Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Further Processing: Part 1 Heat Treatment

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Title

Guidance Document: Further Processing: Part 1 Heat Treatment

About this document

This Part applies to the heat treatment of non-dairy animal products, but more specifically for the processing of meat (including poultry), and seafood. Other non-dairy animal product processors e.g. processors of egg products, may find the guidance useful during development and validation of 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
- Australia New Zealand Food Standards Code (FSC)

Document history

Version Date	Section Changed	Change(s) Description
February 2018	New Part	New Part to be added to the Further Processing COP.

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1 Purpose

Heat treatment is the process of heating product to achieve certain sensory attributes, eliminate or minimise spoilage and pathogenic organisms and enzymes, and to extend shelf life. The temperatures applied are often mild, ranging between 65 and 90°C, and are held for the time necessary to eliminate or reduce the target microorganisms to the required levels and achieve the desired sensory attributes. The heat treatment processes addressed in this Part are generally not sufficient to eliminate bacterial spores, so resulting products are usually refrigerated or have other control measures applied to ensure their safety and suitability.

This Part applies to non-dairy animal products, such as meat, poultry, and seafood, with the aim of applying a heat treatment to achieve either a:

- non-lethal (technological) effect, where the reduction of microbiological hazards is not the purpose of the heat treatment and products are often cooked prior to consumption; or
- pasteurisation effect and the reduction of microbiological hazards to acceptable levels. This will be referred to as pasteurisation.

This Part focuses on the control of microbiological hazards, particularly foodborne bacterial pathogens. When developing and validating a heat treatment process, operators should also consider:

- the impact of heat treatment on spoilage organisms and other risk factors such as chemical hazards; and
- additional control measures that may contribute to the preservation of the product e.g. refrigeration, anti-microbials, reduced water activity (a_w) or pH, or other preservatives.

The heat treatment methods used may be dry heat (e.g. oven roasting, broiling, grilling or hot smoking[1]), or hot liquid or steam heat (e.g. retorting, water immersion, stewing, braising, or sous vide). Although heat treatment may be applied in a continuous or batch wise manner, continuous liquid pasteurisers (e.g. heat treatments applied using heat exchangers or direct steam injection) are not considered here.

This Part does not apply to shelf stable commercially sterilised products. Guidance on commercial sterilisation of low acid canned products can be found in Part 2 of this Guidance Document.

1.1 Layout of part

This Part is laid out in sections to align with the activities carried out as an operator develops, validates and operates a heat treatment process. Some or all of the sections may be relevant, depending on the process and equipment being operated.

This Part contains:

- References to regulatory requirements are made throughout the document with citations to the legislation given in square brackets, in particular:
  - Animal Products Regulations 2000 [Ap Reg];
  - Animal Products Notice: Specifications for Products Intended for Human Consumption [HC Spec];
  - Animal Products (Risk Management Programme Specifications) Notice 2008 [RMP Spec]; and
  - Australia New Zealand Food Standards Code [FSC].

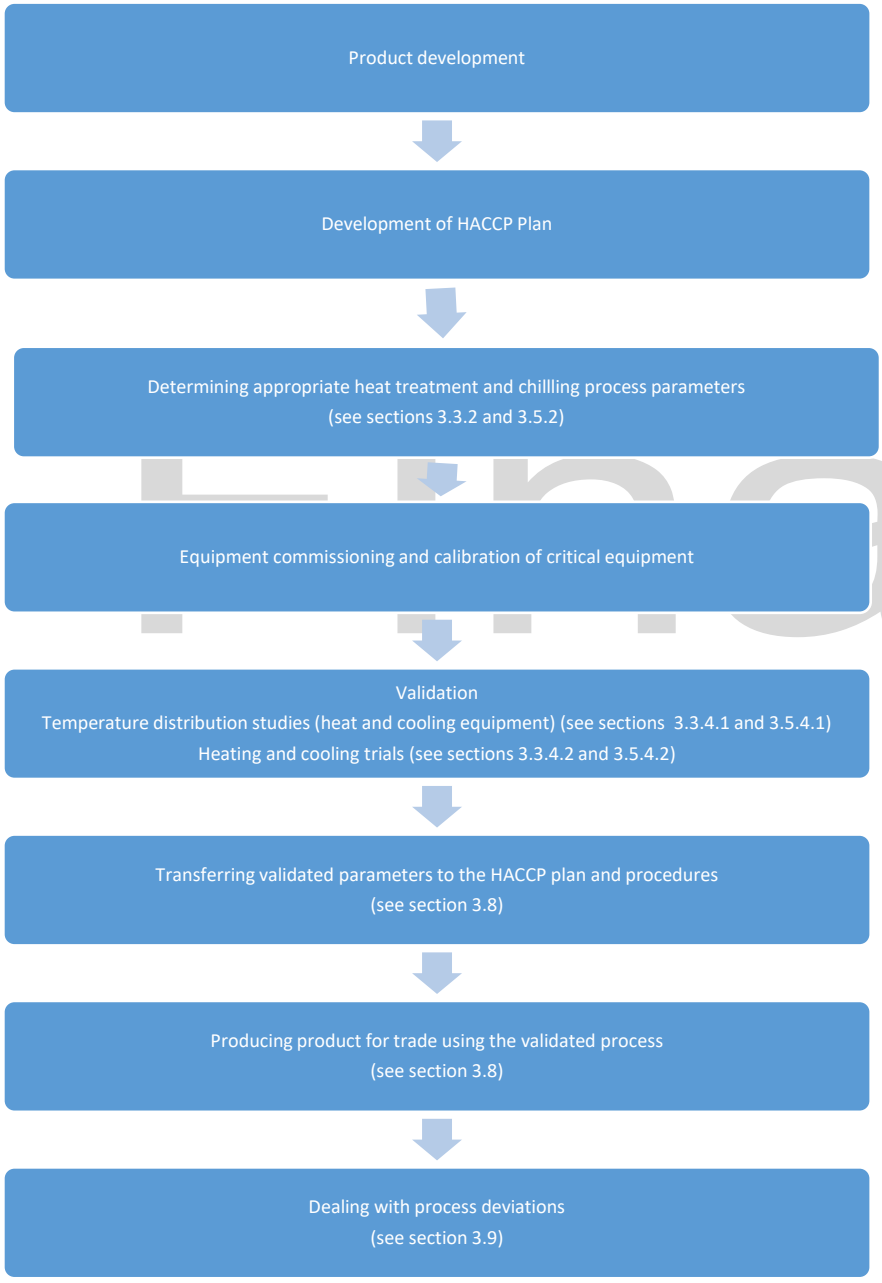
[1] Smoking is covered in Part 5 of the FP COP. This Part applies to the heat treatment component of hot smoking.

- Procedures to assist with compliance; and
- Additional information (shown in boxes).

Processors must comply with regulatory requirements and should follow the procedures for compliance unless alternative practices have been included in their registered RMP. Additional information is given in boxes to assist with understanding.

Figure 1 summarises the steps in the development and validation of a heat treatment process, with references to the sections in this Part where further information is provided.

Figure 1: Steps in developing and validating a heat treatment process



2 Definitions

In this Guidance Document/Code, unless the context otherwise requires:

cold spot in the equipment means the location that is slowest to deliver the required heat treatment to the product

Critical Control Point (CCP) means 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

decimal reduction time (*D* value) means the time taken (usually expressed 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. The time required to kill 99.9999% of a population is equivalent to a 6*D* process (a 6 log reduction)

dry bulb temperature means the temperature of the air when measured with a dry temperature probe

heat penetration test involves measuring the temperature in a product (usually at the slowest heating point located at the cold spot in the equipment) to determine the temperature profile of the product during the heat process

heat treatment means the application of heat to a food. In this Part, heat treatment includes pasteurisation and non-lethal heat treatments

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

non-lethal heat treatment means the application of heat to a product to achieve a technological effect (such as changing a quality or sensory attribute, or causing a chemical reaction or physical effect), and is not intended as a pasteurisation step

operator-defined limit means a measurable limit established by the operator to manage the fitness for intended purpose of a product and is not defined in legislation

pasteurisation means any process, treatment or combination thereof (in this case heat treatment), applied to product to reduce the most resistant microorganism(s) of 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)

pasteurisation value (P value) means 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** means the z value for the target microorganism and **r** is the reference temperature (°C) 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. This means the total killing effect of the heat treatment is equivalent to holding the slowest heating point in the product at 70°C for 2.4 minutes

z value means 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)

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

pathogen means an organism such as bacteria (e.g. *Salmonella*), viruses (e.g. norovirus, hepatitis A virus), or parasites (e.g. Giardia, Cryptosporidium) that may causes disease in human beings

regulatory limit means a measurable regulatory requirement that is critical to the fitness for intended purpose of a particular product

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

shelf life means 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 means microorganisms which cause deterioration of a product and limit their shelf life by producing objectionable flavours, odours and slime

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

temperature distribution study means a study carried out to investigate temperature stability and uniformity in a piece of equipment to determine whether there is even temperature distribution or areas of higher or lower temperatures (e.g. the equipment cold or hot spots or zones)

validation means a process by which evidence is obtained to demonstrate the process operating at defined parameters, is consistently capable of producing animal material or products that meet the requirements to be fit for purpose

water activity (a_w) means 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: $a_w = p/p_o$

wet bulb temperature means the temperature measured by fitting a wet, moisture wick cloth over an ordinary dry bulb probe and placing it in the oven air stream

3 Heat Treatment Procedures

3.1 General requirements

(1) The operator must document and meet any regulatory limits applicable to 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 must demonstrate that the process is capable of consistently achieving the regulatory and/or operator-defined limits [RMP Spec 18].

(4) Processes should be developed and validated[2] by suitably skilled persons.

(5) People carrying out key tasks must be identified in the RMP and any required competencies specified [RMP Spec 15].

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

Additional Information - Suitably skilled persons

Suitably skilled persons who develop and validate heat treatment processes should have a good working knowledge of factors critical to heat treatment. 'Hands-on' experience with the equipment types and processes being developed is an advantage. It is recommended that suitably skilled persons have knowledge of:

a) heat treatment equipment installation and commissioning;
b) pathogens of concern;
c) product and packaging characteristics;
d) validation techniques (e.g. equipment commissioning, temperature distribution studies, heating and cooling trials, and shelf life studies);
e) thermal process calculations and analysis of validation data; and
f) identifying and assessing process deviations.

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

If you are looking for a consultant to assist with this work, a good starting point is the MPI "registers and lists", for example the list of Animal products recognised persons - evaluators.

(7) A report of the validation work must be documented by the suitably skilled person [RMP Spec 18].

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

(9) Equipment and process lines should be assessed at least annually, or at a frequency based on performance for any variation or modification that has been made to the design, installation or operation of equipment, process lines or essential services that would impact on food safety.

(10) The frequency of assessment under (9) should be documented in the RMP.

(11) 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.

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

(12) Calibrated equipment with sufficient accuracy should be used during any validation work and routine processing and calibration records must be kept [HC Spec Part 6].

3.2 Non-lethal heat treatments

(1) Parameters for non-lethal heat treatments should be established by a suitably skilled person, considering:

a) the potential for pathogen growth and/or toxin formation to unacceptable levels in the product e.g. during the come up time, heat treatment and subsequent cooling;
b) the potential for pathogen growth and/or toxin formation on equipment surfaces;
c) the potential for exposure of microorganisms to sub-lethal temperatures for a time that could lead to thermal conditioning (increasing their heat resistance to any subsequent cooking steps). (Seafood NIC, 2006).

Additional Information – Purpose of non-lethal heat treatment

Non-lethal heat treatments are generally applied to achieve a technological effect in the product and are not intended as a pasteurisation step. Because of this, these steps are often overlooked during process development or validation. It is important that the steps are well understood and controlled to ensure that unexpected outcomes (e.g. providing conditions that will favour the growth of pathogens) do not occur.

Examples of non-lethal heat treatments are where heat is applied to:
- support microbiological or chemical reactions (e.g. fermentation, enzyme hydrolysis);
- inhibit chemical reactions (e.g. certain enzyme reactions);
- enhance physical, sensory or palatability characteristics (e.g. grill marking, browning by flash frying);
- ease product handling (e.g. reducing viscosity to assist in pumping viscous materials, dissolving powders, melting fats).

3.3 Pasteurisation

Additional Information

The microbial reduction achieved by a pasteurisation process will depend on the times and temperatures applied. The point in the process where pasteurisation occurs will often impact on how much validation is needed, and whether post-heat treatment contamination needs to be considered.

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

3.3.1 Outcome of pasteurisation

(1) Pasteurisation must ensure the elimination or reduction to acceptable levels of the pathogens of concern, identified by applying the principles of HACCP. The pathogens may include:

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

(2) The pasteurisation process should be sufficient (either alone or in combination with other preservation control measures) to ensure the product is fit for its intended purpose, method of storage and shelf life.

Additional Information – Other considerations

Reduction in the levels of spoilage organisms also needs to be considered when developing appropriate heat treatment parameters, to ensure that the product will remain suitable for its shelf life.

When dealing with spore forming bacteria, pasteurisation usually targets the elimination or reduction to acceptable levels of the vegetative cells only. Other control measures are applied to ensure that the remaining spores cannot germinate and grow. An exception to this in this Part is the heat treatment of products to eliminate the spores of non-proteolytic (psychrotrophic) *C. botulinum* (see section 3.3.3.3 Elimination or Reduction to Acceptable Levels of Non-Proteolytic *C. botulinum*).

3.3.2 Development of pasteurisation parameters

(1) When determining appropriate pasteurisation parameters (such as heating times and temperatures), the operator should consider the:

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

(2) Pasteurisation parameters should be developed for each product, group of products or product that represents the worst case, considering all relevant factors.

Additional Information – Source of pasteurisation parameters

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

Pasteurisation parameters maybe derived from:
- calculations;
- data from similar processes;
- scientific publications or other reference material;
- predictive modelling programmes; or
- the default pasteurisation parameters in Section 3.3.3 Pasteurisation Parameters.

If appropriate parameters are not available from these sources, the operator may need to carry out trials to develop their own parameters. This may require a microbial challenge trial, which put simply, is where a cocktail of strains of the target pathogen(s) is inoculated into the product and it is then processed to determine whether the required pathogen reduction is achieved. Challenge trials involving microbial pathogens should not be carried out in the commercial processing environment.

In some cases, the desired quality attributes or heat treatment parameters needed to reduce the levels of spoilage organisms will be higher than are necessary for food safety. In meeting the higher parameters, the pathogens will also be controlled. Other control measures could also impact on the heat treatment parameters needed to ensure food safety, for example if the product has a reduced pH or a_w. These factors should be considered when determining appropriate pasteurisation parameters to apply.

3.3.3 Pasteurisation parameters

Table 1 is useful for identifying the appropriate pathogens of concern for particular pH and a_w combinations. The choice of pathogen for thermal inactivation should be based on the likelihood of the pathogen in the food, its thermal resistance, the outcome to be achieved and the intended use of the product. For example, non-proteolytic strains of *C. botulinum* might be selected as the target organisms for some chilled foods and *L. monocytogenes* for others depending on factors such as which pathogens are likely to occur and the shelf life of the product (NACMF, 2010).

Table 1: Potential pathogens of concern for growth studies based on interaction of product pH and Aw (NACMF, 2010)

Aw	**pH**					
	<3.9	**3.9 to < 4.2**	**4.2-4.6**	**>4.6-5.0**	**>5.0-5.4**	**>5.4**
<0.88	NG[a]	NG	NG	NG	NG	NG
0.88-0.90	NG	NG	NG	NG	*S. aureus*	*S. aureus*
>0.90-0.92	NG	NG	NG	*S. aureus*	*S. aureus*	*S. aureus* *L. monocytogenes*
>0.92-0.94	NG	NG	*L. monocytogenes* *Salmonella*	*B. cereus* *C. botulinum* *L. monocytogenes* *Salmonella* *S. aureus*	*B. cereus* *C. botulinum* *L. monocytogenes* *Salmonella* *S. aureus*	*B. cereus* *C. botulinum* *L. monocytogenes* *Salmonella* *S. aureus*
>0.94-0.96	NG	NG	*L. monocytogenes* *Pathogenic E. coli* *Salmonella* *S. aureus*	*B. cereus* *C. botulinum* *L. monocytogenes* *Pathogenic E. coli* *Salmonella* *S. aureus* *V. parahaemolyticus*	*B. cereus* *C. botulinum* *L. monocytogenes* *Pathogenic E. coli* *Salmonella* *S. aureus* *V. parahaemolyticus*	*B. cereus* *C. botulinum* *C. perfringens* *L. monocytogenes* *Pathogenic E. coli* *Salmonella* *S. aureus* *V. parahaemolyticus*
>0.96	NG	*Salmonella*	*Pathogenic E. coli* *Salmonella* *S. aureus*	*B. cereus* *C. botulinum* *L. monocytogenes* *Pathogenic E. coli* *Salmonella* *S. aureus* *V. parahaemolyticus*	*B. cereus* *C. botulinum* *L. monocytogenes* *Pathogenic E. coli* *Salmonella* *S. aureus* *V. parahaemolyticus* *V. vulnificus*	*B. cereus* *C. botulinum* *C. perfringens* *L. monocytogenes* *Pathogenic E. coli* *Salmonella* *S. aureus* *V. parahaemolyticus* *V. vulnificus*

[a] NG, no growth; when no pathogen growth is expected, but formulation or process inactivation studies may still be needed.

Additional Information – Default pasteurisation parameters

To assist operators in identifying appropriate 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) for a range of red meat and poultry products. The values in the report do not apply to products with an a_w of less than 0.95[3], fat content

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

of greater than 30% or a pH of less than 5. The *D* and z values from the report have been used to generate the pasteurisation parameters in Tables 2 and 4 for red meat and poultry products.

The parameters for seafood products have been taken from a range of sources, identified in the text.

Pasteurising at 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.

Alternative parameters can be used if the operator can provide evidence to support this. Justification for alternative parameters may include:

- the default *D* and z values for the target pathogen are too high and the operator has evidence of alternative parameters that are more appropriate for their product[4];
- higher or lower microbiological loading in the inputs such that a 6 $\log_{10}$ reduction in concentration of *the* target pathogen is not appropriate or necessary;
- an alternative pathogen is identified as the target to be reduced or eliminated by pasteurisation; or
- additional control measures are used to preserve the product, reducing the required log reduction needed from the pasteurisation process.

3.3.3.1 Elimination or reduction to acceptable levels of L. monocytogenes

(1) Pasteurisation of 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*.

Additional Information

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

The times and temperatures in Tables 2 and 3 will achieve a 6 $\log_{10}$ reduction in the concentration of *L. monocytogenes* in moist red meat, poultry and seafood 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 time/temperature combinations to achieve a 6 $\log_{10}$ reduction in the concentration of *L. monocytogenes* in red meat and poultry products[5]

Temperature (°C)	*D* (minutes)	Process Time (minutes) to achieve 6*D*
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**

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

[5] Horn B, 2015.

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**

Table 3:Calculated *D* values and time/temperature combinations to achieve a 6 log_{10} reduction in the concentration of *L. monocytogenes* in seafood

Temperature (°C)	Process Time (minutes) to achieve 6*D*			
	Green shell mussel[6]	Salmon[7]	Cod[6]	Other seafood[6]
58	**103.14**	**55.5**	**26**	**103.5**
59	**68**	**38**	**17.5**	**68**
60	**44.8**	**26.5**	**12**	**45**
61	**29.5**	**18**	**8**	**29.5**
62	**19.4**	**12.5**	**5.5**	**19.5**
63	**12.8**	**8.5**	**4.2**	**13**
64	**8.4**	**6**	**3.0**	**8.5**
65	**5.5**	**4.5**	**2.2**	**6**
66	**3.7**	**3.3**	**1.6**	**4.2**
67	**2.4**			
68	**1.6**	**1.8**	**1.0**	**2.3**
70		**1.1**	**12 (sec)**	**1.5**
72	**18 (sec)**	**18 (sec)**	**6 (sec)**	**1.1**

3.3.3.2 Elimination or reduction to acceptable levels of Salmonella and pathogenic E. coli

(1) If *Salmonella* spp. or pathogenic *E. coli* is identified as the most heat resistant pathogen of concern to be controlled by the pasteurisation process, the process should achieve a 6 log_{10} reduction in the identified pathogen.

Additional Information

The times and temperatures in Table 4 will achieve a 6 log_{10} reduction in the concentration of *Salmonella* spp. and/or pathogenic *E. coli* in moist red meat or poultry products and can be applied to RTE chilled products with a shelf life of less than 5 days. The temperature is the minimum that should be achieved and

[6] Bremer and Osborne, 1997.

[7] Adapted from Crop and Food Research, 1998.

maintained at the slowest heating point in the product, for the corresponding time. **The temperature is not the operating temperature of the cooker.**

Table 4: Default *D* values, and time/temperature combinations s to achieve a 6 $\log_{10}$ reduction in concentration of *Salmonella* spp. and pathogenic *E. coli* in red meat and poultry products[8]

***Salmonella* spp.**			***E. coli***		
Temperature (°C)	***D* (minutes)**	**Process Time (minutes) to achieve 6D**	**Temperature (°C)**	***D* (minutes)**	**Process Time (minutes) to achieve 6*D***
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**

3.3.3.3 Elimination or reduction to acceptable levels of non-proteolytic C. botulinum

(1) If non-proteolytic (psychrotrophic) *C. botulinum* is identified as a hazard that is reasonably likely to occur and is to be controlled only by the pasteurisation process, a heat treatment of 90°C for 10 minutes or equivalent, measured at the slowest heating point in the product, should be applied.

Additional Information

The times and temperatures in Table 5 will achieve at least a 6 $\log_{10}$ reduction in the concentration of non-proteolytic (psychrotrophic) *C. botulinum*. 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.** These parameters should be considered for chilled vacuum packed or modified atmosphere product in which non-proteolytic (psychrotrophic) *C. botulinum* is reasonably likely to occur and has a shelf life of 10 days or more.

Table 5: Equivalent time/temperature combinations to achieve a 6 $\log_{10}$ reduction in concentration of non-proteolytic *C. botulinum* spores (UKFSA, 2017)

Temperature (°C)	**Process Time (minutes) to achieve 6*D***
80	**129.0**
85	**36.0**
90	**10.0**
95	**3.2**
100	**1.0**

[8] Horn B, (2015).

Currently, for ingredients and raw materials of New Zealand origin, non-proteolytic (psychrotrophic) *C. botulinum* is **not** considered to be a hazard that is reasonably likely to occur.

If imported ingredients are being used, the operator needs to evaluate whether non-proteolytic *C. botulinum* is reasonably likely to occur in the ingredient. Where necessary, control measures should be implemented for this hazard.

Non-proteolytic *C. botulinum* is more likely to be a hazard of concern in vacuum packed or modified atmosphere products stored between 3°C and 8°C, with a shelf life of 10 days or more. If an operator chooses not to use pasteurisation as a control measure, other measures could be applied to control this pathogen (in combination with refrigeration) including:

- 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
- an a_w of 0.97 or less in all components of the product (UKFSA, 2017).

As an example, operators using imported fish to process ready-to-eat vacuum packed fish product with a chilled shelf life of 10 days or more, would be expected to investigate implementing controls for non-proteolytic *C. botulinum*.

For more information about this pathogen and the recommended control measures, see "The safety and shelf life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum* (UKFSA, 2017) and Section 10.2 of the MPI guide "How to Determine Shelf Life of Food".

Note that the control measures listed above may be inadequate for the control of other pathogens that may be reasonably likely to occur in the product (for example *L. monocytogenes*). The operator needs to implement appropriate control measures to ensure that any other hazards will be appropriately addressed.

3.3.3.4 Elimination or reduction to acceptable levels of Hepatitis A virus or Norovirus in bivalve molluscan shellfish

(1) If Hepatitis A virus or 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 process, a heat treatment of 90°C for 90 seconds or equivalent (EFSA, 2015) measured at the slowest heating point in the product should be applied.

3.3.3.5 Elimination or reduction to acceptable levels of V. parahaemolyticus in oysters

(1) If *V. parahaemolyticus* is identified as a hazard that is reasonably likely to occur in oysters and is to be controlled by the pasteurisation step, a heat treatment of 48-50°C for 5 minutes or equivalent (Andrews et al, 2000) measured at the slowest heating point in the product should be applied.

Additional Information

The authors reported that this process reduced *V. parahaemolyticus* in oysters from 1.2×10^5 MPN/g to non-detectable levels (<3 MPN/g).

3.3.4 Pasteurisation validation

(1) Trials should be carried out to validate the pasteurisation process and provide evidence that:

a) the pasteurisation parameters are appropriate for the product; and
b) when applied, will produce safe product; and
c) all products within and across batches will receive the intended pasteurisation process.

Additional Information – Validation activities

In some cases validation may not be needed. The process may simply be monitored for every batch, for example by:

- measuring the temperature at the centre of the largest product(s), located at the slowest heating point in the equipment, for the duration of the process; or
- measuring the product temperature at the coolest point while it is cooking and making sure the minimum time is achieved, (e.g. if using a steam kettle or jacketed pan).

Validation activities that could be carried out include:

- temperature distribution studies of the equipment;
- heating trials e.g. measuring the temperature inside the product to confirm that the pasteurisation parameters will be met;
- product testing (e.g. microbiological testing) to confirm that regulatory or operator-defined limits are met;
- challenge trials;
- shelf life trials.

3.3.4.1 Temperature distribution studies for pasteurisation equipment

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

Additional Information – Purpose of temperature distribution studies

When validating a pasteurisation process, it is important to know that the equipment (such as an oven) will deliver the required heat treatment to all product. Temperature distribution studies are used to assess the temperatures throughout a piece of equipment during processing and determine how evenly they are distributed. The equipment set up, type of product and packaging, and packing configurations can all impact on temperature distribution within the equipment. To account for this, studies should be completed for each configuration, or significantly different mass of products to check if the temperature distribution is affected.

Temperature distribution data can also be used to modify the equipment set-up to minimise temperature variation. Once the temperature variation has been minimised and any cold spots have been located, processes can then be developed taking those locations into account to ensure that all product will receive adequate heating.

During routine processing, the temperature of products placed at the location(s) delivering the least pathogen reduction (e.g. the cold spot) can then be monitored. If the cold spot is not readily accessible due to the design of the equipment, the offset between the cold 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 cold spot may need to have a measurable temperature of 77°C at the accessible monitoring point.

It is noted that temperature distribution studies may not always be appropriate or necessary. For example:

- if the equipment design and use ensures that the heat will always be evenly distributed, e.g. pasteurisation in a small steam jacketed pan with good product mixing. The temperature at the coldest point would still need to be monitored during processing; or
- 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).

(2) Where temperature distribution studies are carried out:

a) the location in the equipment that would deliver the least pathogen reduction should be identified;

b) if the temperature variation in the equipment could impact on the reliability and safety of the process, the variation should be minimised before further validation is carried out; and
c) any factors that are critical to achieving even temperature distribution in the heating equipment should be identified in the RMP and managed.

Additional Information

The location in the equipment that delivers the least pathogen reduction is usually the cold spot(s). However depending on the process and the product this may not always be the case. For example if the product is also dried as it is heated, the heat tolerance of the target pathogens may increase as the moisture content reduces, in which case the hot spot may actually be the location delivery the least pathogen reduction.

(3) Temperature distribution studies should be:

a) carried out under the most demanding normal operating conditions (e.g. loading configurations, equipment operating at full capacity, capacity of essential services);
b) repeated if there are changes to the equipment design, installation, operation (e.g. after maintenance or repairs), essential services, or product arrangement that could impact on food safety;
c) if no other changes have been made, repeated at least every 3 years to check that the results remain valid.

3.3.4.2 Heating trials (heat penetration tests)

(1) The operator should ensure that the critical product and process factors that could impact the temperatures reached (usually at the slowest heating point(s)) in the product are considered. These could include:

a) the product, for example:

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

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

i) product/container dimensions and/or maximum thickness;
ii) product weight;
iii) packaging material;
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 pathogen reduction (e.g. cold spot), if any;
ii) maximum capacity;
iii) potential for surface fouling;
iv) equipment settings for example:

1) temperature (wet and dry bulb temperature);
2) pressure;
3) time to reach process temperature (come up time);
4) process time, line/belt speed;
5) relative humidity; and
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) repeated if a change is made to the product or process that could impact on food safety;
c) if no other changes have been made, repeated at least every 3 years to check that the results remain valid.

(3) The process or product factors that are critical to achieving safe and suitable product, and that would require revalidation if changed, should be identified in the RMP and managed appropriately.

Additional Information – Validation trials

The suitably skilled person should have confidence that the process will be safe under worst case processing conditions. In determining the number of validation trials to carry out, the following should be considered:

- equipment performance;
- variability of the process including variation across process shifts or seasons;
- product homogeneity; and
- the safety margin of the process.

It is recommended that at least 6 heat trial 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 (often after the process has been modified).

3.4 Post-heat treatment handling[9]

3.4.1 General requirements

Additional Information – Application of section

This section applies to product that has been non-lethally heat treated or pasteurised. Post-heat treatment handling can include any holding, reheating, cooling and packaging after the heat treatment step, until the packaged product has reached its final preservation temperature.

(1) Post-heat treatment handling must be carried out in a manner that prevents recontamination and minimises pathogen growth and toxin formation in the product [AP Reg 9].

Additional Information

Some products require ingredients or inputs to be added after the heat treatment step. The suitably skilled person should assess whether there is potential for hazards to be introduced and ensure that they have been or will be controlled (e.g. by an ingredient supplier or an earlier processing step) or that they will be controlled by a subsequent control measure.

(2) The operator must identify any uncontrolled hazards that are likely to be present in the product leaving the in the RMP and must justify that it is appropriate considering the intended use of the product [RMP Spec 10].

[9] 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 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.

3.4.2 Hot holding

(1) Product that is held hot should be held above the maximum growth temperature for the pathogen(s) of concern.

Additional Information – Hot holding temperatures

Typically hot holding occurs at product temperatures of 60°C or above. 60°C is higher than the maximum growth temperature for *C. jejuni*, *C. coli*, *S. aureus*, *Salmonella* spp., *STECs*, *C. perfringens*, *L. monocytogenes*, *Y. enterocolitica and B. cereus*. For further information see the MPI report "Maximum growth temperatures of foodborne pathogens and appropriate temperatures for hot holding prepared" prepared by Hudson (2011).

3.4.3 Hot filling

Additional Information – Purpose of hot filling

Products such as chilled sauces and soups may be hot filled to allow for the pasteurisation of the internal container surfaces. To ensure that the lids and headspace are also pasteurised, the sealed containers may be:

- inverted; or
- passed through a tunnel pasteuriser.

The required temperature must be maintained for long enough to pasteurise the container surfaces, and the product is then rapidly cooled to prevent spore germination. Hot filling should take place under clean conditions so that bacterial contamination is prevented and the risks are only from air-borne yeast and mould spores. These are easier to kill by heat (Tucker and Featherstone, 2011).

3.4.4 Separation

(1) There must be adequate separation of pasteurised and raw product handling to prevent recontamination of pasteurised product [Ap Reg 9].

(2) Access of personnel from raw or unprocessed product areas into pasteurisation and post-heat treatment areas involving exposed product, should be controlled.

(3) People moving into the pasteurisation or post-heat treatment area must complete an appropriate hygiene routine [Ap Reg 12].

(4) Operators must comply with the requirements in Part 15 of the HC spec "*Listeria* requirements for processors of certain ready-to-eat animal products", if applicable.[10]

3.5 Cooling

Additional Information – Purpose of controlled cooling

A valid pasteurisation process will reduce pathogens such as *Salmonella* spp., *E. coli* O157:H7, *C. jejuni*, *L. monocytogenes, S. aureus* and vegetative cells of *Clostridia* to acceptable levels. However, spores from pathogens such as *C. perfringens* and *B. cereus* will survive and if product is cooled slowly these could

[10] These provisions apply to processors of some chilled ready-to-eat animal products with a shelf life of greater than 5 days.

germinate and grow (particularly if there are no other control measures in place such as a_w, pH or preservatives).

Pathogens may be present in heat treated product if:
- the heat treatment was insufficient to eliminate or reduce level of the vegetative cells sufficiently; or
- the heat treatment was insufficient to eliminate or reduce the level of spores; or
- there was post-heat treatment contamination.

It is particularly important to consider the potential for the germination and growth of *C. perfringens* in meat products, and *B. cereus*[11] in battered, or coated products or products containing dried spices or herbs, when developing cooling regimes.

3.5.1 Outcome of cooling

(1) Where necessary, heat treated product should be rapidly cooled:

a) to minimise the germination and growth of spores; and
b) in the case of non-lethally heat treated products, to prevent the growth of any vegetative pathogens present to unacceptable levels.

3.5.2 Development of cooling processes

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

Additional Information – Source of cooling parameters

Cooling parameters may be derived from:
- calculations;
- data from similar processes;
- scientific publications or other reference material;
- predictive modelling programmes; or
- the default cooling parameters in Section 3.5.3 Cooling Parameters.

3.5.3 Cooling parameters

Additional Information – Default cooling parameters

When determining the appropriate cooling parameters to apply, the operator could use either the default parameters given below or develop their own. If developing their own parameters operators could also consider whether any additional control measures could assist in slowing or inhibiting 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.

OR:

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

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 are not applied, the operator should have evidence to support any alternative parameters.

Additional Information

Of the 3 key pathogenic spore formers (*C. perfringens, B cereus* and *C. botulinum)*, *C. perfringens* is often considered first when developing cooling regimes, as it has the shortest lag and fastest generation time. It grows most rapidly between 54°C and 26°C, with a minimum growth temperature of 10°C (NZFSA, 2010). Not to be forgotten however is *B. cereus,* as some strains are psychrotrophic and are capable of growth at 4°C (Tucker et al 2011).

Predictive modelling programmes can be used to assist in justifying alternative cooling regimes for the control of *C. perfringens*. Mohr *et al* (2015) evaluated a selection of cooling models that predict the growth of *C. perfringens* during cooling of cooked, uncured meat and poultry products and found that the following models were reliable:

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

3.5.4 Cooling validation

(1) The operator should have evidence that the cooling process will result in safe product and that the cooling parameters can be consistently achieved within and across all product batches [RMP Spec 18].

Additional Information – Validation activities

Validation may simply involve collecting data to demonstrate compliance with the selected cooling times and temperatures. This may be measuring the temperature at the centre of the largest products, located at the warmest location(s) in the cooling equipment, for a number of batches. Alternatively it may involve developing appropriate cooling times and temperatures and then collecting data to demonstrate that those parameters are being met.

Some products (such as frankfurters) cool very rapidly due to their size and so are unlikely to exceed established cooling rates. If this is the case, the operator could place them in a chiller or cold water bath soon after pasteurisation, and arrange them in a way that ensures rapid cooling. If there is no potential for spore germination or toxin formation, validation work may be limited or unnecessary (i.e. ongoing monitoring and verification may be sufficient).

When validating cooling regimes, the activities that could be carried out include:

- temperature distribution studies of the cooling equipment;

- cooling trials e.g. measuring the temperature inside the product to confirm that the cooling parameters will be met; and
- product testing (e.g. microbiological testing) to confirm that regulatory or operator-defined limits are met.

3.5.4.1 Temperature Distribution Studies in Cooling Equipment

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

Additional Information – Purpose of temperature distribution studies

When developing a cooling process it is important to know that the equipment can reliably and effectively cool all product. Temperature distribution studies are carried out to determine if there is even temperature distribution within the equipment. Equipment set up, product, packaging and packing configurations can all impact on temperature distribution and should be considered when validating the process.

Temperature distribution data can also be used to modify the equipment set-up to minimise temperature variation and if warmer spots are identified, the cooling processes can be developed taking these into account.

During routine processing, the temperature of products placed at the worst case location(s) can be monitored. However, if that location is not readily accessible, the offset between the temperature at the warm spot and the temperature at the location that is accessible for routine monitoring can be built into the process.

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

(3) 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) carried out under the most demanding normal operating conditions (e.g. loading configurations, equipment operating at full capacity, capacity of essential services);
b) repeated if there are changes to the equipment design, installation, operation (e.g. after maintenance or repairs), essential services or product arrangement, that could impact on food safety;
c) if no changes have been made, repeated at least every 3 years to check that the results remain valid.

3.5.4.2 Cooling trials

(1) Trials should be carried out, where necessary, to validate cooling processes and ensure the process will consistently produce safe and suitable product.

(2) When validating a cooling process, the operator should ensure that all critical product and process factors that could impact the temperature achieved at the slowest cooling points in the product are taken into account. These factors may 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;
iv) slowest cooling point in the product;
v) batch sizes, loading configuration;
vi) impact of adding warm product during the cooling cycle;

c) the cooling equipment, for example:

i) temperature distribution and location that Is slowest to cool;
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 most demanding normal 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) Cooling processes for products made up of separate components that have been cooled to various temperatures, and then reduced to their final preservation temperature should be developed on the basis of cooling the worst case component.

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

3.5.5 Cooling medium

(1) The cooling medium must not be a source of contamination to the product [AP Reg 6].

(2) Water or ice used for cooling must be:

a) potable or of an alternative standard as determined from an analysis of hazards or other risk factors [HC Spec 2.5]; and
b) checked regularly and replaced as necessary so as to not contaminate the product [AP Reg 6].

(3) Where necessary, the operator must have a procedure to maintain the cooling medium so that it is not a source of contamination.

(4) Cooling water maybe treated with a processing aid permitted under FSC Schedule 18 — Processing Aids, to minimise microbial contamination in cooling water.

Additional Information

Cooling water has the potential to allow for growth of microorganisms, which can then directly contaminate the product or attach to the product packaging and contaminate the product when opened.

As a guide, the Codex CAC/RCP 23-1979 document for the processing of canned products recommends operators aim for a detectable amount of free residual chlorine at the point where the water leaves the cooling tank. A free residual chlorine of 0.5 to 2ppm is usually adequate, and an APC of less than 100cfu/ml.

Wherever possible, hot products should be reduced 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.

3.6 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 designed for a specific purpose, such as 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 such checking that complete seals are being formed, no cracking or wrinkling, and that the vacuum is being maintained.

(3) Materials used for sealing product such as metal clips must be controlled to ensure that they are not a source of physical contamination to the product [AP Reg 6]

(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 be used assist with validating cooking instructions.

3.7 Shelf life and storage

(1) The operator should have evidence to support the shelf life of the product.[12]

Additional Information – Chilled storage temperatures

When selecting storage temperatures at which to carry out shelf life trials, operators should be aware that the maximum chilled storage temperature at retail required under the Food Act 2015 is 5°C.

3.8 Routine processing

(1) The process must be operated in accordance with the established parameters documented in the RMP [RMP Spec 11].

Additional Information

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

(2) The operator must handle raw materials and products to avoid any additional contamination that the process is not designed to eliminate [AP Reg 5].

[12] Refer to the MPI Guidance document "How to Determine the Shelf Life of Food" for further guidance.

(3) Heat treatment should commence promptly after product preparation. Any delays or holding of product between preparation and the heat treatment must be in accordance with the documented RMP [RMP Spec 11].

(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) Heat treatment and cooling processes must 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, RMP Spec 20].

(6) Any other parameters that had been applied when validating the process but that are not routinely monitored during processing should be periodically verified to ensure that the process continues to operate within those parameters (e.g. maximum loading or loading configuration if not verified for every batch) [RMP Spec 16].

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

(8) Mandatory verification of compliance with the microbiological limits in FSC Part 1.6 Standard 1.6.1.is required for certain products.

Additional Information

It is good practice to verify the records from each batch prior to product release.

Routine microbiological testing of all product batches is not required, but it is recommended that batches are tested periodically as part of operator verification.

3.9 Deviation from the validated process

(1) The operator must take immediate action if there is a process deviation that could impact on the food safety or suitability of the product, including if any regulatory or operator-defined limit is not met [RMP Spec 8].

Additional Information

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

- the possibility of pathogen growth to high numbers that cannot then be reduced to acceptable levels 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 (*S. aureus* toxin can withstand heating at 149°C for over 100 minutes);
- whether affected product could have contaminated product contact surfaces.

The suitably skilled person should consider whether the validated parameters are adequate for reprocessing purposes. For example, the initial processing may have altered the heating characteristics of the product so that the processing parameters are no longer effective.

(2) Product affected by the process deviation 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 and preventative actions.

(4) A record must be prepared by the suitably skilled person, appropriate to the nature of the deviation. The report should include:

a) date and time of deviation;
b) equipment involved;
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 who carried out the assessment [RMP Spec 20].

4 References

Andrews, L. S., Park, D. L. and Chen, Y. P. (2000). Low temperature pasteurization to reduce the risk of Vibrio infections from raw shell-stock oysters. Food Additives and Contaminants; 17: pp787-791.

Australian New Zealand Food Regulation Ministerial Council. Food Regulation Standing Committee. (2007). Australian Standard for the hygienic production and transportation of meat and meat products for human consumption: AS 4696:2007.

Bremer, P. J., Osborne, C. M. (1997). Thermal Death Time of *Listeria monocytogenes* Cells in Artificially Contaminated Greenshell Mussels (Perna canaliculus). J. of Aquatic Food Product Technology, 6:1, pp. 21-36.

Canadian Food Inspection Agency. Meat Hygiene Manual of Procedures, Chapter 4. Meat Processing Controls and Procedures.

Campden and Chorleywood Food Research Association, Guideline No. 51. Gaze, J. E. (2006). Pasteurisation: a food industry practical guide (second edition).

Campden and Chorleywood Food Research Association, Review No 8, Project No. 16286. Gaze et Al, (1998) Identification and Prevention of Hazards associated with Slow Cooling of Hams and Other Large Cooked Meats and Meat Products.

Codex Alimentarius Commission: (CAC/RCP 23-1979). Code of Hygienic Practice for Low Acid and Acidified Low-Acid Canned Foods.

Cox, B., Bauler, M. 2008. Cook chill for Foodservice and Manufacturing. Guidelines for the safe production, storage and distribution. The Australian Institute of Food Science and Technology Incorporated.

Decision tree "Process Validation Decision" (Guidelines on General Principles of Process Validation, Process Validation Workshop for Meat and Poultry Products (section E).

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2015. Scientific opinion on the evaluation of heat treatments, different from those currently established on the EU legislation, that could be applied to live bivalve molluscs from B and C production areas, that have not been submitted to purification or relaying, in order to eliminate pathogenic microorganisms. EFSA Journal 2015; 13(12): 4332, 76 pp.

Food Standards Agency UK (UKFSA). 2017. The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum.* https://www.food.gov.uk/business-industry/manufacturers/shelf-life-storage/vacpac

Horn, B. 2015. D and z values for the heat inactivation of pathogens in raw meat. Client Report FW15001 for the Ministry for Primary Industries. Institute of Environmental Science and Research, Christchurch.

Horn, B., Hewitt, J. 2016. Review of Microbial Pathogen Inactivation Relevant to Sous Vide Pasteurisation at Temperatures Below 55°C. Client Report FW15038 for the Ministry for Primary Industries. Institute of Environmental Science and Research, Christchurch.

Hudson, J. A. (2011). Maximum growth temperatures of foodborne pathogens and appropriate temperatures for hot holding. Client Report FW 10047 for the Ministry for Primary Industries. Institute of Environmental Science and Research, Christchurch.

Meat and Livestock Australia Ltd. 2015. Guidelines for the safe manufacture of smallgoods. 2nd Edition.

Mohr, T. B.; Juneja, V. K.; Thippareddi, H. H.; Schaffner, D. W.; Bronstein, P. A.; Silverman, M.; Cook, Jr., L. V. (2015). Assessing the Performance of *Clostridium perfringens* Cooling Models for Cooked, Uncured Meat and Poultry Products. J Food Prot. 8:1428-1617, pp. 1512-1526(15).

NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS (NACMCF) (2006) Requisite Scientific Parameters for Establishing the Equivalence of Alternative Methods of Pasteurization. J Food Prot 69(5), pp. 1190-1216.

NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS (NACMCF) (2010) Parameters for Determining Inoculated Pack/Challenge Study Protocols. J Food Prot 73(1), pp. 140-202 supp.

New Zealand Institute for Crop and Food Research Limited. (1998). Guidelines for the Safe Preparation of hot-smoked seafood in New Zealand.

New Zealand Food Safety Authority. 2010. *Clostridium perfringens* Hazard Data Sheet.

Scott. J., and Weddig. L. Principles of Integrated Time-Temperature Processing, National Food Processors Assn, Process Validation Workshop for Poultry and Meat Products).

Seafood Network Information Center. (Seafood NIC) Chapter 3: Cooked Fish and Fishery Products. Accessed November 2016. http://seafood.oregonstate.edu/.pdf%20Links/Compendium/Chapter-3-Cooked-Fish.pdf

Smith-Simpson, S., and D. W. Schaffner. 2005. Development of a model to predict growth of *Clostridium perfringens* in cooked beef during cooling. J Food Prot. 68:336-341.

Tucker. G. and Featherstone. S. 2011. Essentials of Thermal Processing. Blackwell Publishing Ltd.

United States Department of Agriculture Food Safety and Inspection Service (2017). FSIS Directive 7111.1 Verification Procedures for Lethality and Stabilization.

USDA-FSIS. 2017. FSIS Compliance Guideline for Stabilization (Cooling and Hot-holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B 2017 Compliance Guideline.

Warne, D. (2011). Low temperature cooking of meats. Meat and Livestock Australia.

Warne, D. (2017) Approved Persons Course for UHT Processing and Aseptic Packaging Course Manual.

Appendix

The default pasteurisation parameters given in Tables 2-5, do not consider the contribution from the heating and cooling of the product on the elimination of bacterial pathogens. This means the product may be subject to a more severe heat treatment process than is needed to achieve the required reduction in concentration of the target pathogen.

An example of an alternative approach could be to calculate the lethality of the process, rather than heating the product to the required minimum temperature (measured at the slowest heating point in the product) and holding it for the corresponding time. This approach includes the lethality delivered during the heating and cooling phases, as well as that delivered during the hold phase to determine the overall process lethality, but requires good knowledge of the temperatures at the slowest heating point of the product for the duration of the process.

To use this approach, the temperature is recorded at the slowest heating point in the product at set time intervals throughout the process (e.g. every 30 seconds or minute). The time and temperature data can be collected by inserting probes or loggers 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 collected for a number of runs to ensure the process variation is captured[13].

The following equation (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 developed using *L. monocytogenes* as the target pathogen and a z value of 6.25°C (taken from the MPI report) with data recorded at 1 minute intervals.

The cumulative lethality for the process can be calculated for each run to determine the P value achieved by the process.

Table 6: 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

e.g. $=10^{\left(\frac{55-70}{6.25}\right)}\times 1$

e.g. =0 004+0.0083

[13] 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 $P_{70}^{6.25}$)
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	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 12.02 minutes with instantaneous heating and cooling.

If this approach is to be used, the work should be carried out by suitably skilled persons.