



16 May 2014

FDA CIRCULAR

No. **2014-014**

SUBJECT: MINIMUM NUMBER OF SAMPLE UNITS REQUIRED FOR EACH TEST ANALYSIS

For the information and guidance of all concerned, hereunder is the list of the minimum number of sample units for each test analysis appropriate for the product collected or submitted. This Circular shall supersede Bureau Circular No. 6-A series 2001 for the Revised Minimum Required Samples for Laboratory Analysis.

I. FOOD PRODUCTS

a. Microbiological Test

Reference: FDA Circular No. 2013-010 Revised Guidelines for the Assessment of Microbiological Quality of Processed Foods

NOTE: Multiple tests can be run on a single sample as long as it has a sufficient amount for testing. Tests with a specific weight or volume indicated (*Campylobacter*, *Cronobacter* spp., *Listeria monocytogenes* and *Salmonella*) must meet required amount of sample for testing.

SAMPLE TYPE	TEST/MICROORGANISM	NUMBER OF SAMPLE UNITS
MILK AND DAIRY PRODUCTS		
Milk powders e.g. whole, nonfat or filled milk, buttermilk, whey and whey protein concentrate (intended for adults and children more than 36 months of age)	<ul style="list-style-type: none">• <i>Salmonella</i>/25 g-Normal routine -High risk population	10 commercial presentations with a net weight of not less than 50 g each 30 commercial presentations with a net weight of not less than 50 g each
Sweetened condensed milk	<ul style="list-style-type: none">• Coliforms, cfu/mL• Yeast and Molds Count, cfu/mL• Standard plate count, cfu/mL	5 commercial presentations with a net volume of not less than 25 mL each
Liquid Milk (evaporated or ready to drink) and Cream (UHT/sterilized)	<ul style="list-style-type: none">• Commercial Sterility	6 commercial presentations with a net volume of not less than 10 mL each

SAMPLE TYPE	TEST/MICROORGANISM	NUMBER OF SAMPLE UNITS
Pasteurized Milk	<ul style="list-style-type: none"> Coliforms, cfu/g <i>Salmonella</i>/25 mL <i>Listeria monocytogenes</i>/25 mL <i>Psychrotrophic bacteria</i>, cfu/mL Standard plate count, cfu/mL ➤ For flavoured milk 	5 commercial presentations with a net volume of not less than 100 mL each
Pasteurized Cream	<ul style="list-style-type: none"> Coliforms, cfu/g <i>Salmonella</i>/25 g <i>Listeria monocytogenes</i>/25 g <i>Psychrotrophic bacteria</i>, cfu/g Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 100 g each
Yogurt and other fermented milk	<ul style="list-style-type: none"> <i>Staphylococcus aureus</i> (coagulase +), cfu/mL Coliforms, cfu/mL <i>Salmonella</i>/25 mL 	5 commercial presentations with a net volume of not less than 50 mL each
Cheese and cheese products e.g. Cottage cheese, soft and semi-soft cheese	<ul style="list-style-type: none"> <i>Staphylococcus aureus</i> (coagulase +), cfu/g <i>Escherichia coli</i>, MPN/g Coliforms, MPN/g <i>Psychrotrophic bacteria</i>, cfu/g <i>Salmonella</i>/25 g <i>Listeria monocytogenes</i>/25 g 	5 commercial presentations with a net weight of not less than 100 g each
Processed Cheese Spread	<ul style="list-style-type: none"> Coliforms, cfu/g <i>Staphylococcus aureus</i> (coagulase +), cfu/g Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 20 g each
All raw milk cheese; raw milk un-ripened cheese	<ul style="list-style-type: none"> <i>Campylobacter</i>/25 g <i>Salmonella</i>/25 g <i>Listeria monocytogenes</i>/25 g <i>Staphylococcus aureus</i> (coagulase +), cfu/g 	5 commercial presentations with a net weight of not less than 100 g each
FATS, OILS AND FAT EMULSIONS		
Butter (whipped, pasteurized)	<ul style="list-style-type: none"> <i>Enterococci</i>, cfu/g Molds and yeast count, cfu/g Proteolytic bacteria, cfu/g Coliforms, cfu/g <i>Staphylococcus aureus</i> (coagulase +), cfu/g <i>Psychrotrophic bacteria</i>, cfu/g Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 25 g each
Butter made from unpasteurized milk or milk products	<ul style="list-style-type: none"> Coliforms, cfu/g <i>Escherichia coli</i>, MPN/ g <i>Staphylococcus aureus</i> (coagulase +), cfu/g 	5 commercial presentations with a net weight of not less than 25 g each

SAMPLE TYPE	TEST/MICROORGANISM	NUMBER OF SAMPLE UNITS
	<ul style="list-style-type: none"> • <i>Salmonella</i>/25 g • <i>Listeria monocytogenes</i>/25 g • Standard plate count, cfu/g 	
Margarine	<ul style="list-style-type: none"> • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • Faecal coliform, MPN/g • <i>Listeria monocytogenes</i>/25 g • <i>Salmonella</i>/25 g • Standard plate count, cfu/g • Molds and yeast count, cfu/g 	5 commercial presentations with a net weight of not less than 75 g each
EDIBLE ICES, INCLUDING SHERBET AND SORBET		
Ice Cream and Sherbet (plain and flavoured) and Ice Cream with added ingredients (nuts, fruits, cocoa, etc.)	<ul style="list-style-type: none"> • Coliforms, cfu/g • <i>Listeria monocytogenes</i>/25 g • <i>Salmonella</i>/25g • Standard plate count, cfu/g • <i>Staphylococcus aureus</i> (coagulase +), cfu/g 	5 commercial presentations with a net weight of not less than 75 g each
Flavored Ice (e.g Ice candy)	<ul style="list-style-type: none"> • Standard plate count, cfu/g • Coliforms, MPN/g • Molds and yeast count, cfu/g • <i>Salmonella</i>/25 g 	5 commercial presentations with a net weight of not less than 50 g each
CONFECTIONERIES		
Cocoa Powder, Chocolate Confectionaries (chocolate bars, blocks, bonbons), Sugar Confectionaries (Hard and soft candies, toffees, caramel, fondants, creams, nougats and pastes) and Chocolate products	<ul style="list-style-type: none"> • Molds, cfu/g • <i>Salmonella</i>/25 g • Coliforms, MPN/g • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 50 g each
FRUITS AND VEGETABLES, NUTS AND SEEDS		
Frozen Vegetables & Fruits and Dried Vegetables	<ul style="list-style-type: none"> • <i>Escherichia coli</i>, MPN/g 	5 commercial presentations with a net weight of not less than 25 g each
Fermented Vegetables, Ready to Eat (e.g. Kimchi)	<ul style="list-style-type: none"> • Molds and yeast count, cfu/g • Coliforms, MPN/g • <i>Escherichia Coli</i>, MPN/g • <i>Salmonella</i>/25 g • <i>Staphylococcus aureus</i>, cfu/g 	5 commercial presentations with a net weight of not less than 50 g each
Fruits & Vegetable products in Hermetically sealed	<ul style="list-style-type: none"> • Commercial sterility 	6 commercial presentations with a net weight of not

SAMPLE TYPE	TEST/MICROORGANISM	NUMBER OF SAMPLE UNITS
containers (thermally processed)		less than 25 g each
Coconut (dessicated)	<ul style="list-style-type: none"> • <i>Salmonella</i>/25 g • Total plate count, cfu/g • Coliform, cfu/g • Yeast, cfu/g • Molds, cfu/g • <i>Escherichia coli</i> , MPN/g 	5 commercial presentations with a net weight of not less than 50g each
Peanut Butter & other Nut Butters <ul style="list-style-type: none"> • Consumed without heating or other treatment to destroy microbes • Used as ingredient in high moisture food 	<ul style="list-style-type: none"> • <i>Salmonella</i>/25 g • <i>Salmonella</i>/25 g 	5 commercial presentations with a net weight of not less than 50 g each 5 commercial presentations with a net weight of not less than 25 g each
Sun Dried Fruits	<ul style="list-style-type: none"> • Molds, cfu/g • Osmophilic Yeasts, cfu/g • <i>Escherichia coli</i>, MPN/g 	5 commercial presentations with a net weight of not less than 25 g each
EGG AND EGG PRODUCTS		
Pasteurized Egg Products (liquid, frozen or dried)	<ul style="list-style-type: none"> • Coliforms, cfu/g • <i>Salmonella</i>/25 g • Molds and yeast count, cfu/g (for dried products) • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 50 g each
CEREALS AND CEREAL PRODUCTS		
Breakfast Cereals	<ul style="list-style-type: none"> • Molds, cfu/g • Yeast & yeast-like fungi, cfu/g • Coliform, cfu/g • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 25 g each
Cereals/Cereal Grains	<ul style="list-style-type: none"> • Molds and yeast count, cfu/g • Standard plate count, cfu/g • Coliforms, cfu/g • <i>Escherichia coli</i>, MPN/g 	5 commercial presentations with a net weight of not less than 25 g each
Cultured seeds and grains (e.g. bean sprouts, alfalfa etc.)	<ul style="list-style-type: none"> • <i>Escherichia coli</i>, MPN/g • Coliforms, cfu/g • <i>Salmonella</i>/25 g 	5 commercial presentations with a net weight of not less than 50 g each
Soya Flours, Concentrates and Isolates	<ul style="list-style-type: none"> • Molds, cfu/g • <i>Salmonella</i>/25 g 	5 commercial presentations with a net weight of not less than 50 g each

SAMPLE TYPE	TEST/MICROORGANISM	NUMBER OF SAMPLE UNITS
Flour, Corn meal, Corn grits, Semolina	<ul style="list-style-type: none"> • Molds, cfu/g • Yeast & yeast-like fungi, cfu/g • Coliforms, cfu/g • <i>Bacillus subtilis</i>, cfu/g • "rope spores" 	5 commercial presentations with a net weight of not less than 25 g each
Frozen entrees containing Rice or Corn Flour as main ingredient	<ul style="list-style-type: none"> • <i>Bacillus cereus</i>, cfu/g 	5 commercial presentations with a net weight of not less than 25 g each
Soy Protein	<ul style="list-style-type: none"> • Coliforms, cfu/g • <i>Escherichia coli</i>, MPN/g • Psychrotrophic bacteria, cfu/g • <i>Clostridium perfringens</i>, cfu/g • Molds and yeast count, cfu/g • <i>Salmonella</i> / 25 g • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 50 g each
Tofu	<ul style="list-style-type: none"> • <i>Bacillus cereus</i>, cfu/g • <i>Escherichia coli</i>, MPN/g • <i>Staphylococcus aureus</i> (coagulase +), cfu/g 	5 commercial presentations with a net weight of not less than 25 g each
Pasta Products and Noodles Uncooked (wet & dry)	<ul style="list-style-type: none"> • Coliforms, cfu/g • Molds and yeast, cfu/g • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • <i>Salmonella</i> / 25 g • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 50 g each
Starch	<ul style="list-style-type: none"> • Coliforms, cfu/g • YMC, cfu/g • <i>Salmonella</i>/25 g • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 50 g each
BAKERY PRODUCTS		
Frozen Bakery products (ready to eat) with low-acid or high a_w fillings or toppings	<ul style="list-style-type: none"> • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • <i>Salmonella</i>/ 25 g 	5 commercial presentations with a net weight of not less than 50 g each
Frozen Bakery Products (to be cooked) with low-acid or high a_w fillings or toppings (e.g. meat pies, pizzas)	<ul style="list-style-type: none"> • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • <i>Salmonella</i>/ 25 g 	5 commercial presentations with a net weight of not less than 50 g each
Frozen and Refrigerated Doughs (Chemically leavened)	<ul style="list-style-type: none"> • Molds, cfu/g • Yeasts & yeast-like fungi, cfu/g • Coliforms, cfu/g • Psychrotrophic bacteria, cfu/g • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 50 g each

SAMPLE TYPE	TEST/MICROORGANISM	NUMBER OF SAMPLE UNITS
	<ul style="list-style-type: none"> • <i>Salmonella</i>/ 25 g • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • <i>Escherichia coli</i>, MPN/g 	
Frozen & Refrigerated Doughs	<ul style="list-style-type: none"> • Molds, cfu/g • Yeasts & yeast-like fungi, cfu/g • Coliforms, cfu/g • Psychrotrophic bacteria, cfu/g • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 25 g each
Baked Goods (microbiologically sensitive types e.g containing eggs & dairy products)	<ul style="list-style-type: none"> • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • Mold and yeast count, cfu/g • Standard plate count, cfu/g • Coliforms, cfu/g 	5 commercial presentations with a net weight of not less than 25 g each
Coated or Filled, Dried Shelf-Stable Biscuits	<ul style="list-style-type: none"> • Coliforms, MPN/g • <i>Salmonella</i>/25g 	5 commercial presentations with a net weight of not less than 50 g each
READY TO EAT SAVOURIES		
Snack Foods	<ul style="list-style-type: none"> • Molds, cfu/g • Yeast & yeast-like fungi, cfu/g • Coliform, cfu/g • Standard plate count/APC, cfu/g 	5 commercial presentations with a net weight of not less than 25 g each
SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS		
Dry Mixes for Soup and Sauces	<ul style="list-style-type: none"> • <i>Clostridium perfringens</i>, cfu/g • YMC, cfu/g • Coliforms, cfu/g • Standard plate count, cfu/g • <i>Salmonella</i>/25 g 	5 commercial presentations with a net weight of not less than 50 g each
Yeast	<ul style="list-style-type: none"> • <i>Salmonella</i>/25 g 	5 commercial presentations with a net weight of not less than 50 g each
Spices	<ul style="list-style-type: none"> • <i>Molds</i>, cfu/g • <i>Standard plate count</i>, cfu/g 	5 commercial presentations with a net weight of not less than 25 g each
Spices (ready to eat)	<ul style="list-style-type: none"> • Coliforms, cfu/g • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • <i>Salmonella</i>/ 25 g • <i>Molds</i>, cfu/g • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 50 g each
Salad Dressing, pH ≤ 4.6	<ul style="list-style-type: none"> • Standard plate count, cfu/g • Molds and yeast, cfu/g 	5 commercial presentations with

SAMPLE TYPE	TEST/MICROORGANISM	NUMBER OF SAMPLE UNITS
(e.g. Mayonnaise, Thousand Island, Ranch, French)	<ul style="list-style-type: none"> • <i>Salmonella</i>/25 g • <i>Listeria monocytogenes</i>/25 g 	a net weight of not less than 75 g each
BEVERAGES		
Non Alcoholic Beverages (e.g. Ready to drink, softdrinks, iced tea, energy drinks)	<ul style="list-style-type: none"> • Molds and yeast count, cfu/mL • Coliforms, cfu/mL • Standard plate count, cfu/mL 	5 commercial presentations with a net volume of not less than 25 mL each
Frozen Juice Concentrate	<ul style="list-style-type: none"> • Standard plate count, cfu/mL • Molds and yeast, cfu/mL 	5 commercial presentations with a net volume of not less than 25 mL each
Powdered Beverages (e.g. iced tea, powdered juices/mixes)	<ul style="list-style-type: none"> • Standard plate count, cfu/g • Coliforms, cfu/g 	5 commercial presentations with a net weight of not less than 25 g each
Bottled water	<ul style="list-style-type: none"> • Heterotrophic Plate Count, cfu/mL • Coliform (must not be <i>Escherichia coli</i>), MPN/mL • <i>Pseudomonas aeruginosa</i>/100 mL • Faecal <i>Streptococci</i>/100 mL 	5 commercial presentations with a net volume of not less than 350 mL each
FOOD FOR INFANTS AND YOUNG CHILDREN		
Powdered Infant Formula	<ul style="list-style-type: none"> • <i>Cronobacter</i> spp. / 10 g • <i>Salmonella</i> / 25 g • <i>E. coli</i>, MPN/g (for complaint samples) 	60 commercial presentations with a net weight of not less than 75 g each
Follow-up Formula/Milk Supplement	<ul style="list-style-type: none"> • <i>Salmonella</i> / 25 g • Coliforms, MPN/g (for complaint samples) • <i>Escherichia coli</i>, MPN/g (for complaint samples) 	60 commercial presentations with a net weight of not less than 75 g each
Infant Formula - liquid (UHT/sterilized) and Baby foods in hermetically sealed containers	<ul style="list-style-type: none"> • Commercial Sterility 	6 commercial presentations with a net weight of not less than 25 g each
Dried and Instant products requiring reconstitution	<ul style="list-style-type: none"> • Coliforms, MPN/g • Standard plate count, cfu/g • <i>Salmonella</i> /25 g • <i>Listeria monocytogenes</i>/25 g 	60 commercial presentations with a net weight of not less than 75 g each
Dried products requiring reconstitution	<ul style="list-style-type: none"> • Coliforms, cfu/g • <i>Salmonella</i>/25 g 	5 commercial presentations with

SAMPLE TYPE	TEST/MICROORGANISM	NUMBER OF SAMPLE UNITS
and boiling before consumption	<ul style="list-style-type: none"> • Standard plate count, cfu/g 	a net weight of not less than 50 g each
Cereal based foods for infants	<ul style="list-style-type: none"> • <i>Bacillus cereus</i>, cfu/g • <i>Clostridium perfringens</i>, cfu/g • Standard plate count, cfu/g • <i>Salmonella</i>/25 g • Coliforms, MPN/g 	10 commercial presentations with a net weight of not less than 50 g each
FISH AND FISH PRODUCTS		
Fresh Frozen Fish and Cold-Smoked	<ul style="list-style-type: none"> • <i>Escherichia coli</i>, MPN/g • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • <i>Vibrio parahaemolyticus</i>, cfu/g • <i>Salmonella</i>/25 g • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 50 g each
Pre-Cooked Breaded Fish	<ul style="list-style-type: none"> • <i>Escherichia coli</i>, MPN/g • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 25 g each
Frozen Raw Crustaceans	<ul style="list-style-type: none"> • <i>Escherichia coli</i>, MPN/g • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • <i>Salmonella</i> /25 g • <i>Vibrio parahaemolyticus</i>, cfu/g • Standard plate count, cfu/g 	5 commercial presentations with a net weight of not less than 50 g each
Frozen Cooked Crustaceans	<ul style="list-style-type: none"> • <i>Escherichia coli</i>, MPN/g • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • <i>Salmonella</i> /25 g • <i>Vibrio parahaemolyticus</i>, cfu/g • Standard plate count, cfu/g 	20 commercial presentations with a net weight of not less than 50 g each
Cooked, Chilled & Frozen Crabmeat	<ul style="list-style-type: none"> • <i>Escherichia coli</i>, MPN/g • <i>Staphylococcus aureus</i> (coagulase +), cfu/g • <i>Vibrio parahaemolyticus</i>, cfu/g • Standard plate count, cfu/g 	10 commercial presentations with a net weight of not less than 50 g each
Fresh & Frozen Bivalve Molluscs	<ul style="list-style-type: none"> • <i>Escherichia coli</i>, MPN/g • <i>Salmonella</i>/25 g • <i>Vibrio parahaemolyticus</i>, cfu/g • Standard plate count, cfu/g 	20 commercial presentations with a net weight of not less than 50 g each
Fish & Shellfish products in hermetically sealed containers (thermally processed)	<ul style="list-style-type: none"> • Commercial Sterility 	6 commercial presentations with a net weight of not less than 25 g each

b. Physico-chemical Tests

SAMPLE TYPE	TEST PARAMETER	NUMBER OF SAMPLE UNITS
Milk and Dairy Products (milk powder, cream powder, liquid milk, cheese and cheese products)	<ul style="list-style-type: none">• Melamine• Mycotoxin(Aflatoxin M₁)• Vitamins and Minerals• Proximate Analysis/pH• Fat	For each test parameter: 2-5 commercial presentation with total average minimum weight/volume of 250 (mL or grams)
Fats and Oils, and Fat Emulsions (butter, margarine, vegetable oils and fats)	<ul style="list-style-type: none">• Vitamin A• Fat• Sodium Benzoate	
Fruits and Vegetables, Nuts and Seeds (fruits in hermetically container, dried fruits, jams, jellies, marmalades, pulp, purees)	<ul style="list-style-type: none">• Colorants• Sodium Cyclamate/Aspartame• Preservative (Sodium Benzoate, Potassium Sorbate)	
Ready-to-eat savouries (snack foods)	<ul style="list-style-type: none">• Vitamin A/Iron• Proximate Analysis• Mycotoxin(Aflatoxin)• Sodium Chloride	
Processed Fish and Fish Products (smoked, dried, canned, salted)	<ul style="list-style-type: none">• Heavy Metals• Sodium Chloride• Proximate Analysis• Histamine	
Sweeteners, including honey (refined and raw sugars, brown sugars, honey)	<ul style="list-style-type: none">• Total Sugar	
FOOD SUPPLEMENT		
Tablet and capsule	<ul style="list-style-type: none">• Heavy Metals• Vitamins and Minerals	250 tablets/capsule 50 tablets/capsule
Granules/ powder for suspension/ syrup <ul style="list-style-type: none">• 10- 15mL• 30 mL• 60-120 mL	<ul style="list-style-type: none">• Heavy Metals• Vitamins and Minerals	For each test parameter: 25 bottles 10 bottles 6 bottles
SPICES, HERBS, SOUPS, SAUCES, SALADS, VINEGARS, SEASONINGS AND CONDIMENTS		
Spices	<ul style="list-style-type: none">• Colorants	For each test parameter:
Salad dressings	<ul style="list-style-type: none">• Fat	

SAMPLE TYPE	TEST PARAMETER	NUMBER OF SAMPLE UNITS
Ketchup	<ul style="list-style-type: none">• Colorants• Vitamin A	2-5 commercial presentation with total average minimum weight/volume of 250 (mL or grams)
Fish sauce	<ul style="list-style-type: none">• Sodium Chloride• Proximate analysis• Histamine	
Soy sauce/seasoning	<ul style="list-style-type: none">• 3-MCPD• Sodium Chloride	
Salt	<ul style="list-style-type: none">• Iodine content• Sodium Chloride	
Vinegar	<ul style="list-style-type: none">• Total acidity	
BEVERAGES		
Alcoholic Beverages (beer and malt beverages, wine)	<ul style="list-style-type: none">• Alcohol content• pH	For each test parameter: 2-5 commercial presentation with total average minimum weight/volume of 250 (mL/ grams)
Non-alcoholic Beverages (canned/bottled fruit/vegetables juices, powdered beverages, energy drinks and concentrates)	<ul style="list-style-type: none">• Vitamins and Minerals• Sodium Cyclamate/Aspartame• Preservative (Sodium Benzoate, Potassium Sorbate)• DEHP• Caffeine	
Coffee and Tea	<ul style="list-style-type: none">• Caffeine• Mycotoxin (Ochratoxin)• Heavy Metals	
Bottled Water	<ul style="list-style-type: none">• Physical Test (Color, Taste, Odor, Turbidity)• pH• Total Dissolved Solids• Conductivity• Aluminum• Free Cyanide• Nitrates• Heavy Metals (Lead, Cadmium)	5 bottles of 300mL for all test parameters
CEREALS AND CEREAL PRODUCTS		
Cereal/cereal grains, flour, corn/corn meal, grits, starch, oats	<ul style="list-style-type: none">• Vitamin A/Iron/Potassium Bromate• Mycotoxin(Aflatoxin)• Gliadin	For each test parameter: 2-5 commercial presentation with total average minimum weight/volume of 250 (mL or grams)
Pasta products (*fortified)	<ul style="list-style-type: none">• *Vitamin A/Iron• Mycotoxin(Aflatoxin)	
Noodles (*fortified)	<ul style="list-style-type: none">• *Vitamin A/Iron• Mycotoxin(Aflatoxin)• Benzopyrene	
Starch-based products (tapioca)	<ul style="list-style-type: none">• Maleic Acid	

SAMPLE TYPE	TEST PARAMETER	NUMBER OF SAMPLE UNITS
BAKERY PRODUCTS		
Bread (*fortified)	<ul style="list-style-type: none"> *Vitamin A Colorants Filth 	For each test parameter: 2-5 commercial presentation with total average minimum weight/volume of 250 (mL or grams)
Crackers	<ul style="list-style-type: none"> Borax Colorants 	
Cookies & Milk based Products (*fortified)	<ul style="list-style-type: none"> *Vitamin A Melamine 	

II. PHARMACEUTICAL PRODUCTS

a. Microbiological Tests for Botanical Ingredients and Products

SAMPLE TYPE	TEST PARAMETER	NUMBER OF SAMPLE UNITS
Dried or Powdered Botanicals	<ul style="list-style-type: none">• Total Aerobic Microbial count• Total Combined Yeast & Mold Count• Bile-tolerant Gram-negative Bacteria• Absence of <i>Salmonella</i> spp. & <i>Escherichia coli</i> in 10 g	2 commercial presentations with a net weight or volume of not less than 50 g or mL for each sample
Powdered Botanical Extracts	<ul style="list-style-type: none">• Total Aerobic Microbial count• Total Combined Yeast & Mold Count• Absence of <i>Salmonella</i> spp. & <i>Escherichia coli</i> in 10g	
Tinctures/ Fluid Extracts/ Infusions/Decoctions	<ul style="list-style-type: none">• Total Aerobic Microbial count• Total Combined Yeast & Mold Count	
Nutritional Supplements with Botanicals and Botanicals to be treated with boiling water before use	<ul style="list-style-type: none">• Total Aerobic Microbial count• Total Combined Yeast & Mold Count• Absence of <i>Salmonella</i> spp. & <i>Escherichia coli</i> in 10g	
OTHER HERBAL PRODUCTS		
Solid/Liquid Products	<ul style="list-style-type: none">• Aerobic bacteria, cfu/g• Yeast and moulds, cfu/g• <i>Escherichia coli</i>• <i>Salmonella</i>• <i>Staphylococcus aureus</i>• Other <i>Enterobacteria</i>, MPN/g	2 commercial presentations with a net weight or volume of not less than 50 g or mL for each sample
NON-STERILE PRODUCTS		
Nonaqueous/ aqueous preparations for oral use	<ul style="list-style-type: none">• Total Aerobic Microbial count• Total Combined Yeast &	Minimum of 2 commercial

	Mold Count <ul style="list-style-type: none">• Absence of <i>Escherichia coli</i> in 1 g or mL	presentations with a total net weight or volume of not less than 50 g or mL
Rectal use	<ul style="list-style-type: none">• Total Aerobic Microbial count• Total Combined Yeast & Mold Count	
Oromucosal/ Gingival/ Cutaneous/ Nasal/ Auricular use	<ul style="list-style-type: none">• Total Aerobic Microbial count• Total Combined Yeast & Mold Count• Absence of <i>Staphylococcus aureus</i> in 1 g or mL• Absence of <i>Pseudomonas aeruginosa</i> in 1 g or mL	
Vaginal use	<ul style="list-style-type: none">• Total Aerobic Microbial count• Total Combined Yeast & Mold Count• Absence of <i>Staphylococcus aureus</i> in 1 g or mL• Absence of <i>Pseudomonas aeruginosa</i> in 1 g or mL• Absence of <i>Candida albicans</i> in 1 g or mL	
Transdermal patches (limits for one patch including adhesive layer and backing)	<ul style="list-style-type: none">• Total Aerobic Microbial count• Total Combined Yeast & Mold Count• Absence of <i>Staphylococcus aureus</i> in 1 patch• Absence of <i>Pseudomonas aeruginosa</i> in 1 patch	
Inhalation use (special requirements apply to liquid preparations for nebulization)	<ul style="list-style-type: none">• Total Aerobic Microbial count• Total Combined Yeast & Mold Count• Absence of <i>Staphylococcus aureus</i> in 1 g or mL• Absence of <i>Pseudomonas aeruginosa</i> in 1 g or mL• Absence of bile-tolerant Gram-negative bacteria in 1 g or mL	
PRODUCTS WITH OFFICIAL MONOGRAPHS		
Refer to the latest issue/version of the US Pharmacopeia		Minimum of 2 commercial presentations with a total net weight or volume of not less than 50g or mL

b. Biological Tests

SAMPLE TYPE	TEST PARAMETER	NUMBER OF SAMPLE UNITS
Liquid Preparations		
a. 1mL to 100mL b. more than 100mL	• Bacterial endotoxins test	20 bottles 6 bottles
a. 1mL to 100mL b. 500mL to 1000mL	• Sterility Test	20 bottles 6 bottles
Solid Preparations	• Sterility Test	20 units

c. Physico-chemical Tests

SAMPLE TYPE	TEST PARAMETER	NUMBER OF SAMPLE UNITS
Tablet/Capsule	<ul style="list-style-type: none">Assay/PotencyDissolutionUniformity of Dosage UnitsIdentification TestDisintegrationTablet Hardness	60 tablets/capsules 50 tablets/capsules 40 tablets/capsules 20 tablets/capsules 20 tablets/capsules 30 tablets/capsules
Granules/ Powder for Suspension/ Syrup	<ul style="list-style-type: none">Assay and Minimum FillpHIdentification Test	10 bottles 2 bottles 3 bottles
Injectables (1mL to 2mL)	<ul style="list-style-type: none">Assay/PotencypH	20 vials/ampules 10 vials/ampules
Injectables (5mL to 10mL)		20 vials/ampules 5 vials/ampules
Injectables (20mL to 100mL)		10 vials/ampules 2 vials/ampules
Ointment/ Cream/ Gel	<ul style="list-style-type: none">Assay/Potency	10 tubes
Aerosol		10 pressurised cans
Suppositories		30 pieces
PHARMACEUTICAL CONTAINERS		
Plastic container for suspension/syrup, oral preparation a. 10 mL b. 30 to 60 mL c. 60 to 100 mL d. 250 mL e. 500 to 1000 mL	<ul style="list-style-type: none">Nonvolatile residueResidue on IgnitionLeadBuffering Capacity	120 pcs 60 pcs 40 pcs 20 pcs 10 pcs
Plastic bottles/IV infusion a. 100 mL		15 pcs

SAMPLE TYPE	TEST PARAMETER	NUMBER OF SAMPLE UNITS
b. 250 mL c. 500 to 1000 mL		10 pcs 6 pcs
Polyampules a. 1 to 2 mL b. 3 to 5 mL c. 6 to 10 mL		300 pcs 250 pcs 200 pcs
Vials a. 10 mL b. 20 to 25 mL c. 30 to 50 mL		120 pcs 60 pcs 30 pcs
Caps a. Diameter ≤ 0.5 cm b. Diameter between 1 & 2.5 cm c. Diameter > 2.5 cm		800 pcs 48 pcs 30 pcs

III. DEVICES

Medical Devices	<ul style="list-style-type: none"> Bacterial endotoxins test Sterility Test 	20 units 20 units
------------------------	---	----------------------

IV. COSMETIC AND OTHER PRODUCTS

a. Microbiological Test

SAMPLE TYPE	TEST PARAMETER	NUMBER OF SAMPLE UNITS
Any cosmetic sample	<ul style="list-style-type: none"> Total Aerobic Mrobia Count Total Yeast & Mold Count <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Candida albicans</i> 	2 commercial products with not less than 30 g (or mL) net weight for each sample

b. Physico-chemical Tests

SAMPLE TYPE	TEST PARAMETER	NUMBER OF SAMPLE UNITS
Creams, emulsions, lotions gels and oils for the skin (hands, feet, etc.)	<ul style="list-style-type: none"> Mercury Lead, Cadmium, Arsenic Hydroquinone Preservative Tretinoin 	5 g 10 g 20 g (or mL) 20 g (or mL) 20 g (or mL)
Tinted bases (liquids, pastes, powders)	<ul style="list-style-type: none"> Preservative 	15 g (or mL)
Make-up powders, after-bath powders, hygienic powders, etc.	<ul style="list-style-type: none"> Preservative Lead 	15 g (or mL) 10 g
Perfume, toilet waters	<ul style="list-style-type: none"> Alcohol 	10 mL

SAMPLE TYPE	TEST PARAMETER	NUMBER OF SAMPLE UNITS
and eau de cologne		
Toilet soaps, etc.	• Sodium hydroxide	20 g
Products for making-up the face and the eyes	• Preservative • Lead	15 g (or mL) 10 g
Products intended for application to the lips a. Stick b. Liquid	• Colorants • Lead	5 g 50 mL 10 g
Products for care of the teeth and the mouth	• Formaldehyde • Diethylene glycol • Fluoride content	10 g (or mL) 10 g (or mL) 10 g (or mL)
Products for nail care and make-up	• Formaldehyde • Lead	10 g (or mL) 10 g
Products for external intimate hygiene	• Preservative	50 g (or mL)
HAIR CARE PRODUCTS		
Hair tints and bleaches	• Lead • Hydrogen peroxide	10 g 20 mL
Products for waving, straightening and fixing	• Sodium hydroxide • Formaldehyde	20 g 10 g (or mL)
Cleansing products (shampoos)	• Formaldehyde	10 g (or mL)
TOYS		
(Quantity pertains to samples of the same color which came from same batch/lot)		
Polymeric a. 9 in x 5 in (or equivalent area) b. 5 in x 3 in (or equivalent area) c. 3 in x 2 in (or equivalent area) d. 1 in x 1 in (or equivalent area)	• Heavy metal (Pb, Cd, Hg)	2 pcs 5 pcs 10 pcs 20 pcs
ART MATERIAL/SCHOOL SUPPLIES		
(Quantity pertains to samples of the same color which came from same batch/lot)		
Coated metal pencil case	• Heavy metals (Pb, Cd, Hg)	5 pcs
Textile/fabric pencil case		4 pcs
Pencil		20 pcs
Colored pencil a. Regular size		10 pcs
b. Small size		25 pcs
Pencil/crayon eraser		3 pcs
Oil Pastel		2 pcs
Crayons		

SAMPLE TYPE	TEST PARAMETER	NUMBER OF SAMPLE UNITS	
a. Jumbo size		2 pcs	
b. Regular size		3 pcs	
Modelling clay		3 pcs/color	
Color glue/ Glue			
a. Less than 5 mL		3 pcs	
b. 5 mL and above		2 pcs	
Glitter powder			
a. Less than 3g		3 pcs	
b. Above 3g		2 pcs	
Popsicle stick		100 pcs/color	
Poster color			
a. Less than 3 mL		3 pcs	
b. More than 3 mL		2 pcs	
Fabric Paint/ Finger Paint			
a. Less than 5 mL		10 pcs	
b. More than 5 mL		5 pcs	
Water color (in tube or in palette)		5 pcs/color	
Chalk		5pcs/color	
FOOD-CONTACT MATERIALS			
(Quantity pertains to samples of the same color which came from same batch/lot)			
Plastic spoon/fork	• Migration and Material Test	30 pcs/color	
Plastic drinking bottle with cover or cap			
a. with capacity of 200 mL and above		15 pcs	
b. with capacity of less than 200 mL		25 pcs	
Feeding bottle			
a. with capacity of 200 mL and above		15 pcs	
b. with capacity of less than 200 mL		25 pcs	
Lunch box		15 pcs	
Ceramic drinking mugs		5 pcs	
Plastic straw		50 pcs/color	
Teat and teether		20 pcs	

This Memorandum Circular shall take effect immediately.


KENNETH Y. HARTIGAN-GO, MD
 Acting Director General