Food Regulation and Research (CFRR) STAFF
2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee as per the system generated Order of Payment Form through any FDA Authorized means (e.g. Landbank LinkBiz).	2) FDA Personnel receives the complete documents and Official Receipt (OR)/ proof of payment through automated transaction.	Day 0	FDAC or CFRR STAFF
4) The applicant company receives Acknowledgement stating the completeness of the submitted documents & Official Receipt of payment.		Day 0	





	3) POSTING OF PAYMENT FDA Cashier will verify and post the payment through FDA FIS.	Day 0	Administrative and Finance Services (AFS) STAFF
	 4) FDAC forwards the application to CFRR receiving. FDAC also updates the FIS indicating that the application is transmitted to CFRR. 	4 Hours (Day 1)	FDAC STAFF
	5) CFRR Personnel receives application and updates the FIS indicating that the application is forwarded to assigned CFRR evaluators	4 Hours (Day 1)	CFRR STAFF
	6) EVALUATION The CFRR Technical Personnel evaluates the correctness of documents and updates the FIS indicating that the application is forwarded to checker for quality assurance.	4 Hours (Day 2)	CFRR EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO)
	7) CHECKING or Quality Assurance (QA) The CFRR Technical Personnel checks if the recommendation is appropriate and updates the FIS indicating that the application is forwarded to the Center Director.	4 Hours (Day 2)	CFRR Technical Personnel (e.g. FDRO)
	8) FINAL DECISION The Center Director renders the final decision on the recommendation and updates the FIS.	4 Hours (Day 3)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
5) The applicant company shall claim the IMPORT PERMIT	9) RELEASING The CFRR personnel forwards the Permit/Authorization to Records section for release and updates the FIS indicating the same.	4 Hours (Day 3)	CFRR STAFF
		TOTAL: 3 Working Days	





ANNEX A

Affidavit of Undertaking

(Name of Applicant) of legal age, (Position in the Company) and/or duly authorized representative of (Name of Company and Address), after having been sworn in accordance with law, hereby declare that:

- 1. The aforementioned company has imported from (Country of Origin) the food products: see attached product list.
- 2. The said importation is covered by Proforma Invoice No. ____ dated _____ of <u>(Source/Principal of the Importer)</u>, copy of which is cross-checked with the original.
- 3. The applicant company has a valid License to Operate as an importer, with LTO No. _____ covering the said shipment.
- 4. The products are not adulterated nor misbranded, and contain ingredients and additives that are permitted for use in human and in accordance with relevant regulations issued by FDA.
- 5. The said product is for use by (Company Name) for sampling purposes and product development only. Moreover, it will not find its way in the market for sale or for distribution.
- 6. The company understands and agrees that the products may be subjected to FDA Laboratory examination at any time to verify the food product safety and quality and that the cost of laboratory examination shall be charged to the importing company.
- 7. This Affidavit is executed to confirm the truth of the foregoing.

(Date) at (Place of Execution)

(Affiant)

Subscribed and sworn to before me this (date) day of (month), (year) at ______.

Notary Public





VI. TITLE OF CERTIFICATION/PERMIT: SALES PROMO PERMIT (INITIAL AND AMENDMENT APPLICATION)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Complex Transaction
Who May Avail	:	Food Manufacturers, Importers, Exporters, Wholesalers/Distributors and Third Party Marketing Agencies
		In accordance to DTI-DOH JAO NO. 1 s. 2000
		Amount of Prizes: (Fees)
		Php 150,000.00- below Php 300,000.00: Php 1,000.00.00 + 1% LRF
		Php 300, 001.00-Php 500,000.00: Php 2,000.00 + 1% LRF
		Php 500,001.00- Php 1,000,000.00: Php 3,000.00 + 1% LRF
		Above Php 1,000.000.00: Php 5,000.00 + 1% LRF
Fees to be Paid	:	Coverage: (Fees) NCR only or in several regions in NCR and Nationwide: Php 1,000.00.00 + 1% LRF More than one (1) region in NCR and Nationwide: Php 750.00 + 1% LRF Several provinces/cities/municipalities within a single region: Php 500.00 + 1% LRF Single province/city/municipality: Php 250.00 + 1% LRF Amendment/Extension: Php 300.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Submit ONE (1) scanned copy of the required document.	
INITIAL APPLICATION	
☑ Integrated Application Form	FDA Website
Completely and accurately filled-up Information Sheet and Mechanics of Sales Promotion	FDA Website
☑ Photocopy of valid Certificate of Product Registration (CPR) and Cosmetic Notification (NN)of the company	FDA Issued
Advertising/Collateral Materials to be used in the promotion, if any	Applicant Company
☑ Proof of Payment of Fees	FDA Cashier/Other FDA Authorized Payment Portals or Banks (where payment was made)





AMENDMENT APPLICATION	
☑ Integrated Application Form	FDA Website
Letter of Intent stating the desired changes	Applicant Company
Photocopy of Approved Permit	FDA Issued
Additional Advertising/Collateral Materials to be used in Promotion if any	Applicant Company
☑ Proof of Payment of Fees	FDA Cashier/Other FDA Authorized Payment Portals or Banks (where payment was made)

SALES PROMO PERMIT (INITIAL AND AMENDMENT APPLICATION) PROCESS FLOW based on <u>FDA Circular No.2021-013</u>: Interim Guidelines of the Center for Food Regulation and Research (CFRR) for the Application and Receiving of Sales Promo Permit Applications in Compliance to the <u>Republic Act No. 11032</u> otherwise known as The Ease of Doing Business and Efficient Government Service Delivery Act Of 2018 or current FDA regulation.

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1) The applicant company	1) RECEIVING	Day 0	Food Drug Action Center
requests for DTN and			(FDAC) or Center for Food
schedule of submission for	FDAC personnel will send the DTN and schedule of submission for pre-		Regulation and Research
pre-assessment to Food	assessment through email to the client.		(CFRR) STAFF
and Drug Action Center			
(FDAC) through email.			
2) Applicant company	2) PRE-ASSESSMENT	Day 0	CFRR EVALUATOR (e.g. Food-
submits documents for			Drug Regulation Officer (FDRO)
pre-assessment through	FDRO will pre-assess the completeness and correctness of the submitted		
email to Center for Food	documents. If complete and correct, an email stating that the company can		
Regulation and Research	proceed with the payment will be sent to the email address of the		
(CFRR) on their assigned	authorized representative. A CFRR pre-assessment slip will also be		
schedule.	attached on the email. Otherwise, an email stating the deficiency/ies noted		
	on the documents for the client to comply and they will be advice to secure		
	another DTN and schedule. FDRO will update the FIS if the application is		
	approved or denied during pre-assessment stage.		





3) Applicant company receives email to proceed with the payment and must pay through any FDA Authorized means (e.g. Landbank LinkBiz).		Day 0	CFRR STAFF
4) The applicant company pays the indicated fee as per Integrated Application Form through any applicable payment system prescribed by FDA	3) POSTING OF PAYMENT FDA Cashier will verify and post the payment through updating the FDA FIS.	Refer FDA Cashier Citizen's Charter	Administrative and Finance Services (AFS) STAFF
	4) FDAC Personnel forwards the application to CFRR and updates the FIS indicating the same.	1 Working Day (Day 1)	FDAC STAFF
	5) CFRR Database controller receives the Sales Promo Permit Application, decks the application to the assigned evaluator and updates the FIS indicating the same.	1 Working Day (Day 2)	CFRR STAFF
	6) EVALUATION The CFRR Personnel checks the consistency of the documents submitted during the pre-assessment stage and the documents received from FDAC. CFRR personnel evaluates further the application, forwards the application to the Checker and updates the FIS indicating the same.	1 Working Day (Day 3)	CFRR EVALUATOR (e.g. FDRO)
	7) CHECKING / QUALITY ASSURANCE (QA) The CFRR Personnel checks if the recommendation is appropriate and updates the FIS indicating that the application is forwarded to the Center Director.	1 Working Day (Day 4)	CFRR CHECKER (e.g. SENIOR FDRO or DIVISION CHIEF)





	8) FINAL DECISION	1 Working Day (Day 5)	CFRR APPROVING AUTHORITY
	The Center Director renders the final decision on the recommendation and updates the FIS.		(e.g. DIRECTOR IV)
	9) CFRR Database controller forwards the Sales Promotion Permit to FDA Records section for release and updates the FIS indicating the same	1 Working Day (Day 6)	CFRR STAFF
6) The applicant company receives the Certificate/Authorization through courier or pick-up.	10) FDA Records will schedule a date for release via FIS of the Certificate/Authorization through courier or pick-up	1 Working Day (Day 7)	FDAC STAFF
		TOTAL: 7 working days	

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