

Code of Practice on HTST Pasteurisation

May 2006

Dairy UK Code of Practice on HTST Pasteurisation

1. Introduction

This Code of Practice is intended to assist those responsible for pasteurising milk or dairy products by the High Temperature Short Time (HTST) method to apply best practice and ensure that adequate controls and monitoring procedures are implemented. This updates the previous code in two main aspects. Firstly to take into account the requirements in the new hygiene package (see section 2), and in particular that EC Regulation 852/2004 requires that operators should apply the principles of HACCP (hazard analysis and critical control points) to ensure the safety of their products. Secondly to apply the findings of research sponsored by the dairy industry (1) into the effects of processing conditions on the destruction of MAP (*Mycobacterium paratuberculosis*).

From a public health view-point pasteurisation is a critical control point in ensuring the safety of milk and dairy products. The intention of this Code is to assist operators in ensuring that their products have been correctly pasteurised and post-pasteurisation contamination has been avoided. This Code applies to conventional HTST pasteurisation, not to high-temperature pasteurisation or ultra-high treatment (UHT) where different considerations apply.

The contents of this Code of Practice can be considered as pre-requisites for the application of HACCP to HTST pasteurisation.

2. The Hygiene Regulations effective from 1.1. 2006

The main hygiene regulations effective from 1.1.2006 relevant to pasteurisation are the following:

Regulation 852/2004 on the hygiene of foodstuffs (2)

Regulation 853/2004 laying down the specific hygiene rules for foods of animal origin (3)

Regulation 2074/2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 (4)

Regulation 2073/2005 on microbiological criteria for foodstuffs (5)

3. Principles of HACCP

EC Regulation 852/2004, which came into effect on 1st January 2006, requires the following:

Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the following HACCP principles:

- (a) identifying all hazards;*
- (b) identifying critical control points;*
- (c) establishing critical limits at critical control points;*
- (d) establishing and implementing effective monitoring procedures at critical control points;*
- (e) establishing corrective actions when monitoring indicates that a critical control point is not under control;*
- (f) establishing procedures to verify that the above measures are working effectively; and*
- (g) establishing documents and records commensurate with the nature and size of the food business.*

To apply HACCP a flow diagram should be drawn up which includes all key steps of the process. The hazards at each step on the flow diagram should be identified and analysed so that the operator can be certain that appropriate control measures have been put in place for them. These control measures, together with critical limits and monitoring procedures, should be documented for possible inspection by food law enforcement officers. All changes to the process and the introduction of new products necessitate a review of the HACCP plan.

Further details of the HACCP process are available from Codex Alimentarius (6) and from Campden & Chorleywood Research Association (7).

4. Definition of Pasteurisation

4.1 Pasteurisation Time – Temperature

Pasteurisation has been defined in Regulation 2074/2005 as a treatment involving:

- (i) a high temperature for a short time (at least 72°C for 15 seconds);
- (ii) a low temperature for a long time (at least 63°C for 30 minutes); or
- (iii) any other combination of time-temperature conditions to obtain an equivalent effect, such that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment.

4.2 Phosphatase

The enzyme alkaline phosphatase is naturally present in all raw milk and is destroyed by pasteurisation under the correct time/temperature conditions (72.0°C for 15 seconds). The legal requirement is “a negative reaction to an alkaline phosphatase test “ immediately after heat-treatment.

A “negative reaction to an alkaline phosphatase test” refers to a result of less than 4µg/l using the current statutory test method (91/180/EC) – this equates to 500 mU/L using a fluorimetric method. A change to the reference method using more sensitive fluorometric or chemoluminescence methods is currently under consideration. It is recommended that where rapid methods are used the baseline for each plant is established and any deviation investigated immediately. This baseline will normally be significantly lower than 350 mU/L.

5. Equipment Requirements

5.1 Equipment Requirements of EC Regulation 852/2004

Regulation 852/2004 does not lay down detailed HTST equipment requirements specific to the dairy industry. Instead the general principles for heat treatment of all food products are stated as follows:

1. any heat treatment process must:
 - (a) raise every part of the product treated to a given temperature for a given period of time; and
 - (b) prevent the product from becoming contaminated during the process;
2. food business operators must check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), and the use of automatic devices;
3. the process used should conform to an internationally recognised standard (here, pasteurisation).

5.2. Equipment Requirements of Directive 92/46/EEC

Directive 92/46/EEC(8), revoked on 1st January 2006, laid down certain equipment requirements for the safe operation of the HTST plant. Although these requirements are not specifically identified in the new hygiene package, they nevertheless constitute good practice and are detailed below:

- i) An automatic temperature control*
- ii) A recording thermometer*
- iii) An automatic safety device preventing insufficient heating*
- iv) An adequate safety system preventing the mixture of heat-treated drinking milk with milk which has not been fully heat-treated; and*
- v) An automatic recording device which records the operation of the safety system referred to in iv) above or a procedure for monitoring the system's effectiveness.*

6. Good Manufacturing Practice or Pre-requisites for HACCP

In order to apply HACCP correctly, it is necessary that certain conditions are satisfied. These can be described as part of Good Manufacturing Practice or pre-requisites for HACCP. Examples of these are given below:

6.1 Constructional Safeguards

- i) Before and during installation of any new plant or modification of an existing one a commissioning process should take place to ensure that design parameters have been met. A formal HACCP plan is essential; section 2 provides an introduction to this process.
- ii) Although the minimum legally required holding time at 72.0°C is 15 seconds, it is recommended that a holding time of 25 seconds is used for drinking milk since there is experimental evidence that this increases the effectiveness of the destruction of *Mycobacterium paratuberculosis* (MAP) under certain conditions.
- iii) Plant for pasteurisation must include a means of controlling the product flow rate to ensure that the minimum specified holding time is maintained at all times. Means of controlling flow rates include positive displacement pumps or flow controllers. Homogenisers must not be used as flow controllers since flow rates will increase when the homogeniser is not being used. Verification of flow rate should be carried out on a regular basis.
- iv) All possible ways of contaminating heat-treated product by raw milk must be eliminated. Any pipe-work connections which link product and raw milk, including those nominally there only for cleaning/CIP purposes, might cause such contamination if not designed with specific safeguards to prevent it.
- v) The safety of the process depends on the performance of the automatic safety device (divert system). The recorder must indicate whether a divert event has occurred and whether the plant is running in automatic or manual modes. Consideration needs to be given to the time the system needs to react when the divert point is reached.
- vi) Consideration should be given to the design and set up of equipment to ensure that the pressure of pasteurised product is greater than that of the heating/cooling mediums within the plate pack. This will help to provide an additional safeguard against leakage due to damaged heat exchanger plates. It is not however an absolute safeguard nor is it suitable for all products. For example, the properties of whipping cream would almost certainly be adversely affected by this procedure.
- vii) Consideration must be given to filtration of dairy products somewhere within the process of transfer from road tanker to sale container. If separation or clarification is included in the process, this acts as a filter. If not, a suitable filter must be incorporated, preferably prior to heat treatment. Cloth "bag" filters are commonly used.
- viii) Ancillary processing equipment (e.g. separators) must be placed before the holding section of the pasteuriser.

6.2 Operational Safeguards

- i) Each HTST plant on site should have a plateage diagram and checks must be made that the plates have been assembled in the correct order. This must be checked again each time the plant is re-gasketed.
- ii) Plate packs must not be over tightened since this can lead to plate-to-plate contact and plate damage.

- iii) Since opening plate packs can cause damage plate packs should not be opened unnecessarily. Use of the correct seals and gasket materials is critical.
- iv) Leakage of raw milk to pasteurised milk/dairy product or cooling water to pasteurised milk/dairy product can occur unless the plant has correctly designed pressure balances built into its design.
- v) Up-to-date pipeline diagrams should be available on site for all processing operations.
- vi) Plates should be examined visually for evidence of corrosion and pinholes, and the rubbers checked whenever the plant is opened. Tests of pack integrity must be carried out at least annually. A variety of methods for pin-hole testing exist including gas, pressure, and conductivity. The plant supplier can advise. Plates should be designed to encourage turbulent flow through the pasteuriser to discourage the deposition of milk components.
- vii) Pipes, tanks and floats should be examined for cracks at intervals laid down in the preventative maintenance schedule. These intervals will depend on the type of plant, product and usage rate.
- viii) All pipe-line systems need to be free from “dead legs”.
- ix) Precautions need to be taken to prevent raw milk gaining access to processed milk through C.I.P systems valves. Separate C.I.P systems for raw and pasteurised milk are recommended.
- x) Divert valves need to be inspected and maintained at intervals laid down in the preventative maintenance schedule. Checks on the operation of the divert valve should include a visual inspection of the valve as it operates.
- xi) Records of all checks and maintenance carried out should be documented for verification and auditing purposes.

6.3 HTST Plant Operation

- i) Calibrated thermometers must be fitted to the plant for indicating heating and cooling of product, and the calibration checked regularly.
- ii) The divert should be set to a minimum of 72.0°C plus the inaccuracy tolerance of the divert thermometer e.g. if +/- 0.5°C this would = 72.5°C minimum.
- iii) The thermograph should be regularly checked against an independent indicating thermometer. If the thermograph reads higher than the indicating thermometer by more than the built in tolerance(+0.5°C in this example), then the divert should be increased to that difference e.g. thermograph 72.5°C , indicator 71.5°C, difference 1°C, reset divert tolerance to 72.0 +1.0= 73.0°C minimum.
- iv) The operation of the automatic safety device must be checked at least daily immediately prior to starting production and a record kept. When an automatic diversion valve is activated the temperature of its operation should be checked both when the device is activated and at the return to normal forward flow.
- v) The holding time must be checked at least annually and after changes to the plant. The holding time must be checked for each new product where the flow characteristics are different to previous products.
- vi) A daily check should be carried out to ensure that any device for maintaining product flow at the required value is in place.
- vii) On conventional charts all pens, including the “events” pen need to be working and records need to be kept for at least six months

viii) Temperature charts should be examined daily at start-up to ensure that plants are never being run in manual mode. Manual mode is generally the cleaning/CIP setting.

6.4 Start-up procedures

Most dairy plants are designed to start up on water and once at operating temperatures milk is introduced. Procedures need to be in place to ensure that the interface between milk and water does not present a food quality or food safety hazard.

The first milk through the plant and fillers should not be despatched without positive laboratory clearance.

6.5 Procedures following a plant diversion

The first milk through the plant when forward flow is resumed should not be despatched without positive laboratory clearance.

6.6 Laboratory checks

The following checks can verify satisfactory operation of the pasteuriser:

6.6.1 Phosphatase

It is recommended that milk is not despatched from the processing dairy without positive laboratory clearance. As well as testing packed product consideration should be given to testing at the cooler exit and finished milk holding tank. Phosphatase tests should also be carried out on a positive release basis on milk leaving a pasteuriser immediately after returning to forward flow following diversion.

Dairy UK guidance on temperature resistant phosphatase is available separately (9).

6.6.2 Microbiological standards

Enterobacteriaceae are bacteria destroyed by pasteurisation, and their presence in pasteurised milk indicates a breakdown in the pasteurisation process, contamination of the product after pasteurisation, cracked plates or poor pasteuriser cleaning. To verify the correct operation of HACCP for pasteurised milk Regulation 2073/2005 replaces the previous coliform requirements by Enterobacteriaceae requirements.

As well as testing packed product consideration should be given, for trouble shooting purposes, to testing at the cooler exit and finished milk holding tank.

Also the sensitivity of both Enterobacteriaceae and coliform testing can be improved by pre-incubating samples.

6.7 Pasteurisation Time – Temperature

Although 72°C for 15 seconds or equivalent is the legal minimum for pasteurisation for drinking milk it is recommended that at least 72.0°C for 25 seconds is used as a precaution against MAP. Products with higher fat or solids content, for instance cream, are generally heated to higher temperatures, typically to around 75°C for 15 seconds. Further information on time/temperature combinations used in practice is given in DIF Guidelines for Good Hygienic Practice in the Manufacture of Dairy-Based Products (10).

6.8 HTST Plant Cleaning

Cleaning in Place (CIP) is recommended for HTST processing plant. The critical elements are detergent strength, temperature, flow rate, and circulation time.

The appropriate conditions for efficient cleaning need to be established, preferably with the detergent supplier, then properly controlled and monitored. A minimum sequence would typically be

- Pre-rinse with cold or warm water until visible product residue at the plant exit is clear.
- Form a CIP circuit from the plant outlet into the top of a feed balance tank, add detergent recommended for HTST plants to produce the appropriate concentration and apply heat to bring the temperature up to the minimum required at the return. Circulate for as long as trials have shown is needed to ensure all product residues have been removed.
- Rinse with cold water after each cleaning step (caustic, alkali) until visible detergent residues are undetectable at the exit.
- Shortly before use, circulate water raising the temperature to at least 80°C at the return for at least ten minutes. Ensure all parts of the product route achieve at least 80°C. Cool to normal operating temperatures before introducing milk or product. It should be noted that higher flow rates from those used in production runs may be required to get effective cleaning and it is necessary to ensure that any such modifications for cleaning (e.g. removal of the flow controller) are restored hygienically in normal operation.

6.9 Operator Training

It is a legal requirement that operators are given instruction and training with regard to hygiene. In particular:

- i) It is essential that all operators of pasteurisers are trained in the operation of the plant, and have a basic understanding of the principles of pasteurisation. External courses are available if necessary.
- ii) Operator competence must be assessed periodically and retraining carried out as necessary.

Written operating instructions must be in place. These must be based on the site HACCP and must include details of the critical control points and associated monitoring.

7. Industry Sponsored Research into the Most Effective Processing Conditions for the Destruction of MAP

The UK dairy industry (Dairy UK and the Milk Development Council) have jointly sponsored research into the most effective processing conditions for the destruction of MAP (*Mycobacterium paratuberculosis*) (3). This research, using raw milk spiked with high levels of MAP and an HTST pilot plant, has demonstrated that HTST pasteurisation (at the then legal standard of 71.7°C for 15 seconds) results in at least a 4 log reduction (i.e. 10,000 –fold reduction) of MAP. Very occasionally survivors occur, but it has been found that the incidence of survivors can be reduced if pasteurisation is carried out in combination with other processes such as homogenisation or centrifugation, or if homogenisation is carried out at pasteurisation temperature. The latter could result in product defects, but much pasteurised milk produced on commercial plant is homogenised or centrifuged or both. The research also indicated that an extending holding time of 25 seconds conferred additional reduction of MAP when combined with homogenisation or centrifugation.

8. Health and Safety

When considering the installation of any new plant or modification of an existing one, consideration should also be given to health and safety implications including the requirements of the Provision and Use of Work Equipment Regulations 1998.

9. Further Reading

Additional information on HTST pasteurisation is to be found in the “Pasteurising Plant Manual”, published by The Society of Dairy Technology (11); “Notes for guidance on high temperature short time (HTST) milk pasteurising plants”, published by the Scottish Office Agriculture and Fisheries Department (12) and from BSI (13).

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