Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Further Processing: Chapter 3 Good Operating Practice

Part 1 Heat Treatment

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Title

Guidance Document: Further Processing: Chapter 3 Good Operating Practice, Part 1 Heat Treatment

About this document

This Guidance document applies to the heat treatment of non-dairy animal products, but has been more specifically written for the processing of meat (including poultry), and seafood. Other non-dairy animal product processors e.g. processors of eggs and egg products, may find the guide useful during development and validation of RMPs involving heat treatment operations.

Related Requirements

- Animal Products Regulations 2000
- Animal Products (Risk Management Programme Specifications) Notice 2008
- Animal Products (Requirements for Risk Management Programme Outlines) 2008
- Animal Products Notice: Specifications for Products Intended for Human Consumption

Document history

Previous Version	Current Version	Section Changed	Change(s) Description
July 2009	July 2017	New section	New section to be added to Part 3 GOP of the Further Processing COP.

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1 Purpose

This Part provides guidance for the heat treatment of animal products (such as meat, poultry, and seafood) to achieve either:

- the inactivation of microbiological hazards (cooking/pasteurisation). In this Part, this will be referred to as pasteurisation; or
- a non-lethal (technological) effect (e.g. partially cooked).

The focus is on the control of microbiological hazards and more particularly foodborne bacterial pathogens. When developing and validating heat treatment processes, operators should also consider the impact on spoilage organisms and other risk factors such as chemical hazards. Operators should also consider all other hurdles that may contribute to the preservation of the product e.g. chilling, water activity (a_w), pH or the use of preservatives.

The heat treatment methods used may include dry heat (e.g. oven roasting, broiling, grilling or hot smoking[1]), and hot liquid or steam heat (e.g. stewing, braising, simmering or sous vide). Heat may be applied in a continuous or batch wise manner, although continuous pasteurisers (e.g. heat treatments applied using heat exchangers) are not considered here. The principles given apply to the heat treatment of all animal products, however, the default parameters in most cases are more specific to red meat and poultry products.

This Part does not apply to shelf stable commercially sterilised products, such as canned or aseptically processed and packaged products. Guidance on commercial sterilisation of canned products can be found in the Further Processing Code of Practice Part 3: Good Operating Practice, Section 2.

2 Background

The Further Processing Guidance document has been developed over a number of years by MPI to assist secondary processors producing products for human consumption, to meet the requirements of the Animal Products Act 1999 (APA). It applies to processors of non-dairy animal products, but has been more specifically written for the processing of meat and seafood. The Guidance document has been developed based on New Zealand regulatory requirements and does not address overseas market access requirements. Exporters must ensure that they meet the overseas market access requirements relevant to their product and intended market. The Guidance document is divided into three chapters:

Chapter 1 (replacing Further Processing Code of Practice Part 1) gives an overview of the Guidance document and the requirements of the APA. It explains the options available to operators for the development of RMPs, and provides guidance on the contents of RMPs. This Chapter also provides web links to other relevant documents published by MPI that may be useful for operators during the development and operation of their RMPs.

Chapter 2 (replacing Further Processing Code of Practice Part 2) provides a summary of the legislation under the APA that is directly relevant to each processing operation addressed in Chapter 3.

Chapter 3 (replacing Further Processing Code of Practice Part 3) provides guidance on the good operating practices that are relevant to selected processing operations. This Chapter sets out the factors that should be

[1] The process of smoking is covered in section 5 of the FP COP Part 3. This section addresses the heating component of hot smoking.

considered when developing and validating these types of processes. This Chapter will continue to be expanded as new sections are developed. This document is Part 1 only of Chapter 3.

Status of Guidance document

This Guidance document contains:

- references to regulatory requirements;
- procedures to assist with compliance; and
- guidance material (shown in boxes).

Processors must comply with the regulatory requirements and should comply with the procedures for compliance unless their alternative practices have been documented within and form part of the registered RMP.

The guidance material in boxes is given to further assist with understanding and applying MPI's expectations.

3 Definitions

Critical Control Point (CCP) is a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit is a criterion which separates acceptability from unacceptability at a critical control point (CCP).

Decimal reduction time (*D* value) is the time taken (in minutes) for a specific microorganism at a specified temperature and in a specified substrate to undergo a 90% or one log reduction of its population.

Dry bulb temperature is the temperature of the air when measured with a clean dry temperature sensor.

FSC is the Food Standards Code

HC Spec is the Animal Products Notice: Specifications for Products Intended for Human Consumption

Heat treatment (in this Part) is the application of heat to a food, which includes pasteurisation and non-lethal heat treatments.

Lethality is the accumulation of lethal rates during a heat treatment which can be expressed as the pasteurisation value (P value) in minutes.

Lethal rate is the value at a specific temperature, which equates to the equivalent heating at the reference temperature, using a specific z value.

Non-lethal heat treatment is the application of a heat treatment to achieve a technological effect in a product, but is not intended as a pasteurisation step (e.g. partially cooked products).

Operator-defined limit is a measurable limit established by the operator to manage the fitness for intended purpose of a product and is not defined in legislation. Operator-defined limits may be taken from sources such as reputable guidance documents, peer-reviewed scientific information, predictive models, from a competent person or organisation, or developed from trials and experiments.

Pasteurisation is any process, treatment or combination thereof, applied to product to reduce the most resistant microorganism(s) or public health significance to a level that is not likely to present a public health risk under normal conditions of distribution and storage (NACMCF, 2006). **Pasteurise** has a corresponding meaning.

Pasteurisation value (P value) is the length of time at a given temperature required to achieve a specified level of destruction of a microorganism whose heat resistance characteristics are known. The heat resistance of a microorganism is characterised by D and z values.

P value can be expressed as $\mathrm{P}_{\mathrm{r}}^{z}$ = process time.

Where z is the z value for the target microorganism and r is the reference temperature (degrees Celsius) at which the equivalent lethality has been calculated. P value should be written with the r and z values otherwise it is meaningless.

For example a standard process for *Listeria monocytogenes* would be: $\mathrm{P}_{70}^{6.25}$ = 2.4 minutes.

Pathogen is a microorganism including bacteria, parasites, viruses, moulds which causes illness. Examples include *Salmonella* spp., *E. coli* O157:H7, *Campylobacter jejuni, Listeria monocytogenes, Staphylococcus aureus,* non-proteolytic *Clostridium botulinum, Clostridium perfringens, Bacillus cereus*, norovirus and hepatitis A virus.

Reference temperature is the selected temperature at which all cumulative lethality data is related to. 70°C, 85°C, 90°C are common pasteurisation temperatures that are used as reference temperatures.

Regulatory limit is a measurable regulatory requirement that is critical to the fitness for intended purpose of a particular product. Regulatory limits are stated in legislation, for example the Food Standards Code or the Animal Products Notice: Specifications for Products Intended for Human Consumption.

Relative humidity of the air is a measure of the amount of moisture in the air compared to the amount of moisture in saturated air at the same dry bulb temperature.

RMP Spec is the Animal Products (Risk Management Programme Specifications) Notice 2008

Shelf life is the period of time, established under intended conditions of distribution, storage, retail and use, that the product would remain fit for its intended purpose.

Spoilage organisms are microorganisms which cause deterioration of a product making it unsuitable for its intended purpose, and may limit its shelf life for example by producing objectionable flavours, odours and slime.

Suitably skilled person is a person, who in the opinion of the operator, is skilled in a particular activity or task through training, experience, or qualifications.

Technological effect means a heat treatment that:

a) is applied to achieve a quality, chemical, physical or some other effect; and
b) is not intended to pasteurise the product.

Validation is a process of obtaining evidence to demonstrate that a particular product will be fit for its intended purpose, through the achievement of any regulatory or operator-defined limits.

Water activity (a_w) is a measure of the water available for microbial growth. It is the ratio of the water vapour pressure of the food (p) to that of pure water (p_o) at the same temperature: $aw = p/p_o$.

Wet bulb temperature is the temperature measured by fitting a wet, moisture wick cloth over an ordinary dry bulb sensor and placing it in the oven air stream. Wet bulb temperature can be controlled by changing fresh air and exhaust dampers or injecting controlled amounts of steam or atomised water into the oven.

z value is the number of degrees Celsius required for the thermal destruction curve to transverse one log cycle (i.e. to give a 10 fold increase or decrease in D value).

4 Heat Treatment Procedures

4.1 General requirements

(1) The operator must document and meet any regulatory limits for the product [RMP Spec 7 & 11].

(2) The operator must establish, document and meet operator-defined limits that are appropriate for the product and have evidence to justify their selection [RMP Spec 7 & 11].

(3) The operator should demonstrate that the process is capable of consistently achieving the regulatory and/or operator-defined limits.

(4) Processes (including any trials and experimentation) should be developed and validated[2] by suitably skilled people, and revalidated if there is a change that would impact on food safety. The requirements of HC Spec 5.3 must be met by people involved in key tasks.

Additional Information - Suitably skilled people

It is important that suitably skilled people who develop and validate heat treatment processes have a good working knowledge of factors critical to heat treatments, and wherever possible, 'hands-on' experience with the equipment types and processes being developed. It is recommended that suitably skilled people have knowledge of:

a) heat treatment equipment installation and commissioning;
b) pathogens of concern;
c) product and packaging characteristics;
d) validation techniques (e.g. temperature distribution studies, heat penetration tests, cooling trials, equipment commissioning and shelf life studies);
e) D and z values and appropriate levels of pathogen inactivation;
f) process calculations and analysis of validation data; and
g) identifying and assessing process deviations.

It is the operator's responsibility to ensure that people with the appropriate knowledge and skills are used.

(5) A report and all records of the validation work should be documented by the suitably skilled person.

(6) Any validation report and associated records must be kept by the operator. This includes the documentation recommended in Part 4.4.3 of the Risk Management Programme Manual [RMP Spec 18].

(7) A suitably skilled person should review the process or product whenever there is a change that could impact on food safety and revalidate where necessary.

(8) Calibrated equipment with sufficient accuracy should be used during the validation work and calibration records kept [HC Spec Part 6].

(9) Equipment and process lines should be assessed at least annually, or at a frequency based on performance and revalidation considered if any changes have been made to the design, installation or operation of equipment and process lines that would impact on food safety. The frequency of the assessments should be documented in the RMP.

[2] For more general information about how to validate a process, refer to the Risk Management Programme Manual.

4.2 Non-lethal heat treatments

Additional Information

Non-lethal heat treatments are generally applied to achieve a certain technological effect in the product and are not intended as a preservation step. It is important that the steps are well understood and controlled.

Examples of heat treatment steps that are applied to achieve a technological effect are:

- to support certain microbiological or chemical reactions (e.g. fermentation, enzyme hydrolysis);
- to inhibit some chemical reactions (e.g. inhibition of certain enzyme reactions);
- to enhance physical, sensory or palatability characteristics of the product (e.g. application of grill marks, browning by flash frying);
- to ease handling of the product or the addition/mixing of ingredients (e.g. pumping and mixing of viscous materials, dissolving certain powders in liquid, melting of fats).

(1) Parameters and conditions for non-lethal heat treatments should be established by suitably skilled people, considering the following:

a) the potential for pathogen growth and/or toxin formation to unacceptable levels in the product during the come up time, heat treatment and subsequent cooling and on equipment surfaces;
b) the potential for exposure of micro-organisms to sub lethal temperatures for a period of time leading to thermal conditioning, which may then increase their heat resistance to any subsequent pasteurisation or reheating steps (Seafood NIC, 2006).

4.3 Pasteurisation

Additional Information

The level of microbial inactivation achieved by pasteurisation will depend on the times and temperatures applied to the product. The point in the process flow at which the pasteurisation occurs will often impact on the validation needed, and whether post-heat treatment contamination needs to be considered. In general, products are can be pasteurised after the product has been filled into packaging (e.g. luncheon rolls), or hot or cold filled into packaging after pasteurisation (e.g. sauces, soups, ready meals).

A pasteurisation step is likely to be a CCP in the HACCP plan.

4.3.1 Outcome of Pasteurisation

(1) Pasteurisation must ensure the inactivation of the pathogens of concern, which were identified by applying the principles of HACCP. The process should be sufficient (either alone or in combination with other hurdles) to ensure the product is fit for its intended purpose, method of storage and shelf life. The pathogens may include:

a) bacteria (e.g. *Salmonella* spp., *E. coli* O157:H7, *Campylobacter jejuni*, *Listeria monocytogenes*, *Staphylococcus aureus*, non-proteolytic *Clostridium botulinum*, *Clostridium perfringens*, *Bacillus cereus*);
b) viruses (e.g. Norovirus or Hepatitis A); and
c) parasites (e.g. *Toxoplasma gondii*, *Trichinella spiralis*).

Additional Information

The Hazard database and model HACCP plans can be used to assist with hazard identification and analysis.

4.3.2 Development of pasteurisation processes

(1) Pasteurisation processes should be developed and validated for each product, group of products or product that represents the worst case, considering all relevant factors as identified by the suitably skilled person.

(2) When deciding on the pasteurisation parameters, the operator should consider the:

a) pathogens of concern as identified during the application of HACCP principles;
b) initial pathogen concentration in the raw materials and other inputs;
c) spoilage organisms and their initial concentrations;
d) potential microbiological growth before pasteurisation, including any product hold steps;
e) D and z value(s) of the most heat resistant target pathogen(s) in the product;
f) pathogen concentration in the final product (regulatory and/or operator-defined limits);
g) level of inactivation or decimal reduction for the target pathogen(s) to be achieved by the process;
h) intended purpose and consumer of the product; and
i) pasteurisation method.

Additional Information

See Section 4.3.4 for examples of default pasteurisation parameters for red meat and poultry products.

Once the operator has selected the pasteurisation parameters to apply, evidence needs to be generated that will demonstrate that all products within and across batches will meet these parameters.

4.3.3 Pasteurisation Validation

(1) The operator should validate pasteurisation processes and provide evidence that:

a) the chosen pasteurisation parameters are appropriate for the particular product; and
b) when applied, will deliver safe product; and
c) all products will receive the validated pasteurisation process.

(2) Trials should be conducted to validate process parameters taken from any of the following:

a) calculations;
b) data from similar processes;
c) reference material;
d) predictive modelling programmes.

Additional Information

Validation may simply involve repetitively collecting evidence to demonstrate that the selected pasteurisation times and temperatures are met, for example by:

- measuring the temperature at the centre of the largest product(s), located at the slowest heating point and other locations in the equipment, for the duration of the process; or
- measuring the product temperature while it is cooked (e.g. jacketed pan) at the point that is likely to be the coolest, for the duration of the process.

Alternatively validation may involve developing appropriate time and temperature parameters for the product and then collecting evidence to demonstrate that these parameters are met.

Validation activities could include:

- temperature distribution studies of the heating equipment;

- confirmation that the pasteurisation parameters are met in the product;
- product testing (e.g. microbiological testing) to confirm that any regulatory or operator-defined limits are met; and
- shelf life trials.

These are discussed in the following sections.

4.3.3.1 Temperature Distribution Studies in Pasteurisation Equipment

Additional Information

When developing a pasteurisation process, it is important to know that the equipment will deliver the required process to all product. Temperature distribution studies look at the range of temperatures throughout a piece of equipment (such as ovens) during processing. They are designed to determine if there is even temperature distribution.

The equipment set up, product, packaging and packing configurations can all impact on temperature distribution. Each type or group of products may have a different temperature distribution and cool spot in the equipment. Studies should be completed for each configuration, or significantly different mass of products.

By determining the temperature distribution throughout the equipment, processes can be developed taking this into account. Temperature distribution data can also be used to modify the equipment set-up if necessary i.e. to minimise temperature variation.

Where possible, the temperature of products placed at the worst case locations (e.g. cold spots) are monitored during routine processing. However, it is noted that for many types of equipment the "cool spot" is not readily accessible for routine monitoring. In these circumstances the offset between the cool spot temperature and the temperature at the location that is accessible for routine monitoring, once validated, can be built into the process. For example, a process that is required to reach 75°C at the cool spot may need to have a measurable temperature of 77°C at the accessible monitoring point.

(1) Temperature distribution studies should be conducted where there is potential for uneven temperature distribution within the equipment that could impact on food safety.

Additional Information

Sometimes temperature distribution studies are not appropriate or necessary. Examples of these are:

- if the equipment design and use ensures that the heat will always be evenly distributed (e.g. pasteurisation in a small agitated steam jacketed pan with good product mixing). The temperature at the coldest point would still need to be monitored;
- the operator has evidence that the process has a large safety margin (e.g. the product is cooked for much longer and/or at higher temperatures than is necessary for food safety);
- the equipment has been installed by the manufacturer and/or in accordance with the manufacturer's instructions and the manufacturer has validated the equipment and provided detailed evidence to the operator.

(2) Where temperature distribution studies are carried out:

a) the location in the equipment that would deliver the lowest pathogen inactivation should be identified. This is usually the coldest spot(s), but would need to be confirmed.
b) factors critical to achieving even temperature distribution in the heating equipment should be identified in the RMP and managed.

c) if the temperature variation in the equipment could impact on the reliability and safety of the process, this variation should be minimised before further validation is carried out.

(3) Temperature distribution studies should be:

a) conducted under the most demanding normal operating conditions (e.g. tight loading configurations, equipment operating at full capacity);
b) repeated if there are changes to the equipment design, installation, operation (e.g. after certain maintenance or repairs), or product arrangement that would impact on heat distribution and transfer;
c) repeated at least every 3 years to check if the results remain valid if no other changes have been made.

4.3.3.2 Achieving Pasteurisation in the Product

Additional Information

Heat penetration tests record the temperature of the product throughout a pasteurisation process to determine whether the required time and temperature parameters are met.

(1) When validating a pasteurisation process, the operator should ensure that those critical product and process factors that could impact heat transfer (to and within the product) are taken into account. These could include:

a) the product, for example:

i) formulation and composition;
ii) any additional preservation factors or inhibitors e.g. pH, a_w;
iii) viscosity;
iv) particulates in the product that could present the highest microbial risk.

b) the preparation, forming, filling and loading, for example:

i) product weight;
ii) packaging material;
iii) product/container dimensions;
iv) lowest initial temperature of the product before pasteurisation commences (consider temperature homogeneity or presence of chilled or frozen particulates);
v) particle orientation;
vi) slowest heating point and slowest heating particulates;
vii) batch sizes, loading configuration;
viii) whether it is a batch wise or continuous process.

c) the equipment, for example:

i) temperature distribution and location in the equipment that would deliver the 'least' thermal process (e.g. cold spots), if any;
ii) maximum capacity;
iii) potential for surface fouling;
iv) equipment settings for example:

1) temperature (wet and dry bulb temperature);
2) steam pressure;
3) time to reach process temperature (come up time);
4) process time, line/belt speed;
5) relative humidity;
6) air flow rate.

(2) Trials carried out to validate a pasteurisation process should be:

a) carried out under the most demanding normal operating conditions;

b) sufficient to prove that the required time and temperature parameters are delivered to all product;
c) repeated if a change is made to the product or process that would impact on food safety;
d) repeated at least every 3 years to check if the results remain valid, if no other changes have been made.

(3) Factors critical to the pasteurisation process or product which would require revalidation if changed should be identified in the RMP and managed appropriately.

Additional Information

The suitably skilled person should have confidence that the process will be safe under worst case processing conditions. In determining the number of trials to carry out, consideration should be given to issues such as equipment performance, product homogeneity and the safety margin of the process.

It is recommended that at least 6 heat penetration data sets are gathered (Warne, 2011) and as a minimum, a well-controlled process with low variability should involve at least 2 confirmatory runs. This number should be increased in situations where there is unacceptable variation within and between runs.

4.3.4 Suggested Pasteurisation Parameters

Additional Information

When determining the most appropriate pasteurisation parameters to apply the operator could either use the default parameters given in this section or develop their own parameters. If developing custom parameters operators should use information about the heat resistance of the microbiological hazards in their product and the level of inactivation to be achieved to ensure the product is safe. In some cases, the inactivation of spoilage organisms or the chemical reactions necessary to produce the product will require higher cooking parameters than are needed for pasteurisation. In meeting these higher parameters, the pathogens will also be reduced to acceptable levels.

The use of other hurdles could also impact on the parameters needed to ensure food safety, e.g. reduced pH or a_w should be considered.

The following table summarises recommended processes to be applied to chilled products that are preserved by pasteurisation.

Table 1: Product type/target microorganism and recommended default parameters

Type of product or pathogen of concern	Recommendation
Pasteurisation of product at an internal product temperature of less than 55°C	Pasteurising at internal temperatures of less than 55°C is not recommended due for the potential for pathogen growth. The MPI report Review of Microbial Pathogen Inactivation Relevant to Sous Vide Pasteurisation at Temperatures Below 55°C (Horn, 2016) discusses this further. Heating to 55°C should occur rapidly to ensure that the growth of any pathogens that could occur in the danger zone (5°- 55°C) is minimised. The temperature should be well controlled to ensure that it does not drop below 55°C during the pasteurisation phase, for example by having a set point of greater than 55°C.

Type of product or pathogen of concern	Recommendation
Product with a chilled shelf life of less than 5 days.	A 6 $\log_{10}$ reduction in the concentration in the most heat resistant vegetative pathogen of concern, as identified through the application of HACCP principles e.g. *E. coli* O157: H7 or other STEC serotypes, or *Salmonella* spp, *L. monocytogenes*.
Chilled ready-to-eat products with a shelf life of 5 days or more.	A 6 $\log_{10}$ reduction in the concentration *L. monocytogenes*.
Vacuum packed product that may contain non-proteolytic *C. botulinum* and has a shelf life of 10 days or more.	A 6 $\log_{10}$ reduction in the concentration non-proteolytic *C. botulinum.*

Additional Information

To assist operators to develop pasteurisation parameters, MPI commissioned the report "D and z values for the heat inactivation of pathogens in raw meat". This report provides default D and z values for *L. monocytogenes, Salmonella* spp., and *E. coli* (including O157:H7) in a range of red meat and poultry products. This report does not apply to products with an Aw of less than 0.95, fat content of greater than 30% and with a pH of less than 5.

The D and z values from this report have been used to generate pasteurisation times and temperatures that can be applied to various red meat and poultry products in the following sections.

4.3.4.1 Inactivation of *L. monocytogenes* in red meat and poultry products

Additional Information

As *L. monocytogenes* is generally accepted as the most heat resistant of the non-sporing pathogens in red meat and poultry products, a process that is designed to inactivate *L. monocytogenes* is sufficient to inactivate all other non-sporing pathogens, such as *Salmonella* spp. and *E. coli.*

(1) Pasteurisation used to control pathogens in chilled ready-to-eat (RTE) products with a shelf life of 5 days or more, should achieve a 6 $\log_{10}$ reduction of *L. monocytogenes* (i.e. a 6D process for *L. monocytogenes*).

Additional Information

The time and temperature combinations in Table 2 will achieve a 6 $\log_{10}$ reduction in *L. monocytogenes* in moist[3] red meat and poultry products. The temperature is the minimum that should be achieved and maintained at the slowest heating point in the product, for the corresponding time. The temperature is not the operating temperature of the cooker.

Table 2: Default D values and times and temperatures to achieve a 6 $\log_{10}$ reduction in the concentration of *L. monocytogenes* in red meat and poultry products

Temperature (°C)	D (minutes)	Process Time (minutes) to achieve 6D
60	15.2	**91**
61	10.5	**63**
62	7.3	**43.8**
63	5.1	**30.6**
64	3.5	**21**
65	2.4	**14.4**
66	1.7	**10.2**
67	1.2	**7.2**
68	0.8	**4.8**
69	0.6	**3.6**
70	0.4	**2.4**
71	0.3	**1.8**
72-73	0.2	**1.2**
74-75	0.1	**0.6**
76 or higher	<0.04	**<0.25**

Source: Horn B. (2015) D and z values for the heat inactivation of pathogens in raw meat.

(2) Alternative pasteurisation parameters to those listed in Table 2 can be used. The operator will need to provide evidence to support this.

Additional Information

Justification for alternative parameters can include:

- the default D and z values from the MPI report for *L. monocytogenes* are too high and the operator has robust evidence of alternative parameters that better reflect their product[4];
- Evidence of higher or lower microbiological loading in the inputs such that a 6 $\log_{10}$ reduction in *L. monocytogenes* is not appropriate or necessary;
- *L. monocytogenes* is not identified as the target microorganism to be inactivated by the pasteurisation process;

[3] As the product dries the heat resistance of microorganisms increase and so these D values may no longer apply.

[4] The ideal D values will be obtained from heating the target microorganism in the product.

- Additional preservation factors (hurdles) are used to preserve the product, reducing the required log reduction needed from the pasteurisation process.

4.3.4.2 Inactivation of *Salmonella* and pathogenic *E. coli* in red meat and poultry products

Additional Information

If the operator has identified *Salmonella* spp. and/or *E. coli* as the target pathogen for the pasteurisation process, the time and temperature combinations in Table 3 will achieve a 6 $\log_{10}$ reduction in moist foods[5]. The temperature is the minimum that should be achieved and maintained at the slowest heating point in the product, for the corresponding time. The temperature is not the operating temperature of the cooker.

Table 3: Default D values and times and temperatures to achieve a 6 $\log_{10}$ reduction in concentration of *Salmonella* spp. and pathogenic *E. coli* in red meat and poultry products

***Salmonella* spp.**			***E. coli***		
Temperature (°C)	**D (minutes)**	**Process Time (minutes) to achieve 6D**	**Temperature (°C)**	**D (minutes)**	**Process Time (minutes) to achieve 6D**
60	12.2	**73.2**	**60**	6.9	**41.4**
61	8.6	**51.6**	**61**	5.0	**30.0**
62	6.1	**36.6**	**62**	3.6	**21.6**
63	4.3	**25.8**	**63**	2.6	**15.6**
64	3.0	**18.0**	**64**	1.9	**11.4**
65	2.1	**12.6**	**65**	1.3	**7.8**
66	1.5	**9.0**	**66**	1.0	**6.0**
67	1.1	**6.6**	**67**	0.7	**4.2**
68	0.8	**4.8**	**68**	0.5	**3.0**
69	0.6	**3.6**	**69**	0.4	**2.4**
70	0.4	**2.4**	**70**	0.3	**1.8**

Source: Horn B. (2015) D and z values for the heat inactivation of pathogens in raw meat.

4.3.4.3 Inactivation of non-proteolytic *C. botulinum*

(1) If non-proteolytic (cold tolerant) *C. botulinum* is identified as a hazard that is reasonably likely to occur and is to be controlled by the pasteurisation step, a heat treatment of 90°C for 10 minutes or equivalent, measured at the slowest heating point in the product, is required (D_{90}=1.7 min z value 9°C[6]). This will provide a 6 $\log_{10}$ reduction in concentration of non-proteolytic *C. botulinum* spores[7].

[5] As the product dries the heat resistance of microorganisms increase and so these D values may no longer apply.

[6] D value/z value source, D. Warne Approved Persons Course for UHT Processing and Aseptic Packaging course, June 2017.

[7] Foods that contain lysozyme (an enzyme that can stimulate spore germination) may require a longer cooking time and/or a shorter shelf life (Cox and Bauler, 2008).

Additional Information

Non-proteolytic (cold tolerant) *C. botulinum* is more likely to be a hazard of concern in chilled, vacuum packed or modified atmosphere products with a shelf life of 10 days or more. Other hurdles that can be applied to control this pathogen is:

- a pH of 5 or less;
- a salt content of 3.5% or more in the water phase throughout all parts of the product; or
- a water activity of 0.97 or less in all components of the product (Food Standards Agency, 2008).

If any of these other hurdles have been validated in the product, the target microorganism then becomes *L. monocytogenes.*

Currently, for NZ sourced ingredients and raw materials, non-proteolytic *C. botulinum* is not considered to be a hazard reasonably likely to occur, but this may not be the case for imported ingredients and raw materials. Operators need to be aware of the source of all inputs when carrying out their hazard identification and analysis and where necessary, ensure that this hazard is controlled. For more information, see section 10.2 of the MPI guide "How to Determine Shelf Life of Food".

4.3.4.4 Inactivation of Norovirus

(1) If norovirus is identified as a hazard that is reasonably likely to occur (e.g. in bivalve molluscan shellfish) and is to be controlled by the pasteurisation step, a heat treatment of 90°C for 90 seconds or equivalent is required. The temperature measured should be measured at the slowest heating point in the product and will provide a 6 $\log_{10}$ reduction in the concentration of norovirus.

4.3.5 Hot filling

Additional Information

Product may be hot filled and typically this occurs between 85-95°C to allow for the pasteurisation of container surfaces. The sealed containers are often inverted to ensure that the lids are also pasteurised. It is important the temperature is maintained for long enough that pasteurisation is achieved. Some operators pass the hot filled product through a tunnel pasteuriser pasteurise the container and headspace (See Part 6 of the Further Processing COP for guidance on acidification).

Hot filling operations are commonly used on acid products (with a pH of less than 4.6) as this inhibits the vegetative pathogens and spore formers capable of growth at that pH. The low pH would also prevent the germination of *C. botulinum* spores so that the product can be safely stored at ambient temperatures.

Hot fill products with a pH greater than 4.6 would need additional hurdles such as chilled storage and more limited shelf-life. In this case internal container surfaces are pasteurised as described and the products are rapidly cooled to ensure spore germination is minimised.

4.4 Post-Heat Treatment Handling[8]

4.4.1 General requirements

Additional Information

This section applies to product that has been non-lethally heat treated and/or pasteurised. Post-heat treatment handling includes all steps after the heat treatment, including holding, reheating, cooling and packaging, until the packaged product has reached its final preservation temperature (i.e. the storage temperature).

(1) Post-heat treatment handling should be performed in a manner that prevents recontamination and minimises pathogen growth and toxin formation in the product.

(2) Some products require ingredients or components to be added after the heat treatment. The suitably skilled person must determine if hazards could be introduced after the heat treatment and ensure that, where appropriate, they have either been controlled previously (e.g. by a supplier or an earlier processing step) or that they will be controlled by the process.

4.4.2 Hot holding

(1) If product is held hot after heat treatment, it should be held at a minimum of 60°C, measured at the coldest point in the product or batch.

(2) Alternative hot holding temperatures may be used where the operator has evidence to justify this.

4.4.3 Separation

(1) There should be adequate separation of cooked and raw product handling to prevent recontamination of cooked product.

(2) When carrying out pasteurisation and post-heat treatment operations involving exposed product, access of personnel from raw or unprocessed food areas should be controlled.

(3) People moving into the pasteurisation or post-heat treatment area should complete an appropriate hygiene routine.

(4) The requirements of Part 15 of the HC spec "Listeria requirements for processors of certain ready-to-eat animal products" apply to processors of some chilled ready-to-eat animal products with a shelf life of greater than 5 days. The operator must comply with these provisions where applicable.

4.5 Cooling

Additional Information

A valid pasteurisation process will inactivate pathogens such as *Salmonella* spp., *E. coli* O157:H7, *C. jejuni*, *L. monocytogenes, S. aureus* and vegetative cells of *Clostridia*. But slow cooling of products, particularly those with no other controls for microbial growth (e.g. a_w, pH or the use of preservatives) can present a

[8] Refer to the "Guidance for the Control of *Listeria monocytogenes* in Ready-to-eat Foods Part 2: Good Operating Practices" for detailed guidance on minimising post-heat treatment contamination. This includes the information about the design of areas used to handle exposed product after the heat treatment step, positive air pressure and managing drainage/waste water flows etc.

problem, as it may allow pathogenic bacteria, including spore formers and toxin producing species, to grow (Gaze et al, 1998).

These microorganisms may be present if:

- the heat treatment was insufficient to adequately inactivate vegetative pathogens, which may then multiply if cooling is slow or uncontrolled; or
- the heat treatment was insufficient to inactivate spores, which may then germinate and multiply if cooling is slow or uncontrolled; or
- there was post-heat treatment contamination.

As an example it is important to consider the control of *C. perfringens* in meat products and *B. cereus*[9] in battered or coated products. However, if the product pH is reduced below 4.6 these two spore-formers will not germinate and grow.

4.5.1 Outcome of Cooling

(1) Cooling processes should be managed to ensure that any remaining pathogenic spore formers will not germinate and grow to unacceptable levels (e.g. *C.* p*erfringens, B. cereus)* and in the case of non-lethally treated products, to also ensure that any vegetative cells of pathogens do not grow to unacceptable levels.

4.5.2 Development of cooling processes

(1) Unless held hot, heat treated products (including product components) should be rapidly cooled to prevent the germination of viable spores, and in the case of non-lethally heat treated foods, the growth of vegetative pathogens.

(2) Cooling processes should be developed and validated for each product, group of products, or product that represents the worst case, considering all relevant factors as identified by the suitably skilled person to ensure that the cooling parameters can be consistently achieved.

4.5.3 Cooling validation

Additional Information

Cooling parameters may be derived from any of the following:

- calculations;
- data from similar processes;
- reference material;
- predictive modelling programmes.

Validation may simply involve collecting data to demonstrate compliance with the selected cooling times and temperatures. An example of this could be measuring the temperature at the centre of the largest products, located at the warmest locations in the cooling equipment for the duration of the process, for a number of batches. Alternatively it may involve developing appropriate time and temperature parameters for cooling and then collecting data that demonstrates those parameters are being met.

Some products (e.g. frankfurters) will cool very quickly due to their size and are highly unlikely to exceed established cooling rates. In this case the operator could just place the products in a chiller or cold water bath soon after pasteurisation and arrange to ensure rapid cooling. If there is no potential for spore

[9] *B. cereus* is not covered in detail in this guidance because if *C. perfringens* is controlled so too will *B. cereus* (FSIS, 2017).

germination or toxin formation because the cooling parameters are easily achieved, validation work may be minimised or unnecessary i.e. ongoing monitoring and verification may be sufficient.

Validation activities could include:

- temperature distribution studies of the cooling equipment;
- cooling trials (confirmation that the cooling parameters are met in the product); and
- product testing (e.g. microbiological testing) to confirm that any microbiological regulatory or operator-defined limits are met.

4.5.3.1 Temperature Distribution Studies in Cooling Equipment

Additional Information

When developing cooling processes it is important to know that the equipment can consistently cool all product. Temperature distribution studies are designed to determine if there is even temperature distribution within the cooling equipment. Equipment set up, product, packaging and packing configurations can impact on the cooling rate.

By determining the temperature distribution in the equipment (e.g. presence of warmer spots), processes can be developed taking this into account. Temperature distribution data can also be used to modify the equipment set-up to minimise temperature variation.

If there is uneven temperature distribution, products placed at the worst case location(s) can then be monitored during the process.

(1) Temperature distribution studies should be conducted where there is potential for uneven temperature distribution within the equipment that could impact on food safety.

(2) If the temperature variation in the equipment is such that it could impact on the reliability of the process, work should be carried out to minimise the variation before further validation is carried out.

(3) Where necessary to ensure good temperature control, any factors critical to even temperature distribution in the cooling equipment should be identified in the RMP and managed.

(4) Temperature distribution studies should be:

a) validated under the most demanding normal operating conditions (e.g. loading configurations, equipment capacity, capacity of essential services);
b) repeated if there are changes to the equipment design, installation, operation, essential services or product arrangement, that could impact on food safety (also see (5));
c) if no changes have been made, repeated at least every 3 years to check that the results remain valid;
d) documented by a suitably skilled person.

(5) Equipment should be assessed at least annually, or at a frequency based on performance, to determine whether any changes have been made to its design, installation or operation that would impact on temperature distribution. The frequency of assessment should be documented in the RMP.

(6) If a temperature distribution study would be expected but has not been carried out, the operator should document justification for this decision.

4.5.3.2 Cooling trials

Additional Information

When determining appropriate cooling parameters, the operator could use either the default parameters given below or develop their own. Operators developing their own parameters should determine whether additional hurdles are present that could slow or inhibit the microbial growth.

Food Standards Code, Standard 3.2.2. Food Safety Practices and General Requirements (Australia Only)

7(3) A food business must, when cooling cooked potentially hazardous food, cool the food –
(a) within two hours – from 60°C to 21°C; and
(b) within a further four hours – from 21°C to 5°C.

Australian Standard (AS 4696:2007)*

Temperature	Maximum time (hours)	
	Uncured meat	Cured meat**
52° to 12°C	6	7.5
5°C	Within 24 hours of the completion of pasteurisation	

* This cooling regime does not apply to heat treated fermented meat products.

**A product is considered cured if curing salts have been added at a level which preserves the product, i.e. a minimum 2.5% salt on the water phase and 100ppm in-going nitrite.

(1) If the default cooling parameters above are not applied, evidence should be available to support the selection of the alternative parameters, and the process validated.

Additional Information

Of the 3 key pathogenic spore formers (*C. perfringens, B cereus* and *C. botulinum)*, *C. perfringens* has the shortest lag and fastest generation time. It grows most rapidly between 54°C and 26°C. Below 12°C growth is much slower, with a minimum growth temperature of 10°C (NZFSA, 2010). If an operator wants to extend beyond the default cooling parameters, slower cooling at temperatures below 12°C presents a lower risk for *C. perfringens*. Consideration would still need to be given to the ability for other pathogens to grow faster in that temperature range.

Predictive modelling programmes can be used to justify alternative cooling curves for the control of *C. perfringens*. Mohr *et al* (2015) evaluated six cooling models that predict the growth of *C. perfringens* during cooling of cooked, uncured meat and poultry products. The models were:

- Agricultural Research Service pathogen modelling programme (ARS PMP 7.0);
- PMIP (on-line ARS PMP);
- Smith-Simpson and Schaffner, version 3;
- UK IFR ComBase Perfringens Predictor;

The researchers found that except for the PMP 7.0 broth model, the other cooling models are reliable tools for evaluating cooling curves in these products.

(2) When validating a cooling process, the operator should consider all aspects that could impact on heat transfer to and within the product. These could include:

a) the product, for example:

i) formulation and composition;
ii) any additional preservation factors or inhibitors e.g. curing agents, pH, a_w;
iii) size and shape.

b) the form, filling and loading, for example:

i) product/container dimensions and/or maximum thickness;
ii) packaging material;
iii) highest initial temperature of the product before cooling commences;
iv) slowest cooling point in the product;
v) product loading;

vi) impact of adding warm product during the cooling cycle;

c) the cooling equipment, for example:

i) temperature distribution;
ii) maximum capacity;
iii) equipment settings;
iv) cooling medium.

(3) Trials carried out to validate a cooling process should be:

a) carried out under the wort case operating conditions;
b) sufficient to prove that the required cooling time and temperature parameters are delivered to all products;
c) repeated if a change is made to the product or process that could impact on food safety;
d) if no changes have been made, repeated at least every 3 years to check if the results remain valid.

(4) The operator should ensure that cooling processes for products made up of separate components that have been cooled to various temperatures, and then reduced to their final preservation temperature is developed on the basis of the worst case component.

(5) Factors critical to the cooling process and that would require revalidation if changed should be identified in the RMP and managed

(6) The cooling medium should not be a source of contamination to the product.

(7) Water or ice used for cooling should be potable, checked regularly and replaced as necessary so as to not contaminate the product.

Additional Information

Water used for cooling packaged cooked product may contain a disinfectant to control microorganisms that may grow in cooling tanks, attach to the packaging and contaminate the product when opened.

Wherever possible, hot products should be cooled to 10°C or cooler before carrying out any further handling such as removing casings, cutting, slicing, dicing, mincing, reforming and/or combining with other product components to minimise microbial contamination and growth.

4.5.4 Packaging and Labelling

(1) The type and composition of the packaging must be appropriate for the intended purpose [HC Spec Part 7].

Additional Information

Packaging that is used for a specific purpose, such as for frozen or microwave products, should be of an appropriate composition. Consideration should be given to the storage conditions and any reheating or cooking that it may be subject to.

(2) Where necessary to ensure the safety of the product, procedures should be implemented to check the packaging seal or closure integrity. This may include visual or physical testing e.g. complete seal, no cracking or wrinkling, maintenance of vacuum.

(3) Materials used for sealing product such as metal clips should be controlled to ensure that they are not a source of physical contamination to the product.

(4) Product that requires cooking by the consumer before consumption must be labelled in accordance with the requirements of the FSC, Directions for Storage and Use, standard 1.2.6.

Additional Information

The operator should have evidence to demonstrate that the cooking instructions, when followed by the consumer, will result in properly cooked product. Discussions and trials with consumers and/or focus groups could assist with validating cooking instructions.

4.5.5 Shelf life and Storage

(1) The operator should have evidence to support the shelf life of the product.[10]

(2) The operator should take all reasonable steps to ensure that products are stored at temperatures that will maintain their safety and wholesomeness for the duration of the shelf life.

Additional Information

The maximum temperature required for chilled storage at retail under the Food Act 2015 is 5°C. This should be considered when carrying out shelf life trials, as should the temperatures likely to be encountered during the distribution and storage in domestic refrigerators.

4.5.6 Routine Processing

(1) The process should be operated in accordance with the established parameters.

Additional Information

All validated critical factors and process parameters should be transferred into the RMP procedures and be readily available to process staff.

(2) The operator should handle the raw materials and products to avoid any additional contamination which the process is not designed to eliminate.

(3) Heat treatment should commence promptly after product preparation. Any delays or holding of product between preparation and the heat treatment should be in accordance with the validated process.

(4) If pre-programmed controls are used to operate and/or control a process, unauthorised access to the programmed parameters must be prevented [HC Spec 14.9].

(5) People carrying out key tasks associated with the heat treatment process must be identified in the RMP and the required competencies specified [RMP Spec 15].

(6) Training records must be kept. [HC Spec 5.3 and RMP Spec 15].

Additional Information

As pasteurisation is likely to be a CCP, training expectations are heightened. Training should address the operation, control, monitoring and corrective actions of that step.

(7) Heat treatment and cooling processes should be monitored (e.g. come up time, process time, internal product and/or equipment temperatures, relative humidity, steam pressure, belt speed etc.) and results recorded to demonstrate that the required parameters are met for every batch [HC Spec Part 9].

[10] Operators should refer to the MPI Guidance document "How to Determine the Shelf Life of Food" for further guidance on how to validate product shelf life.

(8) Periodic verification of any other parameters that had been applied when validating the process but that are not routinely monitored during processing, should be carried out to ensure that the process still operates within those parameters (e.g. maximum loading or loading configuration if not verified for every batch).

(9) Calibrated equipment must be used for critical measurements [HC Spec Part 6].

(10) The operator must implement operator verification procedures. This includes ensuring that regulatory and operator-defined limits for the product are met [RMP Spec 16].

Additional Information

It is good practice to verify the records from each batch prior to product release. Routine microbiological testing of all batches produced using validated parameters is not required, but it is recommended that samples of products are periodically tested as part of operator verification.

Mandatory verification of certain ready-to-eat products for *L. monocytogenes* is a requirement under the Food Standards Code Part 1.6 Standard 1.6.1.

4.5.7 Deviation from the Validated Process

(1) The operator should take immediate action if there is a process deviation that could impact on the food safety or wholesomeness of the product, including if any regulatory or operator-defined limits are not met.

Additional Information

When assessing a process deviation, such as slow heating or long holding times at temperatures optimum for pathogen growth (5°C-55°C), consideration should be given to:

- the possibility of rapid pathogen growth to high levels that cannot be inactivated by the heat treatment process;
- the production of heat stable toxins e.g. by *S. aureus*, that will not be inactivated by the heat treatment process;
- whether affected product could have contaminated product contact surfaces where exposed post-heat treatment product is handled.

The suitably skilled person should consider whether the parameters to be used for any reprocessing should be varied from the established process. Prior processing may have altered the heating characteristics of the product so that the original parameters may not be effective.

(2) Affected product should be identified and segregated until its safety and disposition is assessed by a suitably skilled person.

(3) A suitably skilled person should assess the incident to determine its cause and appropriate corrective actions.

(4) A record of the assessment and corrective actions taken should be prepared by the suitably skilled person. The record should be appropriate to the nature of the deviation and should include:

a) date and time of deviation;
b) equipment involved (where appropriate);
c) description of the nature and scope of the deviation;
d) description of affected product, including batch code and quantity;
e) corrective action taken, including restoration of control, product disposition and prevention of recurrence;
f) records of any tests carried out; and
g) the name and signature of the suitably skilled person.

5 Appendix

Rather than heating product to the required internal temperature and holding it for the corresponding time (i.e. applying parameters from Tables 2 or 3) an operator may choose to calculate the lethality of their process. This approach includes the lethality delivered during the heating and cooling of the process as well as that delivered during the hold phase, but requires good knowledge of the temperatures at the slowest heating point of the product for the duration of the process.

To do this the temperature is recorded at the slowest heating point in the product at set time intervals e.g. every 30 seconds or a minute. The time and temperature data can be collected by inserting a probe or logger into the largest product(s) at the product's slowest heating point, for the products located at the coldest points of the cooker. Data is then collected for a number of runs to ensure the process variation is captured[11].

The General method can then be used to convert the time and temperature data to determine a pasteurisation (P) value using the following equation.

$$P = \int_0^t 10^{\frac{T(t)-T_{ref}}{z}} . dt$$

Where:
T (°C) is the product temperature at each time interval
T_{ref} (°C) is the reference temperature at which the equivalent lethal effect is compared
z is the z value (°C) of the target microorganism for which the process is developed.

Using the equation above, the following example has been created using *L. monocytogenes* as the target pathogen. The cumulative lethality for the process can be calculated for each run to determine the P value achieved by the process. A z value of 6.25°C (taken from the MPI report) has been used.

Table 4: Example calculation of cumulative lethality for a process designed to inactivate *L. monocytogenes*

Process time (minutes)	Internal Temperature at slowest heating point (°C)	Lethal rate (L) at T_{ref} 70°C, z =6.25	Cumulative lethality (Pasteurisation value $P_{70}^{6.25}$)
0	55	0.0040	0.004
1	57	0.0083	0.012
2	59	0.0174	0.030
3	60	0.0251	0.055
4	62	0.0525	0.11
5	63	0.0759	0.18
6	65	0.1585	0.34
7	67	0.3311	0.67
8	68	0.4786	1.15
9	70	1.0000	2.15
10	72	2.0893	4.24

[11] A lot of guidance is available to assist with the development of robust validation protocols and is not repeated here.

Process time (minutes)	Internal Temperature at slowest heating point (°C)	Lethal rate (L) at T_{ref} 70°C, z =6.25	Cumulative lethality (Pasteurisation value $P_{70}^{6.25}$)
11	75	6.3096	10.55
12	70	1.0000	11.55
13	67	0.3311	11.88
14	64	0.1096	11.99
15	60	0.0251	12.02

In this example the product would receive an equivalent process of holding it at an internal temperature of 70°C for 12 minutes with instantaneous heating and cooling, using a z value of 6.25°C.

Looking at Table 2, to achieve a 6 log inactivation of *Listeria monocytogenes* would require the product to be held at an internal temperature of 70° for 2.4 minutes, so this example process would easily achieve a 6 $\log_{10}$ reduction in concentration of *L. monocytogenes*.

If an operator is interested in using this approach, the work should be carried out by suitably skilled people.

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