



Te Pou Oranga Kai O Aotearoa

Operational Guideline: Dairy Heat Treatments

June 2003

New Zealand Food Safety Authority
PO Box 2835, Wellington, New Zealand

Table of Contents

1. What is the purpose of this guideline?	3
2. What is included in this guideline?	3
3. What are the desired outcomes?	3
4. Frequently asked questions	3
5. Glossary of terms	11
6. Useful resources	12
6.1 Suggested solutions	12
6.2 Other resources	12
7. For more information	13
Appendix One Suggested Solutions	14
A1.1 Continuous pasteurisation	14
A1.2 Thermisation using a simple plate heat exchanger	15
A1.2.1 Procedures, documentation and records	15
A1.2.2 Equipment	15
A1.2.3 Operation	16
A1.2.4 Reporting to NZFSA Compliance/TPA	20
A1.2.5 Validation	20
A1.2.6 Evaluation	20
A1.2.7 Verification	20
A1.3 Batch pasteurisation	21
A1.3.1 Procedures, documentation and records	21
A1.3.2 Equipment	21
A1.3.3 Operation	22
A1.3.4 Reporting to NZFSA Compliance/TPA	24
A1.3.5 Validation	24
A1.3.6 Evaluation	24
A1.3.7 Verification	25
A1.4 Stovetop pasteurisation	26
A1.4.1 Procedures, documentation and records	26
A1.4.2 Equipment	26
A1.4.1 Operation	27
A1.4.4 Reporting to NZFSA Compliance/TPA	29
A1.4.5 Validation	29
A1.4.6 Evaluation	29
A1.4.7 Verification	29
Appendix Two Heat Treatment Equipment Checklist	30

1. What is the purpose of this guideline?

This guideline is designed to provide dairy product manufacturers, heat treatment validators, TPA/NZFSA evaluators and verifiers with information to assist in complying and assessing compliance with NZFSA Standard D121.1 *Dairy Heat Treatments*.

2. What is included in this guideline?

This is a NZFSA Dairy and Plant Products Group operational guideline. It outlines:

- Answers to frequently answered questions
- Useful resources relating to heat treatments
- Possible ways (suggested solutions) of meeting the outcomes in NZFSA Standard D121, *Dairy Heat Treatments* for different types of heat treatment situations.

3. What are the desired outcomes?

It is expected that after reading this guideline that readers will have their questions regarding heat treatment answered and

- dairy product manufacturers will be able to put in place heat treatments that will deliver the outcomes in NZFSA Standard D121, *Dairy Heat Treatments*.
- validators, evaluators and verifiers will be able to appropriately assess whether heat treatments deliver the outcomes in NZFSA Standard D121, *Dairy Heat Treatments*.

4. Frequently asked questions

Q1. Why was this Standard (NZFSA Standard D121, *Dairy Heat Treatments*) developed?

- A. NZFSA Standard D121.1, *Dairy Heat Treatments* was developed to replace MAF Standard MRD-Stan 3, Rev 2, *Standard for Pasteurisation Heat Treatments* and MAF Standard MRD-Stan 4 *Standard for Checking the Operation of Pasteurisers*. This was required to:
- clarify the requirements of other manufacturing processes, such as evaporation, which have been considered to be equivalent to pasteurisation;
 - provide the outcomes for thermisation for milk and cream for cheese-making;
 - provide the outcomes for UHT treatment of dairy produce;
 - provide the outcomes for validation, evaluation and verification of heat treatments
 - provide the framework to replace MAF Standard MRD 4 *Standard for Checking the Operation of Pasteurisers* with the acceptable criteria provided as Appendix One of the new NZFSA Standard D121, *Dairy Heat Treatments*;
 - explain the relationship between the NZFSA Standard D121.1, *Dairy Heat Treatments* and the heat treatments required by importing countries;
 - provide a framework for the development, assessment and approval of industry codes of practice which:
 - satisfy the acceptable criteria, and/or
 - provide alternate means of achieving the outcomes described in section 3 of the NZFSA Standard D121, *Dairy Heat Treatments*.

Q2. To be approved by NZFSA, do industry codes of practice need to comply with the acceptable criteria?

- A.** For an industry code of practice to be approved by NZFSA, you need to be able to demonstrate the code delivers the outcomes contained in section 3 of the NZFSA Standard D121.1 *Dairy Heat Treatments*. This can be done by demonstrating that the acceptable criteria provided are being met. However we recognise that in some rare instances a code may be able to deliver the Standard's outcomes without specifically meeting the acceptable criteria. In this situation NZFSA would assess the code (or relevant part) as alternative criteria and be looking for evidence to demonstrate that the Standard's outcomes are being met.

Q3. What sort of evidence will be required to demonstrate compliance?

- A.** During a Product Safety Programme (PSP) verification audit by the TPA/NZFSA CIG the manufacturer may be asked to demonstrate current and recent past compliance of the design, installation, operation and maintenance of the heat treatment equipment to NZFSA Standard D121, *Dairy Heat Treatments*.

The manufacturer's PSP will need to contain sufficient documentation, including design and "as-built" drawings, plating diagrams, computer/PLC programs, operating procedures, training programmes and records, to ensure that:

- staff and contractors
 - have the knowledge and skills necessary to understand the hazards managed by the heat treatment;
 - understand the heat treatment and how it operates;
 - operate, check and maintain the heat treatment including monitoring, taking timely and appropriate corrective action(s) when there is "loss of control", and record keeping; and
- the heat treatment is readily validated by the manufacturer; and
- the heat treatment is readily evaluated and verified by NZFSA Compliance/TPA.

In addition the manufacturer is required to hold the following information to demonstrate compliance:

- the information which shows the equipment complies with the heat treatment equipment criteria (see Table A.1.1 in NZFSA Standard D121.1 *Dairy Heat Treatments*);
- the information which shows the operation of the heat treatment complies with the criteria for operation of heat treatments (see Table A.1.1 in NZFSA Standard D121.1 *Dairy Heat Treatments*);
- reports to NZFSA Compliance/TPA
- copies of the validation and evaluation reports plus evidence of completion and sign-off of corrective actions. Copies of the site reports are sufficient where the final report has been delayed from the TPA/ NZFSA CIG.

The manufacturer may also be asked for other relevant records such as raw milk and heat treated milk quality records, internal audit reports and complaint records.

It is recommended that the manufacturer sets up such a record system that readily provides this information for verification.

Q4. Whose responsibility is it to demonstrate compliance or non-compliance?

- A.** It is up to the manufacturer to demonstrate to the assessor that their PSP, equipment and operation are compliant with NZFSA Standard D121, *Dairy Heat Treatments*.

Q5. I operate a batch pasteuriser, is the absence of micro organisms in the treated milk sufficient demonstration that I comply with the Standard?

A. Pasteurisation is defined by a time temperature combination, for example, rapidly heating and holding milk at 63° for 30 minutes. Therefore to demonstrate compliance you will need to have records for your batch pasteuriser which show that all the dairy produce and all the headspace reached, and was held at, the pasteurisation temperature for the required holding time, specified in your PSP, which in turn needs to comply with the Standard. Since pasteurisation is defined by time temperature combinations, demonstrating the absence of micro-organisms is not sufficient evidence of compliance. Testing for micro-organisms and phosphatase are both ways for you to verify (as part of your HACCP plan) that the pasteurisation was successful.

Q6. I am a manufacturer, what to I do if I can demonstrate I can meet the outcomes in NZFSA Standard D121.1 *Dairy Heat Treatments* but don't meet the acceptable criteria?

A. You can apply to NZFSA for approval for alternative criteria. Your application will need to include your proposal for alternative criteria, the justification for them and the information necessary to demonstrate how the requirements will be delivered. Your application will then be considered by a group of technical experts who, if they agree that the requirements are met, will recommend approval of the alternative criteria. The Director, Dairy and Plant Products will advise you in writing of the outcome.

Q7. Is evaluation of my heat treatment mandatory?

A. Independent evaluation is mandatory for new, relocated or significantly changed heat treatments applications (refer NZFSA Standard D121 *Dairy Heat Treatments*). Similarly verification of the heat treatment is required based on the performance-based verification category to which you are assigned and the requirements of the country you are exporting to. You are welcome to seek approval for alternative arrangements either by proposing these in a code of practice (see Q2 above) or seeking approval for alternative criteria (see Q6 above)

Q8. Why are the standard and guidelines so different from NZCP7, where has all the detail gone?

A. In the past there has been confusion about the role of NZCP7 with respect to NZFSA Standards. Some people mistakenly believed that all dairy manufacturers had to comply with NZCP7. This view caused considerable concern to smaller operators.

In assessing our need to revise MRD-Stan 3 and develop NZFSA Standard D121, *Dairy Heat Treatments* we recognised that many operators wanted the NZFSA Standard to define the outcomes that needed to be delivered. In addition, many operators were also asking for the criteria to judge whether they had successfully delivered the outcomes. Many specifically requested that we remove prescription from the Standard and let operators develop solutions that met the criteria provided. This then was the context we used for preparing NZFSA Standard D121, *Dairy Heat Treatments* and these guidelines. When we analysed much of the detail from previous Standards and drafts, we recognised that we were delivering prescriptive solutions rather than the outcomes and criteria requested. Some of the details we have removed have been incorporated in the "Suggested Solutions" appended to this guideline and we anticipate that much of the detail will be in industry codes of practice such as the Fonterra Standard of Excellence 7.

Q9. What's happening to NZCP7 and other approved codes or standards? I notice the NZFSA Standard D121 *Dairy Heat Treatments* has removed the approvals for these.

A. You're right, we have removed the approvals for codes and standards we had approved in the past. One reason for this is that some of the approvals related to manuals and codes which had been subsequently updated and the revisions not approved. As well, some approvals related to codes which were not being maintained. In addition, there are concerns that some of the codes or standard do not deliver the outcomes specified in the NZFSA Standard D121, *Dairy Heat Treatments*. Finally we were uncertain if there was any demand to maintain some

of the approvals. In removing the approvals we are creating the opportunity for industry to come to us to with applications to approve codes and standards that meet the requirements of the revised NZFSA Standard D121 *Dairy Heat Treatments*. These will then be considered by a group of technical experts who, if they agree that the requirements are met, will recommend approval of the code or standard.

NZCP7 (to be known as the Fonterra Standard of Excellence 7) is currently being revised by Fonterra to deliver the requirements of the new NZFSA Standard D121, *Dairy Heat Treatments* and we anticipate that it will be approved soon after the new Standard is issued in April 2003.

Q10. Where is the detail for what I have to comply with?

- A. If you are looking for details of how to meet the acceptable criteria and thereby deliver the outcomes, we suggest you review:
- the suggested solutions appended to this guideline; or
 - a NZFSA-approved code of practice that is relevant to your operation.

Q11. Given NZFSA's commitment to HACCP, why did the proposed heat treatment standard based on HACCP (draft MAF Standard D121 *Dairy Heat Treatments* dated 21 September 2001) not proceed?

- A. NZFSA is totally committed to HACCP. Work has commenced on amending the *Animal Products Act 1999* (APA) to include dairy operations in the scope of that legislation. This legislation places an increasing emphasis on HACCP as the means of managing hazards, such as pathogenic micro-organisms, in human food and animal feeds. The validated HACCP plan is the platform for an operator's Risk Management Programme (which is the APA version of PSPs)

We have an industry working group, the HACCP Working Group that recently redeveloped our HACCP standard. The Dairy HACCP Working Group is redeveloped the MAF Standard D110, *Dairy HACCP Plans* to:

- ensure consistent and uniform application of HACCP principles;
- ensure the integration of end product testing as part of the internal verification;
- provide for more effective use of information from existing supporting systems; and
- prepare the HACCP documentation required to support the development of Risk Management Programmes in the dairy industry.

The Standard for dairy heat treatment (D121) has been issued recognising that all PSPs for the manufacture of dairy products must include provision for the control of potentially pathogenic organisms. MAF Standard D110, "Dairy HACCP Plans", requires that PSPs for the manufacture of dairy product must include validated HACCP analyses/plans of the processes covered by the PSP. Where such HACCP analyses/plans include heat treatment as a critical control point for the control of pathogens, heat treatments operated in accordance with this Standard (D121) are equivalent to a critical control point developed in accordance with MAF Standard D110.

Q12. What's the difference between HACCP validation and the validation described in NZFSA Standard D121 *Dairy Heat Treatments*?

- A. Validation of a HACCP plan, otherwise known as HACCP validation, is the process of obtaining evidence that the elements of the HACCP plan are effective. In the context of controlling hazards using heat treatments, this process includes the assessment:
- of the effectiveness of the time/temperature combination in controlling the hazard(s), and
 - that, in a specific manufacturing process, this time/temperature combination is then consistently applied, there is no contamination of the heat treated produce and it is maintained in a wholesome condition.

The heat treatments defined in the NZFSA Standard D121 *Dairy Heat Treatments* are historically known to be effective. Therefore the only validation required for heat treatments defined in the Standard is that, in each manufacturing process, the time/temperature combination is consistently applied, there is no contamination of the heat treated produce, and the produce is sufficiently heated or cooled to maintain it in a wholesome condition.

Q13. What's the difference between validation, evaluation and verification activities described in the NZFSA Standard D121 *Dairy Heat Treatments*? Why do we need to do all three?

- A. Validation** is the process undertaken by the manufacturer to satisfy themselves that the heat treatment is operating in a way that the treated dairy produce is safe. As explained in Q12, validation of the defined heat treatments needs to confirm that the time/temperature combination is consistently applied, there is no contamination of the heat treated produce, and the produce is sufficiently heated or cooled to maintain it in a wholesome condition.

Evaluation is the assessment of the heat treatment by a competent individual contracted to an impartial agency (e.g. TPA or Assessor, NZFSA Compliance) to determine compliance with regulatory requirements. Evaluation is the means by which NZFSA determines whether the heat treatment plan should be approved by the Director as part of a PSP. New heat treatment plans require evaluation prior to approval and then are required to be re-evaluated after any significant change. Evaluation is undertaken after validation is completed and where the validation of the heat treatment plan has been undertaken by a competent person and is thorough and well documented then less effort would be required for evaluation.

Verification by assessment of reports and audit is the means by which the NZFSA determines whether the operation is being operated in accordance with the PSP previously approved by NZFSA for that operation and to confirm the ongoing applicability of this. Verification is normally undertaken annually. The verification of the heat treatment is undertaken as part of the regular PSP verification audit. Specialist skills are required for a thorough verification of the heat treatment. However where a manufacturer has an excellent performance history, a full specialist verification is replaced by an audit by a PSP verifier who calls in a heat treatment specialist if problems were identified.

Validation is the most critical activity as manufacturers are vitally interested in determining whether they are delivering safe food to their customers. However, in the past our experience is that some manufacturers do not thoroughly validate their heat treatments. The NZFSA therefore checks via evaluation that the heat treatment plan is adequate and can be approved as part of the PSP. Freedom from conflict of interest is essential in this step, hence the use of independent evaluators.

Finally verification is the regular audit by an independent body that the manufacturer is continuing to operate according to the plan that was approved and that nothing has changed which would jeopardise the safety of food produced by that manufacturer. NZFSA recognises that the risk of producing unsafe food decreases as a manufacturer takes greater responsibility and puts systems in place which provide assurance. As a consequence, the level of verification decreases as a manufacturer's performance improves.

Q14. What's the relationship between NZFSA Standard D121 *Dairy Heat Treatments* and the requirements when dairy moves to the *Animal Products Act 1999*?

- A.** When dairy moves fully into the APA, HACCP will be fully and consistently introduced for all manufacturers. Hazards such as pathogenic micro-organisms, will be controlled via a validated HACCP plan which may include heat treatment such as pasteurisation. We anticipate that the technical content of this Standard (NZFSA Standard D121, *Dairy Heat Treatments*) will ultimately be retained in the APA framework as a model for heat treatment critical control points.

One of the key requirements in HACCP is the ability to scientifically validate the HACCP plan. It has been recognised that for operators to successfully complete these validations, it is necessary to have more complete scientific information on the performance (lethal effects) of the defined heat treatments. Although we have provided some information on the lethal effects, this information is incomplete. NZFSA Dairy and Plant Products is working with

NZFSA Programme Development Group and FSANZ to ensure that this information will be available to enable HACCP to be fully implemented in the New Zealand dairy industry.

Q15. NZFSA Standard D121 *Dairy Heat Treatments* requires all dairy produce used for manufacturing food to be heat treated using pasteurisation, UHT treatment or thermisation for cheese-making. What if I want to use “cold treatments” or produce raw milk products instead of using a heat treatment?

A. If you want to use “cold treatments” or produce raw milk products instead of using a heat treatment to control pathogenic micro-organisms, then this Standard (NZFSA Standard D121, *Dairy Heat Treatments*) does not apply. In this situation you are required to develop and implement a HACCP plan. The HACCP plan is required to be fully validated (refer Q12 and 14 above)

Q16. What’s the difference between outcomes, criteria and suggested solutions? Which ones do I need to comply with?

A. Your heat treatment needs to deliver the outcomes in section 3 of the NZFSA Standard D121, *Dairy Heat Treatments*. In developing the criteria appended to the Standard we are providing what we understand needs to be achieved to successfully meet the outcomes. Suggested solutions provided in this guideline are one way of meeting the criteria and thereby delivering the outcome.

Q17. NZFSA Standard D101 *Product Safety Programmes* (Appendix One section 4.5.2 B) refers to the following NZFSA Standards: MRD-Stan 3 *Standard for Pasteurisation Treatments*, MRD-Stan 4 *Standard for Checking the Operation of Pasteurisers* and D403 *Evaluation of Heat Treatment Plans*. What’s happening with these standards? How does the NZFSA Standard D121.1 *Dairy Heat Treatments* relate to the requirements in D101?

A. NZFSA Standard D121.1 *Dairy Heat Treatments* incorporates all the requirements previously contained (or proposed to be contained) in the three Standards identified in D101. You’ll see that we’ve revoked MRD 3 and MRD 4 when D121 was issued. D403 was never written and the material we had intended to include in it is also included in D121. We are pleased to be able to replace three Standards with just one!

Q18. Why do validators, evaluators and verifiers need to have HACCP qualifications and experience when the NZFSA Standard D121 *Dairy Heat Treatments* does not require HACCP?

A. As you can see from our answer to Q9 above, the dairy industry is moving to an environment where hazards are controlled using HACCP plans. Heat treatments, such as pasteurisation, are identified as critical control points by almost all manufacturers. In the past validation of pasteurisers has focussed on the equipment and has not considered the heat treatment in the context of the HACCP plan or the role of operators, documentation, such as procedures, and records. In having assessors trained in HACCP we look forward to better integration of the assessment of the heat treatment as part of the overall HACCP plan.

In addition to this, we are also concerned that we will have a shortage of people skilled in HACCP when dairy moves under the APA. Given that dairy is highly dependent on heat treatments such as pasteurisation, we see that heat treatment evaluators and verifiers could play a role in the evaluation and verification of HACCP plans in future. Therefore we want evaluators and verifiers trained in HACCP in preparation for their future role in HACCP.

Q19. Would you provide me some information on fluorometric phosphatase testing? How is it different from phosphatase testing?

A. The test to establish that dairy produce has been correctly pasteurised is the alkaline phosphatase test. This test was developed in the 1930’s when scientists found that the enzyme alkaline phosphatase which is present in all milks, was inactivated (denatured) at slightly higher time temperature conditions than those required to kill *Mycobacterium tuberculosis* (the bacteria responsible for tuberculosis) and most other milk-borne pathogens.

The phosphatase test (Aschaffenberg and Mullen) measures the amount of p-nitrophenol liberated by any phosphatase that remains in the dairy produce after heat treatment. Raw cows' milk contains about 10,000 µg p-nitrophenol units of alkaline phosphatase and the lowest level of sensitivity for the phosphatase test, which is based on colour measurement, is about 10 µg p-nitrophenol. This means this 1930's test can only detect up to 0.1 percent of raw milk. Furthermore this method has problems in that the colour of the dairy produce being tested could interfere with the colour measurement of the test.

In the 1990's the more reliable Fluorophos method was developed (Reference: AOAC INTERNATIONAL. 2002. Official Methods of Analysis, 17th ed. 991.24 Alkaline Phosphatase Activity in Fluid Dairy Products, AOAC INTERNATIONAL, Arlington, VA). This fluorometric phosphatase test is based on the same chemistry as the old phosphatase tests however rather than relying on colour measurement, it measures fluorescence. As a consequence it is more sensitive, rapid, and reproducible and less prone to the interference problems encountered by the old method.

This methodology has been extensively tested and approved by AOAC. It is capable of measuring down to 0.003 percent raw milk contamination. Unlike the phosphatase test, which provides a pass or fail result, the fluorometric phosphatase method provides quantitative results. Correctly pasteurised cow's milk yields values of 20-50milliunits/litre. It has been suggested that fluorometric phosphatase rising above 50milliunits/litre should be investigated into the reason for the rise.

Research on other dairy produce has been undertaken (Reference: Painter, C.J. & Bradley, R.L 1997. *Residual Alkaline Phosphatase Activity in Milks subjected to various Time-Temperature Combinations*. Vol 60, no 5 Journal of Food Protection)

[Acknowledgement. The material contained in this answer comes from a paper written by Frank Harding, the former technical director of the Milk Marketing Board of England and Wales, which was published in *Milk Industries International – Technical and Research Supplement*, December 2002]

Q20. Is phosphatase testing mandatory?

- A. You'll see in the operating criteria in Table A1.2 of the Standard that phosphatase testing is required where pasteurised products are released for sale before the results of microbiological tests are available. Phosphatase testing is not mandatory; however as part of their HACCP plan all manufacturers must have some means to verify that their critical control point (pasteurisation) is operating effectively and phosphatase testing is a rapid way of doing this.

Q21. Can I use the Aschaffenberg and Mullen phosphatase method or do I have to use a fluorometric phosphatase method?

- A. The test method used for measuring phosphatase must be a NZFSA-approved method. For NZFSA approval, the method must be current (not obsolete). When the AOAC reviewed the various methods for testing phosphatase in the 1990s, they noted that the fluorometric method is the primary (preferred) method because of its sensitivity, accuracy and precision. All other phosphatase methods were identified as "surplus" and required that the following inserted in the methods' description: "method insensitive to less than 0.1% contamination with raw milk product and may show false-negative and false-positive results". Based on this assessment by the AOAC it is unlikely that NZFSA will approve any phosphatase method other than the fluorometric methods.

Q22. In the Standard you require the heat treatment to be validated after a significant change. Can you provide some examples of significant change relating to heat treatments?

- A. A significant change is any change made to key staff, environment, premises, equipment, process control / automation, facilities, process or product that may affect food safety. Changes to the process control system such as a change to a computer programme are also included in this definition.

There are many changes to a heat treatment plan that may or may not be significant. It is important that the manufacturer has staff with good understanding of the HACCP process so that they are able to make considered judgements. In general, any change made to the heat treatment (pasteuriser) has the potential to be considered a significant change. In each instance a hazard analysis needs to be completed in order to establish the change's significance to food safety.

Some examples of changes to heat treatment plans that may be significant changes include:

- Any change that affects the timing pump, e.g. new motor, new speed controller.
- Any change that affects the length of the holding section, e.g. new tube or repairs to the tube.
- Any change that affects the response time of the temperature sensors, e.g. different sensors or sensor pockets.
- Any change that results in a cooling media pressure change, e.g. increase in cooling water flow rate.

Q23. I am a manufacturer who purchases pasteurised dairy ingredients and I have a heat treatment in my process. Do I need to comply with NZFSA Standard D121, *Dairy Heat Treatments*?

- A. No you don't have to comply with this Standard as there is a specific exclusion in section 1 of the Standard which says "This Standard does not apply where dairy produce already heat-treated in accordance with this Standard are used as ingredients for the manufacture of dairy products, provided that any transport, storage and manufacture following the heat treatment is done in accordance with a NZFSA-approved PSP."

If you are operating a heat treatment as you describe and it is identified as a critical control point or control measure in your HACCP plan then it will need to be validated, refer Q12 above. This validation would include assessing:

- the effectiveness of the time/temperature combination in controlling the hazard(s), and
- that, in a specific manufacturing process, this time/temperature combination is then consistently applied, there is no contamination of the heat treated produce and it is maintained in a wholesome condition.

Q24. Although I have demonstrated my heat treatment plan meets the acceptable criteria in the NZFSA Standard D121, *Dairy Heat Treatments*, the person evaluating or verifying my heat treatment does not agree and says I have to comply with a NZFSA-approved code of practice or standard. Are they correct?

- A. This question raises two concerns.

Firstly you do not have to comply with an NZFSA-approved code of practice or standard. If you choose not to comply with an NZFSA-approved code of practice or standard, your heat treatment plan (as part of your PSP) must describe how you are complying with the NZFSA Standard D121, *Dairy Heat Treatments*. The choice is up to you. However, if you do reference all or part of a NZFSA-approved code or standard in your heat treatment plan (which is part of your PSP) you do have to comply with it.

The second part of this question relates to disputes between a manufacturer and an evaluator or verifier. In this instance, you and the evaluator/verifier need to agree this is a dispute and then notify the responsible NZFSA Compliance Assessor in writing (email or fax) within 24 hours. The assessor advises NZFSA Dairy and Plant Products. NZFSA will investigate and where necessary arrange for an independent assessment of the heat treatment plan at the manufacturer's expense. Based on the outcome of the investigation, NZFSA will advise what action, if any is required. Where the dispute relates to a critical non-compliance relating to food safety or truth of labelling, all dairy produce treated by the heat treatment is managed as non-conforming produce in accordance with MAF Standard D108 *Non-conforming Dairy Produce* until the non-compliance is resolved.

Q25. I have a small scale operation and I plan to use a continuous pasteuriser. Is a manual divert valve acceptable?

Temperatures can change rapidly in continuous HTST heat exchangers. In choosing to use this continuous technology it is important to recognise that the automatic divert valve is the main safety feature of continuous heat exchangers. An automatic divert valve is essential to divert cold milk before it reaches the heat exchanger. Automatic temperature control is also recommended for continuous pasteurisers.

Batch heat treatment is slower and therefore more suited to manual control. If the cost of automation is a concern, we recommend that you use a batch pasteuriser rather than attempting to use manual control on a continuous pasteuriser.

5. Glossary of terms

Clean – Free of soil, food residue, dirt, grease, cleaning or sanitising agents or other objectionable matter.

Corrective action – Action taken to rectify, eliminate the causes of, and prevent recurrence of any problem/failure/non-compliance identified in a plan, procedure, process, product, programme, or system.

Coved – as defined in the Oxford Dictionary, having "curved junction of wall with ceiling or floor".

Dairy produce – Milk, cream, butter, cheese, and any other product of milk or cream.

Dairy product – Dairy produce intended for sale in, or export from, New Zealand for human consumption; and

- a. includes raw milk or cream intended for sale in New Zealand for human consumption as raw milk or cream; but
- b. does not include raw milk or cream intended to be processed before sale in New Zealand for human consumption.

Evaluation – Assessment of an individual, plan, programme, or system to determine compliance with regulatory requirements. This will involve review of documentation and, in some cases, review of operations or observation of practice. It is undertaken by a competent individual contracted to an impartial agency (e.g. TPA or National Assessor, NZFSA Compliance Group).

HACCP – Hazard Analysis and Critical Control Point system adopted by the Codex Alimentarius Commission. HACCP is a systematic identification of hazards and the measures for their control to ensure the safety of food. It focuses on prevention rather than end-product testing.

HACCP plan – A documented system, prepared in accordance with the principles of HACCP, to ensure control of significant food safety hazards in a food handling process.

HAZOP – Hazard Analysis and Operability Review. A systematic identification of possible hazards and operational difficulties in relation to plant and equipment design.

Sanitary – The number of micro-organisms in the environment is at a level that does not compromise product safety or wholesomeness.

Safe – In relation to any dairy product, 'safe' means satisfactory, fit for human consumption, and not having in it or on it any pathogenic organisms

- (a) That are present in an amount that makes the product harmful or injurious to the health of the people who may eat or drink it; or
- (b) That
 - (i) Are not present in an amount that makes the product harmful or injurious to the health of the people who may eat or drink it; but

- (ii) By virtue of their ability to reproduce, to produce toxins, or both, make the product potentially harmful or injurious to the health of the people who may eat or drink it.

In relation to any dairy produce that is not a dairy product, 'safe' means satisfactory, and fit for the manufacture of dairy products.

Significant change – Any change made to key staff, environment, premises, equipment, control systems/automation, facilities, process or product that may affect food safety.

Validation – Obtaining evidence that the elements of the HACCP plan are effective.

Verification (external) – Application of methods, procedures, tests and other checks, in addition to monitoring, to determine compliance with NZFSA-approved plans, programmes and systems, and to confirm the ongoing applicability of those.

6. Useful resources

6.1 SUGGESTED SOLUTIONS

To assist manufacturers, the working group have developed some suggested solutions to the acceptable criteria provided in Appendix One of NZFSA Standard D121 *Dairy Heat Treatments*. These suggested solutions are developed for specific equipment and processing situations and are designed to assist you in identifying ways to meet the acceptable criteria. The suggested solutions are provided in Appendix One of this guideline

6.2 OTHER RESOURCES

The following documents are also useful resources:

- 3-A Accepted Practices 603-06 "Sanitary Construction, Installation, Testing and Operation of High-temperature Short-time and Higher-temperature Shorter-time Pasteuriser Systems". International Association of Milk, Food and Environmental Sanitarians, 1992;
- Grade "A" Pasteurised Milk Ordinance 1999 Revision. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Item 16P and Appendices H and I. (PDF version at www.cfsan.fda.gov/~ear/p-nci.html)
- AS 3993.1 "Equipment for the Pasteurisation of Milk and Other Liquid Dairy Products",
- "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application," Supplement to Volume 1B, Annex to CAC/RCP 1-1969, Rev 3 (1997).Codex Alimentarius Commission, 1997.
- Application of HAZOP and What-if Safety Reviews to the Petroleum, Petrochemical and Chemical Industries, Dennis P Nolan, 1994, Noyes Publications, New Jersey
- HAZOP Guidelines, Hazardous Industry Planning Advisory Paper No 8 Hazard and Operability Studies, Department of Urban Affairs and Planning, New South Wales
- Bulletin 200 (1986), "Monograph on Pasteurised Milk". International Dairy Federation
- CAC/RCP 040-1993. Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods. Codex Alimentarius. (PDF version at: ftp://ftp.fao.org/codex/standard/volume1b/en/RCP_040e.pdf)

Appendix One Suggested Solutions

The following are suggested solutions for heat treatments in the following situations:

1. Continuous pasteurisation
2. Thermisation using a simple plate heat exchanger
3. Pasteurisation with a batch pasteuriser
4. Stove top pasteurisation.

These are single examples of heat treatments that meet the outcome of NZFSA Standard D121.1 *Dairy Heat Treatments*. There are other solutions for heat treatments that also meet the requirements of the Standard.

A1.1 CONTINUOUS PASTEURISATION

Detailed specifications for continuous pasteurisation equipment which meet the outcomes contained in NZFSA Standard D121 Dairy Heat Treatments can be obtained from NZFSA-approved codes of practice and standards for heat treatments.

For a complete list of codes and standards approved by NZFSA to deliver the outcomes of this Standard contact NZFSA Dairy and Plant Products or check its website (www.nzfsa.govt.nz/dairy/registers/app-stds.htm).

These codes and standards provide specifications for equipment which will meet the D121 acceptable criteria for heat treatment equipment, (D121, Appendix One, section 1.2). Some codes and standards also provide specifications for heat treatment operation, documentation, training and records. Each manufacturer's PSP and HACCP plan will be required to provide the following additional information necessary to satisfy the remaining acceptable criteria of D121, where this is not provided in the code or standards:

- documentation and training (D121, Appendix One, section 1.1);
- heat treatment operation (D121, Appendix One, section 1.3);
- reporting (D121, Appendix One, section 1.4); and
- validation (D121, Appendix One, section 2).

A1.2 THERMISATION USING A SIMPLE PLATE HEAT EXCHANGER

This is an example of continuous thermisation using a simple plate heat exchanger for the production of hard cheese in a one person operation.

The equipment is largely manual in operation and has an automatic divert valve, automatic temperature control and continuous temperature recording. Product testing is completed on all batches post thermisation.

Thermisation is continuous in operation but the downstream operation is batch wise. This is essential for final product testing and traceability.

A1.2.1 Procedures, documentation and records

Personnel:

- The operator has demonstrated to NZFSA/TPA assessors, competency in thermiser maintenance and operation.
- The operator is present during the operation of the thermiser at all times. The operation is shut down when the operator is not present.
- Calibrations and checks of temperature, flow and valve response time are undertaken 3 monthly (or more often if required) by the operator. If a contractor is used, they are always under the supervision of the operator.

Documentation:

- Plans and equipment manufacturers' instruction manuals are provided.
- Procedures for operation, maintenance, corrective action, documentation and recording are detailed based on the operational criteria provided below.

Records:

- Records are kept on a floppy disk or in the daily log and are securely stored and available for audit.
- Copies of reports to TPA/NZFSA and validation, evaluation and verification reports and any follow up actions, are stored with the operational records.

A1.2.2 Equipment

A1.2.2.1 *Equipment and operation description*

1. The heat treatment operates for 400 hours/year (150 batches of 5000 litres plus CIP)
2. Milk is held at 7°C in the bulk milk tank and flows by gravity to the balance tank.
3. The divert valve is located at the highest point of the process, above the balance tank overflow to prevent forward siphoning.
4. There is a single, one-speed pump (1450rpm and impellor size of 150mm diameter) between balance tank and the preheating section of the plate heat exchanger. The safe maximum flowrate for the pasteuriser is set from the maximum flowrate measured by the validator and reported in the validation report.
5. The plate heat exchanger has:
 - a. design capacity of 2500 litres/hour;
 - b. thick plates (≥ 0.8 mm) with spare plates on hand. Thick plates are used to minimise the risk of cracks penetrating the full depth of the plate;
 - c. 3 sections (preheating section, regeneration section and final heating section) all with single plates;
 - d. with the exception of the divert valve, manual operation of valves and pumps;
 - e. automatic divert valve with open discharge;
 - f. manual temperature control;
 - g. data-logger for temperature recording and audible alarm when divert operated;
 - h. digital (not glass and mercury) thermometer with accuracy $\pm 0.3^\circ\text{C}$ for monitoring;

- i. 20 second holding section between the final heating section and the divert valve, (based on the maximum flowrate, turbulent flow in the holding tube and a maximum velocity of 1.33 times the average velocity as specified in D121.1);
 - j. demonstration that diversion occurs before the 64.5°C minimum thermisation temperature is reached; and
 - k. demonstration that the divert valve operates within four seconds of a low temperature being logged on the data logger.
6. The heat treated milk flows straight from the regeneration section of the plate heat exchanger into the cheese vat

Note that in thermisation, phosphatase testing is not suitable as a means of verifying successful heat treatment.

A1.2.2.2. Equipment criteria

1. Equipment sanitation:
 - the equipment is properly designed and constructed with no dead ends;
 - product contact surfaces (piping and heat exchanger plates and valves) are constructed of stainless steel 304 or equivalent. All other items, e.g. rubber ware, are of food grade; and
 - CIP flow is at least 1 m/s
2. Particle size:
 - The particle size is controlled by a milk filter between the milk pump and the bulk milk tank; the filter has pore size of 200 µm.
3. Heating temperature of the milk and holding time:
 - the digital monitoring thermometer, accuracy $\pm 0.3^{\circ}\text{C}$, is fitted into the holding tube adjacent to the data logger temperature probe;
 - data logger probe, accuracy $\pm 0.5^{\circ}\text{C}$, with 1 s sampling intervals is fitted 16 seconds after the start of the holding section, i.e. four seconds from the divert valve;
 - automatic divert valve is set at 65°C (this allows for 0.5°C accuracy if reading high);
 - the divert valve has a sealing surface which prevents leakage of 'raw milk' forward while the valve is in the diverted position, and the milk has not reached pasteurisation temperature;
 - pump and holding tube capacity is fixed. The pump is fitted with the nominated impeller size for testing;
 - data logger fitted with second pen to record the full divert flow position of the valve.
 - this equipment satisfies the requirements for demonstrating that diversion occurs before the 64.5°C minimum thermisation temperature is reached.
4. Protection from contamination:
 - thickness of the plates;
 - operator training;
 - service liquids are approved food grade chemicals;
 - only recognised sanitisers and CIP liquids used
 - no cross connections between raw and heat treated products; and
 - operational criteria (see below).
5. Maintaining wholesomeness
 - the temperature of the heat treated milk is set at 29°C, by regulating the amount of hot water in the preheating section.
6. Ease of access
 - all equipment can be easily reached, without ladder/scaffolding and readily checked and inspected.

A1.2.3 Operation

1. Equipment cleaning and sanitation

Operating/maintenance criteria:

- flush with water;
- CIP 3% alkaline (non chlorinated caustic) solution at 75°C for 30 minutes;
- flush with water;
- sanitise thermiser by heating to 75°C with water (note: halides such as chlorine and iodine can cause corrosion of stainless steel);
- rinse with water;
- every 2 weeks in addition to the alkaline CIP, run another CIP 2% acid solution at 65 to 70°C for 30 minutes as recommended by chemical manufacturers; and.
- plate heat exchanger is left full of water, to avoid corrosion caused by the plant drying out.

Monitoring criteria:

- visually check plate heat exchanger plates and balance of plant for cleanliness. At commissioning check daily for the first week of operation, then weekly for the balance of the first month of operation and then monthly thereafter; and
- monitor final product results, as microbiological results may indicate poor CIP.

Corrective action criteria

- Check CIP is occurring as per operating criteria specified. If nothing found contact chemical supply company for help.

Documentation and records criteria:

- Record date and time of CIP, concentration and temperatures of the CIP solutions;
- Record activation of the divert valve during CIP; (note: operating the datalogger during CIP provides a record of the time, temperature and operation of the divert valve during the CIP);
- Record date and location of visual inspection and findings; and
- Record corrective action.
- If there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

2. Particle size

Operating/maintenance criteria:

- The disposable milk filter is inspected prior to CIP and replaced with a new one prior to the next run.

Monitoring criteria:

- After milk is pumped into the bulk milk tank, inspect the used filter for integrity (holes and disintegration) and unusual deposits.

Corrective action criteria:

- if the particle size is exceeded as evidenced by the failure of the filter, the product goes on hold and is subject to NZFSA decision based on MAF Standard D108, *Non-conforming Dairy Produce*.

Documentation and records criteria:

- retain purchase and receipt documentation/packaging for filters to demonstrate that the correct filter and pore size were used;
- record inspection completed in log book; and
- record any problems.
- If there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

3. Heating temperature and holding time

Operating/maintenance criteria:

- All milk is heated to >66.5°C and passed through the holding section of the plate heat exchanger. (Operating temperature is set well above alarm temperature, to allow for variations caused by manual control).
- the person controlling the thermiser

- is present at all times
- monitors the temperature and controls the heating to the set point to avoid triggering the divert valve and alarm.
- the flush water at the start and end of a run is heat treated to the thermising temperature.
- Note the data logger and the alarm are part of the same equipment. The alarm does not have a switch that can silence the alarm when on product..

Monitoring criteria:

- As the system is a manual operation, monitoring is inherent in the control.
- Checks:
 - Data logger is recording properly at the beginning of the operation;
 - Daily read the data logger to confirm all milk reached the minimum heat treatment temperature;
 - Daily collect data from recorder, and clear memory or reset the data logger;
 - Daily compare the digital check thermometer with the recorded temperature;
 - Daily check alarm against the monitoring thermometer at end of run on water flush;
 - On commissioning and following a significant change to the equipment complete a conductivity test to demonstrate the fastest moving particle is heat treated for at least the minimum holding time;
 - Daily the flowrate is calculated by dividing the litres of milk treated by the total thermisation time;
 - Monthly the flowrate is measured with a 10 litre bucket and a stopwatch; and
 - Monthly the divert valve is fully diverted in less than four seconds.

Corrective action criteria:

- when the alarms sounds, the divert valve switches and milk flows back to the balance tank for retreatment;
- all diverted milk is retreated at the correct temperature and holding time;
- where cheese is made from milk that has not reached the required temperature and/or not held for the correct holding time, the cheese is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*;
- the monitoring thermometer and data logger sensor are recalibrated if the variance is more than 0.5°C;
- the alarm is part of the data logger and does not need a separate calibration; and
- where the divert valve diversion time is greater than four seconds, there is a risk of under-temperature milk feeding forward before the valve closes. The batches of cheese produced from the affected milk is treated as if the milk did not reach the required temperature as discussed above.

Documentation and records criteria:

- record the temperatures of the indicating thermometer and the data logger and the difference between them;
- download data logger onto floppy disk;
- record alarm check;
- record any calibrations;
- record the operating hours, milk volume and calculated flow rate;
- record the divert valve diversion time;
- record where milk under treated, quarantining of cheese and outcome; and
- if there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

4. Protection from contamination

Operation/maintenance criteria:

- to allow for heat up during start-up, the divert valve is in the divert position for at least 30 s after reaching 65°C before the valve switches to full forward flow,
- the divert valve is operated to avoid water hammer;
- eliminate water hammer, hydraulic shock, pressure fluctuations, etc which "work/flex" the plate heat exchanger plates causing premature cracking or failure and also dislodgement of

the seals and gaskets, e.g. starting the pump with an empty raw milk balance tank, as the sudden start in flow when water enters the tank will cause work flexing. Instead partially fill the balance tank before starting the pump;

- do not use halides (chlorine, iodophor/iodine) or at least do not let them evaporate to dryness in the equipment as they promote stress-corrosion cracking in stainless steel including 316L SS;
- after the annual strip down of the plate heat exchanger the plates are reinstalled in the correct order. To achieve this a diagonal line is marked along the side of the plate pack before dismantling and checked on reassembly for integrity, and
- when assembling the plate heat exchanger follow the manufacturer's instructions. Don't over-tighten, overload, overheat, over pressurise, "over-anything" the plates.

Monitoring criteria:

- weekly coliform tests are completed on the heat treated milk to detect contamination through pinholes in the plates or other pasteuriser failures. Samples are taken at the discharge of the thermiser into the vat, at the end of the run.
- monthly check divert valve is not leaking produce forward when in the diverted position;
- annually perform a crack test and visually inspect the plates and gaskets. Check for leaks by doing:
 - visual inspections of the plate surfaces for corrosion and defects using competent people, bright lights and positive controls;
 - dye penetration tests using a recognised standard and competent people. Allow plenty of time for the penetrants to work through. Use developers and positive controls;
 - in-situ electrolytic, or helium gas, sonic, or combinations of these types of tests. These tests test the plate packs in-situ without dismantling them. (Dismantling can damage plates, seals and/or gaskets. Reassembling can result in plates being in the wrong order). This type of test is not truly preventative as it only finds cracks which have already developed and may not find the smallest of cracks, whereas properly done visual checking is truly preventive. The in-situ tests may be preventative if they are sensitive enough to find cracks smaller than those which permit a bacterium or virus to pass through the crack.

Corrective action criteria

- Where coliforms are detected, the plate heat exchanger is tested for cracks and the damaged plates are replaced. Where cheese is made from milk treated in the previous week, the cheese is quarantined and managed as non-conforming produce.
- Replace divert valve seals where they are found to be defective.
- Where cheese is made from milk that has been contaminated, the cheese is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*;
- As a consequence of the annual crack test and inspection, cracked/damaged plates and gaskets are replaced.
- Note: have replacement plates immediately available for all types of plates. Use only pre-checked plate heat exchanger plates as some new plates have been found to already have cracks in them.

Documentation and records criteria:

- results of coliform tests and where contamination is found, record corrective action and quarantining of cheese and outcome;
- records of monthly divert valve leakage test;
- record crack test and inspection and the plates and gaskets replaced;
- record where milk contaminated, quarantining of cheese and outcome;
- records of purchase of chemicals for service water treatment; and
- if there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

5. Maintaining wholesomeness

Refer to the *Interim Code of Practice for the Development of a Food Safety Programme or Product Safety Programme for Specialist Cheeses* (Specialist Cheese CoP) which is available from the NZFSA website (www.nzfsa.govt.nz).

If there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, Non-conforming Dairy Produce.

A1.2.4 Reporting to NZFSA Compliance/TPA

Note: This section can be different if NZFSA Compliance is prescribed by a Food Safety Programme

The operator includes in the monthly report to NZFSA Compliance/TPA the following information for each heat treatment:

In the “Status - PSP components” section:

- Number of validations completed in the last period. For each validation, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- Number of evaluations completed in the last period. For each evaluation, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- The date of the last (external) verification, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- The anniversary of the last (external) verification.

In the “Trends” section:

- The results of microbiological/other testing used to demonstrate the effectiveness of the heat treatment and the protection of the heat treated produce from contamination.

In the “Proposed Changes” section:

- Any significant changes to the heat treatment during the last period; and
- Any planned or proposed significant changes and the date of the change.

A1.2.5 Validation

Validation is undertaken by the operator, contracting in specialist expertise as required to meet the competency requirements of validators.

A1.2.6 Evaluation

If the thermiser is new, relocated or significantly changed the TPA/NZFSA Compliance are notified and an external assessment by the heat treatment evaluator is completed to confirm that the heat treatment is compliant with NZFSA Standard D121 *Dairy Heat Treatments*.

A1.2.7 Verification

The next assessments are done as part of the annual PSP verification audit as follows:

Year 1: Heat treatment verifier
Year 2: Heat treatment verifier
Year 3: PSP verifier*
Year 4: Heat treatment verifier
Year 5: PSP verifier*
Year 6: Heat treatment verifier

Subsequent years repeat starting at year 3.

*Where this verification indicates there are problems or significant changes, then that verification is completed by a heat treatment verifier.

Increased verification is possible at any time through failure to meet any of the requirements for the verification category. Reduced assessment is possible after Year 4.

A1.3 BATCH PASTEURISATION

This is an example of pasteurising using a batch pasteuriser for the production of soft cheese in a one-person operation.

A1.3.1 Procedures, documentation and records

Personnel:

- The operator has demonstrated to NZFSA/TPA assessors, competency in pasteuriser maintenance, operation and calibration of thermometers.
- The operator is present during the operation of the pasteuriser at all times. The operation is shut down when the operator is not present.
- Calibrations and checks of temperature are undertaken 3 monthly (or more often if required) by the operator. If a contractor is used, they are always under the supervision of the operator.

Documentation:

- Plans and equipment manufacturers' instruction manuals are provided with the heat treatment plan.
- Procedures for operation, maintenance, corrective action, documentation and recording are detailed in the heat treatment plan based on the operational criteria provided below.

Records:

- Records are kept on a floppy disk or in the daily log and securely stored and available for audit.
- Copies of reports to TPA/NZFSA and validation, evaluation and verification reports and any follow up actions, are stored with the operational records.

A1.3.2 Equipment

A1.3.2.1 *Equipment and operation description*

1. The batch pasteuriser has:
 - a. double skinned stainless steel vat, fully jacketed for hot/cold water circulation;
 - b. cooling water supply totally disconnected from the jacket during heating and holding.
 - c. an insulated, self draining, close fitting lid with a thermometer pocket with a mercury thermometer that cannot touch the milk (With mercury thermometers there is always a danger of breakage and spillage of mercury. With a thermometer pocket there will be a thermal lag in the reading which will affect the accuracy of the reading. The pocket is removable for testing);
 - d. a digital thermometer with long stainless steel stem to reach the milk through opening in lid and supported from side of vat;
 - e. a motorised stirrer which operates during heating and cooling, providing thorough mixing;
 - f. capacity of 200 litres; and
 - g. separate raw milk inlet and treated milk outlet lines without cross connections. The inlet line is self draining into the vat and disconnected during heating, holding and cooling.
 - h. the inlet and outlet valves are close coupled and designed to stop leakage across the valve seat when in the closed position.
 - i. cheese-making is in a separate vat. (Note: although this solution has a separate cheese-making vat, cheese-making may be undertaken in the vat used for heat treatment.)

A1.3.2.2. *Equipment criteria*

1. Equipment sanitation:
 - all stainless steel with coved and sloping bottom; and
 - properly designed and constructed; no dead ends.

2. Particle size
 - particle size is controlled by a milk filter between the milk pump and the bulk milk tank; the filter has pore size 200 µm.
3. Heating temperature of the milk and holding time
 - digital thermometer for the milk with accuracy $\pm 0.3^{\circ}\text{C}$
 - final heating temperature is 64°C
 - holding time is 31 minutes
 - mercury thermometer with accuracy $\pm 0.2^{\circ}\text{C}$ to measure airspace temperature
4. Protection from contamination
 - lid on vat;
 - the agitator is fitted in such a way as to avoid contamination, and is filled with food grade oil; and
 - contamination is avoided by working hygienically as described in the Specialist Cheese CoP.
5. Maintaining wholesomeness
 - the heat treated milk is cooled to 29°C within 30 minutes
6. Ease of access
 - All equipment can be reached, without ladder/scaffolding and piping readily removed for inspection.

A1.3.3 Operation

1. Equipment sanitation

Operating/maintenance criteria:

- daily rinse with water;
- daily scrub vat, lid, stirrer and thermometer stem using 3% alkaline solution at 75°C ;
- daily rinse with water; and
- every 2 weeks following alkaline wash, use 2% acid solution at 65 to 70°C as recommended by the chemical manufacturers.

Monitoring criteria:

- visually check vat for cleanliness; and
- monitor final product results, microbiological results may indicate poor cleaning

Corrective action criteria

- where visual check finds soil, the wash is repeated; and
- check cleaning is occurring as per the operating criteria specified. If nothing found contact chemical supply company for help.

Documentation and records criteria:

- record date and time of cleaning;
- record date and location of visual inspection and findings; and
- record corrective action.
- if there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

2. Particle size

Operating/maintenance criteria:

- The disposable milk filter is inspected prior to cleaning and replaced with a new one prior to the next run.

Monitoring criteria:

- After milk is pumped into the bulk milk tank, inspect the used filter for integrity (holes and disintegration) and for unusual deposits.

Corrective action criteria:

- if the particle size is exceeded as evidenced by the failure of the filter, the product goes on hold and is subject to NZFSA decision based on the Specialist Cheese CoP.

Documentation and records criteria:

- retain purchase and receipt documentation/packaging for filters to demonstrate that the correct filter and pore size were used;
- record inspection completed in logbook
- record any problems
- if there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

3. Heating temperature and holding time

Operating/maintenance criteria:

- as soon as the headspace reaches 67°C, stop hot water;
- wait 31 minutes, monitoring the milk and headspace temperature;
- then run cold water through jacket to cool the milk to 29°C within 30 minutes.

Monitoring criteria:

Operation

- monitor milk temperature with digital thermometer;
- monitor headspace temperature with mercury thermometer; and
- record final milk and headspace temperature.

Checks

- on a daily basis compare the digital thermometer with the mercury thermometer at the start of the holding time; and
- on a daily basis record the temperature of the digital thermometer and the mercury thermometer at the final heat temperature and the difference between them.

Corrective action criteria:

- if the difference between the digital thermometer and mercury thermometer is more than 0.5°C then the digital thermometer is recalibrated.

Documentation and records criteria:

- record milk temperature (digital thermometer) per batch;
- record headspace temperature (mercury thermometer) per batch;
- record the time the holding period commences;
- record the time the holding period ends;
- record calibration check; and
- record any recalibrations.
- if there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

4. Protection from contamination

Operation/maintenance criteria

- keep lid on vat until setting temperature is reached; and
- contamination is avoided by working hygienically as described in the Specialist Cheese CoP.

Monitoring criteria

- pathogen testing results not to exceed limits prescribed in the Specialist Cheese CoP.

Corrective action criteria

- product treated as prescribed in the Specialist Cheese CoP;
- pathogen testing increased as prescribed in the Specialist Cheese CoP; and

- identify problem and resolve

Documentation and records criteria:

- results of pathogen tests; and
- records of purchase of chemicals for service water treatment;
- where contamination is found, record corrective action and quarantining of cheese.
- if there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

5. Maintaining wholesomeness

Operation/maintenance criteria:

- during cooling of the milk from 64°C, starter is added as soon as milk temperature reaches 36°C; and
- the milk is discharged to the cheese vat when it reaches 29°C.

Monitoring criteria:

- as prescribed in the Specialist Cheese CoP

Corrective action criteria:

- As prescribed in the Specialist Cheese CoP

Documentation and records criteria:

- As prescribed in the Specialist Cheese CoP.

A1.3.4 Reporting to NZFSA Compliance/TPA

Note: This section can be different if compliance is prescribed by a Food Safety Programme

Operator includes in the monthly report to NZFSA Compliance/TPA the following information for each heat treatment:

In the “Status - PSP components” section:

- Number of validations completed in the last period. For each validation, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- Number of evaluations completed in the last period. For each evaluation, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- The date of the last (external) verification, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- The anniversary of the last (external) verification.

In the “Trends” section:

- The results of microbiological/other testing used to demonstrate the effectiveness of the heat treatment and the protection of the heat treated produce from contamination.

In the “Proposed Changes” section:

- Any significant changes to the heat treatment during the last period; and
- Any planned or proposed significant changes and the date of the change.

A1.3.5 Validation

Validation is undertaken by the operator, contracting in specialist expertise as required to meet the competency requirements of validators.

A1.3.6 Evaluation

If the pasteuriser is new, relocated or significantly changed the TPA/NZFSA Compliance are notified and an external assessment by the heat treatment evaluator is completed to confirm that the heat treatment is compliant with NZFSA Standard D121 *Dairy Heat Treatments*.

A1.3.7 Verification

The next assessments are done as part of the annual PSP verification audit as follows:

- Year 1: Heat treatment verifier
- Year 2: Heat treatment verifier
- Year 3: PSP verifier*
- Year 4: Heat treatment verifier
- Year 5: PSP verifier*
- Year 6: Heat treatment verifier

Subsequent years repeat starting at year 3.

*Where this verification indicates there are problems or significant changes, then that verification is completed by a heat treatment verifier.

Increased (six monthly) verification is possible at any time through failure to meet any of the requirements for the verification category. Reduced assessment is possible after Year 4.

A1.4 STOVETOP PASTEURISATION

This is an example for pasteurising using a stainless steel saucepan on a stove for the production of fresh cheese in a one person operation.

A1.4.1 Procedures, documentation and records

Personnel:

- The operator has demonstrated to NZFSA/TPA assessors, competency in pasteuriser maintenance, operation and calibration of thermometers.
- The operator is present during the operation of the heat treatment at all times. The operation is shut down when the operator is not present.
- Calibrations and checks of temperature are undertaken 3 monthly (or more often if required) by the operator. If a contractor is used, they are always under the supervision of the operator.

Documentation:

- Plans and equipment manufacturers' instruction manuals are provided with the heat treatment plan.
- Procedures for operation, maintenance, corrective action, documentation and recording are detailed in the heat treatment plan based on the operational criteria provided below.

Records:

- Records are kept in the daily log, securely stored and available for audit.
- Copies of reports to TPA/NZFSA and validation, evaluation and verification reports and any follow up actions, are stored with the operational records.

A1.4.2 Equipment

A1.4.2.1 *Equipment description*

1. The saucepan has:
 - a 10 litre capacity with rounded corners and a lid;
 - stainless steel stem of digital thermometer is used to measure the temperature and stir the milk; and
 - digital thermometer can be held in place by the weight of the lid.
2. The cheese is also made in the saucepan.

A1.4.2.2. *Equipment criteria*

1. Equipment sanitation:
 - all stainless steel with coved bottom on saucepan;
 - all stainless steel utensils and stirrers;
 - properly designed and constructed; and
 - premises suitably equipped to prevent the entry of pests and pathogens, including airborne contaminants.
2. Particle size:
 - particle size is controlled pouring milk into the saucepan through a filter with 200µm pore size.
3. Heating temperature and holding time:
 - digital thermometer to measure both the temperature of the milk and the airspace with accuracy $\pm 0.3^{\circ}\text{C}$;
 - hot milk stays in saucepan;
 - final heating temperature is 75°C ; and
 - holding time is 20 s.

- mercury thermometer with accuracy $\pm 0.2^{\circ}\text{C}$ for calibrating the digital thermometer.
4. Protection from contamination:
 - lid on saucepan
 5. Maintaining wholesomeness:
 - the heat treated milk is cooled to 29°C within 15 minutes by submersing the bottom half of the saucepan in a bath of cool potable water
 6. Ease of access
 - All equipment can be reached easily for inspection.

A1.4.1 Operation

1. Equipment sanitation

Operating/maintenance criteria:

- rinse with water;
- scrub saucepan, lid, and thermometer stem using dishwashing detergent at 75°C ;
- rinse with water;
- visually check saucepan for cleanliness; and
- sterilise by boiling saucepan.

Monitoring criteria:

- visually check saucepan for cleanliness.

Corrective action criteria

- where visual check finds soil, the wash is repeated.

Documentation and records criteria:

- record date and time of cleaning;
- record visual inspection findings; and
- record corrective actions
- if there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

2. Particle size

Operating/maintenance criteria:

- the filter is replaced daily.

Monitoring criteria:

- after milk poured into saucepan, inspect the used filter for integrity and overloading.

Corrective action criteria:

- if for some reason the particle size is exceeded, replace filter and refilter produce.

Documentation and records criteria:

- retain purchase and receipt documentation/packaging for filters to demonstrate that the correct filter and pore size were used;
- record inspection completed; and
- record the loss of control of particle size and corrective action taken.
- if there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

3. Heating temperature and holding time

Operating/maintenance criteria:

- as soon as the headspace reaches 75°C, switch off stove; and
- wait 20 s; and
- then put saucepan in sink with cold water.

Monitoring criteria:

Operation

- monitor milk temperature and headspace with digital thermometer.

Checks

- on a weekly basis compare the digital thermometer with a mercury thermometer.

Corrective action criteria:

- if the difference between digital thermometer and mercury thermometer is more than 0.5°C then the digital thermometer is recalibrated.

Documentation and records criteria:

- record milk temperature per batch;
- record headspace temperature per batch;
- record the time the holding period commences;
- record the time the holding period ends;
- record calibration check; and
- record any recalibrations.
- if there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

4. Protection from contamination

Operation/maintenance criteria

- keep lid on saucepan until setting temperature is reached while occasionally stirring;
- make sure cooling water does not splash; and
- contamination is avoided by working hygienically as described in the Specialist Cheese CoP.

Monitoring criteria

- pathogen testing results not to exceed limits prescribed in the Specialist Cheese CoP.

Corrective action criteria

- product treated as prescribed in the Specialist Cheese CoP;
- pathogen testing increased as prescribed in the Specialist Cheese CoP; and
- identify problem and resolve.

Documentation and records criteria:

- results of pathogen tests; and
- where contamination is found, record corrective action and quarantining of cheese
- if there are no records, the product is quarantined and managed as non-conforming produce as per MAF Standard D108, *Non-conforming Dairy Produce*.

5. Maintaining wholesomeness

Operation/maintenance criteria:

- during cooling of the milk from 73°C, starter is added as soon as milk temperature reaches 36°C

Monitoring criteria:

- As prescribed in the Specialist Cheese CoP.

Corrective action criteria:

- As prescribed in the Specialist Cheese CoP.

Documentation and records criteria:

- As prescribed in the Specialist Cheese CoP.

A1.4.4 Reporting to NZFSA Compliance/TPA

Note: This section can be different if compliance is prescribed by Food Safety Programme.

Operator includes in the monthly report to NZFSA Compliance/TPA the following information for each heat treatment:

In the “Status - PSP components” section:

- Number of validations completed in the last period. For each validation, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- Number of evaluations completed in the last period. For each evaluation, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- The date of the last (external) verification, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- The anniversary of the last (external) verification.

In the “Trends” section:

- The results of microbiological/other testing used to demonstrate the effectiveness of the heat treatment and the protection of the heat treated produce from contamination.

In the “Proposed Changes” section:

- Any significant changes to the heat treatment during the last period; and
- Any planned or proposed significant changes and the date of the change.

A1.4.5 Validation

Validation is undertaken by the operator, contracting in specialist expertise as required to meet the competency requirements of validators.

A1.4.6 Evaluation

If the pasteuriser is new, relocated or significantly changed the TPA/NZFSA Compliance are notified and an external assessment by the PSP evaluator is completed to confirm that the heat treatment is compliant with NZFSA Standard D121 *Dairy Heat Treatments*.

Examples for when TPA/NZFSA Compliance should be notified may include one or more of the following:

- change to the vessel or lid
- change of thermometer
- change of timing device
- change to any agitation devices used

A1.4.7 Verification

The next assessments are done as part of the annual PSP verification audit by the PSP verifier. Increased (six monthly) verification is possible at any time through failure to meet any of the requirements for the verification category.

Appendix Two Heat Treatment Equipment Checklist

Outcome	Solution	
Equipment sanitation	<ol style="list-style-type: none"> 1. Cleaning using appropriate - <ul style="list-style-type: none"> • Chemicals & concentration • Turbulence or scouring • Temperature 2. Appropriate means of control of cleaning process that establishes the above are achieved and repeatable. 3. Appropriate inspection regime for residual product and cleanliness. 	
Particle size	<ol style="list-style-type: none"> 1. Means of determining largest particle size. 2. Sufficient heating to ensure the largest particle is UHT treated / pasteurised / thermised 	
Heating temperature & holding time	<ol style="list-style-type: none"> 1. Accurate representative temperature and time. 2. Means of monitoring temperature and calculation of the temperature measuring system that ensures the inaccuracies do not compromise heat treatment temperature. 3. A means of determining that every particle has been held for the heat treatment temperature, e.g. Flow measurement and/or control for continuous systems, time measurement in batch system. 	
Protection from contamination	<ol style="list-style-type: none"> 1. Contamination can be caused by cooling media or regeneration if heat exchangers are used. For regenerative heat exchangers, a pressure differential is maintained to ensure all leaks flow towards the unpasteurised produce or services. This can be achieved by system geometry or components. 2. Contamination can be caused by a systems failure. A means to ensure that in the event of a systems (plant or operational) failure the produce is diverted and put aside for further treatment. After such an event, the plant will need to be brought back into control. 3. Contamination can be caused by the divert valve leaking. The divert valve is regularly checked for leakage into the forward flow line, while the valve is in the diverted position. 4. Contamination can be caused by raw milk siphoning from the raw milk silo into the pasteurised milk silo. Prevention can be achieved by system geometry or components. 	
Maintaining wholesomeness	To determine a suitable storage temperature, consideration needs to be given to the time the treated produce will be stored before further processing.	
Ease of access	<p>Consideration needs to be given to whether:</p> <ul style="list-style-type: none"> • critical parts of the heat treatment equipment, e.g. the divert valves, the temperature probes, timing pumps and computer programme, can be accessed to enable assessment. • the heat treatment is in a fully operational state, e.g. dairy produce, electricity, steam, compressed air etc. are available. • the dairy produce for which the heat treatment is required to be validated is available. 	