



Republic of the Philippines
Department of Health
BUREAU OF FOOD AND DRUGS
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BUREAU CIRCULAR
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TO : ALL CONCERNED

SUBJECT : **PROPOSED GUIDELINES FOR THE ASSESSMENT OF
MICROBIOLOGICAL QUALITY OF PROCESSED FOODS**

The proposed Guidelines for the Assessment of Microbiological Quality of Processed Foods is being circulated for the information of all concerned, particularly the food processing industry, testing laboratories, and other interested parties.

Comments and suggestions may be submitted to BFAD within a period of three (3) months, **not later than 30 September 2001**. The comments will be evaluated and revisions may be made accordingly as appropriate. Those who may wish to recommend amendments to the prescribed limits should do so by providing relevant data gathered from actual surveys of specified products or from literature which may not have been reviewed by BFAD. Recommendations for reference criteria for food products not yet covered in the proposed guidelines will also be accepted. During this period we will also be identifying specific test methods that will be prescribed as reference methods. Laboratories conducting microbiological analysis for the food industry and for other related purposes are requested to submit to BFAD the test methods that they are using or intend to use.

In the meantime, the prescribed limits in the reference criteria shall serve as interim guidelines for assessment of microbiological quality for the specified food products. Action to be taken by BFAD for failure to meet the reference criteria will be determined in conjunction with other relevant information necessary to evaluate potential risk to health of consumers.

All are enjoined to participate and share views/ideas in our effort to develop guidelines that will promote the mutual interests of consumers and industry.

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Director

PROPOSED GUIDELINES FOR THE ASSESSMENT OF MICROBIOLOGICAL QUALITY OF PROCESSED FOODS

Food regulatory agencies and the food processing industry agree that the traditional approach of end-product testing cannot produce the desired levels of food safety and the application of HACCP throughout the food chain in the more effective means to ensure an acceptable level of food safety. This new approach to food safety management has been recommended by the Codex Alimentarius Commission and countries throughout the world augment their international trade and harmonize common sanitary measures in accordance with HACCP principles.

This document provides guidelines for the assessment of microbiological quality of certain processed foods based on the reference criteria prescribed in the appended Tables. These reference criteria are presented in the format used by the International Commission on Microbiological Specifications for Foods (ICMSF) which include acceptance sampling plans.

The sampling plans are in terms of 2-class or 3-class plans depending on the hazard involved. Two-class plans are used where no viable cell of a specific microorganism (i.e., a pathogen) is tolerated in the food. Three-class plans are used where some viable cells of the microorganism in question are tolerated. A detailed discussion of the concepts of these plans and their application can be found in the second edition of "Microorganisms in Foods, volume 2, Sampling for microbiological analysis: Principles and specific applications," compiled by the ICMSF of the International Association of Microbiological Societies and published in 1986 by the University of Toronto Press.

The Tables contain a description of the food to which a criterion applies, the required test(s) or the microorganism(s) of concern, the number of samples to be tested, the level of microorganisms considered to be acceptable, marginally acceptable or critical, and the number of samples which should conform to the limits.

The symbols used in the plans are defined as follows:

n = the number of sample units selected from a lot of food to be examined.

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

M = the 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 = the maximum allowable number of defective or marginally acceptable units

a lot refers to a quantity of food which is prepared or packed under essentially the same conditions and is usually from a particular preparation or packing unit and prepared during a particular period of time not exceeding 24 hours.

In a 2-class plan, " m " separates sample units of acceptable quality from those that are defective while in a 3-class plan, " m " separates sample units of acceptable quality from those of marginally acceptable quality. Failure to meet reference criteria generally indicates a failure in the process or hygiene procedures and requires action to identify the cause and remedy of the problem.

Actions to be taken when a criterion is not met depends on the type of criterion. If the criterion applies to a finished product, the product must be rejected as unsuitable for its intended use when the criterion is exceeded. However, reprocessing or sorting may be possible. If the criterion applies at some stage during manufacture, the situation should be assessed to determine if end-product safety is impacted, the problem should be identified and rectified, and the HACCP plan should be reviewed for those implementing HACCP in their processing plant.

While microbiological reference criteria can assist with the identification of foods not produced under conditions of good manufacturing practice (GMP), it is recommended that industry develop more stringent "target" levels achievable by using best practice to ensure conformance with the maximum levels specified in the schedules at any point in the shelf life of the product.

The methods to be used for the enumeration or detection of specified microorganisms shall be only those that have been established in comparative or collaborative studies in several laboratories. Such methods are those that can be found in 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
4. International Standards Organization (ISO) Microbiological Methods
5. Standard Methods for Examination of Water and Wastewater

In determining the method of choice, due consideration should be given to the type of criteria and suitability of the method with regards to complexity, reliability, ease of interpretation, time required, and costs.

The appended Tables are for the following food product categories:

Milk and Dairy Products
Food for Infants and Young Children
Meat and Poultry Products

Fish and Shellfish Products
Fruits, Vegetables and Nuts
Cereals and Cereal/Legume-based Products

Reference criteria for other commodities not included in these Tables will be determined as relevant data and other information are generated.

MILK & DAIRY PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Milk Powders (whole, nonfat or filled milk, buttermilk, whey & whey protein concentrate)	Bacillus cereus, cfu/g	5	1	10 ²	10 ³
	S. aureus (coagulase +), cfu/g	5	2	10	10 ²
	¹ Coliforms, cfu/g	5	1	10	10 ²
	Salmonella/25 g normal routine	5	0	0	
	for high risk	15	0	0	
	population	5	2	5 x 10 ⁴	2 x 10 ⁵
Sweetened Condensed Milk	¹ Coliforms, cfu/g	5	1	10	10 ²
	YMC, cfu/g	5	1	10	10 ²
	SPC/APC, cfu/g	5	1	10 ³	10 ⁴
Liquid Milk (evaporated or ready to drink) and Cream Ultra Heat Treated/Sterilized	Commercial Sterility				
Pasteurized Milk	¹ Coliforms, cfu/ml	5	1	10 ²	10 ³
	Salmonella / 25 ml	5	0	0	
	Listeria monocytogenes / 25 ml	5	0	0	
	Psychrotrophic bacteria, cfu/ml	5	1	10	10 ²
	SPC/APC, cfu/ml	5	1	5 x	10 ⁵
	• For flavored milk	5	2	10 ⁴ 5 x 10 ⁴	10 ⁶
Pasteurized Cream	¹ Coliforms, cfu/ml	5	1	10 ²	10 ³
	Salmonella / 25 ml	5	0	0	
	Listeria monocytogenes / 25 ml	5	0	0	
	SPC/APC, cfu/ml	5	1	5 x	10 ⁵
	Psychrotrophic bacteria, cfu/ml	5	1	10 ⁴ 10	10 ²
	Yoghurt & other fermented milk	S. aureus (coagulase +), cfu/g	5	2	10
¹ Coliforms, cfu/ml		5	2	10	10 ²
Salmonella / 25g		5	0	0	
Butter & Whipped Butter	Enterococci, cfu/g	5	1	10	10 ²
	YMC, cfu/g	5	1	20	10 ²
	Proteolytic bacteria, cfu/g	5	1	10 ²	10 ³
Butter made from unpasteurized milk and/or products	Coliforms, cfu/g	5	1	10	10 ²
	E. Coli, MPN/g	5	1	<3	11
	S. aureu (coagulas +), cfu/g	5	1	10	10 ²
	Salmonella / 25g	5	0	0	
	Listeria monocytogenes / 25g	5	0	0	
	SPC/APC, cfu/g	5	0	5 x 10 ⁴	10 ⁵

¹ Coliforms must be negative for E. coli

MILK & DAIRY PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
All cheese made from pasteurized milk	S. aureus (coagulase +), cfu/g	5	2	10 ²	10 ³
	E. coli, MPN/g	5	1	<11	<110
Cottage Cheese	Coliforms, MPN/g	5	1	<11	10 ³
	Psychrotrophic bacteria, cfu/g	5	2	10 ²	10 ³
Soft & Semi-soft cheese (moisture ≥39%, pH > 5)	Salmonella / 25g	5	0	0	
	Listeria monocytogenes / 25g	5	0	0	
All Raw Milk cheese	Listeria monocytogenes / 25g	5	0	0	
	Salmonella / 25g	5	0	0	
Raw Milk Unripened cheese With moisture ?50%, pH>5.0	Campylobacter / 25g	5	0	0	
Processed Cheese Spread	¹ Coliforms, cfu/g	5	1	10	10 ²
	S. aureus (coagulase +), cfu/g	5	1	10	10 ²
	SPC/APC, cfu/g	5	2	10 ⁴	5x10 ⁴
Ice Cream & Sherbet plain & flavored	¹ Coliforms, cfu/g	5	1	10	10 ³
	S. aureus (coagulase +), cfu/g	5	1	10	10 ²
	Salmonella / 25 g	5	0	0	
	SPC/APC, cfu/g	5	2	10 ⁴	5x10 ⁴
Ice Cream with added ingredients (nuts, fruits, cocoa, etc.)	¹ Coliforms, cfu/g	5	2	10	103
	S. aureus (coagulase +), cfu/g	5	1	10	102
	Salmonella / 25 g	5	0	0	
	SPC/APC, cfu/g	5	2	5x10 ⁴	2x10 ⁵

¹ Coliforms must be negative for E. coli

FOOD FOR INFANTS & YOUNG CHILDREN

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Powdered Infant Formula with or without added Lactic acid producing cultures	Bacillus cereus, cfu/g	5	2	10	10 ²
	S. aureus (coagulase +), cfu/g	5	1	0	10
	Coliforms, MPN/g	5	2	<3	11
	E. coli, MPN/g	10	1	<1.8	10
	Salmonella / 25g	10	0	0	
	SPC/APC, cfu/g (prior to addition to lactic acid producing cultures)	5	2	10 ³	10 ⁴
	For complaint investigation Cl. perfringens, cfu/g	5	1	<1	10
	Listeria monocytogenes / 25 g	5	0	0	
Infant formula (liquid) UHT/sterilized	Commercial Sterility				
Baby foods in hermetically sealed containers (Thermally processed)	Commercial Sterility				
Dried * instant products requiring reconstitution	¹ Coliforms, cfu/g	5	1	<3	20
	Salmonella / 25 g	60*	0	0	
	SPC/APC, cfu/g	5	2	10 ³	10 ⁴
Instant Infant Cereal	Bacillus cereus, cfu/g	10	1	10 ²	10 ⁴
	Cl. perfringens, cfu/g	10	1	10 ²	10 ³
Dried products requiring reconstitution and boiling before consumption	Coliforms, cfu/g	5	2	10	10 ²
	Salmonella / 25 g	5	0	0	
	SPC/APC, cfu/g	5	3	10 ⁴	10 ⁵
Infant Formula (liquid) UHT/sterilized	Commercial Sterility				
Coated or Filled, Dried Shelf-Stable Biscuits	¹ Coliforms, cfu/g	5	2	<3	20
	Salmonella / 25 g	10	0	0	

¹Coliforms must be negative for E. coli

* 25g sample units may be composite to a quantity not to exceed 400 g n = 60 4 x 15 (25g) composite units

MEAT & POULTRY PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Dried Animal Products (blood, plasma, gelatin)	S. aureus (coagulase +), cfu/g	5	1	10 ²	10 ⁴
	Cl. perfringens, cfu/g	5	1	10 ²	10 ⁴
	Salmonella / 25g	10	0	0	
Meat Paste & Pate, heat treated	Salmonella / 25g	5	0	0	
	Clostridium perfringens, cfu/g	5	2	10 ²	10 ³
	S. aureus (coagulase +), cfu/g	5	2	10 ²	10 ³
	¹ Coliforms, cfu/g	5	2	10	10 ²
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁵
Cold Cuts, Frozen & Chilled Hot Dogs, Corned Beef Luncheon Meat	E. coli, MPN/g	5	0	<1.8	
	Salmonella / 25g	10	0	0	
	S. aureus (coagulase +), cfu/g	5	2	10 ²	10 ³
	SPC/APC, cfu/g	5	2	10 ⁵	10 ⁶
Packaged cooked Cured/salted meat (ham, bacon)	S. aureus (coagulase +), cfu/g	5	2	10 ²	10 ³
	Salmonella / 25g	5	0	0	
	Listeria monocytogenes / 25 g	5	0	0	
Fermented, comminuted meat, not cooked (dry and semi-dry Fermented sausages)	S. aureus (coagulase +), cfu/g	5	1	10 ³	10 ⁴
	E. coli, MPN/g	5	0	<1.8	
	Salmonella / 25g	5	0	0	
Cooked Poultry Meat, Frozen to be reheated before eating (e.g., prepared frozen meals)	S. aureus (coagulase +), cfu/g	5	1	10 ³	10 ⁴
	Salmonella / 25g	5	0	0	
Cooked Poultry Meat, Frozen, Ready-to-Eat (e.g. Turkey rolls)	S. aureus (coagulase +), cfu/g	5	1	10 ³	10 ⁴
	Salmonella / 25g	5	0	0	
Cured / Smoked Poultry Meat	S. aureus (coagulase +), cfu/g	5	1	10 ³	10 ⁴
	Salmonella / 25g	5	0	0	
Dehydrated Poultry Products	Salmonella / 25g	10	0	0	
Fresh/Frozen Raw Chicken during processing	SPC/APC, cfu/g (at 20°C)	5	3	5x10 ⁵	10 ⁷
Meat Products in hermetically Sealed containers (thermally processed)	Commercial Sterility				
Pasteurized Egg Products (liquid, frozen or dried)	¹ Coliforms, cfu/g	5	2	10	10 ³
	Salmonella / 25g	10	0	0	
	YMC, cfu/g (for dried product)	5	0	10	
	SPC/APC, cfu/g	5	0	2.5x10 ⁴	10 ⁵

¹Coliforms must be negative for E. coli

FISH & SHELLFISH PRODUCTS

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

^a For fish derived for 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.

^b Test for s. aureus recommended for smoked fish.

^c Test for s. aureus recommended for breaded products. Salmonella and V. parahaemolyticus applied for products from warm waters or harvested during summer.

^d SPC/APC for frozen products only

^e 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 mulluscs from endemic areas or harvested from warm waters or during summer.

FRUITS, VEGETABLES & NUTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Frozen Vegetables & Fruits (pH >4.5)	E. coli, MPN/g	5	2	<110	10 ³
Fruit & Vegetable products in Hermetically sealed containers (thermally processed)	Commercial Sterility				
Dried Vegetables	E. coli, MPN/g	5	2	<110	10 ³
Coconut (desiccated)	Salmonella / 25g	10	0	0	
Yeast	Salmonella / 25g	20	0	0	
Peanut Butter & other Nut Butters ➤ consumed without heating or other treatment to destroy microbes ➤ used as ingredient in high moisture food	Salmonella / 25g	10	0	0	
	Salmonella / 25g	20	0	0	
Sun Dried Fruits	Molds, cfu/g	5	2	10 ²	10 ⁴
	Osmophilic Yeasts, cfu/g	5	2	10	10 ³
	E. coli, MPN/g	5	2	<3	11
Spices	Molds, cfu/g	5	2	10 ²	10 ⁴
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁶
Cocoa Powder	Molds, cfu/g	5	2	10 ²	10 ⁴
	Salmonella / 25g	5	0	0	
	Coliforms, MPN/g	5	2	<1.8	10
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁶

CEREAL AND CEREAL/LEGUME-BASED PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Cereals/Cereal Grains	Molds, cfu/g	5	2	10 ³	10 ⁵
Cultured seeds and grains (bean sprouts, alfalfa, etc.)	E. Coli, cfu/g	5	2	10	10 ²
	Coliforms, cfu/g	5	2	10 ²	10 ⁴
Breakfast Cereals and Snack Foods	Molds, cfu/g	5	2	10	10 ³
	Yeasts & Yeastlike Fungi, cfu/g	5	2	10	10 ²
	Coliform, cfu/g	5	2	10	10 ²
	SPC/APC, cfu/g	5	2	10	10 ²
Soya Flours, Concentrates and Isolates	Molds, cfu/g	5	2	10 ³	10 ⁵
	Salmonella, 25g	5	0	0	
Flour, Corn meal, Corn grits, Semolina	Molds, cfu/g	5	2	10 ²	10 ⁴
	Yeasts & Yeastlike Fungi, cfu/g	5	2	10	10 ²
	Coliform, cfu/g	5	2	10	10 ²
	Bacillus subtilis, cfu.g "rope spores"	5	2	10	10 ²
Frozen Bakery products (ready-to- eat) with low-acid or high aw fillings or toppings	S. aureus (coagulase +), cfug/g	5	1	10 ²	10 ⁴
	Salmonella / 25g	5	0		
Frozen Bakery products (to be cooked with low-acid or high aw fillings or toppings (e.g. meat, pies, pizzas)	S. aureus (coagulase +), cfug/g	5	1	10 ²	10 ⁴
	Salmonella / 25g	5	0	0	
Frozen Entrees containing Rice or Corn Flour as main ingredient	B. Cereus, cfu/g	5	1	10 ²	10 ⁴
Frozen & Refrigerated Doughs	Molds, cfu/g	5	2	10 ²	10 ⁴
	Yeasts & Yeastlike Fungi, cfu/g	5	2	10 ⁵	10 ⁶
	Coliform, cfu/g	5	2	10	10 ²
	Psychrotrophic bacteria, cfu/g	5	2	10	10 ³
	SPC/APC, cfu/g	5	2	10 ³	10 ⁶
Baked Goods (microbiologically sensitive types e.g., containing eggs or dry products)	S. aureus (coagulase +), cfug/g	5	2	10 ²	10 ⁴
	YMC, cfu/g	5	2	10 ²	10 ⁴
	Coliforms, cfu/g	5	2	50	10 ³
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁶

CEREAL AND CEREAL/LEGUME-BASED PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Soy Protein	Coliforms, cfu/g	5	2	10 ²	10 ³
	E. Coli, cfu/g	5	1	10	10 ²
	Psychrotrophic bacteria, cfu/g	5	2	10 ²	10 ⁴
	Cl, perfringens, cfu/g	5	2	<10	10 ²
	Molds, cfu/g	5	2	10	10 ²
	Salmonella / 25g	5	0	0	
	SPC/APC, cfu/g	5	2	10 ²	10 ²
Tofu	B. cereus, cfu/g	5	2	10 ²	10 ³
	S. aureus (coagulase +), cfu/g	5	2	10 ²	10 ³
	E. coli, MPN/g	5	0	<1.8	
Pasta Products	Coliforms, cfu/g	5	2	10	10 ³
	YMC, cfu/g	5	1	10	10 ⁵
	Salmonella / 25g	5	0	0	
	S. aureus (coagulase +), cfu/g	5	1	10 ²	10 ⁴
	SPC/APC, cfu/g	5	2	10 ³	10 ⁵
Dry Mixes for Soups and Sauces	Cl, perfringens, cfu/g	5	2	10 ²	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
Starch	Coliforms, cfu/g	5	2	10	10 ²
	YMC, cfu/g	5	2	10 ²	10 ³
	Salmonella / 25g	5	0	0	
	SPC/APC, cfu/g	5	2	10 ³	5x10 ⁴