User guide to Standard 1.6.1 – Microbiological Limits for Food with additional guideline criteria

July 2001

Contents

Background

In this user guide, the 'old Code' means Volume 1 of the *Food Standards Code* (the Australian *Food Standards Code*). The 'new Code' means Volume 2 of the *Food Standards Code* (the Australia New Zealand *Food Standards Code*). The 'New Zealand regulations' means the New Zealand *Food Regulations 1984*.

In adopting the new Code in November 2000, the ministerial council agreed to a two-year transition period. After this, the new Code will replace both the old Code and the New Zealand regulations.

During this two-year phase-in period, foods in Australia may comply with either the old Code or the new Code (but not a combination of these). In New Zealand, foods may comply with the old Code or the new Code or the New Zealand regulations (but not a combination of these).

After this, the old Code and New Zealand regulations will be repealed and all food sold in Australia and New Zealand will have to comply with the new Code.

The new Code will mean changes in the way manufacturers and retailers make and present food for sale.

The Australia New Zealand Food Authority (ANZFA) has developed this user guide, in consultation with Australian and New Zealand government and industry representatives, to help manufacturers and retailers interpret and apply Standard 1.6.1 – Microbiological Limits for Food in the new Code. The guide may also be used by food officers to help interpret food standards in the new Code.

This user guide, unlike the standard itself, is not legally binding. If in any doubt about interpreting the standards, you should seek independent legal advice.

As well as complying with food standards requirements, you must also continue to comply with other legislation. In Australia, this legislation includes the *Trade Practices Act 1974*, the *Imported Food Control Act 1992*, and State and Territory Fair Trading Acts and Food Acts. In New Zealand, this legislation includes the *Food Act 1981* and *Fair Trading Act 1986*.

Purpose

This guide is intended to provide information to help retailers, caterers, manufacturers and food officers interpret and apply Standard 1.6.1 – Microbiological Limits for Food.

Microbiological standards and guideline criteria

Standard 1.6.1 specifies microbiological standards for nominated foods or classes of foods. Foods listed in the standard must meet the prescribed microbiological limits at any stage of their manufacture or sale.

ANZFA has also developed microbiological guideline criteria for various foods that are additional to the standard but not mandatory. These guideline criteria act as an identification point for unacceptable levels of microbial contamination in foods. When these levels are exceeded it generally indicates a failure in the food production process or hygiene procedures. It means that action should be taken to identify and remedy the problem.

The microbiological guideline criteria are in Attachment 1.

Reliance on these microbiological guideline criteria alone does not assure safe food production and handling procedures. For further information on safe food production and handling see ANZFA's Guide to the Food Safety Standards, *Safe Food Australia*.

Food description

The following table gives a general description of the foods for which microbiological standards have been specified in the new Code. The foods must comply with the microbiological limits specified in the standard.

Food	**Description**
Butter made from unpasteurised milk and/or unpasteurised milk products	Milk and milk products sold for human consumption must be pasteurised. However, unpasteurised milk and milk products may be sold where a New Zealand or a State or Territory law specifically permits it. Butter made from unpasteurised milk has historically been called 'farm' butter.

Food	Description
All cheese	The *E. coli* standard applies to all cheese types from soft to hard, unripened, ripened and salt cured, as well as cheese produced from raw milk. A description of cheese types and varieties according to moisture content and ripening methods is in Attachment 2.
Soft and semi-soft cheese	Cheeses with a moisture content >39% and pH >5.0 may include such varieties as camembert, brie and other soft mould-ripened cheeses.
All raw milk cheese	There is provision in the new Code for the production of cheese from unpasteurised milk and milk products where the documented process of production demonstrates an equivalent level of safety to that achieved using heat treatments (see Standard 2.5.4 – Cheese). Permission for raw milk cheeses is given on a case-by-case assessment. Currently, only raw milk Gruyere, Sbrinz and Emmental cheeses produced with appropriate documentation from Switzerland are permitted.
Raw milk unripened cheeses (moisture content > 50%, pH >5.0)	Unripened cheeses with a moisture content >50% (soft cheeses) may include such products as cottage cheese, quark, cream cheese and mozzarella. Currently, the Code does not permit any soft cheeses produced from raw milk.
Dried milk	Dried milk powder refers to whole and skim milk powder as well as other milk-derived powders, including whey.
Unpasteurised milk	While the Code requires that milk and milk products sold for human consumption must be pasteurised, unpasteurised milk for human consumption may be sold where New Zealand, State or Territory law expressly permits it.
Packaged cooked	Cooked cured and cooked salted meat products include meats such

Food	Description
cured/salted meat	as ham, bacon and emulsion-style sausages (e.g. frankfurters). Some products may have natural or liquid smoke applied to them. The standards apply to packaged product as contamination of unpackaged product can occur as a result of poor handling and this should not be mistakenly attributed to the manufacturing process.
Packaged heat-treated meat paste and packaged heat-treated pâté	Meat paste and pâté (including terrine) include all spreads made from a variety of meats and poultry, which may be flavoured with herbs, spices, nuts, fruits or alcohol. Fish-based paste or pâté is not covered by this standard. The standards apply to packaged product, as contamination of unpackaged product can occur as a result of poor handling. This should not be mistakenly attributed to the manufacturing process.
Fermented, comminuted meats which have not been cooked	Fermented, comminuted meats include dry and semi-dry fermented sausage products, including those that may have natural or liquid smoke applied to them. Uncooked products are those that have not been subject to a heating process in which the core temperature of the product has been maintained at 65˚C for a period of at least 10 minutes (or an equivalent combination of time and higher temperature). These products must be labelled as 'not heat-treated'. You can get more information in the ANZFA publication *Advisory Guidelines for the Hygienic Production of Uncooked Fermented Comminuted Meat Products.*
Crustacea, cooked and raw	Crustacea includes prawns, shrimps, crayfish, lobster and other less widely consumed seafoods such as sea urchins. These foods may come from the sea, freshwater or aquaculture.
Ready-to-eat finfish, other than fully retorted finfish	Ready-to-eat finfish includes fish from both salt and freshwater environments that has undergone some processing such as hot or cold smoking, salting, drying, pickling or fermenting. Foods such as sushi and other raw fish foods are not covered by this standard

Food	Description
	as sushi and other raw fish foods are not covered by this standard.
Molluscs, other than scallops	Molluscs include mussels, oysters, clams, octopus and squid. Scallops are excluded from the *E. coli* standard unless the scallop gut is included.
Molluscs that have undergone processing other than depuration	Processing of molluscs includes such treatments as smoking and marinating but does not include physical measures such as half-shelling.
Cereal-based foods for infants	This food category includes those cereal-based foods such as dry cereals and cereal flours and rusks prepared from cereals.
Powdered infant formula	This category covers any powdered human milk substitute, including dairy and soy-based infant formula. Some formulas may contain added cultures of lactic acid producing bacteria. In this case, the standard plate count (SPC) standard should be applied to the product before the addition of the culture.
Pepper, paprika and cinnamon	These three spices in particular have been recognised as posing a particular risk for salmonella contamination. Pepper includes all dried peppercorns, whole or ground. Paprika includes all dried and ground paprika varieties. Cinnamon includes whole quills and ground cinnamon powder.
Coconut: dried, chipped, desiccated	This includes all desiccated and shredded coconut and coconut products, but does not include coconut cream or coconut milk.
Cocoa powder	Cocoa is the dried powder obtained from cocoa beans. The *Salmonella* standard applies to cocoa powder for retail and cocoa intended for further manufacture, such as to make chocolate.
Cultured seeds and grains (bean sprouts,	This category of foods incorporates all salad-type sprouts such as alfalfa, mung bean, lentil, snow pea and onion. The product may be

Food	Description
alfalfa etc.)	in punnets or provided for sale as a loose product.
Pasteurised egg products	Egg products for sale or manufacture must be pasteurised or undergo an equivalent treatment so that the microbiological criteria are met. Minimum time/temperature processes for liquid egg white, liquid egg yolk and liquid whole egg to be sold or used in the manufacture of food are given in Standard 1.6.2 – Processing Requirements.
Mineral water	Mineral water (or spring water) refers to ground water obtained from subterranean water-bearing strata that, in its natural state, contains soluble matter. This standard applies to both packaged mineral water and water sampled at source.
Packaged water	Packaged water refers to any potable water that is manufactured, distributed or offered for sale in food-grade bottles or other containers and is intended for human consumption.
Packaged ice	Packaged ice is any ice intended for human consumption which is packaged for retail sale.

Sampling plans

The schedule to Standard 1.6.1 sets out the microbiological criteria for the acceptance or rejection of sample lots. It sets out:

- the food which must comply with the microbiological limits set in relation to that food;
- the micro-organism or group of micro-organisms of concern;
- the number of sample units to be taken and tested;
- the level of micro-organisms considered acceptable, marginally acceptable or critical (depending on the sampling plan specified); and

- the number of samples that should conform to these limits.

The following terms, as used by the International Commission on Microbiological Specifications for Foods (ICMSF), are defined and used in Standard 1.6.1.

n = the number of sample units which must be examined from a lot* of food. Most sampling plans specify taking five sample units. However, when the risk has been assessed as relatively high, a greater number of sample units is specified. This is the case for *Salmonella* in coconut, cereal-based foods for infants and infant formula where 10 sample units should be examined.

c = the maximum allowable number of defective sample units. This is the number of sample units, which may exceed the microbiological limit specified by 'm'. These are considered marginal results, but are acceptable providing they do not exceed the limit specified by 'M'. For example, the standard for coagulase-positive staphylococci in cooked crustacea allows for two samples (c=2) to exceed the acceptable microbiological level of 10^2 ('m'=10^2), providing no sample exceeds a level of 10^3 ('M'=10^3). In many cases c=0 which means no sample may exceed the specified limit 'm'.

m = the acceptable microbiological level in a sample unit. Sampling plans in which m=0 and c=0 are equivalent to 'absent' or 'not detected' reporting for the stated analytical unit size. In most cases this is 25 g (e.g. not detected in 25 g).

M = the level which, when exceeded in one or more samples, would cause the lot to be rejected.

*A **lot** means a quantity of food, which is prepared or packed under essentially the same conditions, usually:

- from a particular preparation or packing unit; and
- during a particular time ordinarily not exceeding 24 hours. (See Standard 1.1.1).

A **lot** of food does not comply with the standard if the number of defective sampled units is greater than c, or the level of a micro-organism in a food in any one of the sample units exceeds M.

Sampling plans are presented in the format used by ICMSF. More detailed information on their use can be found in the ICMSF publication *Micro-organisms in Foods, Sampling for Microbiological Analysis; Principles and Specific Applications (1986).*

Sampling size and handling

Each sample unit taken for submission to the laboratory should be of sufficient size to allow the appropriate analysis or analyses to be carried out and should, preferably, be much larger than the analytical size needed to allow for further testing if required. A minimum sample size of 100 g or 100 mL is usual. For mineral water, packaged water and ice, a minimum sample size of 250 mL should be taken.

Food samples obtained by an authorised officer as a result of a consumer complaint, or as part of an investigation of a suspected food poisoning incident, may only be single samples. While this is less than the five sample units generally prescribed, the results of an analysis on such a sample is still considered valid.

Food samples provided to the testing laboratory should have undergone only minimum change in their microbiological status since the point of sampling. It is very important, for example, that samples are not contaminated during the process. Knowledge of aseptic sampling techniques and the use of appropriate sampling tools may therefore be necessary. It is also important that the temperature during transport and storage of the food samples is appropriate to minimise microbial growth. Chilled foods should, for example, be transported in an insulated container and frozen foods kept frozen. Every effort should be made to minimise the period between sampling and analysis.

Methods

Standard 1.6.1 prescribes the use of the Australian/New Zealand Standard Methods for Food Microbiology AS/NZS 1766 to determine whether a food has exceeded the maximum permissible levels of food-borne micro-organisms. Alternative methods may be used when their equivalence to the prescribed method has been validated by the protocol provided in AS/NZS 4659. For analyses on packaged water, packaged ice and mineral water, the Australian/New Zealand Standard Methods for Water Microbiology AS 4276 are the reference methods required.

Enumeration of Listeria monocytogenes

The *L. monocytogenes* criterion for ready-to-eat processed finfish other than fully retorted finfish specifies a maximum level, 'M', of 100 cfu per gram. The Australian/New Zealand Standards methods AS/NZS 1766 do not currently contain an enumeration method. As an interim measure, either a most probable number (MPN) or spread plate method based on the current qualitative method can be used. Additional guidance may be found in the USA Food and Drug Administration Bacteriological Analytical Manual or another authoritative source.

Testing of Escherichia coli *in fermented comminuted meats*

The testing method for *E. coli* in fermented comminuted meats (not cooked) is specified in the schedule to Standard 1.6.2 – Processing Requirements.

Where can I get more information?

For more information on the new standards call the:

Standards Information Unit
1300 652 166 (Australia)
0800 441 571 (New Zealand), or
Email: **advice@anzfa.gov.au**

See also

ANZFA's *Advisory Guidelines for the Hygienic Production of Uncooked Fermented Comminuted Meat Products* (1996).

ANZFA's Guide to the Food Safety Standards, *Safe Food Australia* (2001).

Australian/New Zealand Standard Methods for Food Microbiology AS/NZS 1766.0 (1995). www.standards.org.au; www.standards.co.nz

Australian/New Zealand Standard Methods for Water Microbiology AS 4276.0 (1995). www.standards.org.au; www.standards.co.nz

Guide to determining the equivalence of food microbiology test methods AS/NZS 4659 (1999). www.standards.org.au; www.standards.co.nz

International Commission on Microbiological Specifications for Foods (ICMSF) (1986) *Micro-organisms in Foods, Sampling for Microbiological Analysis; Principles and Specific Applications.*

USA Food and Drug Administration Bacteriological Analytical Manual (1995).

Attachment 1

Microbiological guideline criteria

Microbiological guideline criteria for particular foods, or classes of foods, have been developed in conjunction with Standard 1.6.1 – Microbiological Limits for Food in the new Code. Mandatory microbiological standards have been set where risk assessment has shown that the risk of food-borne illness associated with the consumption of certain foods is relatively high and that a standard could contribute to the management of the risks identified. Where the justification for a standard was not found, guideline criteria have been developed for some foods.

These guideline criteria are intended to complement other risk-management strategies undertaken by government and industry. They are **advisory criteria** that provide benchmark levels against which unacceptable microbial contamination of food can be identified and remedial action initiated when limits are exceeded. Failure to meet guideline levels generally indicates a failure in the process or hygiene procedures and requires action to identify the cause and remedy the problem.

Reliance on microbiological criteria alone is not enough to ensure food safety. The development of food safety programs based on the principles of the hazard analysis critical control point (HACCP) system is the best means of ensuring food safety.

Note: While these microbiological guidelines can help identify a process failure, industry should develop more stringent target levels.

The following microbiological guideline criteria have been developed for a number of foods and are provided under their respective food commodity group. The maximum levels of micro-organisms specified apply at any point in the shelf life of a product, from manufacture to retail.

The tables below list **advisory** levels. For **mandatory** levels, please refer to Standard 1.6.1.

Dairy Foods

*SPC = Standard plate count at 30 degrees C.

Food	Micro-organism	n	c	m	M
Pasteurised butter—salted and unsalted	Coagulase-positive staphylococci /g	5	0	10^2	
	Coliforms /g	5	1	10	10^2
	Psychrotrophic organisms /g	5	1	10	10^2
	SPC* /g	5	1	$5x10^4$	10^5
Cheese—all varieties	Coagulase-positive staphylococci /g	5	2	10^2	10^3
Cream—pasteurised	Coliforms /g	5	1	10	10^2
	Psychrotrophic organisms /g	5	1	10	10^2
	Listeria monocytogenes /25 mL	5	0	0	
	1.1.1.1 Salmonella	5	0	0	
	SPC* /mL	5	1	$5x10^4$	10^5
Milk—pasteurised	*Campylobacter* /25 mL	5	0	0	
	Coliforms /mL	5	1	1	10

	Psychrotrophic organisms /mL	5	1	10	10^2
	Listeria monocytogenes /25 mL	5	0	0	
	Salmonella /25 mL	5	0	0	
	SPC* /mL	5	1	$5x10^4$	10^5
Milk and cream—ultra heat-treated/sterilised	Products should comply with a test for commercial sterility.				
Milk—dried powder	*Bacillus cereus* /g	5	1	10^2	10^3
	Clostridium perfringens /g	5	2	<1	10
	Coagulase-positive staphylococci /g	5	2	10	10^2
	Coliforms /g	5	2	10	10^2
	Listeria monocytogenes /25 g	5	0	0	
	SPC* /g	5	2	$5x10^4$	$2x10^5$
Ice cream and edible ices (e.g. soft-serve, gelati)	Coliforms /g	5	2	10	10^2
	Escherichia coli /g	5	0	0	
	Listeria monocytogenes /25 g	5	0	0	
	Salmonella /25 g	5	0	0	
	SPC* /g	5	2	10^4	$5x10^4$

Yoghurt and other fermented milk products (e.g. sour cream)	Coagulase-positive staphylococci /g	5	2	10	10^2
	Coliforms /g	5	2	10	10^2
	Escherichia coli /g	5	0	0	
	Salmonella /25 g	5	0	0	

Standard 1.6.1 – Microbiological Limits for Food includes standards for:

- *butter made from unpasteurised milk and/or unpasteurised milk products;*
- *all cheese;*
- *soft and semi-soft cheese (moisture content >39%, pH >5.0);*
- *all raw milk cheese;*
- *raw milk unripened cheeses (moisture content >50%, pH >5.0);*
- *unpasteurised milk; and*
- *dried milk.*

Seafoods

Food	**Micro-organism**	**n**	**c**	**m**	**M**
Crustacea—raw	1.1.1.2 Escherichia coli	5	1	10^2	10^3
	Vibrio cholerae /g	5	0	0	
Crustacea—cooked	1.1.1.3 Escherichia coli	5	1	10	10^2

	Vibrio cholerae /g	5	0	0	
	Vibrio parahaemolyticus /g	5	2	10^2	10^3

Standard 1.6.1 – Microbiological Limits for Food includes standards for:

- *raw and cooked crustacea;*
- *molluscs, other than scallops;*
- *molluscs that have undergone processing (other than depuration); and*
- *ready-to-eat processed finfish, other than fully retorted finfish*

Meat and meat products

Food	**Micro-organism**	**n**	**c**	**m**	**M**
Meat paste and pâté	*Campylobacter* /25 g	5	0	0	
	Clostridium perfringens /g	5	2	10^2	10^3
	Coagulase-positive staphylococci /g	5	2	10^2	10^3
	Escherichia coli /g	5	2	10	10^2
	SPC* /g	5	2	10^4	10^5

Standard 1.6.1 – Microbiological Limits for Food includes standards for:

- *packaged, heat-treated meat paste and pâté;*
- *packaged cooked cured/salted meat; and*

- *fermented, comminuted meat that has not been cooked.*

Eggs and egg products

Standard 1.6.1 – Microbiological Limits for Food includes standards for:

- *pasteurised egg products.*

Foods for infants

Food	**Micro-organism**	**n**	**c**	**m**	**M**
Cereal-based foods for infants	*Bacillus cereus* /g	5	1	10^2	10^3
	Clostridium perfringens /g	5	1	10	10^2
	Coagulase-positive staphylococci */g*	5	1	10	10^2
	Listeria monocytogenes /25 g	5	0	0	
	SPC* /g	5	2	10^3	10^4
Powdered infant formula, including those with lactic acid-producing cultures	*Clostridium perfringens* /g	5	2	<1	10
	Listeria monocytogenes /25 g	5	0	0	
Infant formula (liquid)—ultra heat-treated/sterilised	Products should comply with a test for commercial sterility.				

Standard 1.6.1 – Microbiological Limits for Food includes standards for:

- *cereal-based foods for infants;*
- *powdered infant formula; and*
- *powdered infant formula with added lactic acid-producing cultures.*

Packaged water and ice

Food	**Micro-organism**	n	**c**	**m**	**M**
Mineral water	Coliforms /250 mL	5	0	0	
	Pseudomonas aeruginosa /250 mL	5	0	0	
Packaged water and ice	Coliforms /250 mL	5	0	0	
	Pseudomonas aeruginosa /250 mL	5	0	0	
	SPC* /mL	5	0	10^2	

Standard 1.6.1 – Microbiological Limits for Food includes E. coli standards for:

- *mineral water;*
- *packaged water; and*
- *packaged ice.*

Pasta

Food	Micro-organism	n	c	m	M
Pasta and noodles—uncooked, wet and dry	Bacillus cereus	5	2	10^2	10^3
	Coagulase-positive staphylococci /g	5	2	10^2	10^3

Fruit and vegetable products

Food	Micro-organism	n	c	m	M
Cultured seeds and grains (e.g. bean sprouts, alfalfa sprouts)	*E. coli* /g	5	0	0	

Standard 1.6.1 – Microbiological Limits for Food includes standards for:

- *pepper, paprika and cinnamon;*
- *dried, chipped and desiccated coconut;*
- *cocoa powder; and*
- *cultured seeds and grains.*

Miscellaneous foods

Food	**Micro-organism**	**n**	**c**	**m**	**M**
Tofu (not ultra heat treated)	Bacillus cereus */g*	5	2	10^2	10^3
	Coagulase-positive staphylococci /g	5	2	10^2	10^3
	E. coli /g	5	0	0	

Attachment 2

Description of cheese types and varieties according to moisture content and ripening methods

Moisture Content	Cheese type
50 – 85%	Soft cheeses Unripened, e.g. Cottage, Quark, Cream, Mozzarella. Ripened, e.g. Camembert, Brie, Neufchatel, Caciotta. Salt-cured or pickled, e.g. Feta, Domiata.
39 – 50%	Semi soft cheeses Ripened principally by internal mould growth, e.g. Roquefort (sheep milk), Stilton, Gorgonzola, Danish Blue. Ripened by bacteria and surface micro-organisms, e.g. Limburger, Brick, Trappist, Port Salut. Ripened primarily by bacteria, eg. Bel Paesa, Pasta Filata, Provolone, Brick, Gouda, Edam.
<39%	Hard cheeses Without eyes, ripened by bacteria, e.g. Cheddar, Caciocavallo. With eyes, ripened by bacteria, eg. Emmental, Gruyere.
<34%	Very hard cheeses e.g. Asiago old, Parmesan, Romano, Grana.