



## 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

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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	Administrative Order No. 2014-0029	FDA Website		
REGISTRATION				
☑ Accomplished Initial Application Form as prescribed by current FDA regulations.	FDA Circular No.2020-033	FDA Website		
e.g. E-Registration System	FDA Circular No.2020-033-A			





☑ Proof of Payment of Fees as prescribed by FDA regulations. Please refer to the table Fees to be Paid:	Administrative Order No. 50 s. 2001	Buyer/Recipient
☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations and <b>shall comply with existing regulations of the importing country.</b>	Administrative Order No. 2014-0029	FDA Philippines
☑ 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, as applicable.	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
☑ For FOOD SUPPLEMENT, a sample in actual commercial presentation shall be submitted.	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
☑ As applicable, documents to substantiate claims, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis, 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.	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
☑ VALID AND APPROPRIATE FDA LICENSE TO OPERATE (REQUIRED FOR ALL TYPES OF CPR APPLICATION)	Administrative Order No. 2014-0029 Republic Act No. 9711	Applicant Company/ Manufacturer/Source/Supplier and FDA Philippines
SOURCE DOCUMENTS		
For locally produced products:  Distributorship Agreement or Contract Agreement signed by duly authorized representative of the establishment or Certificate of Distributorship or Appointment Letter or Memorandum of Agreement from each supplier.	FDA Circular No.2020-033 FDA Circular No.2020-033-A	Applicant Company/ Manufacturer/Source/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 OR valid notarized agreement signed by importing Invoice, whichever is applicable, OR any supporting export market.	and exporting parties OR Proforma		Buyer/Recipient
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. Iodized 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			





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		
B2 - Jams, jellies, marmalades		
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 <b>sugar</b> 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		





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		
e.g. Refined Sugar, Raw Cane Sugar		
G2 - Brown Sugar		
G3 - Sugar solutions and syrups		
e.g. Maple Syrup, Vanilla Syrup 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		
I2 - Herbs, spices, seasonings and		
condiments		
I3 - Vinegars		
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)		
I7 - Yeast and like products		
I8a - Fermented Soybean Paste (e.g. Miso)		





19- 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
<b>MEDIUM RISK FOOD PRODUCTS</b> - 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)	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
(Includes partially dehydrated milk, evaporated	Microbiologicalparameters for	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
milk, sweetened condensed milk, and khoa (cow	SWEETENED CONDENSED		
or buffalo milk concentrated by boiling))	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/g	EDA Circular No. 2013 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 LIQUID	I DA Circulal No. 2022-012	wandacturer/Source/Supplier
	MILK (EVAPORATED): Commercial		
	Sterility		





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





	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		
B1 - Non-Dairy based frozen desserts e.g. Sherbet, sorbet	ADULTS): Salmonella/25g  ☑ 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,	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	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, 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 <b>FLAVORED ICE</b> : SPC/APC cfu/g, Coliforms MPN/g, YMC cfu/g & Salmonella/25g  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





	<ul> <li>☑ 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 &amp; Salmonella/25g</li> <li>☑ 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</li> </ul>		
e.g. Tomato Catsup, tomato sauce, tomato paste			
C2 - Frozen fruits e.g. frozen fruit salad and frozen strawberries	<ul> <li>✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN FRUITS: E. coli MPN/g</li> <li>Or upon effectivity of FDA Circular No. 2022-012</li> <li>✓ Valid Certificate of Analysis for Microbiological parameters for FROZEN FRUITS (pH &gt;4.5): E. coli CFU/g</li> </ul>	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 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 FDA Circular No. 2022-012  ☑ 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)	<ul> <li>✓ Valid Certificate of Analysis for Microbiological parameters for COCOA POWDER: Molds CFU/g, Salmonella/25g, Coliforms, MPN/g &amp; SPC/APC CFU/g</li> <li>Or upon effectivity of FDA Circular No. 2022-012</li> <li>✓ Valid Certificate of Analysis for Microbiological parameters for COCOA POWDER: Molds CFU/g, Salmonella/25g, Coliforms, MPN/g or CFU/g &amp; Aerobic Plate Count CFU/g</li> </ul>	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





		T	
	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		
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 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-zuke), and soy sauce-pickled meat (shoyu-zuke	✓ Valid Certificate of Analysis for Microbiological parameters for PACKAGED COOKED, CURED/SALTED MEAT: S. aureus (coagulase +) CFU/g, Salmonella/25g & Listeria monocytogenes/25g  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 PACKAGED COOKED, CURED/SALTED MEAT: S. aureus CFU/g, Salmonella/25g & Listeria monocytogenes/25g		
	<ul> <li>✓ Valid Certificate of Analysis for Microbiological parameters for CURED/SMOKED POULTRY:</li> <li>S. aureus (coagulase +) cfu/g &amp; Salmonella/25g</li> </ul>	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 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 FDA Circular No. 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  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 CURED/SMOKED POULTRY: S. aureus CFU/g & Salmonella/25g		
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), salamitype 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> 2022-012 ☑ Valid Certificate of Analysis for Microbiological parameters for <b>DRIED</b> 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 FDA Circular No. 2022-012  ☑ 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
	☑ Valid Certificate of Analysis for		





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 Microbiological parameters for PRE-COOKED BREADED FISH: E. coli MPN/g, S. aureus CFU/g & Aerobic	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
H2b - Fish and fish products, includings	Plate Count CFU/g		
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, doughnuts, sweet rolls, scones, muffins, waffles - plain/without filling e.g. pancakes, waffles, filled sweet buns (anpan), Danish pastry, wafers or cones for ice cream, flour confectionery, and trifles	✓ Valid Certificate of Analysis for Microbiological parameters for <b>BAKED GOODS</b> : 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 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	FDA Circular No. 2013-010	Applicant Company/
	Microbiologicalparameters for	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
	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 <u>FDA Circular No.</u>		
	2022-012		
	☑ Valid Certificate of Analysis for		
	Microbiological parameters for		
	FROZEN AND REFRIGERATED		
	DOUGHS: Salmonella/25g		
K1 - Soups and broths			
e.g. bouillon, broths, consommés, water-			
and cream-based soups, chowders, and bisques			
K2a - Emulsified sauces and dips	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
e.g salad dressing (e.g., French, Italian,	Microbiological parameters for <b>SALAD</b>	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
Greek, ranch style), fat-based sandwich spreads	DRESSING, pH ≤ 4.6: SPC/APC		
(e.g., mayonnaise with mustard), salad cream,	CFU/g, YMC CFU/g, Salmonella/25g &		
fatty sauces and snack dips (e.g., bacon and cheddar dip, onion dip	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.		





	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 (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)			
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





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
<ul> <li>✓ Valid Certificate of Analysis for Microbiological parameters for POWDERED BEVERAGE: SPC/APC CFU/g &amp; YMC CFU/g</li> <li>Or upon effectivity of FDA Circular No. 2022-012</li> <li>✓ Valid Certificate for Microbiological parameters for POWDERED BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES): Aerobic Plate Count CFU/g, Yeast and</li> </ul>	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
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





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 FDA Circular No. 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	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 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	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	✓ 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.		manufacture//odurce/odpplier
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 FDA Circular No. 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		
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 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		
L1cii - Non-carbonated water-based flavored drinks e.g. almond, aniseed, coconut-based drinks, and ginseng drink, lemonade, orangeade, citrus-	✓ Valid Certificate of Analysis for Microbiological parameters for NON-ALCOHOLIC BEVERAGES: YMC CFU/mL,	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





based soft drinks, iced tea, fruit-flavoured iced tea, chilled canned cappuccino drinks	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		
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	<ul> <li>☑ Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: SPC/APC CFU/mL &amp; YMC CFU/mL</li> <li>Or upon effectivity of FDA Circular No. 2022-012</li> <li>☑ Valid Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: Aerobic Plate Count CFU/ml &amp; Yeast and Mold Count CFU/ml</li> </ul>	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
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 <b>POWDERED BEVERAGE</b> : 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 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		
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 Office Order No. 22 s 1991		
	☑ 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
	<ul><li>☑ Sample in actual commercial presentation</li><li>*for the procedure on submission,</li></ul>	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 FDA Circular No. 2020-033		
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)  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)	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	✓ Valid Certificate of Analysis for Microbiological parameters for LIQUID MILK (EVAPORATED & READY TO DRINK)-UHT/STERILIZED: Commercial Sterility	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 LIQUID MILK (READY TO DRINK)-		
	UHT/STERILIZED: Commercial Sterility		
	✓ 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		





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 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)		
A2aii - Fermented milks (plain), heat-treated after fermentation e.g. Sterilized or pasteurized plain drinks based on fermented milk	<ul> <li>✓ Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK:</li> <li>S. aureus (coagulase +) CFU/mL, Coliforms CFU/mL, Salmonella/25mL &amp; Lactic acid CFU/mL</li> <li>Or upon effectivity of FDA Circular No. 2022-012</li> <li>✓ Valid Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK:</li> <li>S. aureus CFU/mL, Coliforms CFU/mL, Salmonella/25mL &amp; Lactic acid</li> </ul>	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 cfu/g, Salmonella/25g, Listeria monocytogenes/25g, Aerobic Plate Count cfu/g	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
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 dairy toppings and fillings	<ul> <li>✓ Valid Certificate of Analysis for Microbiological parameters for CREAM (UHT/STERILIZED): Commercial Sterility</li> <li>Or upon effectivity of FDA Circular No. 2022-012</li> <li>✓ Valid Certificate of Analysis for Microbiological parameters for CREAM (UHT/STERILIZED): Commercial Sterility</li> </ul>	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





A3c - Clotted cream (plain)			
A3d - Cream analogues			
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)	<ul> <li>✓ Valid Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS (MOISTURE &gt; 39% &amp; PH &gt; 5): S. aureus (coagulase +) CFU/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria CFU/g, Salmonella/25g &amp; Listeria monocytogenes/25g</li> <li>✓ Or upon effectivity of FDA Circular No. 2022-012</li> <li>✓ 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 &amp; S. aureus CFU/g</li> <li>✓ 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 &amp; S. aureus CFU/g</li> <li>✓ 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, E.coli CFU/g or MPN/g or /25g, and Yeast and Molds CFU/g</li> </ul>	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





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





CHEESE (FROM PASTEURIZE MILK): Enterobacteriaceae CFU E.coli CFU/g, Salmonella/ 25g, monocytogenes/ 25g & S. aureu CFU/g	J/g, Listeria
✓ Valid Certificate of Analysis for Microbiological parameters for Microbiological parameter	HARD  Dli  a
☑ Valid Certificate of Analysis for Microbiological parameters for CR CHEESE PRODUCTS: Coliforms or MPN/g or /25g, E.coli CFU/g or or /25g and Yeast and Molds CFU/g	CFU/g MPN/g
✓ Valid Certificate of Analysis for Microbiological parameters for A RAW MILK CHESE: Campylobacter/25g, Salmonella Listeria monocytogenes/25g anaureus (coagulase +) CFU/g	Por FDA Circular No. 2013-010   Applicant Company/ Manufacturer/Source/Supplier   Manufacture
Or upon effectivity of FDA Circuladorum 2022-012  ☑ Valid Certificate of Analysis for Microbiological parameters for A RAW MILK CHEESE; RAW MI	or ALL





A4bii - Rind of ripened cheese  A4biii - Cheese powder (for reconstitution)  e.g. Spray-dried cheese  A4c - Whey cheese	UN-RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0: Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g		
A4di - Plain processed cheese e.g. American Cheese, requeson	✓ Valid Certificate of Analysis for Microbiological parameters for CHESE 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 CHESE (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 <b>CREAM</b> <b>CHEESE PRODUCTS:</b> 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 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	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 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		
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 CHESE AND CHESE 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 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 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	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 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 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 FDA Circular No. 2022-012  ☑ Valid Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE; RAW MILK UNRIPENED 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	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 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 Aerobic Plate Count CFU/g		
A6a - Liquid whey and whey products			
A6b - Dried whey and whey products			
A7 - Milk for manufacture			
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 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		
B1 - Dried fruits and vegetable - plain/sundried 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)	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	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	✓ Valid Certificate of Analysis for Microbiological parameters for DRIED	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	VEGETABLE: E. coli MPN/g		
	Or upon effectivity of <u>FDA Circular No.</u> 2022-012		
	☑ Valid Certificate of Analysis for		
	Microbiological parameters for <b>DRIED VEGETABLE:</b> 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),	☑ 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
other nut butters (e.g., cashew butter), and pumpkin butter)	Or upon effectivity of <u>FDA Circular No.</u> 2022-012		
	☑ Valid Certificate of Analysis for Microbiological parameters for PEANUT BUTTER & OTHER NUT BUTTERS: Salmonella/25g		
D - Chocolate with nuts	✓ Valid Certificate of Analysis for Microbiological parameters for CHOCOLATE	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	PRODUCTS/CONFECTIONARIES: Molds CFU/g, Salmonella/25g, Coliforms MPN/g & SPC/APC CFU/g		
	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		
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)	✓ 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	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
& 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	FDA Circular No. 2013-010	Applicant Company/
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. 2022-012	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 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		
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 FDA Circular No. 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)	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		
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	✓ 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. 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

☑ 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





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 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
<ul> <li>✓ Valid Certificate of Analysis for Microbiological parameters for MEAT PASTE &amp; PATE: Salmonella/25g, Clostridium perfringens CFU/g, S. aureus (coagulase +) CFU/g, Coliforms CFU/g &amp; SPC/APC CFU/g</li> <li>✓ Or upon effectivity of FDA Circular No. 2022-012</li> <li>✓ Valid Certificate of Analysis for Microbiological parameters for MEAT</li> </ul>	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier





	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 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 FDA Circular No. 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	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
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			
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 FDA Circular No. 2022-012  ☑ 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 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 CRABMEAT: E. coli MPN/g, S. aureus CFU/g, V. parahaemolyticus CFU/g & CFU/g	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 calamari, and fried soft-shell crabs	SPC/APC CFU/g		
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





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 <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		
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 <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		
J1 - Infant formula, follow-on formula and formula for special medical purposes for infants	INFANT FORMULA & FORMULAS  ☑ 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 ☑ 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  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





On the six of the still the st FD	A Circular No	
Or upon effectivity of <u>FD</u>	A Circular NO.	
	ah sain fan	
☑ Valid Certificate of Ana		
Microbiological paramete	ers for INFAN I	
FORMULA- LIQUID		
(UHT/STERILIZED): Cor	mmercial	
Sterility		AIT
	FOLLOW-UP FORMULA/MILK SUPPLEME	
☑ Valid Certificate of Analysis		Applicant Company/
Microbiological parameter	ers for FDA Circular No. 2022-012	Manufacturer/Source/Supplier
FOLLOW-UP FORMULA	Α	
MILK/SUPPLEMENT (IN		
FOR INFANTS 6 MONT	HS ON AND	
FOR YOUNG CHILDRE		
MONTHS): Salmonella/2		
CFU/g & Enterobacteriad	ceae/10g	
Or upon effectivity of FD	A Circular No.	
<u>2022-012</u>		
☑ Valid Certificate of Ana	alysis for	
Microbiological parameter	ers for	
FOLLOW-UP FORMULA	A/MILK	
SUPPLEMENT (FROM (		
INFANTS TO 36 MONTI	HS YOUNG	
CHILDREN); FORMULA	FOR	
SPECIAL MEDICAL PU	RPOSES FOR	
YOUNG CHILDREN: Sa		
Aerobic Plate Count CFU	J/g &	
Enterobacteriaceae/10g		





J2 - Complementary foods for infants and	CEREAL-BASED	FOODS FOR INFANTS & YOUN	G CHILDREN
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, Clostridium perfringes CFU/g, SPC/APC CFU/g, Salmonella/25g &	FDA Circular No. 2013-010 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Coliforms MPN/g  Or upon effectivity of FDA Circular No. 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 FDA Circular No. 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 <b>DRIED PRODUCTS REQUIRING RECONSTITUTION AND BOILING BEFORE CONSUMPTION:</b> Coliforms MPN/g, Salmonella/25g & Aerobic Plate Count CFU/g		
		CANNED BABY FOODS	
	☑ Valid Certificate of Analysis for	FDA Circular No. 2013-010	Applicant Company/
	Microbiological parameters for BABY FOODS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility	FDA Circular No. 2022-012	Manufacturer/Source/Supplier
	Or upon effectivity of FDA Circular No. 2022-012		
	☑ Valid Certificate of Analysis for		
	Microbiological parameters for BABY		
	FOODS IN HERMETICALLY SEALED		
12 Distatis foods intended for excipt	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 FDA Circular No. 2022-012  ☑ 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	Administrative Order No. 2014-0029 Office Order No. 22 s 1991 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	with the prescribed level of Office Order No. 22 s 1991		
	☑ 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
	upon effectivity of 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	FDA Circular No. 2022-012	
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	MPN/ml or CFU/ml  ☑ 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 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 Microbiological parameters for <b>POWDERED BEVERAGE</b> : 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 <b>PRE-</b>			
ASSESSMENT.			





A system generated E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.	If found <b>COMPLETE</b> , an Order of Payment will be automatically generated and will be sent to the email of the account holder/client.  If found <b>INCOMPLETE</b> , a notification with result of Pre-Assessment from FDA will be received.  To refile, the applicant must <b>start a NEW CASE</b> and upload initially submitted documentary requirements together with the documents for compliance to the deficiencies mentioned.  For Food Supplement application, the proof of submission of sample can be re-uploaded to the new application.		
(PRE-ASSESSMENT: COMPLETE) 2) The applicant company receives the Order of Payment	тте тем арривател.	Day 0	
3) The applicant company pays the assessed fee through Systems/Means prescribed by FDA	2) <b>POSTING</b> 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, <b>once payment is posted</b> .	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) <b>EVALUATION</b> 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 recommendation if the application is for Approval or Disapproval, then will forward the	7 Working Days (Days 9-15)	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
same to the APPROVING AUTHORITY.  5) FINAL DECISION  The CFRR Approving Authority will review the checked application, ALL the submitted	5 Working Days (Days 16-20)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)





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 <b>APPROVED</b> , an e-mail notification from FDA regarding the issuance of Certificate of Product Registration (CPR) will be received.  If <b>DISAPPROVED</b> , an e-mail notification from 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.	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	
Always refer to the current FDA regulation/s on the use of the E-Replease be advised that as per RA No.11032 IRR, page 22 of 48, S shall be indicated in the Citizen's Charter.		Days	only once for the same number of days, which

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