

## REPUBLIC OF THE PHILIPPINES DEPARTMENT OF HEALTH FOOD AND DRUG ADMINISTRATION

Filinvest Corporate City Alabang, Muntinlupa City



FDA CIRCULAR NO. 2013 - 010

27 February 2013

TO:

ALL CONCERNED

SUBJECT:

REVISED GUIDELINES FOR THE ASSESSMENT OF MICROBIOLOGICAL QUALITY OF PROCESSED FOODS

As part of the mandate of the Food and Drug Administration to protect the public health and pursuant to the provisions of Republic Act No. 9711 otherwise known as the "Food and Drug Administration Act of 2009", the Bureau Circular No. 01-A s. 2004 *Guidelines for the Assessment of Microbiological Quality of Processed Food* is hereby revised with the following considerations: 1. Addition of new food category/products, 2. The need to update old references, 3. Adoption of approved CODEX Alimentarius Commission Guidelines.

This FDA Circular is hereby issued to serve as guidelines for the assessment of microbiological quality of certain processed foods; and help ensure that food manufacturers comply with Good Manufacturing Practices (GMP).

The reference criteria are prescribed in Tables 1-14. The tables contain a description of the food to which a criterion applies, the required test(s) or the microorganisms considered to be acceptable, marginally acceptable or critical, and the number of samples which should conform to the limits.

The methods used for the enumeration or detection of specified microorganisms shall be those that have been internationally established. Such methods, as well as the cited specifications were obtained from the following internationally recognized references:

- 1. FDA Bacteriological Analytical Manual published by the AOAC
- 2. Compendium of Analytical Methods of the Canadian Health Protection Branch
- 3. Compendium of Methods for the Microbiological Examination of Foods compiled by the American Public Health Association (APHA)
- Specifications and Standards for Foods, Food Additives, etc., Japan External Trade Organization
- 5. Microorganisms in Foods by the International Commission on Microbiological Specifications for Foods (ICMSF)
- 6. Codex Alimentarius Commission Guidelines
- 7. International Standards Organization (ISO) Microbiological Methods
- 8. Australia New Zealand Food Authority (ANZFA)

This FDA Circular shall take effect immediately and supersede other regulations or guidelines inconsistent herewith.

KENNETH Y. HARTIGAN-GO, MI

Acting Director IV

TABLE 1. MILK AND DAIRY PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Milk Powders					
(e.g. whole, nonfat or					
filled milk, buttermilk,	Salmonella/25g, normal routine	10	0	0	
whey & whey protein	for high risk population	30	0	0	
concentrate)	SPC/APC, cfu/g	5	2	$5x10^3$	$5x10^4$
(intended for children	Enterobacteriaceae cfu/g	5	1	10	$10^2$
more than 36 months of					
age and adults)					
Sweetened Condensed	¹Coliforms, cfu/g	5	1	10	10 <sup>2</sup>
Milk	Yeast and Molds Count, cfu/g	5	1	10	$10^2$
WIIIK	SPC/APC, cfu/g	5	1	$10^3$	10 <sup>4</sup>
Liquid Milk	2-12/2-2-28/1-12				
(evaporated or ready to	Commercial Sterility	6	0	Commercially	
drink) &	Commercial Sternity	0	0	sterile	
Cream (UHT/sterilized)					
	<sup>2</sup> Coliforms, cfu/mL	5	1	10 <sup>2</sup>	10 <sup>3</sup>
	Salmonella/25mL	5	0	0	
Pasteurized Milk	Listeria monocytogenes/25 mL	5	0	0	2000
i asteurizeu ivilik	Psychrotrophic bacteria, cfu/mL	5	1	10	$10^2$
	SPC/APC, cfu/mL	5	1	$5x10^4$	10 <sup>5</sup>
	for flavored milk	5	2	$5x10^4$	$10^{6}$
	<sup>1</sup> Coliforms, cfu/g	5	1	10 <sup>2</sup>	$10^{3}$
	Salmonella/25g	5	0	0	
Pasteurized Cream	Listeria monocytogenes/25g	5	0	0	
	Psychrotrophic bacteria, cfu/g	5	1	10	$10^2$
	SPC/APC, cfu/g	5	1	$5x10^4$	10 <sup>5</sup>
	S. aureus (coagulase +), cfu/mL	5	2	10	10 <sup>2</sup>
Yogurt and other fermented milk	<sup>1</sup> Coliforms, cfu/mL	5	2	10	$10^2$
	Salmonella/25mL	5	0	0	
ici menteu milk	Lactic Acid, cfu/mL				
	(required minimum level: $\geq 10^6$ )	-	-	-	-

<sup>&</sup>lt;sup>1</sup> Coliforms must be negative for *E. coli* 

m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M - level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c – maximum allowable number of defective or marginally acceptable units

TABLE 1. MILK AND DAIRY PRODUCTS cont.

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Cheese and Cheese	S. aureus (coagulase +), cfu/g	5	2	10 <sup>2</sup>	10 <sup>3</sup>
Products;	E.coli, MPN/g	5	1	11	110
e.g. Cottage Cheese;	Coliforms, MPN/g	5	1	11	$10^3$
Soft and Semi-soft	Psychrotrophic bacteria, cfu/g	5	2	$10^2$	$10^3$
cheese	Salmonella/25g	5	0	0	
(moisture $\geq$ 39%, pH > 5)	Listeria monocytogenes/25g	5	0	0	
	<sup>1</sup> Coliforms, cfu/g	5	1	10	10 <sup>2</sup>
<b>Processed Cheese Spread</b>	S. aureus (coagulase +), cfu/g	5	1	10	$10^2$
	SPC/APC, cfu/g	5	2	10 <sup>4</sup>	5x10 <sup>4</sup>
All Raw Milk Cheese;	Campylobacter/25g	5	0	0	
Raw Milk Un-ripened	Salmonella/25g	5	0	0	
cheese w/moisture>50%,	Listeria monocytogenes/25g	5	0	0	
pH > 5.0	S. aureus (coagulase +), cfu/g	5	2	$10^2$	$10^{3}$

1 Coliforms must be negative for E. coli

TABLE 2. FATS, OILS AND FAT EMULSIONS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
	Enterococci, cfu/g	5	1	10	$10^2$
	YMC, cfu/g	5	1	20	$10^2$
Butter	Proteolytic bacteria, cfu/g	5	1	$10^{2}$	$10^{3}$
	Coliforms, cfu/g	5	1	10	$10^2$
(whipped, pasteurized)	S. aureus (coagulase +), cfu/g	5	0	$10^{2}$	
	Psychrotrophic bacteria, cfu/g	5	1	10	$10^2$
	SPC/APC, cfu/mL	5	1	5x10 <sup>4</sup>	105
	Coliforms, cfu/g	5	1	10	10 <sup>2</sup>
Butter made from	E.coli, MPN/g	5	1	3	11
	S. aureus (coagulase +), cfu/g	5	1	10	$10^2$
unpasteurized milk or	Salmonella/25g	5	0	0	
milk products	Listeria monocytogenes/25g	5	0	0	
	SPC/APC, cfu/g	5	1	5x10 <sup>4</sup>	10 <sup>5</sup>
	S. aureus (coagulase +), cfu/g	5	0	10	
	Faecal Coliform, MPN/g	5	2	50	$5x10^2$
Manganina	Listeria monocytogenes/25g	5	0	0	
Margarine	Salmonella/25g	5	0	0	1 3 3 3
	SPC/APC, cfu/g	5	2	$2.5 \times 10^4$	2.5x10 <sup>5</sup>
	YMC, cfu/g	5	2	50	$5x10^2$

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M - level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c - maximum allowable number of defective or marginally acceptable units

TABLE 3. EDIBLE ICES, INCLUDING SHERBET AND SORBET

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
	¹Coliforms, cfu/g	5	1	10	10 <sup>3</sup>
I - C 8 Sh - h - 4	Listeria monocytogenes/25g	5	0	0	
Ice Cream & Sherbet	Salmonella/25g	5	0	0	
(plain and flavored)	SPC/APC, cfu/g	5	2	10 <sup>4</sup>	$5x10^4$
	S. aureus (coagulase +), cfu/g	5	1	10	$10^2$
	<sup>1</sup> Coliforms, cfu/g	5	2	10	10 <sup>3</sup>
Ice Cream with added	S. aureus (coagulase +), cfu/g	5	1	10	$10^2$
ingredients (nuts, fruits,	Salmonella/25g	5	0	0	
cocoa etc.)	SPC/APC, cfu/g	5	2	$5x10^4$	$2x10^5$
	Listeria monocytogenes/25g	5	0	0	
Flavored Ice (e.g. Ice candy)	SPC/APC, cfu/g	5	2	10 <sup>2</sup>	104
	Coliforms, MPN/g	5	0	3.0	
	YMC, cfu/g	5	0	$10^2$	
	Salmonella /25g	5	0	0	

<sup>&</sup>lt;sup>1</sup> Coliforms must be negative for *E. coli* 

TABLE 4. CONFECTIONERIES

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
	Molds, cfu/g	5	2	10 <sup>2</sup>	10 <sup>4</sup>
Cocoa Powder	Salmonella/ 25g	5	0	0	
Cocoa i owdei	Coliforms, MPN/g	5	2	1.8	10
	SPC/APC, cfu/g	5	2	104	10 <sup>6</sup>
	Molds, cfu/g	5	2	10 <sup>2</sup>	10 <sup>4</sup>
Charalata Barata	Salmonella/ 25g	10	0	0	
<b>Chocolate Products</b>	Coliforms, MPN/g	5	2	1.8	$10^2$
	SPC/APC, cfu/g	5	2	10 <sup>4</sup>	10 <sup>6</sup>
Chocolate	Molds, cfu/g	5	2	10 <sup>2</sup>	10 <sup>3</sup>
Confectionaries	Salmonella/ 25g	5	0	0	10
(chocolate bars, blocks,	Coliforms, MPN/g	5	2	1.8	10 <sup>2</sup>
bonbons)	SPC/APC, cfu/g	5	2	10 <sup>3</sup>	10 <sup>6</sup>
Sugar Confectionaries	M.11 C./	1_		10	1.02
(Hard and soft candies,	Molds, cfu/g	5	2	10	$10^2$
toffees, caramel, fondants,	Salmonella/ 25g	5	0	0	1.02
creams, nougats and	Coliforms, MPN/g	5	2	1.8	$10^2$
pastes)	SPC/APC, cfu/g	5	2	104	10 <sup>6</sup>

Legend: n - number of sample units selected from a lot of food to be examined
m - acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M - level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c - maximum allowable number of defective or marginally acceptable units

TABLE 5. FRUITS AND VEGETABLES, NUTS AND SEEDS

FOOD DESCRIPTION	TEST/MICROORGANISM	n	c	m	M
	Reference Criteria				
Frozen Vegetables & Fruits (pH >4.5)	E.coli, MPN/g	5	2	110	10 <sup>3</sup>
	YMC, cfu/g	5	2	$10^2$	104
Fermented Vegetables,	Coliforms, MPN/g	5	0	3	
Ready to Eat (e.g.	E.coli, MPN/g	5	0	3	
Kimchi)	Salmonella /25g	5	0	0	
	Staphylococcus aureus, cfu/g	5	0	10	
Fruits & Vegetable products in Hermetically sealed containers (thermally processed)	Commercial sterility	6	0	Comm	ercially
Dried Vegetables	E. coli, MPN/g	5	2	110	10 <sup>3</sup>
Coconut (desiccated)	Refer to PNS/BAFPS 25:2007				
Peanut Butter & other Nut Butters  > consumed without heating or other treatment to destroy microbes > used as ingredient in high moisture food	Salmonella/ 25g  Salmonella/ 25g	10	0	0	
	Molds, cfu/g	5	2	10 <sup>2</sup>	10 <sup>4</sup>
Sun Dried Fruits	Osmophilic Yeasts, cfu/g	5	2	10	$10^3$
	E.coli, MPN/g	5	2	3	11

<sup>&</sup>lt;sup>1</sup>Coliforms must be negative for *E.coli* 

TABLE 6. EGG AND EGG PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Destario dE	Coliforms, cfu/g	5	2	10	$10^3$
Pasteurized Egg	Salmonella/25g	10	0	0	
Products (liquid, frozen or dried)	YMC, cfu/g (for dried products)	5	0	10	
	SPC/APC, cfu/g	5	0	$2.5x10^4$	10 <sup>5</sup>

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TABLE 7. CEREALS AND CEREAL PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
	Molds, cfu/g	5	2	10	10 <sup>3</sup>
D I C C I	Yeast & Yeastllike fungi, cfu/g	5	2	10	$10^2$
Breakfast Cereals	Coliform, cfu/g	5	2	10	$10^2$
	SPC/APC, cfu/g	5	2	$10^3$	$10^4$
	YMC, cfu/g	5	2	$10^2$	10 <sup>4</sup>
6 16 16 :	SPC/APC, cfu/g	5	2	$10^2$	$10^{6}$
Cereals/Cereal Grains	Coliform, cfu/g	5	2	$10^2$	10 <sup>4</sup>
	E.coli, MPN/g	5	2	10 <sup>2</sup>	$10^{4}$
Cultured seeds and		5	2	10	10 <sup>2</sup>
grains	E. coli, MPN/g		2	1200	20
(e.g. bean sprouts, alfalfa	Coliforms, cfu/g	5	2	$10^2$	104
etc.)	Salmonella/25g	5	0	0	
Soya Flours,	Molds, cfu/g	5	2	10 <sup>3</sup>	10 <sup>5</sup>
Concentrates and	Salmonella/25g	5	$\begin{vmatrix} 2 \\ 0 \end{vmatrix}$		10
Isolates	Salmonella/23g	3	U	0	
	Molds, cfu/g	5	2	10 <sup>2</sup>	10 <sup>4</sup>
Flour Com mod Com	Yeast & Yeastllike fungi, cfu/g	5	2	10	$10^2$
Flour, Corn meal, Corn grits, Semolina	Coliform, cfu/g	5	2	10	$10^2$
	Bacillus subtilis, cfu/g	5	2	10	$10^2$
	"rope spores"				
Frozen entrees					
containing Rice or Corn	B. cereus, cfu/g	5	1	$10^2$	104
Flour as main ingredient					
	Coliforms, cfu/g	5	2	10 <sup>2</sup>	10 <sup>3</sup>
	E. coli, MPN/g	5	1	10	$10^2$
	Psychrotrophic bacteria, cfu/g	5	2	$10^2$	$10^{4}$
Soy Protein	Clostridium perfringens, cfu/g	5	2	10	$10^2$
	YMC, cfu/g	5	2	10	$10^2$
	Salmonella / 25g	5	0	0	
	SPC/APC, cfu/g	5	2	$10^2$	10 <sup>5</sup>
	B. cereus, cfu/g	5	2	10 <sup>2</sup>	$10^3$
Tofu	E. coli, MPN/g	5	0	1.8	
	S. aureus (coagulase +), cfu/g	5	2	10 <sup>2</sup>	$10^3$
	Coliforms, cfu/g	5	2	10	10 <sup>3</sup>
Pasta Products and	YMC, cfu/g	5	2	$10^{2}$	105
Noodles Uncooked (wet	S. aureus (coagulase +), cfu/g	5	1	10 <sup>2</sup>	104
& dry)	Salmonella / 25g	5	0	0	
	SPC/APC, cfu/g	5	2	$10^3$	10 <sup>5</sup>
	Coliforms, cfu/g	5	2	10	$10^2$
74	YMC, cfu/g	5	2	$10^2$	$10^3$
Starch	Salmonella/25g	5	0	0	10
	SPC/APC, cfu/g	5	2	$10^3$	5x10 <sup>4</sup>

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**TABLE 8. BAKERY PRODUCTS** 

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Frozen Bakery products (ready to eat) with low- acid or high a <sub>w</sub> fillings or toppings	S. aureus (coagulase +), cfu/g Salmonella/ 25g	5 5	1 0	10 <sup>2</sup>	10 <sup>4</sup>
Frozen Bakery Products (to be cooked) with low-acid or high aw fillings or toppings (e.g. meat pies, pizzas)	S. aureus (coagulase +), cfu/g Salmonella/ 25g	5	1 0	10 <sup>2</sup>	104
Frozen and Refrigerated Doughs (Chemically leavened)	Molds, cfu/g Yeasts & Yeastlike Fungi, cfu/g Coliforms, cfu/g Psychrotrophic bacteria, cfu/g SPC/APC, cfu/g Salmonella/ 25g S. aureus (coagulase +), cfu/g E. coli, MPN/g	5 5 5 5 5 5 5	2 2 2 2 2 0 2 0	10 <sup>2</sup> 10 <sup>5</sup> 10 10 10 <sup>2</sup> 0 10 <sup>2</sup> 3.0	10 <sup>4</sup> 10 <sup>6</sup> 10 <sup>2</sup> 10 <sup>3</sup> 10 <sup>7</sup>
Frozen & Refrigerated Doughs	Molds, cfu/g Yeasts & Yeastlike Fungi, cfu/g Coliforms, cfu/g Psychrotrophic bacteria, cfu/g SPC/APC, cfu/g	5 5 5 5 5	2 2 2 2 2 2	10 <sup>2</sup> 10 <sup>5</sup> 10 10 10	$   \begin{array}{c}     10^4 \\     10^6 \\     10^2 \\     10^3 \\     10^6   \end{array} $
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	5 5 5 5	2 2 2 2	10 <sup>2</sup> 10 <sup>2</sup> 10 <sup>4</sup> 50	10 <sup>4</sup> 10 <sup>4</sup> 10 <sup>6</sup> 10 <sup>3</sup>
Coated or Filled, Dried Shelf-Stable Biscuits	<sup>1</sup> Coliforms, MPN/g Salmonella/25g	5 10	2 0	3 0	20

<sup>&</sup>lt;sup>1</sup>Coliforms must be negative for *E.coli* 

TABLE 9. READY TO EAT SAVOURIES

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
	Molds, cfu/g	5	2	10	$10^3$
Snack Foods	Yeast & Yeastllike fungi, cfu/g	5	2	10	$10^2$
Snack Foods	Coliform, cfu/g	5	2	10	$10^2$
	SPC/APC, cfu/g	5	2	$10^3$	104

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c - maximum allowable number of defective or marginally acceptable units

TABLE 10. MEAT AND MEAT PRODUCTS\*\*

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
	S. aureus (coagulase +), cfu/g	5	1	$10^2$	104
<b>Dried Animal Products</b>	Clostridium perfringens, cfu/g	5	1	$10^2$	10 <sup>4</sup>
	Salmonella/25g	10	0	0	
	Salmonella/25g	5	0	0	
Meat Paste & Paté	Clostridium perfringens, cfu/g	5	2	$10^2$	$10^3$
	S. aureus (coagulase +), cfu/g	5	2	$10^2$	$10^3$
(heat treated)	¹Coliforms, cfu/g	5	2	10	10 <sup>2</sup>
	SPC/APC, cfu/g	5	2	$10^4$	10 <sup>5</sup>
Cold Cuts, Frozen &	E.coli, MPN/g	5	0	1.8	
Chilled Hot Dogs,	Salmonella/25g	10	0	0	
Corned Beef, Luncheon	S. aureus (coagulase +), cfu/g	5	2	$10^2$	$10^3$
Meat	SPC/APC, cfu/g	5	2	10 <sup>5</sup>	$10^{6}$
Packaged cooked	S. aureus (coagulase +), cfu/g	5	2	10 <sup>2</sup>	10 <sup>3</sup>
cured/salted meat (ham,	Salmonella/25g	5	0	0	
pacon)	Listeria monocytogenes/25g	5	0	0	
Fermented, comminuted		-		1.0	
meat, not cooked (dry &	E.coli, MPN/g	5	0	1.8	104
semi-dry fermented	S. aureus (coagulase +), cfu/g	5	1	$10^3$	10 <sup>4</sup>
sausages)	Salmonella/25g	5	0	0	
Cooked Poultry Meat,					
Frozen to be reheated	S. aureus (coagulase +), cfu/g	5	1	$10^{3}$	10 <sup>4</sup>
before eating (e.g.	Salmonella/25g	5	0	0	
prepared frozen meals)					The Land
Cured/Smoked Poultry	S. aureus (coagulase +), cfu/g	10	1	$10^{3}$	104
Meat	Salmonella/25g	10	0	0	
Dehydrated Poultry		10			MARK
Products	Salmonella/ 25g	10	0	0	
Fresh/Frozen Raw					
Chicken	SPC/APC, cfu/g (at 20°C)	5	3	5x10 <sup>5</sup>	107
(during processing)					
Meat Products in					
hermetically sealed	Commercial sterility	6	0	Comme	ercially
containers				sterile	

<sup>1</sup>Coliforms must be negative for *E.coli* 

<sup>\*\*</sup> Effective 16 February 2010, all meat and meat products are being handled and regulated by the National Meat Inspection Service (NMIS) of the Department of Agriculture as mandated by RA 9296 "Meat Inspection Code of the Philippines and DA-DOH joint Administrative Order No.1 s 2009". Any guidelines set by the NMIS shall supersede the specifications herein stated once it is made available.

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M - level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c - maximum allowable number of defective or marginally acceptable units

TABLE 11. FISH AND FISH PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM	n	c	m	M
	Reference Criteria				
	E.coli, MPN/g	5	3	11	500
Fresh Frozen Fish <sup>a</sup> and	S. aureus (coagulase +), cfu/g	5	2	$10^3$	104
Cold-Smoked <sup>b</sup>	V. parahaemolyticus, cfu/g	5	2	$10^2$	$10^3$
Cold-Smoked	Salmonella/25g	5	0	0	100
	SPC/APC, cfu/g	5	3	$5x10^5$	10 <sup>7</sup>
Pre-Cooked Breaded	E.coli, MPN/g	5	2	11	500
Fish	S. aureus (coagulase +), cfu/g	5	1	$10^3$	$10^{4}$
1911	SPC/APC, cfu/g	5	2	$5x10^5$	10 <sup>7</sup>
	E. coli, MPN/g	5	3	11	500
	S. aureus (coagulase +), cfu/g	5	2	$10^{3}$	10 <sup>4</sup>
Frozen Raw Crustaceans <sup>c</sup>	Salmonella /25g	5	0	0	1 3
	V. parahaemolyticus, cfu/g	5	1	$10^2$	$10^{3}$
	SPC/APC, cfu/g	5	3	$10^6$	$10^7$
	E. coli, MPN/g	5	2	11	500
Frozen Cooked	S. aureus (coagulase +), cfu/g	5	0	$10^2$	
Crustaceans	Salmonella /25g	20	0	0	
Ciustaceans	V. parahaemolyticus, cfu/g	10	1	$10^2$	$10^3$
	SPC/APC, cfu/g	5	2	$5x10^5$	$5x10^6$
	E. coli, MPN/g	5	1	11	500
Cooked, Chilled &	S. aureus (coagulase +), cfu/g	5	0	$10^3$	
Frozen Crabmeat <sup>d</sup>	V. parahaemolyticus, cfu/g	10	1	$10^2$	$10^3$
	SPC/APC, cfu/g	5	2	10 <sup>5</sup>	10 <sup>6</sup>
	E. coli, MPN/g	5	0	16	
Fresh & Frozen Bivalve	Salmonella/25g	20	0	0	
Molluscse	V. parahaemolyticus, cfu/g	10	1	$10^2$	$10^{3}$
	SPC/APC, cfu/g	5	0	5x10 <sup>5</sup>	
Fish & Shellfish products in hermetically sealed containers (thermally processed)	Commercial Sterility	6	0	Comme	ercially

<sup>a</sup> For fish derived from inshore/inland waters of doubtful bacteriological quality, particularly warm areas or harvested during summer. Tests for *Salmonella* and *V. parahaemolyticus* recommended if fish is to be eaten raw.

<sup>b</sup> Test for *S. aureus* recommended for smoked fish.

<sup>d</sup> SPC/APC for frozen products only

<sup>&</sup>lt;sup>c</sup> Test for S. aureus recommended for breaded products. Salmonella and V. parahaemolyticus applied to products from waters or harvested during summer.

<sup>&</sup>lt;sup>e</sup> Criteria to be used only for molluscs from approved harvesting areas where waters are free from enteric bacteria or virus contamination and no significant contamination by toxic metals or chemicals may be accumulated by animals Tests for Salmonella and V. parahaemolyticus recommended for molluscs from endemic areas or harvested from warm waters during summer.

m - acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c - maximum allowable number of defective or marginally acceptable units

TABLE 12. SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Dry Mixes for Soup and Sauces	Clostridium perfringens, cfu/g	5	2	10 <sup>2</sup>	$10^3$
	YMC, cfu/g	5	3	$10^2$	$10^4$
	Coliforms, cfu/g	5	3	10	$10^3$
	SPC/APC, cfu/g	5	2	$10^{4}$	$10^{6}$
	Salmonella/25g	5	0	0	
Yeast	Salmonella/25g	20	0	0	
Spices	Molds, cfu/g	5	2	$10^2$	10 <sup>4</sup>
	SPC/APC, cfu/g	5	2	10 <sup>4</sup>	$10^{6}$
Spices (ready to eat)	<sup>1</sup> Coliforms, cfu/g	5	2	10 <sup>2</sup>	$10^3$
	S. aureus (coagulase +), cfu/g	5	2	$10^2$	$10^{4}$
	Salmonella/ 25g	5	0	0	
	Molds, cfu/g	5	2	$10^2$	10 <sup>4</sup>
	SPC/APC, cfu/g	5	2	10 <sup>4</sup>	$10^{6}$
Salad Dressing, pH ≤ 4.6 (e.g. Mayonnaise, Thousand Island, Ranch, French)	SPC/APC, cfu/g	5	2	10	10 <sup>2</sup>
	YMC, cfu/g	5	2	10	$10^2$
	Salmonella/25g	5	0	0	10
	Listeria monocytogenes/25g	5	0	0	

<sup>1</sup>Coliforms must be negative for *E.coli* 

TABLE 13. BEVERAGES

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Non Alcoholic Beverages (e.g. Ready to drink, softdrinks, iced tea, energy drinks)	YMC, cfu/mL Coliforms, cfu/mL SPC/APC, cfu/mL	5 5 5	0 0 1	1 1 10	10 <sup>2</sup>
Frozen Juice Concentrate	SPC/APC, cfu/mL YMC, cfu/mL	5 5	2	10 <sup>2</sup> 10	10 <sup>5</sup> 50
Powdered Beverages (e.g. iced tea, powdered juices/mixes)	SPC/APC, cfu/g Coliforms, cfu/g	5 5	0	3x10 <sup>3</sup> 10	

m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M - level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c - maximum allowable number of defective or marginally acceptable units

TABLE 14. FOOD FOR INFANTS AND YOUNG CHILDREN

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Powdered Infant Formula with or without added Lactic acid producing cultures (intended for 0 to 6 months old)	Routine analysis:				
	Cronobacter spp. / 10g	30	0	0	
	*Salmonella / 25 g	60	0	0	
	For complaint investigation (additional to routine analysis):				
	<sup>1</sup> Coliforms, MPN/g	5	2	3	11
	E. coli, MPN/g	10	1	1.8	10
	<sup>2</sup> Process Hygiene Indicators:			?	3
	SPC/APC, cfu/g	5	2	$5x10^2$	$5x10^{3}$
	Enterobacteriaceae/ 10g	10	2	0	<sup>3</sup> NA
Follow-up Formula/Milk Supplement (intended for infants 6 months on and for young children 12-36 months of age)	Routine analysis: *Salmonella / 25 g	60	0	0	
	For complaint investigation (additional to routine analysis):  Coliforms, MPN/g  E. coli, MPN/g	5	2	3 1.8	11 10
	<sup>2</sup> Process Hygiene Indicators: SPC/APC, cfu/g Enterobacteriaceae/ 10g	5 10	2 2	$\begin{bmatrix} 5x10^2 \\ 0 \end{bmatrix}$	5x10 <sup>3</sup> 3NA
Infant Formula - liquid (UHT/sterilized)	Commercial Sterility	6	0	Commercially Sterile	
Baby foods in hermetically sealed containers	Commercial Sterility	6	0	Commercially Sterile	
R	¹Coliforms, MPN/g	5	1	3	20
Dried and Instant	SPC/APC, cfu/g	5	2	$10^3$	10 <sup>4</sup>
products requiring reconstitution	*Salmonella /25g	60	0	0	1
	Listeria monocytogenes/25g	5	0	0	
Dried products requiring reconstitution and	<sup>1</sup> Coliforms, cfu/g	5	2	10	10 <sup>2</sup>
boiling before	Salmonella/25g	5	0	0	
consumption	SPC/APC, cfu/g	5	3	10 <sup>4</sup>	10 <sup>5</sup>
Cereal based foods for infants	Bacillus cereus, cfu/g	10	1	102	10 <sup>4</sup>
	Clostridium perfringens, cfu/g	5	1	10	10 <sup>2</sup>
	SPC/APC, cfu/g	5	2	10 <sup>3</sup>	10 <sup>4</sup>
	Salmonella/25 g	10	0	0	10
	Coliforms, MPN/g	5	2		20
Coliforms must be negative for	Comornis, wir 14/g	13	12	3	20

<sup>1</sup> Coliforms must be negative for E. coli

 $n = 60 \rightarrow 4 \times 15$  (25g) composite units

- m acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP
- M level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage
- c maximum allowable number of defective or marginally acceptable units

<sup>\*25</sup>g sample units may be composited to a quantity not to exceed 400g

Process hygiene criteria to be applied to the finished product (powder form) or at any other previous point that provides the information necessary for the purpose of verification. The criteria is intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs. (CAC/RCP 66-2008)

 $<sup>^{3}</sup>$  NA = not applicable