Developing a Food Safety Program: Pre-requisite programs

A guide to managing microbiological verification testing

A dairy processing business must control its potential food safety hazards by implementing a documented food safety program.

Australia New Zealand Food Standards Code Std 4.2.4-13

A dairy processing business must verify the effectiveness of the control measures implemented to address identified hazards.

Australia New Zealand Food Standards Code Std 4.1.1-4

1. Introduction

Microbiological verification testing helps food businesses confirm that the food safety controls described in their food safety program are working as intended. It forms part of the broader suite of verification activities required under the Food Standards Code (the Code), which requires manufacturers to implement a documented food safety program that includes procedures for verifying the effectiveness of control measures. Microbiological testing supports product release decisions, trend analysis, and continuous improvement, and is generally undertaken alongside other verification activities such as reviewing records, checking monitoring results, and conducting internal audits.

Testing programs should be risk based and reflect the nature of the food produced, the hazards identified in the food safety program, and the controls used to manage those hazards. Additional considerations may include:

- customer or export requirements,
- the need to demonstrate compliance with regulatory standards,
- opportunities to monitor performance trends or set benchmarks, and
- information required for process validation and ongoing control.

The Food Standards Code sets out microbiological limits for dairy foods in Standard 1.6.1 and Schedule 27 but it does not prescribe specific frequencies or numbers of samples. Manufacturers therefore need to determine an appropriate testing approach that aligns with their production volume, product risk profile, and acceptable level of risk. While microbiological testing is an important verification tool, it is not a primary means of ensuring food safety and must not replace well designed and effectively implemented control measures.

An explanation of common terms and useful abbreviations used in microbiological testing for food safety management is provided in Section 1.5 and Section 1.6 of the Compendium.

Testing programs should be planned, documented, and reviewed regularly to support compliance and continuous improvement. This guide focuses on microbiological verification testing for dairy manufacturers.

2. Preparing and implementing a program to manage incoming

2.1 Use the *Compendium of Microbiological Criteria for Food* to design a risk-based testing program

A risk-based testing approach means designing your microbiological verification testing program so that the frequency, type, and extent of testing reflect the actual risks in your product and process. Your testing program should not follow a "one size fits all" approach; it should be reviewed regularly to ensure it remains appropriate as business activities, products, processes and risks change over time. Key considerations include the hazards identified in your food safety program, the characteristics of the product, confidence in your control measures, historical performance, and production volume.

Practical guidance for designing a risk-based testing approach for dairy products is provided in Chapter 5 of the FSANZ *Compendium of Microbiological Criteria for Food* (the Compendium). It serves as a best-practice guide for meeting the requirements of the Code, demonstrating compliance and ongoing verification. Microbiological criteria for each group of dairy products are provided with a recommended *minimum* testing frequency of every 10 or 20 batches depending on the target microorganism, ensuring that testing occurs at least once every two months (see section 5.2 of the Compendium).

The terms "lot" or "batch" are often used interchangeably. Businesses may define lots or batches differently depending on their production processes and scale of production; however, the key consideration is that the definition allows the business to clearly identify when a product was produced and to effectively trace its manufacture and distribution.

The Code defines a *lot* as:
An amount of food that the manufacturer or producer identifies as having been prepared, or from which foods have been packaged or otherwise separated for sale, under essentially the same conditions, for example
a) from a particular preparation or packaging unit; and
b) during a particular time ordinarily not exceeding 24 hours

Australia New Zealand Food Standards Code Std 1.1.2-2

While the Compendium itself is not enforceable, it offers sensible options to help licence holders design testing programs that help demonstrate their food safety measures are effective. A regulator's role is to verify that licence holders are ensuring food safety, and a well-designed sampling and testing program is an important part of demonstrating that controls are working as intended to meet the requirements of the Code.

Section 5.3 of the Compendium discusses the roles and significance of different types of microorganisms, specifically indicator organisms and pathogens, in dairy production, and the control measures used to restrict their growth. A brief overview of this information is provided in Appendix 1.

2.2 Types of criteria to consider in a microbiological verification testing program

Criterion: A specified microbiological limit or condition used to determine whether a result is acceptable.

Criteria: The set of microbiological limits or conditions used to assess compliance with food safety or quality requirements.

The Compendium sets out three main types of microbiological criteria used to verify food safety and process control. Each plays a different role in demonstrating that your food safety program is working as intended.

- **Process Hygiene Criteria (In-process testing)**

Process hygiene criteria help verify typically that hygiene practices and process controls are functioning during production. These criteria involve testing in-process product at set intervals for indicator organisms such as coliforms, *E. coli*, or Enterobacteriaceae. Results provide early signals of loss of control, allowing corrective action before product is finished or released.

- **Microbiological Guideline Criteria (Finished product – verification)**

Microbiological guideline criteria are applied to finished products to confirm that overall handling and hygiene throughout manufacturing have been adequate. They are not regulatory limits but act as a verification tool alongside other measures such as environmental monitoring, CCP records, and prerequisite programs. They help demonstrate that your food safety controls are consistently effective.

- **Food Safety Criteria (Finished product – regulatory compliance)**

Food safety criteria are microbiological limits applied to finished product to assess the safety of each lot or batch. These criteria are enforceable regulatory requirements set out in Standard 1.6.1 and Schedule 27 of the Food Standards Code.

3. Sampling plans

3.1 Introduction to sampling plans

A sampling plan is a structured approach which describes:

- the **type of samples to be taken (e.g. finished product, ingredients, or environmental swabs)**
- **the number of samples to be collected**
- **frequency of testing, and**
- **criteria used to assess results** as part of microbiological verification testing.

Sampling plans are generally applied to a ***lot* or *batch*** of a specific product.

The Compendium uses standard microbiological sampling plans to interpret testing results and determine whether a batch of food products meets microbiological guideline criteria. In most cases, it uses either two-class sampling plans or three-class sampling plans, which are internationally recognised approaches for assessing microbiological results.

3.2 Two-class sampling plans

Two-class sampling plans are used when a microorganism should not be present in the food. This approach is commonly applied to pathogens such as *Salmonella* or *Listeria monocytogenes*.

A two-class plan is defined by the parameters *n*, *c*, and *m*:

n – the number of sample units taken from a lot or batch
c – the maximum number of sample units that may exceed the microbiological limit
m – the microbiological limit used to determine acceptability

For pathogens, the criterion is typically “not detected”, and c is usually zero, meaning that none of the samples may contain the organism. For example, a plan of *n* = 5, *c* = 0, *m* = not detected, means five samples are tested and all must be negative for the organism for the batch to be considered acceptable.

3.3 Three-class sampling plans

Three-class sampling plans are used when low levels of microorganisms may be acceptable, such as indicator organisms used to assess hygiene or process control. These plans distinguish between **acceptable, such as indicator organisms used to assess hygiene or process control. These plans distinguish** between acceptable, marginal, and unacceptable results. It is important to note that three-class plans only apply for testing that produces quantitative or numerical results.

A three-class plan is defined by *n, c, m*, and *M*:

n – number of sample units tested
c – maximum number of samples permitted to exceed m
m – the microbiological limit used to determine acceptability
M – the level that must not be exceeded; results above this level are considered unacceptable

In a three-class sampling plan:

Results ≤ *m* are considered acceptable (or satisfactory)
Results between *m* and *M* are considered marginal
Results > *M* are unacceptable

For example, a plan of *n* = 5, *c* = 1, *m* = 10, *M* = 100 means five samples are tested; one sample may fall between 10 and 100, but none may exceed 100.

3.4 Determining appropriate sample numbers for microbiological testing

Two-class and three-class sampling plans provide a structured way to interpret microbiological results and assess whether a production lot meets guideline criteria. They also recognise that microorganisms may not be evenly distributed in food and that testing only examines a small portion of a batch. Structured plans like these help provide confidence that a food safety control is working effectively while accounting for the natural variability in microbiological contamination

The Compendium acknowledges that the standard sampling plan of five sample units (*n* = 5) may not always be practical for small production batches. For these situations, it allows for a single sample unit (*n* = 1) to be tested from the batch when fewer units are available.

When a single-sample approach is used, the result must meet the acceptable limit (*m*) specified in the criterion as there is no allowance for marginal results. The result must fall within the acceptable range for the batch to be considered acceptable.

This flexibility supports small-volume producers while still ensuring meaningful microbiological verification. The decision to use a single sample (*n* = 1) must be risk-based and documented in the food safety program, considering the product type, the organism being tested, batch size, and the effectiveness of existing food safety controls.

Example of two class and three class sampling plans

Table 5.3 Microbiological guideline criteria for butter and dairy blends

Product types	Test	Sampling plan
Butter and dairy blends (salted)	CPS/g	n = 5 c = 1 m = 100 M =1000
	E. coli/g OR Coliforms/*g* OR Enterobacteriaceae/*g*	n = 5 c = 2 m = 3 M = 10 n = 5 c = 2 m = 10 M = 100 n = 5 c = 2 m = 10 M = 100
	L. monocytogenes/25g	n = 5 c = 0 not detected in 25g

3 class sampling plan

2 class sampling plan

This table from The Compendium shows an example of where 2 class and 3 class sampling plans are applied for different test types.

4. What to consider in a microbiological verification testing program

4.1 Create a robust program

A robust microbiological testing program is one that is well-designed, risk-based and reliably implemented so that it provides meaningful verification that food safety controls are consistently working as intended. “Robust” in this context means the program is scientifically sound, fit for purpose, and capable of detecting a loss of control in time to prevent unsafe food from entering the market. It includes clearly defined sampling plans, appropriate test methods, correct interpretation of results, and documented decision-making and corrective actions.

Microbiological testing on its own cannot make food safe, but it can indicate whether your systems that make food safe are functioning as intended. Robust testing programs are important because microbiological testing only examines a small portion of a much larger batch of food. If the sampling approach, number of samples, or frequency of testing is inadequate, contamination may not be detected even if it is present. A well-designed testing program helps increase confidence that hazards are being effectively controlled and supports early detection of potential problems before unsafe food reaches consumers.

4.2 Key elements to define in the program

Businesses should clearly outline the key elements of their microbiological verification testing program within their food safety program. Defining these elements ensures the testing is well-targeted, scientifically appropriate, and capable of providing meaningful evidence that food safety controls are working effectively. Key elements to consider are described in Table 1.

Table 1: Elements to consider for a microbiological verification testing program

Program element	Description	Key considerations
Product characteristics	The intrinsic properties of the product that influence microbial growth or survival.	pH, water activity, moisture content, salt levels, shelf life, and whether the product is ready-to-eat, requires further processing, or supports pathogen growth.
Target microorganisms	The microorganisms selected for testing based on hazards identified in the food safety program.	May include pathogens, indicator organisms, or process hygiene indicators.
Sampling plan	The approach used to determine how and where samples are collected.	Number of samples, sampling locations, and sampling frequency appropriate to batch size, production volume, and level of risk.
Frequency of testing	How often testing is conducted.	Minimum testing frequency may be guided by the Compendium. Customer specifications and export registration obligations may require more frequent testing.
Sample size and collection method	The quantity of product or environmental material collected and how it is obtained.	Samples should be representative and collected using hygienic sampling procedures
Test methods	The laboratory methods used to analyse samples.	Should use recognised standard methods (e.g. Australian Standards) or other validated methods.
Acceptance criteria	The microbiological limits used to interpret test results.	Also known as specifications, for example, absence in 25 g, <100 cfu/g, or other limits defined in the food safety program.
Response procedures	The actions taken when results do not meet acceptance criteria or are out-of-specification.	May include product assessment, investigation of the cause, and corrective actions (see Section X).
Focus of testing	The stage of production where verification testing is applied.	May include ingredients, in-process controls, finished product testing, or environmental monitoring (see Table 2).

When defining these elements for your program, it is also important to recognise the limitations of microbiological testing, including:

- Results may be unreliable if samples are not representative of the batch or are incorrectly collected (see *Section 6.1*).
- Microbiological testing examines only a small portion of a production batch and cannot by itself confirm that all product is safe. This is why testing should only be used to verify that food safety controls are working effectively, and not as the primary means of ensuring food safety.

Table 2: Microbiological testing focus

Table 2 outlines the differences in microbiological testing focus and differences in the purpose of these.

Testing focus	Purpose/Verification Target	Examples
In-Process Testing	Verifies that key processing steps and hygiene controls are functioning as intended during production. Often used to confirm that process hygiene criteria are being met at critical stages of manufacture.	Testing coliforms or Enterobacteriaceae at stages of powdered infant formula production such as post-pasteurisation handling or drying.
Finished Product Testing	Confirms that the final product meets defined microbiological acceptance criteria and provides verification that overall process controls have been effective for a production batch or lot.	Testing ready-to-eat dairy products for pathogens such as *Salmonella* spp. or *Listeria monocytogenes*.
Environmental Monitoring	Verifies the effectiveness of sanitation and hygiene controls in the production environment and helps identify potential contamination sources before they affect product.	Monitoring for *Listeria* spp *or Listeria monocytogenes* in wet processing areas, drains, floors and food-contact surfaces in dairy processing facilities.
Ingredient Testing	Confirms that incoming ingredients meet microbiological specifications and do not introduce hazards into the production process.	Testing high-risk inclusions or ingredients added post-pasteurisation for pathogens such as *Salmonella* spp. in dairy products.

4.3 Clear guidelines for the interpretation of results and follow-up actions

Results are typically interpreted using the microbiological limits and sampling plans defined in a business's food safety program. This begins with comparing laboratory findings against the relevant microbiological criteria to determine whether the results meet specified limits and requirements. This assessment supports decisions about product disposition, including whether products can be released, should be held, or require further investigation, and informs any actions needed to maintain food safety and comply with regulatory and customer requirements.

Interpreting microbiological results is more than checking numbers against limits. It requires consideration of what those results indicate about product safety, process control, and the ongoing effectiveness of food safety measures. Microbiological results should therefore be reviewed alongside other relevant information, such as process monitoring records, environmental monitoring results, production conditions, and historical trends. Considering this broader context helps provide a more complete understanding of process performance.

Trending results over time can also help identify patterns or gradual changes that may indicate emerging risks in the production process or areas where controls may need to be strengthened.

To support consistent and effective interpretation, a robust microbiological testing program should include clear procedures for reviewing results including how to identify acceptable and unacceptable test results and outline appropriate follow-up actions to be taken in the event of unacceptable results. This forms an important part of the overall verification system, helping ensure that results are consistently assessed and that potential food safety issues are identified and addressed in a timely manner. These procedures should guide actions such as product assessment, investigation of potential causes, and implementation of corrective actions where necessary.

Considerations for responding to microbiological results, including investigation and corrective actions, are discussed in *Section 5.*

4.4 Clear procedures for when to composite samples

Compositing is the process of combining multiple individual samples taken from the same lot or batch into a single sample for microbiological testing. The resulting composite is then analysed as one unit. This approach can help reduce testing costs, particularly when checking for the presence or absence of pathogens in larger lots.

However, compositing can reduce the sensitivity of microbiological testing if not applied appropriately.

Combining samples may dilute any microorganisms present, making them harder to detect. For this reason, the use of composite samples should be clearly defined in documented procedures within your microbiological testing program.

Key considerations when using composite samples include:

- Compositing **is not suitable** for quantitative tests that measure the number of microorganisms, such as *E. coli*, coliforms, standard plate count (SPC), or *Staphylococcus aureus*. These should be tested individually.
- Compositing **may be used** for qualitative (presence/absence) tests, such as detecting pathogens like *Salmonella* spp. or *Listeria monocytogenes*.
- Samples combined in a composite should come from the same lot or batch and be collected in a way that ensures the composite is representative of the batch (see *Section 3.1).*
- If a composite sample tests positive for a pathogen, the individual samples may need to be analysed separately to identify the contaminated unit(s). Your program should include documented procedures explaining how positive composite results will be investigated and what follow-up actions will be taken.

Appendix 2 provides further explanations and examples of how composite sampling may be applied.

4.5 Records to support the testing program

Records of the development and validation of the company's sampling and testing regime need to be maintained under Food Safety Program requirements. Microbiological testing results must be retained as defined in your record management system.

Regular on-going analysis of test results can provide a useful tool for comparing operational trends over time and may be used to support any reassessment of the Food Safety Program.

4.6 Skills and knowledge

Staff responsible for sample collection should be trained in aseptic techniques to prevent cross contamination. This training should be documented within a robust skills and training program. Personnel responsible for managing the microbiological testing program should have the appropriate knowledge and skills to oversee its implementation. This includes interpreting results, initiating appropriate actions when required, regularly reviewing the program, and responding effectively to incidents.

Dairytale case study

At a recent audit, a Corrective Action Request (CAR) was raised against the element of Verification Testing as the microbiological testing program was not being followed as outlined in their Food Safety Program.
There was:

- No formal handover or training framework to ensure continuity during personnel changes
- No automated or visible test schedule
- No secondary review or oversight of verification activities
- Insufficient induction training for key food safety responsibilities
- Over-reliance on one role (Quality Manager) for critical compliance tasks.

5. Environmental monitoring

A key part of a comprehensive microbiological verification testing program is environmental monitoring. This process verifies the effectiveness of hygiene controls such as cleaning, sanitation, and maintenance, and is used proactively to identify potential contamination sources and assess whether controls are sufficient to minimise risk to product. This aligns with a "seek and find" approach to environmental monitoring. More information about this approach can be found in DFSV's Listeria training package.

Microbiological monitoring typically involves swabbing environmental surfaces to test for indicator organisms or specific pathogens. Environmental sampling may also include testing residues from equipment, products, or surrounding areas in either wet or dry form.

Applying a risk-based approach for environmental monitoring which prioritises areas with the highest likelihood of contaminating food products ensures the program delivers maximum value.

Key objectives of a robust environmental monitoring program should include:

- Verifying the effectiveness of cleaning and sanitation practices
- Identifying contamination sites within the environment ("seek and find" approach)
- Monitoring the risk of product contamination by environmental pathogens
- Evaluating the effectiveness of contamination control strategies
- Investigating contamination sources following food safety incidents

There is no one-size-fits-all approach to environmental monitoring programs, as differences in equipment, processes, staff expertise, maturity of food safety culture and premises conditions must be considered. It is the responsibility of each dairy manufacturer to develop a robust program tailored to their operations that effectively meets the intended monitoring objectives.

Chapter 8 of the Compendium outlines best practice guidance for implementing and maintaining a robust proactive environmental monitoring program and recommended actions when monitoring results exceed expected limits.

Module 7 of DFSV's Listeria training package also provides guidance to understanding where contamination may persist in manufacturing environments. Module 3 provides guidance to understanding where contamination may persist in manufacturing environments.

Dairytale case study

Dairytale consistently obtained negative results for their routine Listeria environmental monitoring, suggesting their controls were effective. However, a finished product contamination event prompted further investigation.

As part of the root cause analysis, the site undertook more intensive swabbing. This identified a contamination source in a floor drain located near the packing table. It was also observed that hosing was being carried out during manufacturing, which allowed contaminants from the drain to be spread onto nearby food contact surfaces, including the packing table. This incident highlighted that, although the EMP was being followed, it was not being interpreted in the context of overall site practices. Other important controls, such as hygiene practices during production and staff awareness, were not sufficiently considered.

Key learnings included:

- Environmental monitoring results should not be reviewed in isolation; they need to be considered alongside GMPs and day-to-day practices
- Drains and other wet areas can act as contamination reservoirs, particularly when located near food contact surfaces
- Activities such as hosing during production can spread contamination and should be carefully controlled or avoided
- Effective hygienic zoning and separation of high-risk areas are critical to preventing cross-contamination
- Staff training and awareness are essential to ensure that routine practices do not undermine food safety controls
- A negative EMP trend does not guarantee absence of risk if the sampling program or interpretation is limited

6. Collection and preparation of samples

6.1 Collecting samples

The Compendium outlines detailed guidance for sampling dairy products in Chapter 5, *Section 5.2, Dairy microbiological testing*. Key considerations when sampling dairy products are set out in Table 3.

Table 3: Key considerations for collection and preparation of samples

Sampling consideration	Guidance
Follow the sampling plan in the microbiological verification testing program	Sampling should follow the program outlined in the business's microbiological verification testing program including the specified sampling frequency, number of samples, sample types and microbiological tests to be applied
Aseptic sampling techniques	Samples must be collected using sterile equipment and containers. Personnel conducting sampling should be trained in appropriate aseptic techniques to prevent contamination of the sample.
Representative sampling	Samples should be representative of the entire batch. For large or bulk products, aseptically collect sub-samples that accurately reflect the lot.
Composite samples	Consider whether compositing samples is appropriate. Refer to guidelines in *Section 4.3*.
Sample packaging and labelling	Wherever possible, samples should be submitted in retail packaging. If sub-samples are taken, sterile containers or bags should be used and clearly labelled with the product name and batch identification details.
Temperature control and transport	Maintain the cold chain for perishable samples by keeping them below 4°C and transporting them promptly to the laboratory. Environmental samples should be analysed within 24 hours of collection.
Use of accredited laboratories	Samples should be tested by an accredited laboratory, such as one accredited by the National Association of Testing Authorities (NATA), when testing is undertaken by an external laboratory.

Dairytale case study

A small Dairytale site contacted their Food Safety Manager (FSM) for advice on how much product to submit to their commercial laboratory for E. coli testing from a small batch.

The FSM returned the call and explained that:

- the laboratory could be expected to provide specific guidance on how to prepare the samples and which test to request, based on Dairytale's testing specifications.
- for *E. coli* testing, the laboratory requires a minimum sample size of 10 g. However, it is advisable more than 10 g to allow for contingencies, such as spills, handling errors, or the need to repeat the test.

7. Laboratory services

7.1 Selecting a commercial laboratory

Microbiological verification testing should be conducted by a competent laboratory to ensure results are accurate, reliable and suitable for use in verifying food safety controls. The selection of an appropriate commercial laboratory is therefore an important part of establishing an effective verification testing program.

While laboratory accreditation provides assurance of technical competence, manufacturers remain responsible for ensuring the selected laboratory is suitable for their specific testing requirements. Key considerations when selecting a commercial laboratory are outlined in Table 4.

Table 4: Key considerations when selecting a commercial laboratory

Consideration	Description	Key points
Accreditation and technical competence	The laboratory should demonstrate recognised accreditation and competence in microbiological testing.	Select a laboratory accredited to ISO/IEC 17025 by the National Association of Testing Authorities (NATA) or an equivalent accreditation body. Accreditation confirms the laboratory is competent to perform specific microbiological methods and follows validated procedures.
Scope of testing and method suitability	The laboratory must be capable of performing the required microbiological tests using appropriate methods.	Ensure the laboratory's NATA scope includes the relevant tests and methods (e.g. Australian Standards or other validated methods)

		applicable to dairy products or environmental samples.
Experience with the product category	Experience with relevant food types can support more reliable testing and interpretation of results.	Consider laboratories with demonstrated experience in dairy microbiology, high-risk foods, or environmental monitoring where relevant.
Turnaround times	Timely results are important to support product release decisions and investigation of issues.	Confirm standard and urgent turnaround times, particularly for pathogen testing and environmental monitoring.
Sample handling and logistics	Proper sample handling is essential to maintain sample integrity prior to testing.	Ensure the laboratory provides clear instructions on sample collection, packaging, transport temperatures, registration processes and holding times.
Technical support and communication	Ideally, laboratories should be able to assist with interpretation of results and technical queries.	Access to qualified microbiologists may assist with interpretation of results, investigation of unusual findings and advice on corrective actions.
Data reporting and traceability	Laboratory reports should provide clear and traceable records of testing outcomes.	Reports should align with regulatory requirements and clearly identify sample details, methods used and results obtained. Some laboratories may also provide digital reporting or trend analysis tools.
Cost transparency	Testing costs should be clearly understood when selecting a service provider	Request a schedule of fees, including any additional charges for urgent testing, courier services or confirmatory testing.

7.2 Submitting samples for laboratory analysis

Manufacturers should ensure that samples are submitted with sufficient information to enable the laboratory to perform the correct analysis and report results accurately. Providing clear and complete information helps ensure the appropriate test methods are used and results are interpreted correctly.

Incomplete or unclear information may lead to delays in testing, inappropriate methods being applied, or difficulties interpreting results. Manufacturers should therefore provide all relevant details about the sample, the purpose of testing, and any applicable specifications when submitting samples. Key information to provide when requesting microbiological analysis of dairy products is outlined in Table 5.

Table 5: Information to provide when submitting samples for microbiological analysis

Consideration	Description	Key points
Product identification and description	The laboratory must be able to clearly identify the sample being tested.	Provide the product name, batch or lot number, production date, and any other relevant identification details. It is also important to clearly advise what the product is, eg cultured milk, soft cheese, hard cheese, non-bovine products
Product characteristics	Certain product characteristics may influence testing methods or interpretation of results.	Provide information on factors such as whether the product is ready-to-eat, heat treated, fermented, frozen or dried, as well as shelf life or storage conditions if relevant
Type of test required	The specific microbiological tests to be performed.	Specify the target microorganisms or indicator organisms required (e.g. pathogens, hygiene indicators or spoilage organisms).
Testing against specification or criteria	The microbiological limits or acceptance criteria that results will be assessed against.	Specify any microbiological limits, product specifications, regulatory standards, or customer requirements so the laboratory can select the appropriate test method and report results accordingly.
Sample compositing	Whether multiple samples are combined and analysed as a single test sample.	Specify whether samples should be analysed individually or composited prior to testing, as this may affect the sensitivity of the test and interpretation of results. Compositing should only be used where it is appropriate for the purpose of the test. (See *Section 4.4*)

Sampling details	Information about how and where the sample was collected.	Include the sampling location, date and time of collection, and whether the sample represents a finished product, ingredient, environmental swab or in-process sample.
Sample condition and handling	The condition of the sample can affect the reliability of results	Ensure samples are appropriately packaged, labelled and transported under the correct temperature conditions to maintain sample integrity

8. The importance of clear specifications or testing criteria

When requesting testing against a specification, you should ensure your specifications or testing criteria are appropriate for the analytical method used. Different test methods may produce different results, and microbiological limits are often established based on a specific method.

For example, some microbiological specifications are based on presence/absence methods, such as "*Salmonella* not detected in 25 g". Other specifications may be based on enumeration methods, which report the number of microorganisms present (e.g. <100 cfu/g). These methods measure different aspects of microbiological contamination and may have different detection limits. You should therefore ensure that the specification being applied aligns with the analytical method used by the laboratory.

It is also important to be aware of the limit of detection or reporting limit associated with the test method used. Some methods cannot reliably detect microorganisms below a certain level, and results may therefore be reported as "<10 cfu/g" or "not detected". This does not necessarily mean that microorganisms are completely absent, but rather that they were not detected above the method's reporting limit. Understanding the detection limits of the analytical method is important when interpreting results against microbiological specifications.

9. Receiving results

9.1 What to expect on a laboratory report or Certificate of Analysis

Laboratories typically provide a laboratory report or Certificate of Analysis (CoA) for each sample tested. The report provides the official record of the analysis performed and the results obtained.

You should review laboratory reports carefully to ensure that the correct samples have been tested, the appropriate methods have been used, and the results are clearly reported. Reports should contain sufficient information to allow the results to be interpreted and traced back to the submitted sample. Laboratory reports should be retained as part of your food safety records and made available during regulatory audits or verification activities.

A comprehensive laboratory report or Certificate of Analysis should generally include the information outlined in Table 6.

Table 6: Information typically included in a laboratory report or Certificate of Analysis

Report element	Description/Purpose
Report number, date of issue and sample identification	A unique report number and the date it was issued, and clear identification of the sample tested to allow traceability.
Commercial laboratory identification, accreditation details and testing location	The name and address of the laboratory, along with business details such as the ABN and NATA accreditation number. The location where the testing was performed should be included if the laboratory operates multiple sites.
Customer details	The name and contact details of the organisation submitting the sample.
Sample description and sample receipt details	Description of the sample as provided to the laboratory, including relevant product and batch details, plus the date the sample was received, the temperature at receipt (where relevant), and the condition of the sample on arrival.
Testing dates	The date(s) on which the analysis was sampled and performed.
Test method and units of measurement	Identification of the analytical method used and the units in which results are reported (e.g. cfu/g, MPN/g, presence/absence).
Test results	The microbiological results reported with appropriate units of measurement.

Limit of detection / reporting limit	The lowest level of microorganisms that can be reliably detected or reported by the test method. This helps interpret results reported as “not detected” or “< value”.
Measurement uncertainty (where applicable)	An estimate of the range within which the true value is expected to lie, reflecting the inherent variability of the test method.
Method deviations or exclusions	Any additions to, deviations from, or exclusions relating to the test method used.
Subcontracted testing	Clear identification where any testing has been performed by an external or subcontracted laboratory.
Report authorisation	Identification of the person responsible for authorising or approving the report.

9.2 Reviewing and assessing laboratory results

Laboratory results and reports should be reviewed in a timely manner to confirm that microbiological controls are operating as intended. Results should be assessed against the acceptance criteria or specifications defined in your Food Safety Program, relevant regulatory requirements, and any applicable customer or export specifications.

It is important that results are not considered in isolation. Individual results should be interpreted in the context of historical data, product characteristics, and the stage of production where the sample was taken. Trend analysis can assist with identifying gradual changes in microbiological performance and signal opportunities for early intervention.

Where results exceed defined acceptance criteria, you should follow the response procedures outlined in your Food Safety Program. This may include product assessment, investigation of potential causes, and implementation of corrective actions to address any identified issues. This is discussed further in *Section 10*.

Remember that testing alone does not ensure food safety.

Dairytale case study

Dairytale received a laboratory report showing *E. coli* levels exceeding the microbiological criteria specified in The Code. These unacceptable results were neither identified nor acted upon by the business and were only noticed during the most recent external audit.

The investigation found that:

1. Dairytale staff did not have sufficient skills and knowledge to correctly interpret verification testing results from a food safety perspective.
2. The FSP did not clearly define acceptable, marginal, and unacceptable microbiological limits, and it did not specify corrective actions required for unacceptable results.

The investigation also discovered:

3. Repeated elevated coliform results were found in the same product Prior to the *E. coli* contamination. Coliforms are recognised indicator organisms for hygiene and process control.
4. Failure to respond to elevated coliform levels represented a missed early warning sign that preceded the subsequent *E. coli* contamination event.

9.3 Using a non-conformance approach to address laboratory reporting issues

Issues may arise occasionally in laboratory reports such as unexpected results, suspected errors in reporting or sample identification, or results that appear inconsistent with historical data or product expectations. It is important that you address such issues systematically using a non-conformance or corrective action approach, rather than relying on ad hoc or informal discussions with the commercial laboratory.

Using a formal non-conformance approach ensures that all unusual or unexpected laboratory results are managed consistently and documented. It maintains confidence in the verification testing program and demonstrates that you actively manage your verification data. A structured approach helps satisfy regulatory expectations that verification results are reviewed and acted upon appropriately, in line with your Food Safety Program.

1. **Identify the non-conformance**
   Any laboratory result, reporting inconsistency, or suspected error should be documented and treated as a non-conformance. This includes missing data, incorrect units, unclear sample identification, or deviations from the agreed test method or process (eg using composite samples where not required or requested)

2. **Initiate an investigation**
   Investigate the non-conformance in a timely manner. This may involve:
   - Reviewing the laboratory report and associated documentation
   - Reviewing the information that was provided to the laboratory with the sample
   - Confirming sample details, testing methods, and conditions with the laboratory
   - Comparing the result against historical data and expected test result range

3. **Engage with the laboratory**
   Communicate with the laboratory to clarify the issue, and if necessary, request an investigation into the cause of the issue. The laboratory should be expected to provide a written response which can be recorded as part of your non-conformance records. Accredited laboratories can be expected to provide technical support to explain discrepancies, and, if required, provide additional information to resolve the issue.

4. **Assess the impact**
   Determine whether the non-conformance affects product safety, compliance with specifications, or regulatory reporting obligations. In some cases, additional testing or precautionary measures may be required.

5. **Document actions and outcomes**
   All investigations, communications, and corrective actions should be documented as part of the manufacturer's food safety records. This provides traceability and supports continuous improvement.

6. **Review and prevent recurrence**
   After resolution, review the event to identify any process or procedural improvements. This may include updating sampling instructions, clarifying reporting requirements, or reviewing laboratory selection processes.

Dairytale case study

Dairytale received a report from their commercial laboratory and noticed that an incorrect test method was used. This did not align with their microbiological verification testing program.

- In response, Dairytale raised a non-conformance with the laboratory.
- The laboratory conducted an investigation and discovered that the sample had been registered incorrectly.
- Once the laboratory had clarified the methodology error, they tested a new sample and issued a new report to Dairytale.
- The laboratory implemented corrective action by updating their procedures and verifying that staff were trained in the revised procedures to prevent recurrence.
- The laboratory provided a brief report on the investigation outcomes, which Dairytale recorded for their own verification and records.

10. Interpreting and acting on microbiological verification testing

10.1 What to do when product testing results do not meet specifications

An out of specification microbiological verification result requires a structured, system-based response because the Code requires verification activities to demonstrate that food safety controls are consistently effective to ensure food safety. When results fall outside acceptable limits, the primary objective is to understand what control failure or contributing factor may have allowed the deviation to occur.

Additional microbiological testing may be appropriate in some circumstances, but it should not automatically be

the first or primary response. Retesting the same product may not resolve the underlying issue and can be limited in its ability to confirm product safety, particularly given that microbiological testing examines only a small portion of a batch. It is also important to acknowledge that retesting does not invalidate the original result.

Procedures for investigating out of specification results should include instructions about notifying the regulator as required, and outcomes should be captured as part of your non-conformance reporting.

11. Prioritise Root Cause Analysis over retesting

11.1 Retesting does not demonstrate that controls are effective

FSANZ requires that food businesses maintain evidence that controls are effective. Retesting alone cannot demonstrate this. When a non-compliant result occurs, the focus should shift to identifying and investigating:

- Control measures that may have failed
- The adequacy of the hazard analysis in reflecting the current process
- Compliance with validated pasteurisation, fermentation or drying parameters
- Changes in processing conditions that may have influenced microbial growth or contamination
- Any deviations from procedures by operational staff

This investigation should be undertaken using a structured root cause analysis (RCA) approach to ensure that the underlying cause of the deviation is correctly identified.

Correct identification of the underlying cause of the deviation is essential to restoring control. A structured root cause analysis (RCA) should be undertaken to determine why the failure occurred and what corrective actions are required (see DFSV's publication *Root Cause Analysis: A guide for investigating food safety issues*). Once the root cause has been addressed, further testing may be used to verify that controls have been reinstated and are operating effectively to achieve sustained outcomes.

11.2 Review key process controls

Because dairy products are sensitive to growth of pathogens and indicator organisms, investigation should place strong emphasis on control measures specified or implied under the Food Standards Code. Areas to review include:

- Pasteurisation time and temperature, including flow rates and divert valve operation
- Homogenisation and heat treatment records for relevant products
- Fermentation profiles and culture performance for yoghurt and cultured dairy
- Environmental hygiene in wet and dry areas, including drains, filler heads and packaging zones
- Cleaning in place and sanitation cycle performance, especially in raw milk lines, heat exchangers and storage silos
- Raw milk quality and supplier history
- Water quality used for rinsing and cleaning
- Maintenance and calibration of flow meters, thermometers and pasteurisation monitoring systems
- Cleaning chemical concentrations, effectiveness and contact times

These controls often provide more insight into system performance than repeating testing.

11.3 Assessing contributing factors

Microbiological contamination is rarely caused by a single issue. It is often the result of multiple causes including contributing factors such as:

- Temperature control issues during raw milk collection or storage
- Variability in raw milk impacting process effectiveness (e.g. pasteurisation)
- Inadequate cleaning or biofilm build-up in equipment
- Poor separation of raw and pasteurised product streams
- Extended hold times or production runs beyond validated limits
- Contamination from ingredients or post-pasteurisation handling

- Environmental contamination in high hygiene areas
- Staff not consistently following procedures or hygiene practices

11.4 Interpreting and understanding environmental testing results

As mentioned earlier, the aim of an environmental monitoring program is to detect the presence of microorganisms in the processing environment and to identify potential contamination sources before they affect product. A consistent absence of detections does not necessarily indicate that the environment is free from contamination. In some cases, it may suggest that the monitoring program is not sufficiently robust to identify contamination sources. This may occur if sampling locations are not targeted to higher-risk areas, sampling methods are inadequate, or sampling is not conducted at times when contamination is most likely to be present.

Where this is identified, the monitoring program should be reviewed and adjusted to ensure sampling is targeted, representative, and capable of identifying potential contamination sources.

Environmental monitoring results should be reviewed over time to identify trends and recurring contamination sites. Detecting microorganisms in the environment should not automatically be viewed as a failure; rather, it can provide valuable information that allows manufacturers to identify contamination niches and implement targeted cleaning, sanitation, or process improvements.

12. Ongoing management and continuous improvement of microbiological verification testing programs

Ongoing management and review of your microbiological verification testing program is an important element of a food safety program. Your program should be reviewed regularly to ensure it remains appropriate for the products, processes and risks associated with the business. Changes in ingredients, equipment, processing conditions, production volumes, or new scientific information may require the testing program to be adjusted.

The effectiveness of your microbiological verification testing program can be reviewed through activities such as:

- Review and trending of microbiological test results over time
- Investigation of out-of-specification results and implementation of corrective actions
- Periodic review of sampling locations, sample numbers and testing frequency
- Review of environmental monitoring results and identification of recurring contamination sites
- Internal and external audits of the food safety program
- Review of laboratory performance, reporting and test methods

Key takeaways

• Microbiological testing supports, but does not replace, preventive food safety controls. The safety of dairy products is primarily achieved through effective process control and hygienic practices.

• Testing programs should be risk-based and regularly reviewed. Sampling locations, testing frequency and target organisms should reflect the specific products, processes and risks of the facility.

• Unexpected or out-of-specification results should trigger investigation, not just retesting. Identifying and addressing the underlying cause of a deviation is essential to restoring control and preventing recurrence.

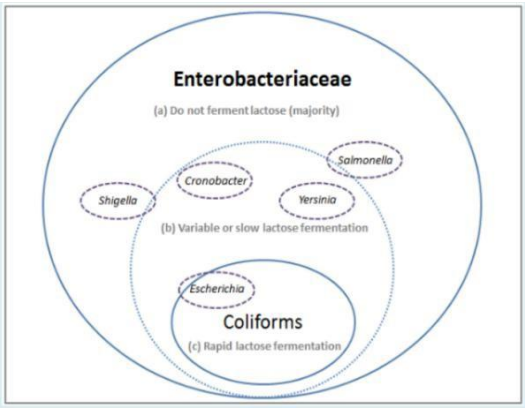
Appendix 1: Microorganisms of importance in the dairy industry

Section 5.3 of the Compendium discusses the roles and significance of different types of microorganisms, specifically indicator organisms and pathogens, in dairy production, and the control measures used to restrict their growth.

Indicators

Indicator organisms are bacteria that can signify the potential presence of pathogenic bacteria and/or indicate the effectiveness of process control. In the food industry, the most common indicator organisms are the coliform group, *Escherichia coli*, and Enterobacteriaceae, as shown in Figure 2.

Figure 2: Relationship of indicators



Testing dairy products for these organisms is a valuable way to verify the effectiveness of process controls, GMP, and hygienic practices. Positive detections indicate potential failures in these areas. Testing for indicators is usually quicker and more cost effective than testing for specific pathogens and allows more frequent monitoring of process control

Appendix 2 of The Compendium contains detailed information about indicator microorganisms commonly tested in foods

Pathogens

Key pathogens of concern in dairy products include *Salmonella* spp., *Campylobacter* spp., *Listeria monocytogenes*, enterohaemorrhagic *E. coli*, and *Cronobacter sakazakii*. These organisms can pose serious health risks to the general population and particularly to vulnerable groups, potentially causing life-threatening infections or long-term illness.

The survival and growth of these pathogens depend on the characteristics of the specific dairy product. Understanding how different pathogens behave in specific niches within the dairy processing environment is essential for effective risk management.

Appendix 2 of The Compendium provides detailed information about several pathogenic organisms, associated foods, control measures and growth/survival characteristics.

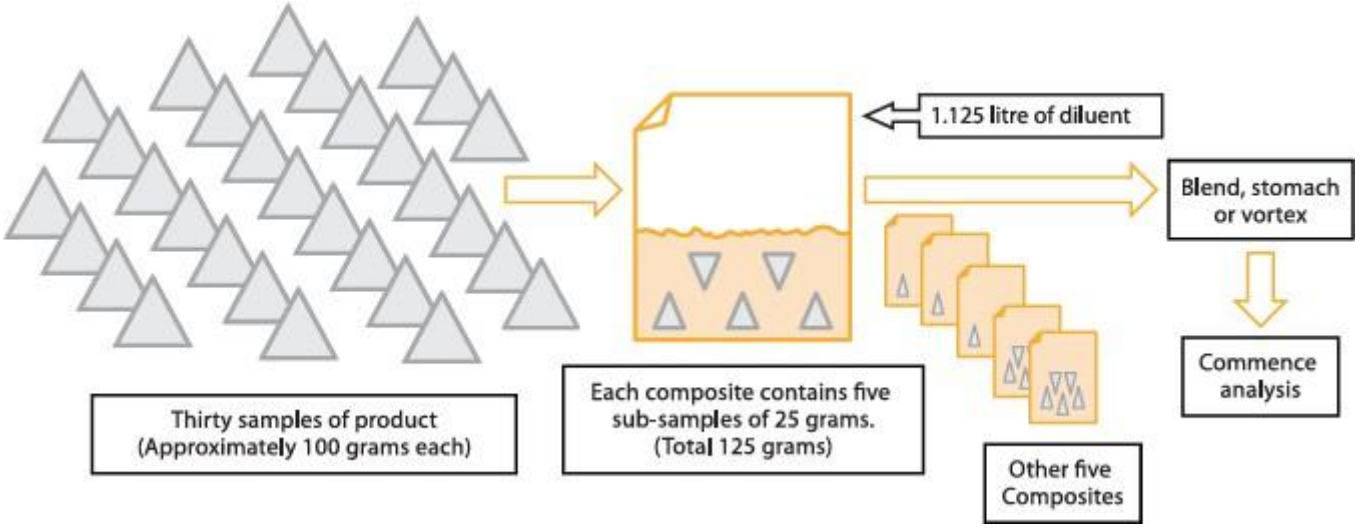
Between 2020 and 2021 DFSV undertook a surveillance project which focused on management of Listeria risks at Victorian dairy factories. An aim of the project was to deliver the outcomes of the project and provide targeted guidance back to industry based on key observations. DFSV's Listeria training package consists of seven modules, each dedicated to a specific aspect of Listeria risk management.

Appendix 2: Composite samples

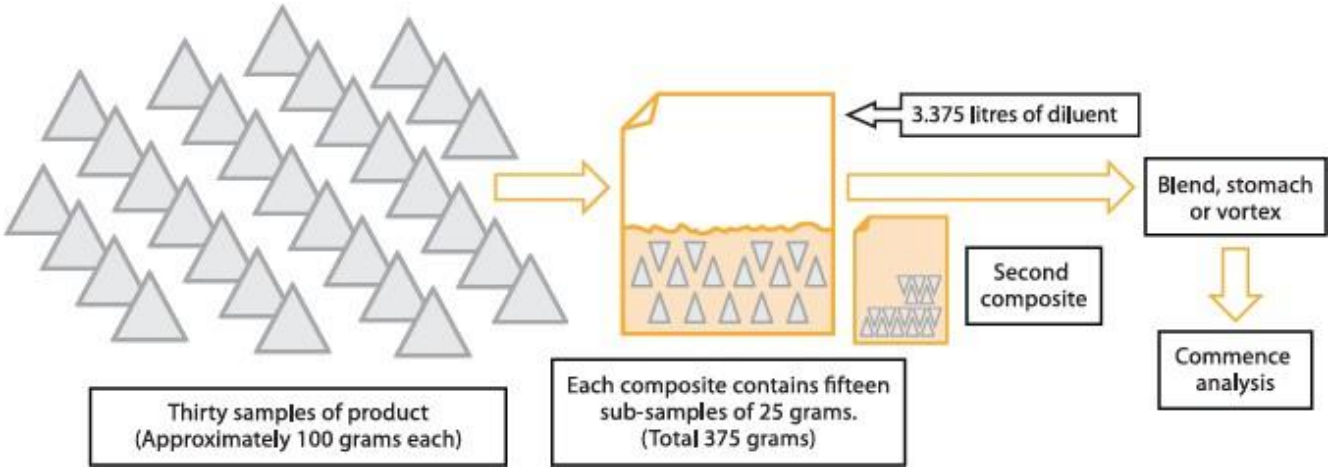
Compositing is the process of combining multiple samples from the same lot/batch to produce a single sample for microbiological testing only. Compositing can be done as either 6 sets of 5 test portions or 2 sets of 15 test portions. For example, if a composite of 6 sets is analysed, each set would contain a sub-sample of five test portions of 25 grams or 25 millilitres (125 grams), which are combined, and dissolved or dispersed in 1.125 litres of diluent or enrichment medium by blending, stomaching or vortexing.

The following graphics show compositing samples of dairy products using either six sets of 5 test portions or 2 sets of 15 test portions.

a) Compositing of six sets of 5 test portions

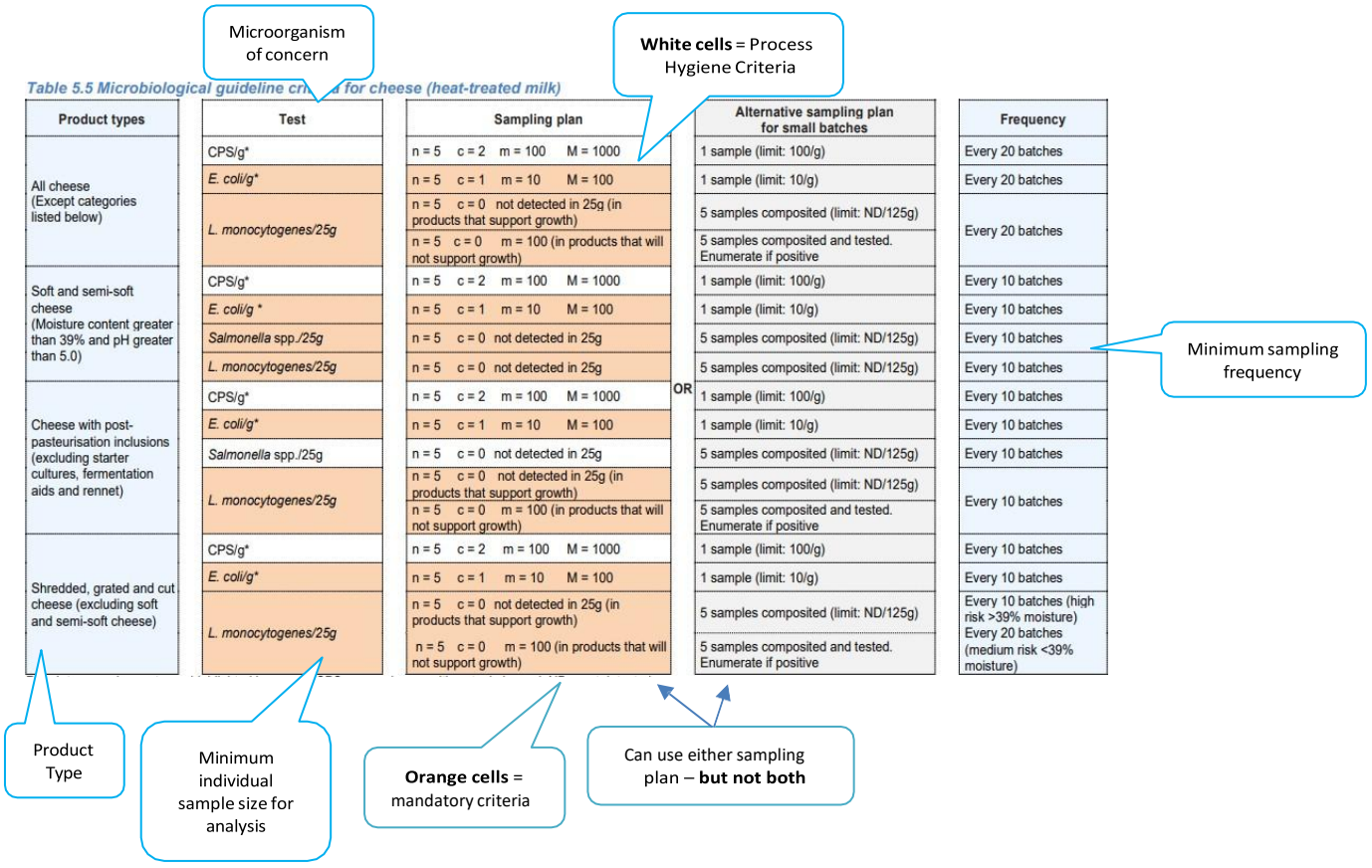


b) Compositing of two sets of 15 test portions



Appendix 3 – **Example** of Microbiological guideline criteria

Example of Microbiological guideline criteria for cheese



Product types	Test	Sampling plan	Alternative sampling plan for small batches	Frequency
All cheese (Except categories listed below)	CPS/g*	n = 5 c = 2 m = 100 M = 1000	1 sample (limit: 100/g)	Every 20 batches
	*E. coli/g**	n = 5 c = 1 m = 10 M = 100	1 sample (limit: 10/g)	Every 20 batches
	L. monocytogenes/25g	n = 5 c = 0 not detected in 25g (in products that support growth)	5 samples composited (limit: ND/125g)	Every 20 batches
		n = 5 c = 0 m = 100 (in products that will not support growth)	5 samples composited and tested. Enumerate if positive	
Soft and semi-soft cheese (Moisture content greater than 39% and pH greater than 5.0)	CPS/g*	n = 5 c = 2 m = 100 M = 1000	1 sample (limit: 100/g)	Every 10 batches
	E. coli/g *	n = 5 c = 1 m = 10 M = 100	1 sample (limit: 10/g)	Every 10 batches
	Salmonella spp./25g	n = 5 c = 0 not detected in 25g	5 samples composited (limit: ND/125g)	Every 10 batches
	L. monocytogenes/25g	n = 5 c = 0 not detected in 25g	5 samples composited (limit: ND/125g)	Every 10 batches
Cheese with post-pasteurisation inclusions (excluding starter cultures, fermentation aids and rennet)	CPS/g*	n = 5 c = 2 m = 100 M = 1000	1 sample (limit: 100/g)	Every 10 batches
	*E. coli/g**	n = 5 c = 1 m = 10 M = 100	1 sample (limit: 10/g)	Every 10 batches
	Salmonella spp./25g	n = 5 c = 0 not detected in 25g	5 samples composited (limit: ND/125g)	Every 10 batches
	L. monocytogenes/25g	n = 5 c = 0 not detected in 25g (in products that support growth)	5 samples composited (limit: ND/125g)	Every 10 batches
		n = 5 c = 0 m = 100 (in products that will not support growth)	5 samples composited and tested. Enumerate if positive	
Shredded, grated and cut cheese (excluding soft and semi-soft cheese)	CPS/g*	n = 5 c = 2 m = 100 M = 1000	1 sample (limit: 100/g)	Every 10 batches
	*E. coli/g**	n = 5 c = 1 m = 10 M = 100	1 sample (limit: 10/g)	Every 10 batches
	L. monocytogenes/25g	n = 5 c = 0 not detected in 25g (in products that support growth)	5 samples composited (limit: ND/125g)	Every 10 batches (high risk >39% moisture) Every 20 batches (medium risk <39% moisture)
		n = 5 c = 0 m = 100 (in products that will not support growth)	5 samples composited and tested. Enumerate if positive	

Appendix 4: Glossary of Terms

An explanation of common terms and useful abbreviations used in microbiological testing for food safety management is provided in Section 1.5 and Section 1.6 of the Compendium.