Interpretive Summary
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HEALTH PRODUCTS AND FOOD BRANCH

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HEALTH PRODUCTS AND FOOD BRANCH (HPFB) STANDARDS AND GUIDELINES FOR MICROBIOLOGICAL SAFETY OF FOOD

- AN INTERPRETIVE SUMMARY

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1. INTRODUCTION

The purpose of this document is to provide the Canadian Food Inspection Agency (CFIA) and all interested parties a reference of the current regulatory standards, guidelines and their associated methods developed and/or evaluated by the Health Products and Food Branch (HPFB)in consultation with regional staff of HPFB, CFIA and other agencies, regarding foods following identification of a microbiological health and safety concern. These methods may have originated from the HPFB, CFIA or other internationally recognized agencies, and have been approved for inclusion in the *Compendium of Analytical Methods* by the Microbiological Methods Committee. This document should be of assistance to the Canadian Food Inspection Agency in determining the appropriate compliance action. Recommended actions are to be based on the risk posed by the microbiological hazard found in a food including consideration of the severity of the hazard and the potential exposure e.g. if the food is to be sold to a sensitive population. **Note: this revised document replaces the one entitled "Health Protection Branch Standards and Guidelines for Microbiological Safety of Food - an Interpretive Summary", dated July 2006.**

With this guidance the CFIA can respond to situations which contravene existing standards and guidelines. Where no standards or guidelines exist the CFIA must consult Health Canada (HC) for determining the appropriate product action.

The classification of the nature of concern (risk) associated with contravention of the standard and guideline listed may be impacted by additional factors. In these situations it is appropriate for the CFIA to consult HC to determine the appropriate response to the specific situation.

2. STANDARDS

Food offered for sale in Canada is required to be manufactured, stored, transported and otherwise handled under conditions that provide for its microbiological safety and general cleanliness. For certain foods, microbiological standards have been established. These standards, which have legal status and are defined in the Regulations under the Food and Drugs Act, have been developed on the basis of survey data over the years as an aid to the administration of those sections of the Act and relate to the microbiological safety and general cleanliness of food.

The Regulations deal with specifics whereas the Act itself deals with generalities. Sections 4, 5, 6 and 7 of the Food and Drugs Act relate to the food offered for sale. Those sections dealing with the microbiological safety and the cleanliness of foods read as follows:

Sections of the Food and Drugs Act

4. No person shall sell an article of food that
   (a) has in or upon it any poisonous or harmful substance;
   (b) is unfit for human consumption;
   (c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
   (d) is adulterated; or
   (e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

5. No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

6. Where a standard has been prescribed for a food, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for such food, unless the article complies with the prescribed standard.

7. No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions.

Section 2 of the Food and Drugs Act defines "unsanitary conditions" as "such conditions or circumstances as might contaminate a food, drug or cosmetic with dirt, filth or render the same injurious to health".

3. GUIDELINES

In addition to standards, HPFB also develops microbiological and extraneous matter guidelines related to health and safety issues. Although these guidelines are not defined in the Regulations, as are the standards, they may also be used in judging compliance with Sections 4, 5 and 7 of the Food and Drugs Act.

A given guideline may embody the same limiting criteria that would be employed in a standard. Frequently, however, they are based on fewer data than those used in developing a standard but they serve as useful indicators of levels achievable using Good Manufacturing Practices (GMPs). Since guidelines are not part of the Regulations, they can be readily modified, if necessary, as additional data become available.

There are two distinct groups of guidelines related to health and safety; microbiological guidelines and injurious extraneous material guidelines. The latter includes foreign matter associated with objectionable conditions or practices in manufacturing, processing, storing, transporting and handling of food that could lead to an injury (e.g. glass in jam, splinters, etc).

4. TWO-CLASS AND THREE-CLASS ATTRIBUTES LOT ACCEPTANCE SAMPLING PLANS

Standards and guidelines are expressed in terms of 2-Class Plans or 3-Class Plans depending on the degree of hazard involved. Two-Class Plans are used where no living cells of a specific organism or where no piece of a specific type of extraneous material is tolerated in foods. Three-Class Plans are used where some cells of the organism in question, or, where the presence of certain amounts of extraneous material are tolerated. For a detailed discussion of the concepts that these plans involve and their application, refer to the second edition of "Microorganisms in Foods, Volume 2, Sampling for microbiological analysis: Principles and specific applications," compiled by The International Commission on Microbiological Specifications for Foods (ICMSF) of the International Association of Microbiological Societies and published in 1986 by the University of Toronto Press.

The symbols used in the plans and their definitions are as follows:

Lot: A batch or production unit which may be identified by the same code. When there is no code identification, a lot may be considered as (a) that quantity of product produced under essentially the same conditions, at the same establishment and representing no more than one day's production; or (b) the quantity of the same variety of product from one and the same manufacturer available for sampling at a fixed location.

n: The number of sample units usually but not always selected at random from a lot and examined in order to satisfy the requirements of a particular acceptance plan used. This is the sample.

m: The numerical value of "m" represents acceptable concentrations of microorganisms or amounts of extraneous material, usually per g or mL. In a 2-class plan, "m" separates sample units of acceptable and defective quality; in a 3-class plan, "m" separates sample units of acceptable quality from those of marginally acceptable quality. The "m" values listed in the following tables are based on levels achievable under GMP.

M: (Only in a 3-class plan), the numerical value of "M" represents unacceptable concentrations of microorganisms or amounts of extraneous material, usually per g or mL, that indicate a (potential) health or injury hazard, imminent spoilage or gross insanitation; "M" separates sample units of marginally acceptable quality from those of defective quality. A value determined for any one sample unit of a sample that is greater than that of "M" renders the pertaining lot unacceptable.

c: The maximum allowable number of marginally acceptable sample units. "c" is the acceptance number of a plan. When this number is exceeded, the lot becomes unacceptable.

Standards and guidelines can be applied only when the appropriate method of analysis (or equivalent) is used.

10 samples per lot required for Packaged ice

More than one failure out of the 10 required means entire lot needs to be destroyed.

Reference Page 9 for requirements specific to Packaged Ice

Packaged Ice is considered to be in the lowest risk category - HR3

5. RISK ASSESSMENT

Risk assessment is composed of four elements: hazard identification, exposure assessment, hazard characterization and risk characterization.

Hazard Identification

The purpose of hazard identification is to identify the microorganisms or the microbial toxins of concern with food. Hazard identification will predominately be a qualitative process. Hazards can be identified from relevant data sources. Information on hazards can be obtained from scientific literature, from databases such as those in the food industry, government agencies, and relevant international organizations and through solicitation of opinions of experts. Relevant information includes data in areas such as: clinical studies, epidemiological studies and surveillance, laboratory animal studies, investigations of the characteristics of microorganisms, the interaction between microorganisms and their environment through the food chain from primary production up to and including consumption, and studies on analogous microorganisms and situations.

Exposure Assessment

Exposure assessment includes an assessment of the extent of actual or anticipated human exposure. It might be based on the potential extent of food contamination by a particular agent or its toxins, and on dietary information. Exposure assessment estimates the level of microbiological pathogens or microbiological toxins, and the likelihood of their occurrence in foods at the time of consumption. The presence, growth, survival, or death of microorganisms, including pathogens in foods, are influenced by processing and packaging, the storage environment, including the temperature of storage, pH, moisture content or water activity (a_w), the presence of antimicrobial substances, and competing microflora. Predictive microbiology can be a useful tool.

Hazard Characterization

This step provides a qualitative or quantitative description of the severity and duration of adverse effects that may result from the ingestion of a microorganism or its toxin in food. Several factors need to be considered in hazard characterization. They are related to both the microorganism, and the human host. In relation to the microorganism the following are important: microorganisms are capable of replicating; the virulence and infectivity of microorganisms can change depending on their interaction with the host and the environment; genetic material can be transferred between microorganisms leading to transfer of characteristics such as antibiotic resistance and virulence factors; microorganisms can be spread through secondary and tertiary transmission; the onset of clinical symptoms can be substantially delayed following exposure; microorganisms can persist in certain individuals leading to continued excretion and continued risk of spread of infection; low doses of some microorganisms can cause a severe effects; the attributes of a food may alter the microbial pathogenicity, e.g. high fat content of a food vehicle (for example, the fat content in contaminated cheese and chocolate can protect *Salmonella* so that the infectious dose could be <10 CFU/g). In relation to the host the following may be important: genetic factors; increased susceptibility due to breakdowns of physiological barriers; status, concurrent infections, immune status and previous exposure history; population characteristics such as population immunity, access to and use of medical care, and persistence of the organism in the population.

Risk Characterization

Risk characterization represents the integration of the hazard identification, hazard characterization, and exposure assessment determination to obtain a risk estimate. Risk characterization brings together all of the qualitative or quantitative information of the previous steps to provide a sound estimate of risk for a given population. Risk characterization depends on available data and expert judgements.

The following categories have been used to characterize the health risks:

Health Risk Definitions

The level of Health Risk is determined by taking into account the hazard identification, the exposure assessment and the hazard characterization.

Health Risk 1 (HR 1):

The health risk identified represents a situation where there is a reasonable probability that the consumption/exposure to a food will lead to adverse health consequences which are serious or life-threatening, or that the probability of a foodborne outbreak situation is considered high.

Health Canada Advice:

Appropriate actions should be taken immediately to prevent exposure of the population to the product, including product at the consumer level. Follow-up action should try to determine the cause of the problem, and determine if appropriate and timely corrective measures have been taken.

Health Risk 2 (HR 2):

The health risk identified represents a situation where there is a reasonable probability that the consumption/exposure to a food will lead to temporary or non-life threatening health consequences, or that the probability of serious adverse consequences is considered remote.

Health Canada Advice:

Appropriate actions should be taken in a timely manner to prevent exposure of the population to the product or to prevent further distribution of the product. Follow-up action should try to determine the cause of the problem and determine if appropriate and timely corrective measures have been taken.

Health Risk 3 (HR 3): Packaged Ice in this category

This represents a situation where there is a reasonable probability that the consumption/exposure to a food is not likely to result in any adverse health consequence. The situation identified may be an indication of a breakdown in Good Manufacturing Practices (e.g., sanitation, quality issues, etc.); in Good Agricultural Practices (e.g. pesticide residue in food above the established MRL); in Good Practices in Veterinary Medicine (e.g. animal drug residue in food above the MRL) or some other relevant factor (e.g., food containing non-permitted nutrients or food additives above the permitted levels, nutrients that do not meet label claim, health-related labelling infractions, etc.).

Health Canada Advice:

Follow-up action should try to determine the cause of the problem and determine if appropriate and timely corrective measures have been taken.

***Approved by HC/CFIA Science and Policy Advisory Committee Working Group on Communicating Health Risk Assessments,* HC/CFIA Research and Surveillance Sub-Committee, and HC/CFIA Science and Policy Advisory Committee.**

6. EQUIVALENT METHODS

While a complete description of method development, status and definitions is provided in the document entitled "Procedure for the Development and Management of Food Microbiological and Extraneous Material Methods" the following is offered to clarify the term "equivalent methods" and their use:

As described in the document on method development, all methods have been categorized in accordance to their degree of validation. All Official Methods (MFOs), HPB Methods (MFHPBs), and Laboratory Procedures (MFLPs) meet the minimum criteria of a Compendium method specified for that category. For any compliance activity and routine analysis any Compendium method that is the most effective (as described below) may be used. Although MFLPs may not have been validated to the same extent or degree as HPB Methods in Canada, they often have greater analytical sensitivity and specificity according to available data.

Laboratories involved in compliance activity should use the most effective method **(i.e., the best or most suitable)** so that: 1. the method is "fit for purpose" and can be used to analyse the commodity in question so that the analytical results are reliable; 2. the analysis are completed in a timely manner; 3. the health and safety of Canadians are ensured ; and 4. the shelf-life of the product is not jeopardized. If a non-compendial method is used in compliance activity, then validation data must be available.

Screening methods (e.g. "rapid kits") published as MFLPs may be used to screen large numbers of food samples for specific bacteria and/or pathogens. When presumptive positive results are found using a rapid kit, **confirmation** and possibly reanalysis may proceed using a higher classification of methods (i.e. MFHPB or MFO) as long as it is the most effective method for the purpose.

HPB Methods and Laboratory Procedures or internationally validated methods can be used to determine compliance with the Food and Drugs Act in circumstances where there are no microbiological criteria stated in the Regulations. Where an alternative method, when approved by the MMC, is equivalent or better than the Official Method specified in the Regulations of the Food and Drugs Act, it can be used to determine compliance with these Regulations. It is to be noted that a Laboratory Procedure or other validated method can be deemed to be acceptable for use in the administration of either the Food and Drugs Act and Regulations, when the method is equivalent or better (e.g., equivalent or increased analytical sensitivity, equivalent or increased specificity etc.) to the available MFO or MFHPB. Therefore, a Laboratory Procedure or other validated method can be deemed to be acceptable for use in the administration of either the Food and Drugs Act and Regulations.

NOTE: It is imperative that the "Application Section" of each method be reviewed before use to determine the method's applicability to the food or environmental sample in question. Applicability of methods to new matrices requires validation. It is strongly recommended that the validation data be submitted to the MMC for review and possible amendment of the method.

7. SUMMARIES OF HPFB STANDARDS AND GUIDELINES AND ANALYTICAL METHODS

The following tables present summaries of the current standards, guidelines and methods of analysis. They have been developed by the Bureau of Microbial Hazards, Food Directorate, with input from Regional personnel and the food industry.

NOTE: In conjunction with the information provided in the following tables, please consult the following HPFB Policies on Food Safety, which are published at www.hc-sc.gc.ca/fn-an/legislation/pol/index_e.html.

- Policy on Managing Health risk Associated with the Consumption of Sprouted Seeds and Beans.
- Policy Development for Raw Foods of Animal Origin; contains links to:
  - Food Directorate Guideline no.10 - Guidelines for Raw Ground Beef Products Found Positive for Escherichia coli O157:H7. The guidelines outline public health measures to be taken when ground beef and beef products are tested and found positive for *E. coli* O157:H7.
  - Food Directorate Guideline no.12 - Interim guideline for the control of verotoxinogenic Escherichia coli including E.coli O157:H7 in ready to eat fermented sausages containing beef or a beef product as an ingredient. The guideline describes five intervetions, one of which must be used when manufacturing dry or semi dry fermented sausages.
- Managing Health Risk Associated with the Consumption of Unpasteurized Fruit Juice/Cider Products.
- Low-Acid and Acidified Low-Acid Foods in Hermetically Sealed Containers (Visual Inspection Protocol).
- Policy on *Listeria monocytogenes* in Ready-to-Eat Foods.
  - Frequently asked Technical Questions on the “Policy on *Listeria monocytogenes* in Ready-to-Eat Foods”.

TABLE 1a. Foods for which there is a Microbiological Standard.

FOOD CATEGORY	REGULATION #	MFO #	STANDARD	NATURE OF CONCERN	SAMPLING PARAMETERS			
					n	c	m	M
Chocolate[A]	B.04.012	11	*Salmonella*	HR 2[B]	10	0	0	-
Cocoa[A]	B.04.012	11	*Salmonella*	HR 2[B]	10	0	0	-
Milk Powder	B.08.014	12	*Salmonella*	HR 2[B]	20	0	0	-
Flavoured Milks	B.08.016 B.08.018 B.08.026	7	Aerobic colony count (ACC)	HR 3	5	2	5x10^4	10^6
Milk for Manufacture	B.08.024	7	ACC	HR 3	5	0	2x10^6	-
Cheese from Pasteurized Milk	B.08.048(1a)	14	*Escherichia coli*	HR 2[C]	5	2	10^2	2x10^3
	B.08.048(1b)	14	*Staphylococcus aureus*	HR 2	5	2	10^2	10^4
Cheese from Unpasteurized Milk	B.08.048(2a)	14	*E. coli*	HR 2[C]	5	2	5 X 10^2	2x10^3
	B.08.048(2b)	14	*S. aureus*	HR 2	5	2	10^3	10^4
Cottage Cheese	B.08.054	4	Coliforms	HR 3	5	1	10^1	10^3
Ice Cream	B.08.062	2	ACC	HR 3	5	2	10^5	10^6
	B.08.062	2	Coliform	HR 3	5	1	10^1	10^3
Ice Milk	B.08.072	2	ACC	HR 3	5	2	10^5	10^6
	B.08.072	2	Coliforms	HR 3	5	1	10^1	10^3
Tomato Products	B.11.016	5	Mould	HR 3	See MFO-5 for criteria in Vol 1 of the Compendium			

[A] See Table 3a for Guidelines for ACC.

[B] This becomes a HR 1 concern if targeted or distributed to a sensitive population, such as children less than five years of age, the elderly, or immunocompromised individuals (AIDS patients, transplant recipients, cancer patients etc).

[C] This becomes a HR 1 concern if verotoxin-producing strains are detected.

TABLE 1b. Foods for which there is a Microbiological Standard

FOOD CATEGORY	REGULATION #	MFO #	STANDARD	NATURE OF CONCERN	SAMPLING PARAMETERS			
					n	c	m	M
Mineral or Spring Water	B.12.001	9	Coliforms	HR 3	10	1	<1.8/100 mL	10/100mL
Water in Sealed Containers	B.12.004	15	ACC	HR 3	5	2	10^2	10^4
	B.12.004	15	Coliforms	HR 3	10	1	<1.8/100mL	10/100mL
Pre-packaged Ice	B.12.005	15	Coliforms	HR 3	10	1	<1.8/100mL	10/100mL
Froglegs	B.21.031	10	*Salmonella*	HR 2[A]	5	0	0	-
Egg Products	B.22.033	6	*Salmonella*	HR 2[A]	10	0	0	-

[A] This becomes a HR 1 concern if targeted or distributed to a sensitive population, such as children less than five years of age, the elderly, or immunocompromised individuals (AIDS patients, transplant recipients, cancer patients etc.).

TABLE 2. Foods for which there are Additional Standards other than the Microbiological Standards

FOOD CATEGORY	REGULATION #	MFO #	STANDARD	NATURE OF CONCERN
Dairy products made from pasteurized milk	B.08.002	3	Phosphatase Test.	HR 1
Low Acid Foods in Hermetically Sealed Containers[A]	B.27	n/a	Commercial Sterility, Refrigeration at $\leq 4^{\circ}C$.	HR 1
Smoked Fish in Hermetically Sealed Containers[B]	B.21.025	n/a	Commercial Sterility, Freezing, 9% salt (NaCl).	HR 1

[A] If serious defects are detected in low acid canned food, as described in the Metal Can Defect Manual, take the appropriate action to limit exposure in the population following guidance in the Visual Inspection Protocol.

[B] Some smoked fish products may be exempted from the provisions of B.21.025. There is a separate compliance guide.

TABLE 3a. Foods for which Microbiological Guidelines have been established.

These guidelines are based on existing HPFB parameters or those proposed by ICMSF if the ICMSF guidelines were more stringent and Health Canada monitoring results indicate that the more stringent requirements can be met.

FOOD CATEGORY	METHOD OR EQUIVALENT	GUIDELINE	NATURE OF CONCERN	SAMPLING PARAMETERS			
				n	**c**	**m**	**M**
Cocoa[A]	MFHPB-18	ACC includes aerobic sporeformers	HR 3	5	2	10^5	10^6
	MFHPB-22	Yeast and Moulds	HR 3	5	2	2X10^3	10^4
	MFHPB-19	Coliforms	HR 3	5	2	<1.8	10^1
Chocolate[A]	MFHPB-18	ACC includes aerobic sporeformers	HR 3	5	2	3x10^4	10^6
	MFHPB-19	Coliforms	HR 3	5	2	<1.8	10^2
Instant Infant Cereal and Powdered Infant Formula (if **M** exceeded Health 1; if **c** exceeded Health 2)	MFHPB-18	ACC	HR 3	5	2	10^3	10^4
	MFHPB-19	*E. coli*	HR 2[B]	10	1	<1.8	10^1
	MFHPB-20	*Salmonella*	HR 1	20	0	0	0
	MFHPB-21	*S. aureus*	HR 2	10	1	10^1	10^2
	MFHPB-42	*Bacillus cereus*	HR 2	10	1	10^2	10^4
	MFHPB-23	*Clostridium perfringens*	HR 2	10	1	10^2	10^3

[A] There is a standard for *Salmonella* in this product. See Table Ia.

[B] This becomes a HR 1 concern if verotoxin-producing strains are found.

TABLE 3b. Foods for which Microbiological Guidelines have been established

FOOD CATEGORY	METHOD OR EQUIVALENT	GUIDELINE	NATURE OF CONCERN	SAMPLING PARAMETERS			
				n	c	m	M
Fresh and Dry Alimentary Paste (noodles, spaghetti, and macaroni, etc.)	MFHPB-18	ACC	HR 3	5	2	5x10^4	10^6
	MFHPB-22	Yeast and moulds	HR 3	5	2	2x10^3	10^4
	MFHPB-19	*E. coli*	HR 2[B]	5	2	<1.8	10^3
	MFHPB-21	*S. aureus*	HR 2	5	2	5x10^2	10^4
	MFHPB-20	*Salmonella*	HR 2[C]	5	0	0	- -
Bakery Products[A]	MFHPB-18	ACC	HR 3	5	2	5x10^4	10^6
	MFHPB-19	Coliforms	HR 3	5	2	5x10^1	10^4
	MFHPB-19	*E. coli*	HR 2[B]	5	1	<1.8	10^3
	MFHPB-22	Yeast and mould	HR 3	5	2	5x10^2	10^4
	MFHPB-21	*S. aureus*	HR 2	5	2	10^2	10^4
	MFHPB-20	*Salmonella*	HR 2[C]	5	0	0	- -
Heat Treated Fermented Sausage	MFHPB-19	*E. coli*	HR 2[B]	5	1	10^1	10^3
	MFHPB-21	*S. aureus*	HR 2	5	1	5x10^1	10^4
Raw Fermented Sausage	MFHPB-19	*E. coli*	HR 2[B]	5	1	10^2	10^3
	MFHPB-21	*S. aureus*	HR 2	5	1	2.5x10^2	10^4
Non-fermented Ready-to-eat Sausage	MFHPB-19	*E. coli*	HR 2[B]	5	2	10^2	10^3
	MFHPB-21	*S. aureus*	HR 2	5	2	10^2	10^4

A Bakery products that are microbiologically sensitive, i.e., containing eggs or dairy products. Cream pies likely represent the worst case of this product type.

B This becomes a HR 1 concern if verotoxin-producing strains are found.

C This becomes a HR 1 concern if targeted or distributed to a sensitive population, such as children less than five years of age, the elderly, or immunocompromised individuals (AIDS patients, transplant recipients, cancer patients etc.).

TABLE 3c. Foods for which Microbiological Guidelines have been established.

FOOD CATEGORY	METHOD OR EQUIVALENT	GUIDELINE	NATURE OF CONCERN	SAMPLING PARAMETERS			
				n	c	m	M
Heat Treated Sausage, Raw Fermented Sausage and Non-fermented Sausage	MFHPB-20	*Salmonella*	HR 2	5	0	0	- -
	MFLP-46	*Campylobacter coli* or *C. jejuni*[A]	HR 2	5	0	0	- -
	MFLP-48	*Yersinia enterocolitica*[A]	HR 2	5	0	0	- -
	MFLP-80	*E. coli* O157	HR 1	5	0	0	- -
Deboned Poultry Products (Precooked)	MFHPB-18	ACC	HR 3	5	3	10^4	10^6
	MFHPB-19	*E. coli*	HR 2[B]	5	2	10^1	10^3
	MFHPB-21	*S. aureus*	HR 2	5	1	10^2	10^4
	MFHPB-20	*Salmonella*	HR 2	5	0	0	-
	MFLP-46	*C. jejuni or C. coli*[A]	HR 2	5	0	0	-
	MFLP-48	*Y. enterocolitica*[A]	HR 2	5	0	0	-
Dry Mixes (Gravy, Sauce, Soup) Heat and Serve	MFHPB-18	ACC	HR 3	5	3	10^4	10^6
	MFHPB-19	Coliforms	HR 3	5	3	10^1	10^3
	MFHPB-22	Yeast and Moulds	HR 3	5	3	5x10^2	10^4
	MFHPB-19	*E. coli*	HR 2[B]	5	2	10^1	10^3
	MFHPB-21	*S. aureus*	HR 2	5	2	10^2	10^4
	MFHPB-23	*C. perfringens*	HR 2	5	2	10^2	10^3
	MFHPB-20	*Salmonella*	HR 2	5	0	0	-

[A] Designates an optional analysis. It is not expected that these determinations will be done routinely but possibly during an investigation of illness or consumer complaints.

[B] This becomes a HR 1 concern if verotoxin-producing strains are found.

TABLE 3d. Foods for which Microbiological Guidelines have been established.

FOOD CATEGORY	METHOD OR EQUIVALENT	GUIDELINE	NATURE OF CONCERN	SAMPLING PARAMETERS			
				n	c	m	M
Soybean Products (Ready-to-eat)	MFHPB-18	Psychrotrophic bacteria[A]	Sanitation	5	2	10^5	10^7
	MFHPB-19	*E. coli*	HR 2[D]	5	2	10^2	10^3
	MFHPB-21	*S. aureus*	HR 2	5	2	10^2	10^4
	MFHPB-20	*Salmonella*	HR 2[E]	5	0	0	-
	MFLP-48	*Yersinia enterocolitica*[B]	HR 2	5	0	0	-
Spices (Ready-to-eat only)	MFHPB-23	*C. perfringens*	HR 2	5	2	10^4	10^6
	MFHPB-42	*B. cereus*	HR 2	5	2	10^4	10^6
	MFHPB-19	*E. coli*	HR 2[D]	5	2	10^2	10^3
	MFHPB-21	*S. aureus*	HR 2	5	2	10^2	10^4
	MFHPB-20	*Salmonella*	HR 2[E]	5	0	0	-
	MFHPB-22	Yeast and Mould	HR 3	5	2	10^2	10^4
Bottled Water[C]	MFLP-61B	*Pseudomonas aeruginosa*	HR 3	5	0	0/100 mL	-
	MFLP-58B	*Aeromonas hydrophila*	HR 3	5	0	0/100 mL	-
Sprouted Seeds (e.g. Alfalfa and Bean Sprouts)	MFHPB-19	Faecal Coliforms	HR 3	5	2	10^3	10^5
	MFHPB-19	*E.coli*	HR 2[D]	5	2	10^2	10^3
	MFHPB-20	*Salmonella*	HR 2[E]	5	0	0	-

A m and M values modified according to Health Canada monitoring results.

B Designates an optional analysis. It is not expected that these determinations will be done routinely but possibly during an investigation of illness or consumer complaints.

C Includes Mineral or Spring Water, or Water in Sealed Containers. There are standards for ACC and coliforms in these products. See Table 1a. Does NOT apply to packaged ice

D This becomes a HR 1 concern if verotoxin-producing strains are found.

E This becomes a HR 1 concern if targeted or distributed to a sensitive population, such as children less than five years of age, the elderly, or immunocompromised individuals (AIDS patients, transplant recipients, cancer patients etc.).

TABLE 3e. Foods for which Microbiological Guidelines have been established.

FOOD CATEGORY	METHOD OR EQUIVALENT	GUIDELINE	NATURE OF CONCERN	SAMPLING PARAMETERS			
				n	c	m	M
Health Foods a) Raw Organ Derived Products and Herbal Products (in tablets, capsules or powders, consumed at <10 g/day)	MFHPB-18	ACC	HR 3	5	3	10^4	10^5
	MFHPB-19	*E. coli* [B]	HR 2	5	1	10^1	10^3
	MFHPB-20	*Salmonella*	HR 1	5	0	0	-
	MFHPB-21	*S. aureus* [B]	HR 2	5	2	10^2	10^4
	MFLP-42	*B. cereus*	HR 2	5	1	10^4	10^5
	MFHPB-23	*C. perfrigens*	HR 2	5	2	10^4	10^5
b) Powdered Protein, Meal Replacements, and Dietary Supplements	MFHPB-18	ACC	HR 3	5	2	10^3	10^4
	MFHPB-19	*E. coli* [B]	HR 2	5	1	<1.8	10^1
	MFHPB-20	*Salmonella*	HR 1	5	0	0	-
	MFHPB-21	*S. aureus* [B]	HR 2	5	2	10^1	10^2
	MFLP-42	*B. cereus*	HR 2	5	1	10^2	10^4
	MFHPB-23	*C. perfringens*	HR 2	5	2	10^2	10^3

[A] This becomes a HR 1 concern if targeted or distributed to a sensitive population, such as children less than five years of age, the elderly, or immunocompromised individuals (AIDS patients, transplant recipients, cancer patients etc.)

[B] This becomes a HR 1 concern if toxin-producing strains are found.

TABLE 3f. Foods for which Microbiological Guidelines have been established (May and July 2006).

FOOD CATEGORY	METHOD OR EQUIVALENT	GUIDELINE	NATURE OF CONCERN (Health Risk (HR))	SAMPLING PARAMETERS			
				n	c	m	M
Raw Oyster	MFLP-37	*Vibrio parahaemolyticus*					
		at retail	HR 2	5	1	10^2	10^4
Unpasteurized apple juice	MFLP-80	*E. coli* O157	HR1	5	0	0	
	MFHPB-19	*E. coli*	HR 2	5	2	10^2	10^3
Fresh fruits and vegetables	MFLP-80	*E. coli* O157	HR1	5	0	0	
	MFHPB-19	*E. coli*	HR 2	5	2	10^2	10^3

TABLE 3g. Foods for which Microbiological Guidelines have been established.

FOOD CATEGORY	METHOD OR EQUIVALENT	GUIDELINE	NATURE OF CONCERN
Low-acid foods processed to commercial sterility	MFHPB-01	If heat process alone is to achieve commercial sterility F_0=3 must be achieved	$F_0 < 3$ HR 1
		If a retorted product is not commercially sterile but heat process is known to be $F_0 = 3^A$ or above	HR 2
		If the product is judged to be underprocessed F_0 <3	HR 1
		If contamination is assessed at postprocessing	HR 2

[A] The heat process should be sufficient to destroy *C. botulinum* spores but would not be sufficient to destroy other microorganisms that could grow in the product and cause spoilage.