Significant Change to Dairy Heat Treatment Equipment and Systems

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1 Background

Requirements for the assessment of dairy heat treatment equipment and systems have been reviewed because of several key drivers:

The move of the dairy sector to coverage by the Animal Products Act 1999 which has made some terminology in the Approved Criteria and associated guidance material obsolete.

The requirements were not clear or easy to comply with.

The requirements are not consistent with the way that heat treatment equipment and systems are assessed in other food sectors.

The working group has tried to develop a framework that is simple and more consistent with other sectors.

The working group also felt that it was important to be clear on what constitutes a significant change to heat treatment equipment and systems. A significant change is a trigger for a variety of actions which will potentially incur cost and/or resource hence the need for clarity.

This document is an attempt to provide guidance for risk management programme operators, recognised agencies and other affected parties.

2 Explanation of a Heat Treatment Significant Change

A significant change to a heat treatment is a:

- Change to a heat treatment critical control point critical limit that may adversely affect its value, measurement, accuracy, calibration, reliability or ability to be checked (e.g. change to the divert temperature set point, holding time, filter mesh type and size etc).
- Mechanical, process and instrumentation changes to the heat treatment equipment that will alter the heat treatment applied to the Product in an adverse manner. E.g. Plant breakdown repair causing a change to processing conditions, instrumentation failure, process control system modification/improvement etc.
- Change to a corrective action system that may adversely affect its operation, reliability, ability to be checked (e.g. temperature divert, flow divert, differential pressure divert, etc).

- Change to a supporting system that may affect a critical control point critical limit or a corrective action system (computers/software, operator training, etc).
- Changes to the scope of the products being heat treated as listed in the registered risk management programme (e.g. addition of a new product, changes to product specifications of an existing product, changes to % fat, % total solids etc).

Ultimately, the Risk Management Programme (RMP) operator is responsible for determining if a change is significant or not. The Heat Treatment Guideline requires that a HACCP review be carried out for each significant change.

All significant changes must be validated by the operator. The Heat Treatment Evaluator evaluates the significant change before it is implemented.

3 Examples of Significant vs. Non-Significant Changes

	Area of Change	**Change**	**Significant when:**	**Non-Significant when:**
1	Premises.	Relocating heat treatment that has previously been evaluated/verified.	Does not use the same facilities, services and connections to the upstream and downstream processes, CIP or control systems – services and interconnections to the existing process may not be adequate or safe.	Moved within the same area and uses the same facilities, services and connections to the upstream and downstream processes, CIP and control systems – services and interconnections to the existing process are known to be adequate and safe.
2	Premises.	Re-installing an existing heat treatment back into a rebuilt premises. Note: If plant has been mothballed then there is a need to consider sanitary implications prior to start-up.	The project has included changes to the process, pipework, services, as well as to the building - the upstream and downstream processes, interconnections services, and the environment, may have adversely changed.	The project has not included changes to the process and the services (unlikely) - the upstream and downstream processes, interconnections, services, and the environment have not adversely changed.

	Area of Change	Change	Significant when:	Non-Significant when:
3	Equipment.	Replacing a complete plate heat exchanger, replacing a complete plate pack section, or replacing/reconfiguring individual plates.	Different make, model or specification from the old equipment – may have inadequate leak paths in the plates, inadequate section separators. Single skin plate on plate heat exchanger where pressure control is by engineering design - may make chilled water pressure higher than product pressure.	Identically the same as the old equipment – design and construction known to be safe. Plate heat exchanger with air gap plates or pressure differential control with recycle on loss of differential - if the configuration and / or recycle set point has not changed then the pressure differential control will be maintained.
4	Equipment.	New holding time section, changes to length of holding section or repairs/reconfiguration to an existing holding section. Note that a repair may not be significant.	Always – may not have enough holding time, may not have divert probes in the correct position, may not have holding time measurement sections in the correct places, may have air pockets, etc.	Always a Significant Change.
5	Maintenance/ breakdown equipment replacements associated with flow rate control.	Mechanical and electrical replacements/work affecting product flow rate through the holding tubes. 1. Product pump. 2. Repairs/modifications to a positive timing pump which will impact on the holding time, eg replacing impellor, replacing speed control, reconfiguring pump motor frequency range, altering homogeniser pressure settings etc.	Where the heat treatment step is a fixed flow rate pasteuriser, e.g. a positive displacement pump (e.g. homogeniser) controls the flowrate. There is no flow control of a control valve or VSD raw milk pump via a flow meter.	Where there is a flow diversion system controlled by a flow meter.

	Area of Change	Change	Significant when:	Non-Significant when:
6	Control and data logging systems/ automation/ software logic.	1. New software / PLC / data logging facility. 2. Modifications to the control system. 3. Logic changes to an existing control system. 4. New data logger/chart recorder.	New or modified software logic – *may not function correctly or food safety criteria may be missing.* Data logging / trend may not reproduce an accurate or full record of the heat treatment.	Always a significant change.
7	Control systems/ automation.	New control systems or automation.	Uses new software – may not function correctly.	Always a significant change Must ensure that software is installed correctly and operating properly.
8	Process changes.	Examples: 1. Increasing and decreasing the divert / maximum flow rate. 2. Decreasing the divert temperature to less than the nominated temperature in the heat treatment plan.	Always – *may result in insufficient holding time.*	Always a significant change.
9	Product specifications where product density and viscosity impact on heat treatment. This is one area that can be easily overlooked.	1. New product/ingredients with different composition 2. Existing product specification changes. e.g. altering % fat, % total solids, addition of ingredients / particle size etc.	Falls into a new category in Table A4.3 in DPC3 the manufacturing approved criteria- *requires a new holding time and temperature combination.*	Always a significant change. This is a change to the scope of the Heat Treatment Plan, and needs to be evaluated before the new product/product specification change is manufactured.

4 Serious Non-compliance Examples

The following are examples of when a RMP Operator is not following their registered RMP and should be reporting the following examples to the recognised agency.

	Area of Change	Change	Serious when:	Not Serious when:
1	New Personnel.	New operator / supervisor. Changing a heat treatment training course provider. Note: In theory, the operator operates the plant before he is 'deemed' to be competent by the operators formal training system. The training system would have been assessed as part of evaluation and verification. This becomes a non-compliance during evaluation of the risk management programme.	Staff not trained in heat treatment and no heat treatment trained supervisor.	Staff are trained in heat treatment, or under training and supervision by a competent person.
2	The loss of key personnel / change of personnel.	A change in either personnel (operator or supervisor) or the formal training system.	1. Not being able to replace the knowledge and experience of personnel who leave and who are a critical component / support for training operators / supervisors. 2. Changing the formal training system e.g. changing / removing external heat treatment training provider.	Because operator / supervisor knowledge and experience criteria is relatively new to the Industry, it is recommended that changes to the formal training system and critical personnel be assessed by the Heat Treatment Evaluator before deciding if there needs to be any action taken.

3	Maintenance / breakdown equipment replacements. E.g. straight out replacement of equipment or equipment component.	Mechanical and electrical replacements where processing conditions remain the same. Examples: 1. Divert valve and valve components such as valve seals. 2. Temperature sensors. 3. Pump seal.	Different make, model or specification from the replaced equipment - may not have a fast enough response time.	Identical - the same as the old equipment / part change control and calibration records are available.
4	Facilities / services.	Changing the freezing point depressant chemical in the chilling water. Any change that results in a cooling media pressure change, e.g. increase in cooling water flow rate. Impacts on back pressure.	Single skin plate heat exchanger where pressure control is by engineering design. Not NZFSA approved for this application - may be toxic.	NZFSA approved – known to be non-toxic for this application. Plate heat exchanger with air gap plates or pressure differential control with recycle on loss of differential - if the configuration and / or recycle set point has not changed then the pressure differential control will be maintained.

5 Notification to the Recognised Agency

The company is required to notify its allocated recognised risk management programme verifier in writing of a significant amendment to its risk management programme. A significant change to a heat treatment system may be a significant amendment to its risk management programme, but not always.

All proposed changes to a heat treatment critical control point must be notified in writing to the recognised agency.

The company is not required to notify NZFSA.

Non-significant changes shall be recorded by the operator, and should be advised to the recognised agency at time of the change and made available for verification.

6 When is Heat Treatment Evaluation Required?

The company shall notify the recognised agency in writing of a significant change to a heat treatment before the change is made.

The operator shall notify the recognised agency of a proposed change to the heat treatment if it is not absolutely clear whether the proposed change is significant or not.

The Heat Treatment Evaluator can decide if the proposed change is significant.

If the Heat Treatment Evaluator decides that the proposed change is not significant then they may log the notification and take no further regulatory action. The company may request the recognised agency to perform further work for its own commercial purposes.

Note that a verification visit may be a condition of RMP registration and that this visit has to occur within a specified timeframe.

7 Actions Taken by the Heat Treatment Evaluator for a Significant Change

The Heat Treatment Evaluator will decide what actions they and the operator will take depending on the impact (food safety, regulatory, market access, certification) of the proposed change, and on the Heat Treatment Evaluator's assessment of the operators ability to successfully make the change based on previous experience, competency, compliance and history of previous changes.

The Heat Treatment Evaluator shall carry out a desktop and possibly an on-site evaluation of the proposed change. The evaluation will include the assessment of the validation report, and whether the validator meets competency requirements. This assessment could include desktop and/or on-site evaluation of any relevant drawings, specifications, software, equipment, the revised HTP, documented procedures, records, and personnel. Some physical checking and testing may also take place if there is some doubt about the work of the validator.

The Heat Treatment Evaluator shall evaluate the proposed change and advise the operator whether the proposed change is acceptable or unacceptable and give details of any non-compliances.

The Heat Treatment Evaluator may subsequently confirm on site, both during the course of the change and at its completion, that the change has been carried out correctly by the operator and any contractors used in construction. This may include visits to contractors' premises.

The validation, evaluation and verification activities may take place concurrently and sequentially.

8 Records

The RMP operator and the recognised agency shall keep auditable records of a significant change to a heat treatment system that show the scope, validation, evaluation, verification, non-compliance corrective action, and the recognised agency acceptance of the significant change.

Any justification for decisions made must be included in the evaluation report.

A summary form should be used to track the progress of a change. Diary notes and emails could be used as a record for minor changes.