

Microbiological testing criteria

Minimum testing requirements
for manufacturers of dairy food products

June 2015



Contents

Preamble	1
Introduction.....	1
Qualitative and quantitative testing	1
Sampling	2
Composite samples	2
When is compositing appropriate?	2
Frequency of testing and number of samples tested	3
Laboratory accreditation	3
Sampling methods.....	3
Minimum testing requirements	4
1. Milk and cream.....	4
2. Butter and dairy blends.....	4
3. Cheese	5
4. Dried milk powder (including dried powder blends)	6
5. Ice cream and frozen products (including frozen dairy desserts)	7
6. Fermented milk products	8
7. Dairy-based dips and desserts.....	9
Summary	10
Appendix I - Ready-to-eat (RTE) foods	11
Glossary of terms.....	12
References.....	13
Further information.....	13

Acknowledgement

Dairysafe wishes to acknowledge the great work done by Dairy Food Safety Victoria. DFSV's leadership in updating the ADASC (2000) standards and putting the basic testing procedures into a more comprehensive and easy to use document is a great service to the dairy industry generally.

This document was accepted by the board of Dairysafe on May 6th 2015

Preamble

Under their approved food safety program, manufacturers of dairy products are required to test finished products. This document describes the minimum testing requirements for such products, the results of which provide:

- data that a manufacturer's food safety program is delivering a product which meets the parameters for safe food, and
- confidence in the capacity of the food safety program to consistently deliver the required result.

All licensees are encouraged to test more frequently than these minimum requirements.

Introduction

With the dairy manufacturing industry using HACCP¹-based food safety programs and adhering to good manufacturing practices (GMP), the microbiological testing of finished products serves the prime purpose of verifying the effectiveness of process control actions. The type of tests and their frequency are influenced by the risk-status of the dairy food, and while testing every batch is desirable, it is not practical, so the sampling and testing frequency outlined in this document is judged as the minimum.

The testing of finished products also has a role in confirming process capability (validation); investigative testing; verifying remedial activity; and assisting in establishing benchmarks and identifying trends.

While finished product testing can provide information that helps to assure the safety of food products, it cannot be relied upon to guarantee the safety of a food because of limitations associated with sampling plans. For this reason, the greatest emphasis is placed upon the development and implementation of preventative approaches, and these are documented in each manufacturer's food safety program.

The Australia New Zealand Food Standards Code (Code) lists microbiological criteria for dairy foods in **Standard 1.6.1–Microbiological Limits for Food** and complementary limits in the **User guide to Standard 1.6.1**. The standard establishes the maximum permissible levels of foodborne microorganisms in nominated foods. Risk assessment has shown that the likelihood of foodborne illness following consumption of these foods is relatively high when these criteria are exceeded.

The microbiological criteria listed in the standard and user guide serve as benchmarks, against which unacceptable levels of dairy food contamination can be identified. Test results exceeding these limits should trigger remedial action. Failure to meet these levels generally indicates a failure in either the process or hygiene procedures, and requires action to identify the cause and remedy the problem.

Qualitative and quantitative testing

Microbiological testing involves either qualitative or quantitative tests. Qualitative tests establish the **presence or absence** of an organism, such as a pathogen in food *e.g. Listeria monocytogenes*. Quantitative tests determine the **number** of organisms in a sample *e.g. 150 E. coli/gram*.

Testing of foods then involves either two-class or three-class sampling plans.

Two-class sampling plans are performed when the microorganism of concern is not permitted in the food, and are described using parameters such as $n = 5$ and $c = 0$. This is an example of a plan for testing dairy products for the presence or absence of *Salmonella* spp. or *L. monocytogenes*.

¹ HACCP – Hazard analysis critical control point system

n = number of sample units drawn from a lot/batch
c = maximum allowable number of sample units yielding a positive result (presence/absence testing) or exceeding the microbiological limit m. For pathogens, c is usually 0

If some microorganisms are permitted in a unit-volume, a three-class sampling plan is usually adopted and involves quantitative testing. These plans separate **good** quality, from **marginally acceptable** quality, and **unacceptable** quality using the terms m and M. For example: n = 5, c = 1, m = 1, M = 10.

m = microbiological limit which separates good quality from non-acceptable or defective quality.
The maximum number of samples which may exceed this limit is given by c
M = microbiological limit above which results are unacceptable or defective

The term m reflects the upper limit under good manufacturing practice (GMP), while M marks the limit beyond which the level of contamination is considered hazardous or unacceptable.

Sampling

A sample is a small part or quantity from a lot/batch that, when tested, is deemed to represent the lot/batch as a whole. Samples taken for verification or regulatory requirements must be of finished product at the end of the manufacturing and packing process.

A lot or batch of food typically represents one day's production on one production line. Food from a batch is expected to have uniform character and quality, and is produced during the same cycle of manufacture *i.e.* a shift, a single day's production. If samples are not collected properly, are mishandled, or not representative of the sampled lot, the test results will be meaningless.

Where different dairy products are manufactured in a premise, it is necessary to conform to the minimal sampling requirements for each product. However, where different products are made on the same production line during the course of a single day, the requirement is to test only one of those products. Each different product needs to be tested on a rotation basis over time.

A batch represents one day's production on one production line

Where a Dairysafe-licensed manufacturer also produces non-dairy foods *e.g.* non-dairy dips or desserts, they need to address the appropriate product sampling and testing criteria for these products in their food safety program.

Composite samples

A composite sample is the consolidation of a number of samples from the same lot/batch to produce a single sample (or test portion) for qualitative (absence or presence) microbiological testing.

Compositing is used when the number of samples required to assess the microbiological quality of a lot/batch is large in terms of laboratory resources or cost. Compositing of samples must not reduce the sensitivity of an analytical method at very low levels of contamination such that a potentially positive result is missed. Hence the maximum number of samples that may be composited is fifteen.

When is compositing appropriate?

Compositing is not appropriate for quantitative tests. Compositing is only appropriate for qualitative microbiological tests (those that establish the presence or absence of an organism).

Examples include testing products for the presence or absence of *L. monocytogenes* or Salmonella. In these cases a composite sample may involve 5 separate samples of 25 grams from a batch, producing a composite sample of 125 grams. While up to fifteen samples may be composited, lower numbers may be necessary depending on laboratory equipment and the capacity to handle large volumes of diluents.

Compositing of samples is not appropriate for quantitative tests.

Frequency of testing and number of samples tested

Although it is desirable to test every lot/batch against the relevant microbiological criteria in the Code and User Guide, Dairysafe recognises this places a significant burden on small-scale dairy manufacturers. Dairysafe has established minimum testing frequency (typically every 10 or 20 batches) based on historical trends and the risk profile of different dairy products. Where different products are made on the same production line during the course of a single day, the frequency of testing should be consistent with the highest risk product on that line.

Where dairy products are manufactured infrequently, an extended period may elapse before every 10 or 20 batches are tested, in which case testing should occur at least once every two months.

Under the minimum sampling regime, a single sample may be used to represent a batch for quantitative testing, as an alternative to the five samples listed in the Code. Where only a single sample is tested ($n=1$), no sample ($c=0$) is permitted to exceed the value of m in the tables. For example, the limit in the Code for *E. coli* in cheese is $n=5$, $c=1$, $m=10$, $M=100$. If a manufacturer chooses to test only one sample, the limit becomes 10 *E. coli*/gram.

Note that there may also be instances where Dairysafe will require more intensive sampling regimes to be adopted *e.g.* following a failure to meet microbial limits, a poor audit record. New entrants to dairy processing are also expected to undertake more frequent product testing. Where a clearance program has been initiated following a pathogen detection, this overrides these minimum testing requirements.

Manufacturers of product for export will still need to meet the sampling requirements of the Code *e.g.* when cheese is being tested for *E. coli*, $n=5$ samples must be tested.

Laboratory accreditation

All finished product testing performed for the purpose of meeting the minimum testing requirements described in this document must be undertaken by a certified laboratory. Usually this will be a National Association of Testing Authorities, Australia (NATA) accredited laboratory. Such laboratories comply with relevant international and Australian standards and provide consistently reliable testing data to industry.

Sampling methods

A sample drawn from a batch should reflect as accurately as possible the properties of the entire batch from which it is taken. It may be an individual sealed or wrapped dairy food item (carton of milk, tub of yoghurt), or a sub-sample from a larger unit *e.g.* 100 grams from a 20 kilogram block of cheese. Equipment such as spatulas, triers, or pipettes; sterile bottles and bags; and sterilising equipment will be required for taking sub-samples.

The microbiological integrity of the unit needs to be protected at all times, so sub-samples must be aseptically taken and placed in sterile containers. All samples for microbiological analysis should be transported under temperature controlled conditions (where appropriate) to the testing laboratory as soon as possible.

Minimum testing requirements

1. Milk and cream

Product types	Test to be conducted	Limit - FSC or User Guide	Dairysafe minimum requirements	
			Sampling	Frequency
Pasteurised liquid milk products (Includes flavoured milk and extended shelf-life (ESL) products)	<i>E. coli</i> /ml	n = 5 c = 1 m = 1 M = 10	1 sample (Limit: 1/ml)	Every 10 batches
	<i>Listeria monocytogenes</i> /25ml	n = 5 c = 0 Not detected in 25ml	5 samples composited (Limit: ND/125ml)	Every 10 batches
Pasteurised liquid cream products	<i>E. coli</i> /ml	n = 5 c = 1 m = 1 M = 10	1 sample (Limit: 1/ml)	Every 10 batches
	<i>Listeria monocytogenes</i> /25ml	n = 5 c = 0 Not detected in 25ml	5 samples composited (Limit: ND/125ml)	Every 10 batches
General Comments:				
<ul style="list-style-type: none"> <i>E. coli</i>: Testing for coliforms is an acceptable screening method. Further testing or confirmation of whether <i>E. coli</i> is present is required when coliform numbers exceed the limits for <i>E. coli</i> described above. Positive coliform results must be followed up with appropriate corrective action <i>L. monocytogenes</i>: Absence in 25 ml is required in dairy products that will support the growth of <i>L. monocytogenes</i>. Qualitative results for <i>L. monocytogenes</i> are reported as present or absent in 25 ml (as testing involves 5 samples of 25 ml, it may also be reported as absent in 125 ml) 				

2. Butter and dairy blends

Product types	Test to be conducted	Limit - FSC or User Guide	Dairysafe minimum requirements	
			Sampling	Frequency
Butter and dairy blends (salted)	Coagulase-positive staphylococci/g	n = 5 c = 0 m = 100	1 sample (Limit: 100/g)	Every 20 batches
	<i>E. coli</i> /g	n = 5 c = 2 m = 1 M = 10	1 sample (Limit: 1/g)	Every 20 batches
All unsalted butter, dairy blends, and reduced fat and reduced salt spreads	Coagulase-positive staphylococci/g	n = 5 c = 0 m = 100	1 sample (Limit: 100/g)	Every 10 batches
	<i>E. coli</i> /g	n = 5 c = 2 m = 1 M = 10	1 sample (Limit: 1/g)	Every 10 batches
	<i>Listeria monocytogenes</i> /25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches
All butter and dairy blends with post pasteurisation ingredients and inclusions	Coagulase-positive staphylococci /g	n = 5 c = 0 m = 100	1 sample (Limit: 100/g)	Every 10 batches
	<i>E. coli</i> /g	n = 5 c = 2 m = 1 M = 10	1 sample (Limit: 1/g)	Every 10 batches
	Salmonella/25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches
	<i>Listeria monocytogenes</i> /25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches

General Comments:

- Butter and dairy blends are considered to be a low risk product. This is because the combination of low moisture content (<16%) and high salt (up to 2% all within the water phase) contribute to salted butter providing a hostile environment for both spoilage and pathogenic microorganisms
- Unsalted or salt-reduced butter or dairy blends are more likely to support survival and growth of microorganisms, hence the increased frequency of testing. Similarly low fat dairy spreads have a higher moisture content and present higher risk
- Testing for Salmonella may not be required if the relevant post-pasteurisation ingredients have been tested by a certified laboratory (i.e. NATA certified)

3. Cheese

Product types	Test to be conducted	Limit - FSC or User Guide	Dairysafe minimum requirements	
			Sampling	Frequency
All cheese (Except categories listed below)	Coagulase-positive Staphylococci/g	n = 5 c = 2 m = 100 M = 1000	1 sample (Limit: 100/g)	Every 20 batches
	<i>E. coli</i> /g	n = 5 c = 1 m = 10 M = 100	1 sample (Limit: 10/g)	Every 20 batches
	<i>Listeria monocytogenes</i> /25g	Refer to Appendix I (RTE Foods)*	Recommend 5 samples composited and tested	Every 20 batches
Soft and semi soft cheese (Moisture content greater than 39% and pH greater than 5.0)	Coagulase-positive Staphylococci/g	n = 5 c = 2 m = 100 M = 1000	1 sample (Limit: 100/g)	Every 10 batches
	<i>E. coli</i> /g	n = 5 c = 1 m = 10 M = 100	1 sample (Limit: 10/g)	Every 10 batches
	Salmonella/25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches
	<i>Listeria monocytogenes</i> /25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches
Cheese with post pasteurisation inclusions	Coagulase-positive Staphylococci/g	n = 5 c = 2 m = 100 M = 1000	1 sample (Limit: 100/g)	Every 10 batches
	<i>E. coli</i> /g	n = 5 c = 1 m = 10 M = 100	1 sample (Limit: 10/g)	Every 10 batches
	Salmonella/25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches
	<i>Listeria monocytogenes</i> /25g	Refer to Appendix I (RTE Foods)*	Recommend 5 samples composited and tested	Every 10 batches
Shredded, grated and cut cheese (excluding soft and semi soft cheese)	Coagulase-positive Staphylococci/g	n = 5 c = 2 m = 100 M = 1000	1 sample (Limit: 100/g)	Every 10 batches
	<i>E. coli</i> /g	n = 5 c = 1 m = 10 M = 100	1 sample (Limit: 10/g)	Every 10 batches
	<i>Listeria monocytogenes</i> /25g	Refer to Appendix I (RTE Foods)*	Recommend 5 samples composited and tested	See below [†]

General Comments:

- All cheese needs to be tested for *Listeria*. The physio-chemical properties of each cheese will determine which limit applies (See Appendix I)
- Soft and semi-soft cheeses are predominately mould-ripened cheeses and are considered high risk
- Starter culture, fermentation aids, rennet, and starter are not classified as post-pasteurisation inclusions

* Establish if product will or will not support the growth of *L. monocytogenes*

† The likelihood of *Listeria* contamination of shredded, grated, and cut cheese is quite high, so monitoring of these products should be maintained, although the frequency of testing and the methodology will depend upon the properties of the cheese. Where a product contains greater than 39% moisture, it should be considered **high risk** and every 10 batches should be tested for absence in 25 grams. For medium risk shredded, grated, and cut cheese (less than 39% moisture), enumeration every 20 batches is considered adequate

4. Dried milk powder (including dried powder blends)

Product types	Test to be conducted	Limit - FSC or User Guide	Dairysafe minimum requirements	
			Sampling	Frequency
Dried milk powder*	Salmonella/25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 20 batches
	<i>Bacillus cereus</i> /g	N = 5 c = 1 m = 100 M = 1000	1 sample (Limit: 100/g)	Every 20 batches
Powdered infant formula products with added lactic acid producing cultures	Salmonella/25g	n = 10 c = 0 Not detected in 25g	10 samples composited (Limit: ND/250g)	Every 10 batches
	<i>Bacillus cereus</i> /g	n = 5 c = 1 m = 100 M = 1000	1 sample (Limit: 100/g)	Every 10 batches
	Coagulase-positive Staphylococci/g	n = 5 c = 1 m = 0 M = 10	1 sample (Limit: <1/g)	Every 10 batches
	Coliforms/g	n = 5 c = 2 m = 10 M = 100	1 sample (Limit: 10/g)	Every 10 batches
Powdered infant formula†	Salmonella/25g	n = 10 c = 0 Not detected in 25g	10 samples composited (Limit: ND/250g)	Every 10 batches
	<i>Bacillus cereus</i> /g	n = 5 c = 0 m = 100	1 sample (Limit: 100/g)	Every 10 batches
	Coagulase-positive Staphylococci/g	n = 5 c = 1 m = <1 M = 10	1 sample (Limit: <1/g)	Every 10 batches
	Coliforms/g	n = 5 c = 2 m = <3 M = 10	1 sample (Limit: <3/g)	Every 10 batches
	SPC/g	n = 5 c = 2 m = 1,000 M = 10,000	1 sample (Limit: 1,000/g)	Every 10 batches

General Comments:

- Routine testing for *L. monocytogenes*, coagulase-positive Staphylococci, and *Clostridium perfringens* (**User guide to Standard 1.6.1**) is not required as the risk in dried milk products is considered to be very low
- *B. cereus*: Testing is required because this organism can survive pasteurisation and drying processes, and has the capacity to grow when the powder is reconstituted. Monitoring is also important as seasonal conditions may see spikes in *B. cereus* levels in powders

- *Cronobacter sakazakii*: There are increased concerns regarding the risk associated with *C. sakazakii* in powders that are provided to vulnerable populations (predominantly low birth weight neonates less than two months old and the elderly who are immunocompromised). The organisms is an environmental contaminant, hence effective sanitation in the production facility can reduce overall contamination. Product testing is recommended where the target consumers include vulnerable persons
- * Includes whole milk powder, skim milk powder, and other dairy derived powders including whey powder
- † Infant formula also includes follow-on and growing-up formulae

5. Ice cream and frozen products (including frozen dairy desserts)

Product Types	Test to be conducted	Limit - FSC or User Guide	Dairysafe minimum requirements	
			Sampling	Frequency
Frozen ice cream, frozen ice cream mix, and edible frozen ices	<i>E. coli/g</i>	n = 5 c = 0 m = 0	1 sample (Limit: <1/g)	Every 20 batches
	<i>L. monocytogenes</i>	n = 5 c = 0 m = 100	Recommend 5 samples composited and tested, then enumerate if a positive result	Every 20 batches
Frozen ice cream, frozen ice cream mix, and edible frozen ices with high-risk post-pasteurisation inclusions	<i>E. coli/g</i>	n = 5 c = 0 m = 0	1 sample (Limit: <1/g)	Every 20 batches
	Salmonella/25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 20 batches
	<i>L. monocytogenes</i>	n = 5 c = 0 m = 100	Recommend 5 samples composited and tested, then enumerate if a positive result	Every 20 batches
Refrigerated ice cream mixes (e.g. soft serve mix)	<i>E. coli/g</i>	n = 5 c = 0 m = 0	1 sample (Limit: <1/g)	Every 10 batches
	<i>L. monocytogenes</i>	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches
General Comments:				
<ul style="list-style-type: none"> • Testing for Salmonella may not be required if the relevant post-pasteurisation inclusions have been tested by a certified laboratory (<i>i.e.</i> NATA certified) • Note ice cream and related products has a nil tolerance for E Coli as specified in the Guidelines to 1.6.1. Should E Coli be detected an assessment will be made of the level and whether a pathogenic E Coli test can be used to clear the product. 				

6. Fermented milk products

Product types	Test to be conducted	Limit - FSC or User Guide	Dairysafe minimum requirements	
			Sampling	Frequency
Yoghurt and other fermented milk products (e.g. sour cream)	<i>E. coli</i> /g	n = 5 c = 0 m = 0	1 sample (Limit: <1/g)	Every 20 batches
Yoghurt and other fermented milk products with high-risk post-pasteurisation inclusions	Coagulase-positive Staphylococci/g	n = 5 c = 2 m = 10 M = 100	1 sample (Limit: 10/g)	Every 10 batches
	<i>E. coli</i> /g	n = 5 c = 0 m = 0	1 sample (Limit: <1/g)	Every 10 batches
	Salmonella/25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches
General Comments: <ul style="list-style-type: none"> Under the Food Standards Code, the fermented milk product yoghurt must have a pH <4.5. Because of this low pH, these products are considered to be of low risk The addition of inclusions (e.g. fruit purees, nuts, syrups) increases the risk associated with these products Where the pH of a fermented milk product is >4.5, they are classified as dairy desserts. These products present a greater risk to consumers (see Section 7 for minimum testing requirements) Testing for Salmonella and <i>S. aureus</i> may not be required if the relevant post-pasteurisation inclusions have been tested by a certified laboratory (i.e. NATA certified) 				

7. Dairy-based dips and desserts

Product types	Test to be conducted	Limit - FSC or User Guide	Dairysafe minimum requirements	
			Sampling	Frequency
Dairy-based desserts and dips with a pH above 4.5 (e.g. custard, mousse, etc)	Coagulase-positive Staphylococci/g	n = 5 c = 2 m = 100 M = 1000	1 sample (Limit: 100/g)	Every 10 batches
	<i>E. coli</i> /g	n = 5 c = 1 m = 10 M = 100	1 sample (Limit: 10/g)	Every 10 batches
	<i>Listeria monocytogenes</i> /25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches
Dairy-based desserts and dips with a pH above 4.5 with high-risk post pasteurisation inclusions	Coagulase-positive Staphylococci/g	n = 5 c = 2 m = 100 M = 1000	1 sample (Limit: 100/g)	Every 10 batches
	<i>E. coli</i> /g	n = 5 c = 1 m = 10 M = 100	1 sample (Limit: 10/g)	Every 10 batches
	<i>Listeria monocytogenes</i> /25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches
	Salmonella/25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches
Dairy-based desserts and dips with a pH below 4.5	Coagulase-positive Staphylococci/g	n = 5 c = 2 m = 100 M = 1000	1 sample (Limit: 100/g)	Every 20 batches
	<i>E. coli</i> /g	n = 5 c = 1 m = 10 M = 100	1 sample (Limit: 10/g)	Every 20 batches
	<i>Listeria monocytogenes</i> /25g	n = 5 c = 0 m = 100	Recommend 5 samples composited and tested, then enumerate if a positive result	Every 20 batches
Dairy-based desserts and dips with a pH below 4.5 with high-risk post-pasteurisation inclusions	Coagulase-positive Staphylococci/g	n = 5 c = 2 m = 100 M = 1000	1 sample (Limit: 100/g)	Every 10 batches
	<i>E. coli</i> /g	n = 5 c = 1 m = 10 M = 100	1 sample (Limit: 10/g)	Every 10 batches
	<i>Listeria monocytogenes</i> /25g	n = 5 c = 0 m = 100	Recommend 5 samples composited and tested, then enumerate if a positive result	Every 10 batches
	Salmonella/25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g)	Every 10 batches
General Comments:				
<ul style="list-style-type: none"> Testing for Salmonella may not be required if the relevant post-pasteurisation ingredients have been tested by a certified laboratory (i.e. NATA certified) Where products are hot-filled (e.g. custards), the above tests may not be relevant. In such cases the manufacturer will be required to provide a product testing regime to meet other microbial testing criteria (e.g. <i>B. cereus</i>) 				

Summary

The management of dairy food safety is built around a documented food safety program which incorporates adherence to pre-requisite programs based on good manufacturing practices. Product safety requires effective implementation of HACCP, its validation, application of monitoring and control measures at critical control points, and corrective action in the event of non-conformances.

The testing of finished products provides information that assists manufacturers assess their performance in controlling the safety of dairy products *i.e.* testing finished product provides evidence that the food safety program is working effectively and verifies process control.

The range of tests a manufacturer performs and the frequency of testing are influenced by the risk-status of the dairy food and their history of compliance with the Australia New Zealand Food Standards Code. While testing every batch is desirable, it is not practical for all manufacturers, so the sampling and testing frequency outlined in this document is considered as the minimum. By tracking their microbiological test data, manufacturers can demonstrate process control and can identify emerging issues or trends which may necessitate an increased frequency of sampling and testing.

Manufacturers are encouraged to test more frequently than the minimum requirements

Licensees are encouraged to test more frequently than the minimum requirements outlined in this document.

This is especially important when introducing a new product, commissioning new plant and equipment, supplying product to a vulnerable population sub-group, etc. A manufacturer may also be directed by a Dairysafe authorised officer to undertake sampling at a frequency exceeding these minimum requirements. Similarly, where a manufacturer is required to implement a clearance program, this takes priority over the minimum sampling requirements.

Products destined for export will need to meet the criteria in the Food Standards Code as opposed to the sampling and testing regimes in this document.

Licensees who wish to introduce alternate testing arrangement to those described above must present Dairysafe with a written request via their food safety manager.

Appendix I - Ready-to-eat (RTE) foods

Ready-to-eat food is food that is ordinarily consumed in the same state as that in which it is sold or distributed. Most dairy foods can be considered RTE foods.

Standard 1.6.1 in the Australia New Zealand Food Standards Code was recently revised, and now includes limits for *Listeria monocytogenes* in RTE foods. The limits vary depending on whether a food will or will not support the growth of the *L. monocytogenes*.

These limits recognise that the potential for a food to support the growth of *L. monocytogenes* is a main factor in the risk of consumers contracting listeriosis. For foods in which the growth of *L. monocytogenes* will not occur, occasional low level detections (less than 100 cfu/g) are not considered to present a public health risk. For example, in cheeses where physico-chemical properties don't allow *L. monocytogenes* to grow, such as romano or parmesan, the acceptable limit will be <100 *L. monocytogenes*/g. Where the physico-chemical properties of the cheese do allow *L. monocytogenes* to grow, such as surface-ripened soft cheese, the organism must not be detected in 125 grams.

Product types	Test to be conducted	Limit - FSC	Dairysafe minimum requirements	
			Sampling	Frequency
Ready-to-eat foods that will support the growth of <i>L. monocytogenes</i>	<i>Listeria monocytogenes</i> /25g	n = 5 c = 0 Not detected in 25g	5 samples composited (Limit: ND/125g or ml)	Every 10 batches
Ready-to-eat foods that will not support the growth of <i>L. monocytogenes</i>	<i>Listeria monocytogenes</i> /g	n = 5 c = 0 m = 100	Recommend 5 samples composited and tested, then enumerate if a positive result	Every 20 batches
<p>General Comments:</p> <ul style="list-style-type: none"> Growth of <i>L. monocytogenes</i> will not occur in a ready-to-eat food if: <ul style="list-style-type: none"> (a) the food has a pH less than 4.4 regardless of water activity; or (b) the food has a water activity less than 0.92 regardless of pH; or (c) the food has a pH less than 5.0 in combination with a water activity of less than 0.94; or (d) the food has a refrigerated shelf life no greater than 5 days; or (e) the food is frozen (including foods consumed frozen and those intended to be thawed immediately before consumption); or (f) it can be validated that the level of <i>L. monocytogenes</i> will not increase by greater than 0.5 log cfu/g over the food's stated shelf life. RTE products which are hot filled (e.g. custard, processed cheese, etc filled at ~80°C) and where recontamination is highly unlikely present a low risk, hence testing for <i>L. monocytogenes</i> is not normally required. Food safety is managed by monitoring the production process With any detection of <i>Listeria spp.</i> in a dairy food, the licensee must advise Dairysafe and undertake a clearance program 				

Glossary of terms

Batch/Lot	<p>A lot or batch of food typically represents one day's continuous production on one production line.</p> <p>Food from a batch is expected to have uniform character and quality, and is produced during the same cycle of manufacture <i>i.e.</i> a shift, a single day's production. Where different products are made on the same production line during the course of a single day, they may be considered as a single batch for the purpose of these microbiological testing criteria. The term batch has the same meaning as lot.</p>
Dairy product(s)	Products defined by Standard 4.2.4 Primary production and processing standard for dairy products of the Australia New Zealand Food Standards Code
Foodborne illness	Is any illness resulting from the consumption of contaminated food
High-risk inclusions	High-risk inclusions/ingredients may introduce pathogenic microorganisms into a dairy product when they are added post-pasteurisation. Examples include herbs and spices (dried and fresh), cookie dough, nuts, fruits and syrups. Where inclusions have been heat treated, acidified, or contain preservatives they are considered low-risk.
Pathogen	Any microorganism capable of causing foodborne illness
Qualitative testing	Laboratory analysis which establishes the presence or absence of a microorganism such as a pathogen in a defined quantity of food
Quantitative testing	Laboratory analysis which quantifies the number of microorganisms in a defined quantity of food
Routine sampling and testing	Regular and on-going sampling and testing that is conducted to detect microorganisms in dairy products and the processing environment. Routine sampling and testing is an essential element of a dairy manufacturer's Food Safety Program
Three-class sampling plan	<p>If a number of microorganisms in a unit-volume is allowable, a three-class sampling plan is usually adopted. Three-class plans separate good quality, from marginally acceptable quality, and unacceptable quality using the terms n, c, m, and M</p> <div style="border: 1px solid black; padding: 5px; background-color: #f0f0f0;"> <p>n = number of sample units drawn from a lot/batch</p> <p>c = maximum allowable number of sample units yielding a positive result (presence/absence testing) or exceeding the microbiological limit m. For pathogens, c is usually 0</p> <p>m = microbiological limit which separates good quality from non-acceptable or defective quality. The maximum number of samples which may exceed this limit is given by c</p> <p>M = microbiological limit above which results are unacceptable or defective</p> </div>
Two-class sampling plan	Tested product falls into one of two classes – conforming or nonconforming. A two-class sampling plan is performed when the microorganism of concern is not permitted in the food sample

References

- Australia New Zealand Food Standards Code – [Standard 1.6.1 – Microbiological Limits for Food](#). (Commonwealth of Australia, Canberra, 2015)
- Australia New Zealand Food Standards Code - Standard 4.2.4 – [Primary Production and Processing Standard for Dairy Products](#) (Commonwealth of Australia, Canberra, 2015)
- Dairy Food Safety Victoria, Information note – [Microbiological testing of finished dairy products](#). (Dairysafe, Melbourne, 2014)
- FSANZ (2001). [User guide to Standard 1.6.1 – Microbiological Limits for Food with additional guideline criteria](#).
- ICMSF (2011). *Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance*. (International Commission on Microbiological Specifications for Foods, New York, Springer)

Further information

Further information is available at www.daosa.net.au or contact Dairysafe on (08) 82232277 or admin@daosa.net.au

CURRENT

This document is intended to be used as a general guide only and is not a comprehensive statement of all the relevant considerations with respect to your particular circumstances, nor does it comprise, or substitute for, legal or professional advice. Dairysafe does not guarantee the accuracy, reliability, currency or completeness of the information. Links to other websites are provided as a service to users and do not constitute endorsement, nor are we able to give assurances of the accuracy of their content. Dairysafe accepts no legal liability arising from, or connected to, or loss due to any reliance on this document.

PROPOSED

In Australia, state or territory government agencies are responsible for enforcing and interpreting the Australia New Zealand Food Standards Code (the Code). This document describes the minimum testing requirements for dairy products manufactured in Victoria under the regulatory oversight of Dairysafe. Dairysafe does not guarantee the currency or completeness of the information on microbiological limits in the Code or its subsidiary documents. Links to other websites are provided as a service to users and do not constitute endorsement, nor are we able to give assurances of the accuracy of their content. Dairysafe accepts no legal liability arising from, or connected to, or loss due to any reliance on this document.