NATIONAL GUIDELINES - PATHOGEN MANAGEMENT

Guidelines for Dairy industry response to pathogen detections in dairy product and the processing environment

Foreword

The Implementation Sub-Committee for Food Regulation (ISFR) Chair acknowledges this is a national guideline developed and agreed by all jurisdictions.

The development of these national guidelines is an initiative of various Australian and New Zealand Food and Dairy regulators and has been developed to operate as a guideline document supporting the implementation of FSANZ Standard 4.2.4. Jurisdictions that assisted in the development of this guideline were:

Dairy Authority of South Australia
Dairy Food Safety Victoria
Department of Agriculture, Fisheries and Forestry
Department of Health Western Australia
Food Standards Australia New Zealand
New South Wales Food Authority
New Zealand Food Safety Authority
Safe Food Production Queensland
Tasmanian Dairy Industry Authority

Note that this document is to be used as an aid only and is not a legal document.

The Australian and New Zealand dairy industries have developed a reputation for the production and manufacture of safe, high quality products that are preferentially chosen around the world. These industries have introduced HACCP-based food safety programs that ensure the products meet the requirements of markets both domestically and abroad.

Contents

1 Purpose and Scope

These Guidelines replace the following publications that are currently in use by the Australian dairy industry:
- 'Australian Manual for Control of Listeria' (ADASC, July 1999); and
- 'Australian Manual for Control of Salmonella' (ADASC, July 1999).

The purpose of this Guideline document is to act as an aid to dairy processing businesses with a suggested Response Plan in the event that their products or processing environment becomes contaminated with pathogens. It provides advice on what actions can be taken when pathogens are detected in product or the processing environment for any testing program.

This *National Guidelines - Pathogen Management* document is intended to support the implementation of the dairy primary production and processing standard (applicable to Australia only) set out in the Food Standards Code (FSC), and as such, needs to be read in conjunction with the FSC. Note that New Zealand dairy processors must comply with the Animal Products Act regime and the Food Act regime as applicable.

This Guideline document provides assistance as to what actions dairy processing businesses may take in the event of a product or environmental contamination with a known pathogen, it also provides processors with the option of providing an alternate Response Plan, customised to their operations, for approval by the relevant authority in their jurisdiction. It should be noted that regulatory agencies may have a requirement for the notification of prescribed pathogens.

This Guideline document does not provide guidance on requirements for routine pathogen sampling and testing of dairy products and the processing environment that are required as part of verification of a processor's Food Safety Program (FSP).

This Guideline document only covers the bacterial pathogens and their toxins that are more commonly associated with dairy products in relation to foodborne illness.

2 Pathogen Testing

Table 1 outlines pathogen and pathogenic toxin levels for dairy products and the processing environment. The corrective actions that may be taken will depend on the levels detected. These actions are described in section 3.

It is noted that the FSC (Standard 1.6.1) provides the legal threshold for pathogens in particular foods.

- Any detection of a pathogen or pathogenic toxin in the processing environment can be regarded as an indicator to which a processor would be expected to implement some form of corrective action. For this reason, although quantitative levels have not been set for pathogens detected in environmental samples, precautionary action is recommended to be taken to prevent contamination from spreading into the product.

- Additionally, Table 1 includes the microorganism *Escherichia coli.* This microorganism has been included in Table 1, as *E. coli* levels are currently specified in the FSC for specific dairy products.

- Where *E. coli* is detected in product, additional microbiological testing may be carried out to determine the level present (quantification). If the levels breach the requirements in the FSC, the processor should consult with their regulatory authority to determine if additional action needs to be taken. Additional action could include additional testing to determine if the *E. coli* present are a

pathogenic strain. Where *E. coli* levels are not breached or the product type is not covered by the requirements as set out in the FSC, then the product may be released.

- It should be noted that *Listeria monocytogenes* is the only species of the genus *Listeria* to be included in Table 1, as it is the only known species of this genus to be pathogenic to humans. In cases where the genus *Listeria* is detected in product, it is required that processors continue testing to confirm whether the species is *L. monocytogenes*.

- In cases where the genus *Listeria* is detected in Zone A of the environment (i.e. product contact surfaces), it is recommended that processors continue testing to determine if the species is *L. monocytogenes*. Implementing further corrective action in the event of detections of the genus *Listeria* in Zone A is strongly recommended as it is a high risk zone and demonstrates that the conditions are suitable for survival and/or growth of *L. monocytogenes.*

- For explanation of zones A – D in respect of environmental sampling for *Listeria* please refer to the Definitions section of this document.

3 Responding to pathogen and pathogenic toxin detections

Table 2 shows a summary of the actions that could be considered and implemented when a pathogen or pathogenic toxin is detected in product or in the environment. Note that these actions have been presented in no particular order and it is recognised that some of these activities will occur concurrently. Further details regarding each of these actions are given in sections 3.1 to 3.17. Additional information relating specifically to actions for environmental monitoring detections is shown in Table 3.

If the level of contamination in the product is known, then the actions in Table 2 are recommended. If the level of contamination is not known, for those pathogens where zero tolerance is not the legislative threshold in the FSC, the processor should place the product on hold whilst further tests are performed to determine the level of pathogen present. In any case the product could be considered as non-conforming and needs to be reported to the relevant regulatory authority.

Consideration could also be given to advising authorities of those products that are suspected of being contaminated such as; product(s) produced on the same line prior to or after the detection, or product(s) produced in close proximity.

Table 1
Expected Assurance Levels for Pathogens and Pathogenic Toxins in Dairy Products

In Dairy Products					
Pathogen	**Type of Product**	**n**	**c**	**m**	**M**
Salmonella / 25g	All products. Infant formula products	5 10	0 0	0 0	
Listeria monocytogenes / 25g (or 25mL)	All products.	5	0	0	
Coagulase Positive *Staphylococci* / g	All products except Infant formula products. Infant formula products.	5 5	2 1	100 0	1000 10
Pathogenic *Escherichia coli* / g	All products.	5	0	0	
Bacillus cereus / g	All products except Infant formula	5	1	100	1000

	products. Infant formula products.	5	0	100	
Campylobacter / 25g	All products.	5	0	0	
Clostridium perfringens / g	All products except Infant formula products and Dried milk products. Infant formula products and Dried milk products.	5 5	1 2	100 <1	1000 10
Cronobacter (Enterobacter) sakazakii / 10g	Infant formula products.	5	0	0	
Bacterial toxins of coagulase positive *Staphylococci, Bacillus cereus, Clostridium botulinum* etc.	All products.	5	ND	ND	
In the Environment					
Pathogen	**Environment**	**Test Result**			
Any bacterial pathogen*	Any product contact surface or material in the processing environment	Any positive detection			

Key/Footnotes:

ND – Not detected

* Applies to detections of pathogenic organisms (eg: *Salmonella spp*., *Listeria monocytogenes*, pathogenic *Escherichia coli)* in any of the environmental zones and detections of the genus Listeria in Zone A (i.e. product contact surfaces). Acting on detections of the genus Listeria in Zone A is expected since its presence suggests that conditions may also be suitable for survival and/or growth of Listeria monocytogenes. Action could also be taken (e.g. heightened environmental sampling, clean up) under the FSP requirements when indicator organisms are detected in the environment (eg: *Escherichia coli*) since these organisms often indicate a breakdown in hygienic practices or hygienic control procedures.

n - Whenever these pathogens are tested for in product, this represents the minimum number of sample units which must be examined from a batch of food to comply with the requirements of the FSC.

c - The maximum allowable number of defective sample units. A defective sample unit means a sample unit in which a microorganism is detected in a sample unit of food at a level greater than m.

m - The acceptable microbiological level in a sample unit.

M - The level when exceeded in one or more samples would cause the batch to be rejected.

Table 2 – Decision matrix of actions for pathogen & pathogenic toxin detections in product and the environment

	Actions	Product^		Environmental Zones*			
		At Levels Exceeding Table 1	At Levels Lower Than Table 1	A	B	C	D
3.17 Documentation, Records & Reporting	**3.1 Isolate affected product(s)**	✓	Consider†	Consider†			
	3.2 Notify the relevant authorities	✓	Consider†	Consider†			
	3.3 Halting production on the affected process line(s)@	Consider†	Consider†	Consider†			
	3.4 Isolate affected equipment and process areas	Consider†	Consider†	Consider†			
	3.5 Records trace-back on affected product	✓	✓	✓			
	3.6 Withdrawal and recall (where necessary)$ **of affected product(s)**	✓	Consider†	Consider†			
	3.7 Sampling and testing product possibly affected (to determine the extent of contamination and the safety / clearance / disposal status of finished product(s)	✓	✓	✓			
	3.8 Environmental Sampling (Review pest control logs and undertake environmental swabs)	✓	✓	✓	✓	✓	
	3.9 Raw materials and in-process materials testing (to assist in the identification of the contamination source)	✓	✓	✓	Consider†		
	3.10 Production records review (e.g.: efficacy of process controls, cleaning/disinfection program, access restrictions, GHP & operational procedures)	✓	✓	✓	✓	✓	✓#
	3.11 Cleaning & disinfection (affected equipment, utensils and areas)	✓	✓	✓	✓	✓	
	3.12 Verification of cleaning and disinfection (of equipment, utensils & process areas for recommencement of processing)	✓	✓	✓	✓	✓	
	3.13 Clearance programs (post-clean / post-disinfection)	✓	Consider†	Consider†	Consider†	Consider†	
	3.14 Rectifying the cause of contamination (and implement actions to prevent a recurrence)	✓	✓	✓	✓	✓	✓
	3.15 Disposal of product	✓	Consider†				
	3.16	✓	✓	✓	✓	✓	✓

✓ = expected

Key/Footnotes:

^ - Whilst the above actions apply to product with confirmed results for those microorganisms and their toxins listed in Table 1, they could also be applicable for a genus *Listeria* result undergoing species identification. It is also suggested that, where applicable, these actions be considered and commence for presumptive rapid screening test results (eg: presumptive *Salmonella* and presumptive *Listeria*).

* - Applies only to detections of pathogenic organisms (eg: *Salmonella spp., Listeria monocytogenes*, pathogenic *Escherichia coli*) in any of the environmental zones (see Table 3 for definitions) and detections of the genus Listeria in Zone A (ie product contact surfaces). Acting on detections of the genus *Listeria* in Zone A is expected since its presence suggests that conditions may also be suitable for survival and/ or growth of Listeria monocytogenes. Consideration should also be given to taking actions (eg heightened environmental sampling, clean up) for indicator organisms detected in the environment (eg: *Escherichia coli*) since these organisms often indicate a breakdown in hygienic practices or hygienic control procedures.

† - When considering and assessing if this action should be taken, consider the percentage incidence of the microorganism in the production batches and areas affected, the levels (cfu per gram) of the microorganism found and the potential for initial levels of the microorganism/toxin to increase during the remaining shelf-life of the products.

@ - In these instances where manufacture is halted, production should not recommence until clearance to do so has been given by authorities.

$ - The decision to recall can be mandated by the authority, but this decision can be voluntary and is usually made by the food company in consultation with the authority.

- Only need to review the efficacy of the cleaning / sanitising program.

Table 3 - Specific actions recommended for environmental monitoring detections

Product contact surfaces (Zone A)	**Non-product contact surfaces in close proximity to product (Zone B)**
• Intensify sampling of individual sites in this zone to pinpoint contamination source and to ensure that the barriers of this zone have not been breached. • Reassess access/entry restrictions to this zone and review staff hygiene training & knowledge. • Review trends of Zone B results to identify any areas that may require control reassessment. • Reassess cleaning and sanitising program. • Reassess manufacturing and product handling procedures. • Reassess sanitary design of equipment. • Clean and sanitise this zone and any suspect areas. • Resample all sites in this zone to verify cleaning and sanitising efficacy. • Sample and test any batches of product, or retention samples of short shelf life products, associated with the area manufactured on the day of, day before and day after the positive environmental result. If any batches are positive, then corrective actions should be taken. If there is no product available to test, then the next available batch of product manufactured after the date of the environmental positive should be tested.	• Intensify sampling of individual sites in this zone to pinpoint the source of the contamination. • Reassess access/entry restrictions to this zone and review staff hygiene training & knowledge. • Review trends of Zone C results to identify any areas that may require control reassessment. • Reassess cleaning and sanitising program. • Reassess manufacturing and product handling procedures. • Reassess sanitary design of equipment. • Intensify sampling in Zone A to ensure that Zone A barriers have not been breached. • Clean and sanitise this zone and any suspected areas. • Resample all sites in this zone to verify cleaning and disinfection efficacy.
Non-product contact surfaces located further away from product (Zone C)	**Surfaces outside of the processing area (Zone D)**
• Intensify sampling of individual sites in this zone to pinpoint the source of the contamination. • Reassess access/entry restrictions to this zone and review staff hygiene training & knowledge. • Review trends of Zone D results to identify any areas that may require control reassessment. • Reassess cleaning and disinfection program. • Reassess manufacturing and product handling procedures. • Sampling in Zone B to ensure that Zone B barriers have not been breached. • Clean and disinfect this zone and any suspect areas. • Resample all sites in this zone to verify cleaning and disinfection efficacy.	• Reassess cleaning and disinfection program for Zone C. • Sampling in Zone C to ensure that access/ entry controls are intact and effective.

3.1 Isolate affected product

The identification, labelling, isolating, holding or withdrawal of affected product minimises the risk of being mistaken for other uncontaminated product. It also helps prevent any affected product from being used, sold or further distributed.

Contaminated product should be clearly and effectively labelled to indicate its status (*e.g.* marked with "Quarantine" or "Hold" labels), or otherwise effectively managed so as to negate any risk of accidental release or use. The isolation and storage of the contaminated product needs to be done in a manner that minimises the potential for direct contact or cross-contamination with other product, packaging or clean material, equipment and surfaces. (e.g. physical isolation/segregation of the contaminated product from other uncontaminated products may be a suitable option if the products are not packaged).

Keeping the affected product on hold also allows time for more information to be gathered about the level of risk posed by the identified food safety hazard, so that appropriate decisions and corrective actions can be implemented.

In addition to product that is known to be contaminated, consideration should be given to identifying, labelling and holding any other product(s) that may also be contaminated, such as product processed on the same line, or product processed in close proximity to the contaminated line.

3.2 Notify the relevant authorities

The processor should notify the relevant regulatory authority at the earliest opportunity after learning of the product contamination and provide written confirmation within 24 hours. (Refer to Australian Authorities listed in Appendix III).

If the contaminated product has, in part or full, the potential to be exported, then the Department of Agriculture, Fisheries and Forestry (DAFF) should also be contacted.

Processors would also be aware that relevant authorities will question the safety of product processed on the same line, or product processed on lines in close proximity to the contaminated line.

Processors will be expected to address any potential for contamination of other batches of product through additional testing (see 3.7).

After production has recommenced, product should be tested to verify the effectiveness of cleaning and sanitising (see 3.13).

3.3 Halting production on the affected process line(s)

The processor should assess the effectiveness of the cleaning processes undertaken following a detection. The processor should consider halting production on the affected process line as soon as possible after detection of a pathogen in product to allow an assessment of the condition of the plant and equipment so as to minimise the potential spread of the pathogen.

The affected line should be cleaned and sanitized (see 3.11 & 3.12)

The relevant regulatory authority should be consulted prior to production recommencing on the affected process line(s) (see 3.2). The regulatory authority may request additional information to verify the effectiveness of the corrective action, which may entail further testing.

3.4 Isolate associated equipment and process area(s)

It is recommended that an evaluation be undertaken on the associated process line(s) and immediate area to determine whether they should be isolated in order to determine the effectiveness of the cleaning procedures, so that they are available for visual inspection and environmental sampling.

This visual inspection takes place in order to identify equipment and area that may be the source and harborage point of pathogens. Isolating the equipment and area also allows them to be accessible for environmental sampling prior to the equipment and area being cleaned and sanitised. This environmental sampling and testing is expected to help identify of the source of the contamination.

3.5 Records trace-back on affected product

It is recommended that processors review and trace-back production records and microbiological test results in an attempt to identify the possible extent of the contamination.

This review of the production records and microbiological test results also aids in determining which product may need to undergo additional microbiological testing to help ascertain the level of pathogenic hazard associated with the product.

The ingredients used in the contaminated batch of product need to be identified and assessed to determine if they may be the source of the contamination. Any subsequent product using these same ingredients can be placed on hold whilst an assessment is made of their food safety status.

3.6 Withdrawal or recall of affected product(s)

If contaminated product has left the processing premises, it should be identified, labelled, isolated, placed on hold or withdrawn from the market until a decision is made about the level of pathogenic hazard associated with it.

Food recalls are required where there is a reasonable possibility that use or consumption of the food would cause adverse health consequences, or where the product has a serious defect that poses a potential health risk (FSANZ, 2008). The decision to recall may be mandated by an authority, but this decision is usually made by the food processor in consultation with the authority.

Australia has two types of food recalls: trade withdrawals and consumer recalls.

It is a legal requirement that food processors must have in place a 'food recall plan', and that it must be followed the event of a recall (FSANZ 3.2.2.12).

For further details on what needs to be included in the 'food recall plan' and how to conduct a recall refer to:

> **'Food Industry Recall Protocol – A guide to conducting a food recall and writing a food recall plan'** (FSANZ, September 2008). This document can be found at: **www.foodstandards.gov.au/industry/foodrecalls/firp/documents/Food%20Recall_WEB.pdf**

In addition to product that is known to be contaminated, consideration should be given to recalling or retrieving any other product(s) that may also be contaminated, such as product processed on the same line, or product processed in close proximity to the contaminated line.

In addition to product that is known to be contaminated, consideration should be given to recalling or withdrawing any other product(s) that may also be contaminated, such as product processed on the same line, or product processed in close proximity to the contaminated line, back to the batch where the product was last tested and found to be free of pathogens (the last clearance point).

3.7 Sampling and testing product possibly affected

In addition to the review and trace-back of product and production records, it is also advisable to test further samples of any other potentially contaminated products, so as to more accurately determine the extent of the contamination.

A procedure needs to be developed by the processor and incorporated in their approved FSP to include an assessment of the process possibly implicated (that is, product produced on the implicated line or lines in close proximity). These procedures should also incorporate the relevant authority's requirements

(e.g. number of samples per batch) and the appropriate clearance arrangements. , (Refer to sections 3.15 and 3.16). For further information on the number of product samples that could be tested refer to Appendix V and your relevant authority.

Both the product sampling and testing methods used should be considered. (Refer to Appendix IV).

3.8 Environmental sampling

The processing environment can often be the source of a contamination and it is recommended that actions be taken to identify the source so that appropriate measures can be undertaken to correct the problem.

A review of pest activity records and control measures needs to be undertaken immediately.

It is recommended that environmental sampling be initiated to try and pinpoint the source of the contamination. This may include increasing not only the number of samples taken but the points from where the samples are taken. It is recommended that compositing of samples does not occur during trace-back environmental monitoring. This trace-back sampling is not usually restricted to the sample points taken as part of the routine environmental monitoring program. This type of sampling is more intensive and is for trace-back purposes so that other sampling points are included, for example:

- hard to clean surfaces/equipment,
- equipment that has recently been repaired,
- worn equipment or equipment and surfaces that might be suspected as harborage points for pathogens.

It is important however not to have preconceived ideas about the location of the source, as this can sometimes prolong the detection of the contamination source. (Refer also to Appendices I and II).

3.9 Raw materials & in-process materials testing

Pathogens can be introduced into the processing premises and finished products through contaminated raw materials (i.e. ingredients, additives and processing aids or introduced during the various stages of production. Therefore, to help identify the source of the pathogen, samples of raw and in-process materials (also known as in-line or intermediate materials/products), can also be tested.

Packaging materials, such as inners, outers and pallet wrapping, can also be considered as potential sources of contamination for the product or processing environment.

3.10 Production records review

A range of production and processing records could be reviewed to determine a possible cause or link to the contamination. This review should also attempt to determine whether or not the process was under control and that the procedures were adequate and being followed.

The identification of unusual or atypical data often assists in the determination of a possible cause or link to the contamination. Examples of this are:

- Was there a loss in a process control, such as the milk pasteurisation records showing that the target temperature was not being met, or possible cross-contamination with raw product or other medium?
- Do records show that the cleaning and sanitation procedures were not followed correctly, short-circuited, or bypassed?
- Was the correct strength of detergents and sanitiser used, or did a human or mechanical dosing error occur?
- Was there an equipment breakdown or maintenance work being carried out on or near the process line at a time close to when the contamination occurred?
- Did any modifications or repairs to or near the affected line take place during this time, such as replacing of flooring or repairing a refrigeration unit?

- Were there changes to product formulation or ingredient substitutions that occurred on that production line during the time of the contamination?
- Was there new or inexperienced staff on the affected process line during or near the time of the contamination?
- Were there frequent changes in the speed of the process line or several changes in packaging films/containers during or near the time of the contamination?

Identifying a possible cause of the contamination at this stage allows for specific actions to be put in place that will minimise the risk of the problem recurring.

3.11 Cleaning and disinfection

It is important to undertake a comprehensive clean and disinfection of any areas, equipment and utensils that are associated with the contaminated product. In most cases this should involve the disassembly, inspection and cleaning of individual processing equipment components. Environmental sampling of this area, equipment and utensils should take place prior to the cleaning and disinfection to assist in determining the source of the contamination. (Refer to section 3.8).

For details on best practice for cleaning and disinfection refer to:

Australian/New Zealand Standards (www.sai-global.com.au):

- AS 1162:2000 - Cleaning and sanitizing dairy factory equipment.
- AS/NZS 1400:1997 - Heavy duty alkaline detergents for 'in-place' cleaning in dairy factories.
- AS/NZS 1389:1997 – Acidic detergents for use in the dairying industry.
- AS 1803:1998 – General purpose detergents for use in the dairying industry.
- AS 1398:1998 – Iodophors for use in the dairying industry.
- AS/NZS 2541:1998 - Guide to the cleaning-in-place of dairy factory equipment.
- AS 4709:2001 – Guide to cleaning and sanitizing of plant and equipment in the food industry.

Others useful resources include:

- Dairy Food Safety Victoria: November 2006 – Preparing a Cleaning Program.
- Dairy Food Safety Victoria: November 2006 – Cleaning in Place (CIP) Systems.

3.12 Verification of cleaning and disinfection

Prior to recommencing production it is important to check that the cleaning and disinfection of the affected area, equipment and utensils was effective. This checking process is commonly known as 'environmental verification testing.'

The cleaned and disinfected area, equipment and utensils should be inspected to determine if they are visually clean, and environmental samples of the area, equipment and utensils should be taken. (Refer to Appendices I and II)

3.13 Clearance Arrangements

The recommended clearance arrangements are described in detail in Appendix V. This example satisfies the minimum requirements prior to release. Approval for an alternative clearance arrangement could be included in a processor's FSP. Applications can be submitted in writing to the relevant authority. .

Products under a clearance arrangement are recommended to be withheld from sale and supply until the test results satisfy the levels suggested in Table 1. It is recommended the clearance arrangements continue until test results indicate that manufacturing food safety systems are under control and products comply with the FSC. Dairy processing businesses need to ensure that there is an appropriate system for reviewing any results and authorizing the release of product. The results of this testing may also form part of a processor's product disposal system (Refer to sections 3.15 and 3.16). If test results for any batches fail to comply with the pathogen levels described in Table 1, the relevant authority may require the program to be recommenced.

3.14 Rectifying the cause of contamination

Corrective actions need to be implemented to rectify the cause of the contamination so that the likelihood of the problem reoccurring is minimised. For example, if the cause of the contamination was ineffective cleaning, then the cleaning and disinfection program should be modified and validated to assess its efficacy.

3.15 Product Disposal

Prior to disposing of product, a processor should obtain written approval from the relevant authorities. It is important to recognise that the disposal of product does not always mean the product should be destroyed. In some cases, the product may undergo alternative disposal options such as reprocessing, sub-lotting, use as animal feed, or use in non-food applications.

It is suggested that information to regulatory authorities on disposal of product includes details on the following:

- The location of the contaminated product(s)
- The quantity, identification and labeling information of the contaminated product(s)
- The level of hazard associated with the contaminated product(s)
- The means of contamination (if known) and how this will be addressed (i.e. comply with the standards corrective and preventative actions to implemented) so as to minimise the potential for recurrences
- Intended disposal options
- The type of disposal (eg: animal feed, destruction, reprocessing)
- The location of the disposal premises/area
- The quantity of product(s) for disposal
- The date and time the proposed disposal would occur
- The method of disposal (eg: heat treatment, filtration, burial, burning)
- The level of risks (food safety, OH&S and security) associated with the proposed option of disposal and how these risks will be managed
- Conditions and controls for the method of disposal
- In the case of reprocessed product, the following (where appropriate);
    - specifications
    - location and storage details
    - quantity, identification and labeling information
    - distribution, use and sale information
    - microbiological sampling and testing
- Sub-lotting details (where appropriate)
- Destruction details (where appropriate)

Appendix VI has further details on the various options for disposal and the request, including; a suggested template for a product disposal form, a decision-making tree for the various disposal options and sub-lotting criteria.

3.16 Disposal of product

It is suggested that disposal of non-conforming product not commence until written consent has been provided by the relevant authorities. The disposal should be conducted in accordance with the details outlined in the approved product disposal proposal.

3.17 Documentation, records and reporting

All records, actions, reports and relevant information relating to the contamination incident and investigation (FSANZ 3.2.1.5(f)) are to be kept and made available upon request from the relevant authority.

4 Abbreviations

- ADASC Australian Dairy Authorities Standards Committee
- DAFF Department of Agriculture, Fisheries and Forestry
- DFSV Dairy Food Safety Victoria
- FSANZ Food Standards Australia New Zealand
- FSC Australia New Zealand Food Standards Code
- NSWFA New South Wales Food Authority
- NZFSA New Zealand Food Safety Authority
- SFPQ Safe Food Production Queensland

5 Definitions

Animal feed – Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing animals (Codex, 2004).

Authority – A state, territory or national government agency or agencies having the legal authority to implement and enforce legislation and standards.

Batch/Lot – A definitive quantity of a commodity produced essentially under the same conditions (Codex, 1991). E.g. Up to 24 hours of continuous production of a product, or products from a specific line, or a lesser period of continuous production between cleaning and disinfecting procedures having been completed. The term 'batch' is used in this Guidelines document, having the same meaning as 'lot'.

Cleaning – The removal of soil, food residue, dirt, grease or other objectionable matter (Codex, 2003). Where referred to in the text, a comprehensive clean would generally indicate a requirement to disassemble, inspect and clean individual manufacturing equipment components.

Dairy product(s) – For Australia those products as defined by *Standard 4.2.4 Primary production and processing standard for dairy products* of the *Australia New Zealand Food Standards Code*, as well as dairy-based dips, dairy-based desserts and kashta

Destruction/Destroy – The product or material is rendered unusable through burial in a controlled landfill, burning or a similar suitable operation.

Disinfection – the reduction, by means of chemical agents and/or physical methods, of the number of microorganisms in the environment, to a level that does not compromise food safety or suitability (Codex, 2003).

Disposal/Dispose – To change the purpose/intended use of the product such as: to destroy, reprocess so that the risk is reduced to a safe level, sub-lot, use as animal feed or use in a non-food application.

Foodborne illness – a disease or condition that causes a consumer of a food to suffer a detrimental medical condition.

Food recall – An action taken to remove from distribution, sale and consumption, food which may pose a health and safety risk to consumers (FSANZ, 2008).

Non-conforming – Product that is suspected or known not to meet regulatory requirements.

Pathogen – In the context of this Guidelines document it applies to any organism capable of causing foodborne illness.

Pathogenic toxin – a toxic substance produced by a micro-organism that is responsible for the onset of foodborne illness.

Qualitative testing – is where the laboratory detects that a pathogen is present, but are unable to provide the level of the pathogen present.

Quantitative testing – enables the level of pathogens present to be determined. The use of quantitative testing is required before a batch or code containing pathogens could be possibly considered for release and sale.

Routine pathogen sampling and testing programs – Routine (i.e. regular and on-going) sampling and testing that is conducted to detect pathogens present in dairy products and the processing environment. Routine sampling and testing is seen as an essential element of a dairy processor's FSP to meet the requirements in terms of monitoring and verification.

Sub-lotting – The process of dividing a lot or batch of product into two or more separate and distinct lots or batches.

Written confirmation – Correspondence received in writing (via email, letter, fax or any other written medium), which may follow an initial (verbal or written) notification.

Traceback - The process of tracing back through the various stages of production and processing to determine the cause of a problem.

Zone A - Product contact surfaces. The environmental zone of highest risk.

Zone B - Non-product contact surfaces in close proximity to product. The second highest risk environmental zone.

Zone C - Non-product contact surfaces located furthest away from product but still within the processing area. The third highest risk environmental zone

Zone D - Surfaces outside of the processing area but within the production facility. The environmental zone of lowest risk.

6 References

Australian Dairy Authorities Standards Committee, *Australian Manual for Control of Listeria* (July 1999).

Australian Dairy Authorities Standards Committee, *Australian Manual for Control of Salmonella* (July 1999).

Australian Dairy Authorities Standards Committee, *Minimum sampling guidelines for dairy products* (2000).

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7 Appendices

Appendix I
Environmental monitoring

Environmental monitoring provides verification that the pathogen control systems are effective.

Environmental monitoring is also used to:

- assess the risk of product contamination; and
- try and identify the source of contamination when it occurs, and assist in determining what actions need to be taken to prevent a recurrence.

The sampling sites for environmental monitoring are usually designed on the principle of different levels of risk. This is commonly referred to as the 'zone concept', where the zone of highest risk is classified as zone A and the lower level of risk is classified as zone D. Descriptions and examples of these zones are shown in Table 4. Note that the 'zone concept' has not been standardized, and the areas, surfaces, items and equipment designated to each zone differ among food manufacturing premises and will be dependent upon of the history and experience of each individual premises (ICMSF, 2002).

Table 4 – Descriptions and examples of environmental monitoring zones

Zone	Description	Examples
A	Surfaces over or through which product passes during processing, (ie product contact surfaces/direct contact surfaces).	Conveyors, tables, racks, holding vats & tanks, utensils, pumps, valves, slicers, freezers, packing/filling machines.
B	Surfaces that are in close proximity to the flow of product and may indirectly lead to product contamination (ie non-product contact surfaces/in-direct contact surfaces that are close to product).	Conveyors, exterior of processing equipment, refrigeration units. Equipment control panels, keyboards, door handles
C	Surfaces that are located further away from the flow of products. These surfaces are less likely to lead to product contamination, but may hinder efforts to control pathogens (ie non-product contact surfaces/in-direct contact surfaces that are further away from product).	Telephones, forklifts, walls, floors, drains.
D	Surfaces outside of the processing area.	Locker rooms, cafeteria, entry/access ways, roofs, gutters, waste pits, rubbish areas.

It is recommended that a well designed environmental monitoring program includes a processing layout/map that indicates the selected sampling sites. The test results from the environmental monitoring, both positive and negative results, can then be plotted on this map and can be examined to determine any patterns or trends over time. Examples of the different potential sampling sites for environmental monitoring in a milk powder premises and a cut cheese premises are shown diagrammatically in Figures 1a and 1b, respectively.

Figure 1a – Flow process diagram for milk powder

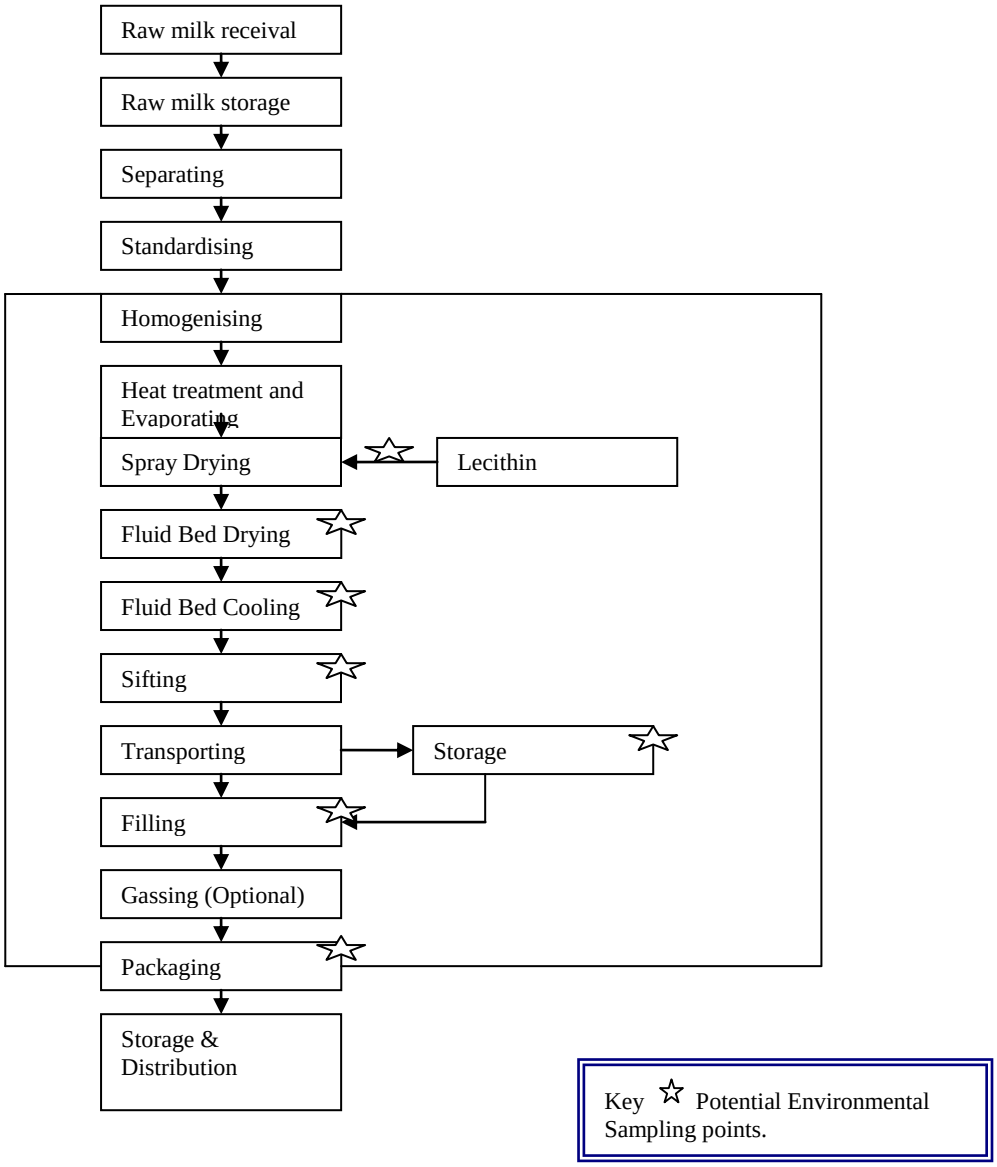
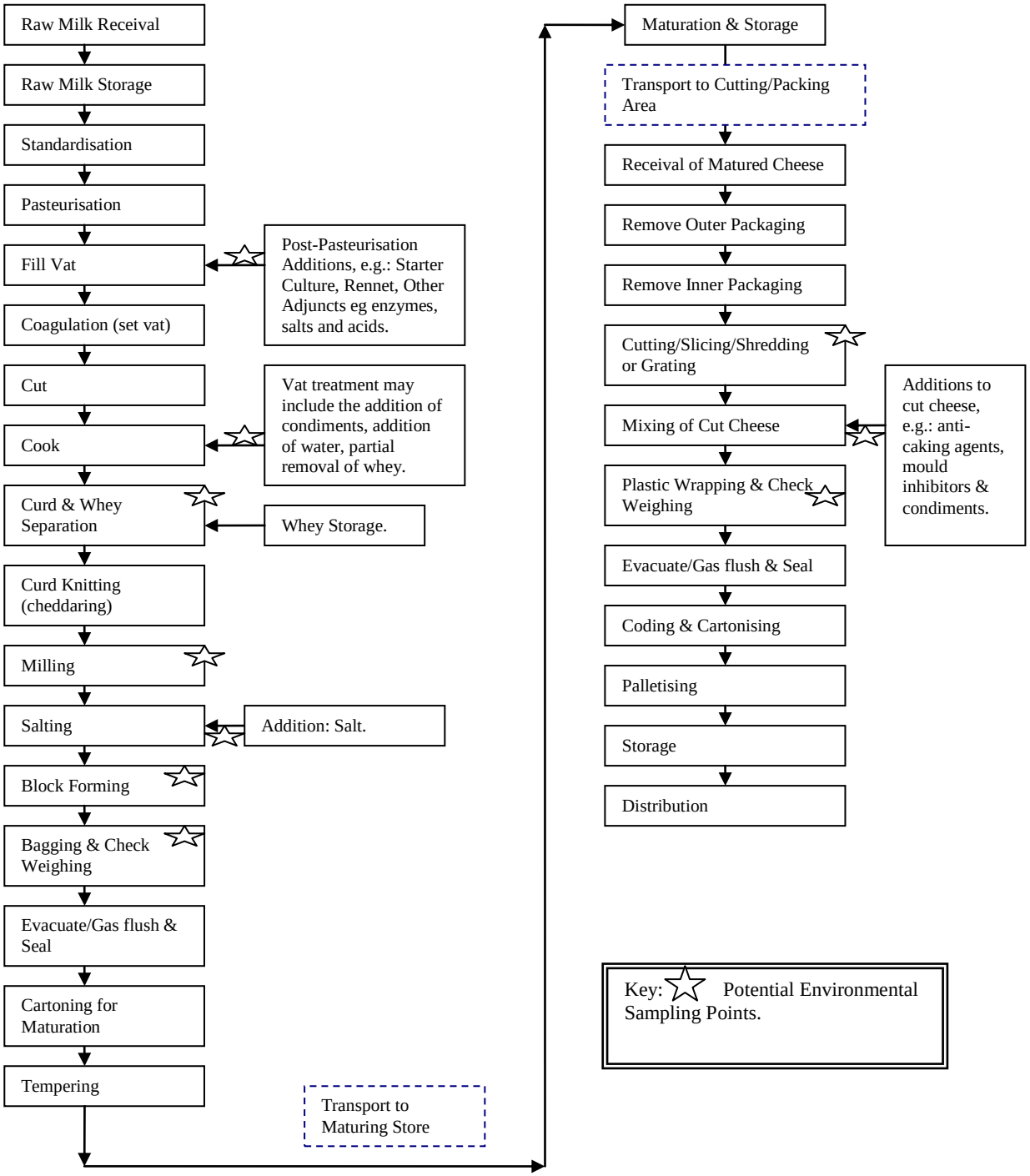


Figure 1b – Flow process diagram for cut cheese production



As a general rule, when taking environmental samples, the larger the number of samples taken the more likely environmental contamination will be detected. To minimize testing costs, it is possible to reduce the number of samples to be tested by combining the samples prior to testing (i.e. 'compositing'). Compositing of environmental samples is acceptable for routine environmental monitoring; however it is not practicable or recommended during trace-back environmental monitoring.

The following should be adhered to if compositing samples:

- only composite samples within a single zone (ie do not mix samples from different zones);
- do not composite wet with dry samples; and
- document the sample sites for all areas/points that make up a composite.

The two main types of environmental samples that can be taken are:

i) those from surfaces, these samples are usually in the form of swabs or sponges; and
ii) residues from products, materials or surroundings in dry or wet form
    - dry examples: shavings/scrapings from slicing/cutting machines or rubbish/dust/sweepings from the floor
    - wet examples: water, condensate, liquid residues.

Shown in Table 5 are examples of possible sampling sites and sample types for environmental monitoring in two different dairy food processing premises, a milk powder plant and a cut cheese plant. Tables 6 and 7 give examples of intensified environmental monitoring if a pathogen detection occurred in these two types of premises.

Table 5 – Examples of possible environmental sampling sites and sample types in different dairy food processing premises (milk powder and cut cheddar cheese)

	Milk powder premise	**Cut Cheese premise**
	Food contact surfaces (sponge/swab samples)	
Equipment	After dryer After cooler After sifter Pipes Conveyor belts Tote bins Silos Packaging machines Packaging (inners)	Cheese vats Whey drainers Milling equipment Block formers and presses Maturing racks Cutters/shredders Mixers Conveyor belts Packaging machines Packaging (inners)
Utensils	Brushes Scrapers Scoops Buckets/containers	Stirrers Knives Scoops Buckets/containers
	Environmental sponge/swab samples (Indirect contact but close to product)	
Equipment	Lids/covers External surfaces of silos	Lids/covers Control panels
	Environmental sponges/swab samples (Indirect contact and further away from product)	
Environment	Floors Walls Pipes Ducts Overhead structures Door handles	Floors Walls Pipes Refrigeration and air-conditioning units Ducts Overhead structures Door handles Drains

Table 6 – Example of an environmental sampling plan for *Salmonella* in a milk powder premise

Types of Samples	Sampling Levels	
	Normal level	Increased level
Environmental sponge/swab samples		
Area zone drying tower	1 x week	Several points
Area lecithination room	1 x week	Several points
Area zone after dryer	1 x week	Several points
Area zone after cooler	1 x week	Several points
Area zone after sifter	1 x week	Several points
Area zone storage silos	1 x week	Several points
Area zone packaging	1 x week	Several points
Packaging (inners)	1 x week	Various daily
Equipment sponge/swab samples		
Rotary valves	1 x week	1 x day
Filters	1 x month	Several points
Cyclone residues	1 x week	1 x day
Sieves after cooler	1 x day	Several points
Silos	1 x week	1 x day
Packaging machine	First product daily	10 x day

Table7– Example of an environmental sampling plan for *Listeria* in a cut cheddar cheese premise

Types of Samples	Sampling Levels	
	Normal level	Increased level
Environmental sponge/swab samples		
Area zone vats/post-pasteurisation additions	1 x week	1 x day
Area zone curd separating/whey drainage	1 x week	1 x day
Area zone milling	1 x week	1 x day
Area zone forming and pressing	1 x week	1 x day
Area zone packaging inners (prior to maturation)	1 x week	1 x day
Area zone maturation room	1 x week	1 x day
Area zone cutting/shredding	1 x week	1 x day
Area zone mixing	1 x week	1 x day
Area zone packaging inners (post- maturation)	1 x week	1 x day
Packaging (inners)	1 x week	1 x day
Equipment sponge/swab samples		
Cheese vats	1 x week	1 x day
Whey drainers	1 x week	1 x day
Milling equipment	1 x week	1 x day
Block formers/presses	1 x week	1 x day
Maturing racks	2 x week	Various daily
Cutters/Shredders	2 x week	Various daily
Mixers	2 x week	Various daily
Conveyor belts	2 x week	Various daily
Packaging machines	2 x week	Various daily

Appendix II - Environmental swabbing technique

Introduction

Traditionally, moistened sterile swabs, generally made from cotton, have been used to take surface samples from food processing areas and equipment. Sponges are now considered to be preferable to swabs, as they have demonstrated to be more effective in bacterial recoveries.

Outlined here is the surface swabbing technique developed by Food Science Australia (2008). Note that the sponge type referred to in this method is a proprietary brand, however other brands are available and suitable.

Preparation of sponges

- Re-hydrate Whirlpak® sponges in the laboratory before entering the factory. To do this, open each Whirlpak® bag by tearing along the perforated line, aseptically add 20 mL of universal neutraliser and manipulate the sponge to the bottom of the bag. The sponge should absorb the whole volume of liquid. Fold the top of each bag over 5 times and fasten the bag closed using the yellow wire strip. (Note that is important to use a neutraliser in the diluent to inactivate any residual sanitisers that might be present).

- Place the Whirlpak® bags in an upright position into the esky containing the freezer bricks or on ice if using another carrying container.

Procedure for swabbing surfaces

- Samples should never be taken immediately after the cleaning of equipment as residues of detergents and sanitisers will reduce the viability of any bacteria present. If samples must be taken during non-production times, several hours should have elapsed since cleaning and sanitising.

- Remove a Whirlpak® bag from the esky and manipulate the sponge so that it is approximately 5 cm from the bottom of the bag. Squeeze the sponge and allow the liquid to collect in the bottom of the bag.

- Unfold the opening of the Whirlpak® bag and open the top by pulling the two white tags. Manipulate the sponge to position it approximately half-way up the bag. Put a fresh sterile glove onto your hand and remove the sponge from the bag using the gloved hand.

- Do not touch the sponge or the inside of the bag with bare skin – always use a gloved hand. Use a fresh sterile glove for each sponge.

- Holding the sponge in your gloved hand, apply a moderate amount of pressure and swab a surface area of approximately 10 cm x 10 cm. Swab the whole area twice in the forward-back direction and twice in the left-right direction.

- Return the sponge to the Whirlpak® bag. Fold the top of the bag over 5 times and fasten the bag closed using the yellow wire strip. Manipulate the sponge in the bag to re-absorb the liquid. Remove and discard the glove.

- Label the sample

- Return the Whirlpak® bag to the esky. The sample should be stored and transported on ice or in refrigeration conditions until testing.

Appendix III – List of Relevant Authorities

Table III

Department of Agriculture, Fisheries and Forestry (DAFF) – Dairy Export Program PO Box 1006 Tullamarine 3043 T: 1300 723 241 F: 8308 5055 E: Shayne.daniels@daff.gov.au	**Tasmanian Dairy Industry Authority** PO Box 303 Devonport, Tasmania, 7310 T: 03 6421 7689 F: 03 6421 7667 E: Carolyn.Harris@dpiw.tas.gov.au
Dairy Food Safety Victoria (DFSV) PO Box 840 Hawthorn Vic 3122 T: 03 9810 5900 F: 03 9819 4299 E: info@dairysafe.vic.gov.au	**Food Standards Australia New Zealand (FSANZ)** PO Box 7186 Canberra BC ACT 2610 Ph: +61 2 6271 2222 Fax: +61 2 6271 2278 Reception: reception@foodstandards.gov.au
Dairy Authority of South Australia 33 Hutt Street, Adelaide, SA 5000 T: (08) 8223 2277 F: (08) 8232 2463 E: dasa@sa.chariot.net.au	**New South Wales Food Authority** PO Box 6682 Silverwater NSW 1811 T: 1300 552 406 F: (02) 9647 0026 E: contact@foodauthority.nsw.gov.au
Department of Health Western Australia PO Box 8172 Perth Business Centre Perth WA 6849 Australia T: (08) 9222 4222 F: (08) 9388 4976 E: Bill.calder@health.wa.gov.au	**Safe Food Production Queensland** PO Box 440 Spring Hill Q 4004 T: 07 3253 9800 F: 07 3253 9810 E: info@safefood.qld.gov.au

Appendix IV – Routine sampling and testing of product

Routine product sampling and testing is undertaken to verify that the manufacturing process has resulted in product that conforms to the FSC.

When this testing indicates the presence of a pathogen, and depending on the conformance to the FSC, a more intensive sampling and testing program may be required to demonstrate the extent of contamination.

Sampling of contaminated product

It is recommended that all samples taken be representative of the contaminated product and that the proportion of sample that is tested be representative of the product.

Representative samples can be taken from a batch/lot using procedures outlined in Australian Standard AS1166 – 1992 Milk and Milk Products – Methods of Sampling.

Alternative sampling procedures can be used as long as equivalence can be demonstrated and approved by the relevant authority.

The sampling program specified by the International Commission on Microbiological Specifications for Foods (ICMSF – Microorganisms in Foods 7 - Microbiological Testing in Food Safety Management, Table 8.3) can be used to provide an additional assessment to a positive qualitative result obtained under the FSC method.

Testing of contaminated product

In the case of qualitative testing, a positive result can be followed up by additional quantitative testing to determine if the levels of pathogens pose a risk to the consumer, however all detections need to be referred to the relevant authority for available options.

All product sampling and testing conditions (e.g. sampling technique, sample volume/weight, compositing of samples, sample handling and test methods) should be conducted in accordance with the most recent published version of the AS/NZ Standards (www.sai-global.com.au).

Alternative test methods may be used as long as equivalence can be demonstrated as determined by the provisions of AS/NZS 4659 (Standards Australia 1999, and Amendment 2002).

All personnel and laboratories conducting sampling and/or testing need to be able to demonstrate competency and proficiency.

Appendix V - Clearance program testing of finished product

The detection of pathogens in any routine testing of a batch or lot of dairy product indicates a failure of that processor's FSP. Any product processed on the affected line within the same batch of the implicated product could be considered to be potentially contaminated.

The recommencement of production on the affected processing line should only commence following corrective action and approval from the relevant authority. After this process the product clearance arrangements can commence.

The following sampling and testing clearance arrangements is based on the criteria suggested by the ICMSF (2002), and the previous ADASC *Listeria* and *Salmonella* Manuals (1999).

A suggested minimum clearance arrangement could be as follows:

30 samples are to be taken per batch from the affected production line at the following intervals:
30 samples to be taken on Day 1 (immediately following comprehensive clean),
30 samples to be taken on Day 3
30 samples to be taken on Day 5
30 samples to be taken on Day 12

NOTE:
The 30 samples of each batch may be tested:

(i) individually; or
(ii) composited into 6 lots of 5 samples; or
(iii) composited into 2 lots of 15 samples.

This clearance arrangement needs to be completed in full for optimum effectiveness. If test results for any batches fail to comply with the pathogen levels in Table 1, or indicate unacceptable levels of microorganisms, then the relevant authority may require the arrangement to be recommenced.

It is the product processor's responsibility to take the samples. The relevant authority representative may provide assistance if needed. The clearance arrangement will be deemed complete when the results of all tests meet the levels specified in Table 1 and advice to this end has been received from the relevant authority.

Any product from the associated processing line which was produced prior to the original contamination that is available (ie. still within the distribution chain), should also be tested at 30 samples per batch and withheld until cleared.

Product should be tested back to a clearance point, which may be a previous plant clearance, or three consecutive days production from the same processing line, which had been tested and cleared at 30 samples per batch.

It is strongly recommended that all product from other production lines in the same processing area be tested for the contaminant detected, on the day of, the day before, and day after the original contamination.

Appendix VI – Example Template

Product disposal request form, product disposal options and sub-lotting criteria
VI(a) – Product disposal request form

Product Disposal Request Form – Example Only
Date:
Contact Person:
Contact details: Phone _____Mobile_____Fax_____Email_____
Name of the Premise:
Premise identification number:
Establishment number (AQIS registered premises only):
Name of contaminated product:_____ _____ _____ _____
Identification codes of contaminated products:_____ _____ _____ _____
Dates of manufacture for contaminated products:_____ _____
Use-by / Best before dates:_____ _____
Quantity of contaminated products:_____ _____
Location(s) of contaminated products:_____ _____ _____ _____
Method being used to currently hold the contaminated products Physical ☐ Labelling ☐ Segregation ☐ Electronic ☐ Other ☐
Type of Non-conformance/Defect: Name of the Contaminant - genus, species (and toxin if relevant and if known) _____ Level of Contaminant (if known)
_____ _____
Intended disposal option: Destruction (state method) _____ _____ Reprocessing for human consumption (state method, final product type and the intended market)

Reprocessing for animal consumption (state method, final animal feed type and intended market

Reprocessing for non-food or non-animal feed (state method, final material/product type and intended market

Sub-lotting (state method)

Other (state method, material/product type and intended market

Justification to support disposal options (i.e. attached data to support disposal option, eg; operating logs, investigative findings, laboratory test results, traceback findings, corrective actions, other relevant documents): ----------

Details of the disposal:

Location and Name of where the disposal will take place

Quantity of product for disposal

Details of the disposal method (i.e. equipment, conditions and controls)

Time, Duration and Date of the disposal:

The level of risk (food safety, OH&S, environmental, and security) associated with the proposed method of disposal, and attached details to show how these risks will be managed
---

Microbiological specifications for reprocessed food/feed and sub-lotted products
---

Microbiological sampling details and test results for reprocessed food/feed and sub-lotted products
---

Details of Sub-lotting

Location, transportation and storage details for reprocessed food/feed and sub-lotted products
---

Quantity, identification and labeling information for reprocessed food/feed and sub-lotted products

---

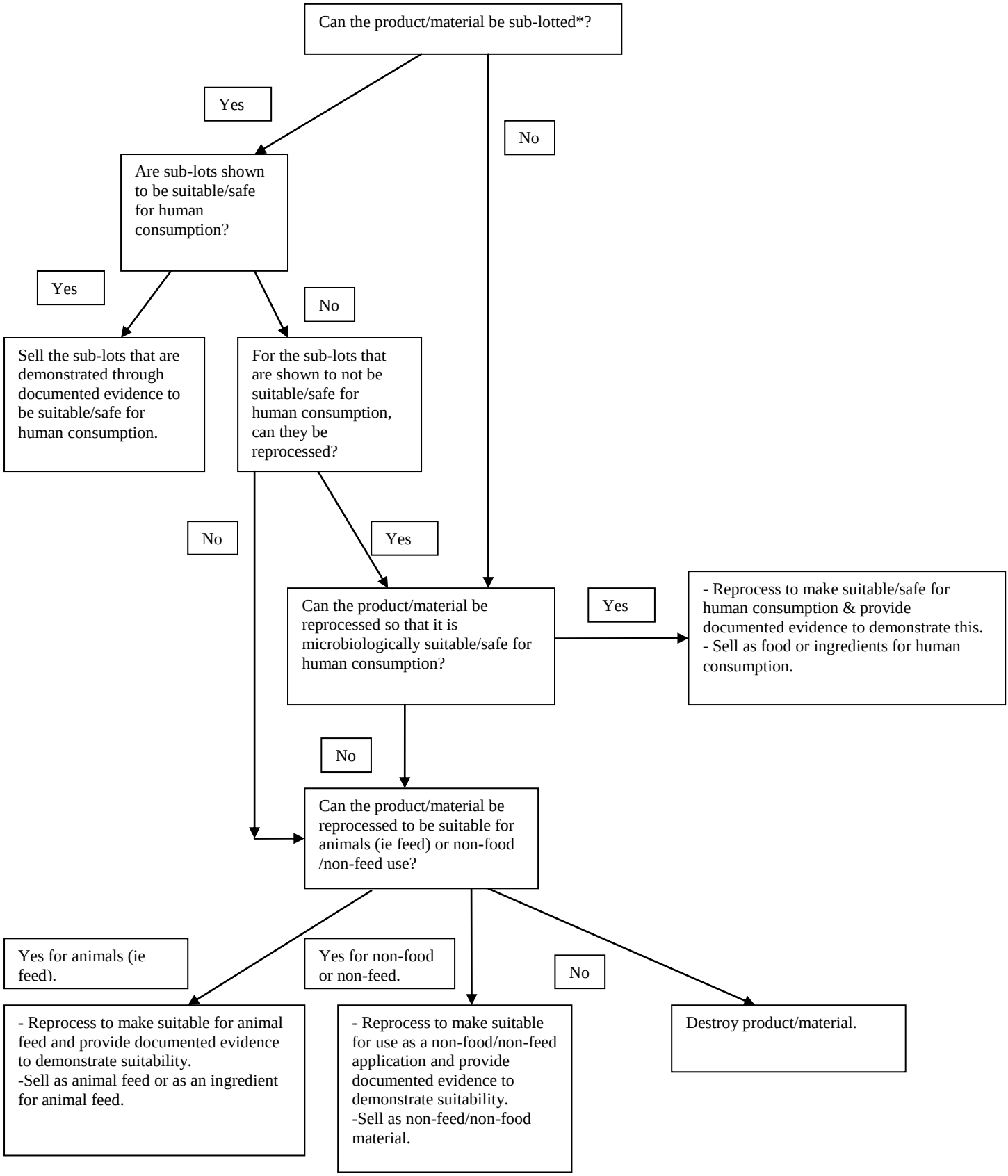
Product distribution, use and sale information for reprocessed food/feed and sub-lotted products

---

Transportation and final location details of destroyed products

---

VI (b) – Decision making tree for product disposal options



(*refer to Appendix VI c for sub-lotting criteria and conditions).

VI (c) – Product Disposal - Sub-lotting Criteria.

The suggested criteria for sub-lotting are:

1. All sub-lotting proposals, as part of the product disposal request, should clearly separate the two categories of product/material and detail the disposal options for each sub-lot.

2. In any proposal for sub-lotting the dairy product/material will be divided into 2 categories:
    - product/material that meets the pathogen levels;
    - product/material that does not meet the pathogen levels or is at risk of not meeting the pathogen levels (e.g.: a product/material buffer zone).

3. There can normally only be one instance of sub-lotting for food safety permitted per lot/batch. Proposals for more than one sub-lot per lot/batch will be considered on a case by case basis and will require supporting information.

4. A traceback is expected to have been carried out and the source and cause of the contamination to have been determined. The contaminated dairy product/material should be isolated to a specific part of the lot/batch. The traceback investigations are expected to have included the following:
    - changes to the process or equipment;
    - discrepancies in process controls, procedures, standard operating practices, support programs, equipment or discontinuities in test results; and
    - corrective actions undertaken to eliminate the source and cause to minimise any reoccurrence of the contamination.

5. The conforming sub-lot should be safely and adequately segregated from the non-conforming sub-lot.

6. The contaminant level in the proposed conforming sub-lot must be within the prescribed pathogen limits outlined in FSC 1.6.1 and is recommended to be in accordance with Table 1.

7. Additional testing can be performed at a sufficient frequency to provide an assurance that each sub-lot is suitable/safe for human consumption. The non-conforming sub-lot can include an appropriate buffer of conforming dairy product/material on one side, where it occurs at beginning or end; or both sides if in the middle of a production run. This should be confirmed with the relevant authority.

8. Product known to be contaminated with *Salmonella spp* or pathogenic *E.coli* can not be sub-lotted (because these bacteria may have a very small infective dose), and it is strongly recommended that product be clearly identified or labeled so as to ensure that any potential for accidental release or use is minimised. For casein powders, approval can be received from the regulatory authority for the product to be labeled “Industrial use only: not for edible use”.